UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

PROMETHEUS BIOSCIENCES, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation or organization)

2834
(Primary Standard Industrial Classification Code Number)

9410 Carroll Park Drive
San Diego, California 92121
858-824-0895

(Registrant’s principal executive offices)

Mark C. McKenna
President and Chief Executive Officer
Prometheus Biosciences, Inc.
9410 Carroll Park Drive
San Diego, California 92121
858-824-0895

(Name, address, including zip code, and telephone number, including area code, of agent for service)

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Approximate date of commencement of proposed sale to the public: As soon as practicable after this Registration Statement is declared effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

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The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.
EXPLANATORY NOTE

Pursuant to the applicable provisions of the Fixing America’s Surface Transportation Act, we are omitting from this draft Registration Statement our interim consolidated financial statements as of and for the six months ended June 30, 2019 and 2020 because they relate to historical periods that we believe will not be required to be included in the prospectus at the time we first file this Registration Statement publicly. We intend to amend this Registration Statement on or prior to the date of such public filing to include all financial information required by Regulation S-X under the Securities Act of 1933, as amended (the Securities Act), including audited financial statements as of and for the six months ended June 30, 2020.
This is the initial public offering of Prometheus Biosciences, Inc. We are offering shares of our common stock. The initial public offering price is expected to be between $ and $ per share.

Prior to this offering, there has been no public market for our common stock. We intend to apply to list our common stock on the Nasdaq Global Market under the symbol “RXDX.”

We are an “emerging growth company” under applicable Securities and Exchange Commission rules and have elected to comply with certain reduced public company reporting requirements for this prospectus and future filings.

Investing in our common stock involves a high degree of risk. See “Risk Factors” beginning on page 12.

Neither the Securities and Exchange Commission nor any other state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

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<th>Per Share</th>
<th>Total</th>
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<tr>
<td>Initial public offering price</td>
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<tr>
<td>Underwriting discounts and commissions(1)</td>
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<tr>
<td>Proceeds, before expenses, to us.</td>
<td>$</td>
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(1) See the section titled “Underwriting” for additional information regarding compensation payable to the underwriters.

We have granted the underwriters an option for a period of 30 days to purchase up to additional shares of common stock from us at the public offering price, less the underwriting discounts and commissions.

The underwriters expect to deliver the shares of common stock to purchasers on , 2020 through the book-entry facilities of The Depository Trust Company.

SVB Leerink Credit Suisse BMO Capital Markets Guggenheim Securities

Neither we nor the underwriters have authorized anyone to provide you with information other than that contained in this prospectus or any free writing prospectus prepared by or on behalf of us or to which we have referred you. We and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We and the underwriters are offering to sell, and seeking offers to buy, common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus or any free writing prospectus is accurate only as of its date, regardless of its time of delivery or of any sale of shares of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

Through and including , 2020 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This delivery is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

For investors outside of the United States: We have not, and the underwriters have not, done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than the United States. Persons outside of the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside of the United States.
PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus. This summary does not contain all of the information you should consider before investing in our common stock. You should read this entire prospectus carefully, especially the section titled “Risk Factors” and our consolidated financial statements and related notes included elsewhere in this prospectus, before making an investment decision. As used in this prospectus, unless the context otherwise requires, references to “we,” “us,” “our,” “the Company,” “Prometheus Biosciences” and “Prometheus” refer to Prometheus Biosciences, Inc. and, where appropriate, its subsidiary.

Overview

We are a biotechnology company pioneering a precision medicine approach to the discovery, development, and commercialization of novel therapeutic and companion diagnostic products for the treatment and diagnosis of inflammatory bowel disease (IBD). We leverage our proprietary precision medicine platform, Prometheus 360, which includes one of the world’s largest gastrointestinal (GI) bioinformatics databases, to identify novel therapeutic targets and develop therapeutic candidates to engage those targets. In parallel, we are developing companion diagnostic tests designed to identify patients more likely to respond to our therapeutic candidates. We have generated a robust initial pipeline of therapeutic development programs for the treatment of IBD. Our lead product candidate, PRA023, is an IgG1 humanized monoclonal antibody (mAb) that has been shown to block the tumor necrosis factor (TNF)-like ligand 1A (TL1A), a target associated with both intestinal inflammation and fibrosis that was clinically-validated in a third-party Phase 2a clinical trial in ulcerative colitis (UC). PRA023 has the potential to substantially improve outcomes for moderate-to-severe IBD patients who are predisposed to increased TL1A expression. We are developing PRA023 for the treatment of UC and Crohn’s disease (CD), and we expect to initiate a Phase 1a clinical trial in normal healthy volunteers in the fourth quarter of 2020. Our goal is to revolutionize the treatment of IBD with a precision medicine approach for patients with significant unmet medical needs.

Inflammatory Bowel Disease

IBD is a complex disease with many contributing factors, including genetic, environmental and immunologic. UC and CD are two of the most common forms of IBD. Both UC and CD are chronic, relapsing, remitting, inflammatory conditions of the GI tract that begin most commonly during adolescence and young adulthood. UC involves the innermost lining of the large intestine, and symptoms include abdominal pain and diarrhea, frequently with blood and mucus. CD can affect the entire thickness of the bowel wall and all parts of the GI tract from mouth to anus. CD symptoms include abdominal pain, diarrhea, and other more systemic symptoms such as weight loss, nutritional deficiencies, and fever.

The current standard of care for the treatment of patients with moderate-to-severe IBD is typically anti-inflammatory agents; however, none of these therapies address fibrosis, or scarring, in IBD. Since the approval of the first anti-TNF agent for the treatment of CD in 1998, the availability of JAK inhibitors and newer biological agents, including anti-integrin and anti-IL12/23, has improved the care of moderate-to-severe IBD (JAK inhibitors in UC only). However, these subsequently approved therapies have generally failed to demonstrate a clinical remission effect size of more than 15% relative to placebo. Moreover, among those patients who do respond to therapy, up to 45% will lose response over time. Current therapies used for the treatment of UC and CD apply a one-size-fits-all approach without regard to biologic variations amongst patients, and substantial unmet need remains.

IBD is estimated to affect over 2,000,000 people in the United States and over 5,000,000 people globally. The IBD market was approximately $12.5 billion in the United States and $18.4 billion globally in 2019 and is expected to grow to approximately $14.2 billion in the United States and $21.4 billion globally by 2024.
Our Precision Medicine Approach

Precision medicine involves the discovery and development of therapies that integrate clinical and molecular information based on the biological basis of disease to improve clinical decision-making and patient outcomes. We are pioneering the application of precision medicine in IBD because we believe that by leveraging Prometheus 360 we can identify novel therapeutic targets impacting the underlying pathways involved in IBD and the patient subgroups that will be responsive to a particular therapy.

We believe we have the potential to transform the entire IBD pharmaceutical value chain from discovery to commercialization with our precision medicine approach. Our Prometheus 360 platform includes our extensive clinical database and associated biobank, which is one of the world’s largest collections of biospecimens from patients suffering from IBD and other GI disorders. This database and biobank, which we exclusively license from Cedars-Sinai Medical Center (Cedars-Sinai), includes more than 200,000 samples linked to extensive clinical data from over 20,000 patients collected over more than 20 years. This, in combination with our state-of-the-art machine-learning methodologies, makes Prometheus 360 a discovery engine for novel precision therapeutics and companion diagnostics. IBD development programs can take seven to ten years to complete and physicians are often challenged with the task of enrolling patients from a limited pool of qualified candidates into a large number of trials with undifferentiated mechanisms of action. By using companion diagnostics to target a specific subset of the IBD population, we expect to reduce overall development time and cost through smaller trials and faster enrollment rates. We believe our precision medicine approach will result in a greater likelihood of identifying and developing the right drug for the right patient, help to maximize patient and trial outcomes, improve label claims, accelerate adoption of targeted therapeutics for addressable patients and provide attractive treatment options from a cost-benefit perspective for payors.

Our Portfolio

We have a robust pipeline of therapeutic development programs to address several clinical IBD patient subpopulations, and plan to develop a companion diagnostic for each program. The following table summarizes our key current internal and partnered programs.

<table>
<thead>
<tr>
<th>PROGRAM</th>
<th>DISCOVERY</th>
<th>LEAD OPTIMIZATION</th>
<th>IND ENABLING</th>
<th>PHASE 1</th>
<th>PHASE 2</th>
<th>PHASE 3</th>
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<tbody>
<tr>
<td>PRA023</td>
<td>Anti-TL1A mAb</td>
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<td>PR600</td>
<td>Anti-TNF Super Family Member mAb</td>
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<td>Takeda</td>
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<td>PR399</td>
<td>GPCR Modulator Small Molecule</td>
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<td>TPR15</td>
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<td>Takeda</td>
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(1) We retain all commercialization rights to PR600 outside of Europe, Australia and New Zealand.
(2) We are developing a companion diagnostic in tandem with Takeda’s drug discovery and development efforts. Takeda has an option to collaborate on an additional program.

In addition, we have five other programs with different mechanisms of action targeting UC and/or CD that are in the discovery stage of development.
PRA023 Overview – anti-TL1A mAb

Our lead product candidate, PRA023, is an IgG1 humanized mAb that has been shown to block TL1A. Third-party antibody programs against this target have been shown to reduce both intestinal inflammation and fibrosis in preclinical studies, and this target has been clinically-validated in a third-party Phase 2a clinical trial in UC. PRA023 binds both soluble and membrane-associated human TL1A with high affinity and specificity and has the potential to substantially improve outcomes for moderate-to-severe IBD patients predisposed to increased TL1A expression. We are developing PRA023 for the treatment of UC and CD, and expect to initiate a Phase 1a clinical trial in normal healthy volunteers in the fourth quarter of 2020. Assuming favorable safety results in this trial, we expect to commence in parallel in 2021 a Phase 1b/2a randomized placebo-controlled clinical trial in patients with moderate-to-severe UC and an open-label Phase 1b clinical trial in patients with moderate-to-severe CD, with data reported in the second quarter of 2022 for both indications. We are also developing a genetic-based companion diagnostic to identify patients who are predisposed to increased expression of TL1A and therefore potentially more likely to respond to PRA023. We intend to evaluate and use this companion diagnostic starting with the Phase 1b/2a UC trial and the Phase 1b CD trial.

PR600 Overview – Anti-TNF Super Family Member mAb

Our PR600 program targets a member of the TNF super family, whose expression is limited to immune cells. It has been shown that blocking this target inhibits disease in multiple third-party IBD animal models. We believe that a therapeutic developed against this target is likely to impede both the reactivation and propagation of the pathogenic immune response in IBD. We have identified multiple genetic variants linked to patient subpopulations with a complicated course of disease. We have conducted functional genetic studies in patient samples and have identified genetic variations associated with an increase in target expressing immune cells in CD peripheral blood and an increased capacity to produce inflammatory cytokines. We intend to leverage Prometheus 360 in combination with functional assays to identify patients with these genetic variants. We entered into a co-development and manufacturing agreement (the Falk Agreement) with Dr. Falk Pharma GmbH (Falk) for our PR600 program, in order to leverage Falk’s experience in GI drug development and commercialization in Europe. Under this agreement, we granted to Falk exclusive commercialization rights in Europe, Australia and New Zealand, while we retained commercialization rights in the United States and the rest of the world for therapeutics developed from our PR600 program. We expect to submit an IND for a therapeutic candidate from the PR600 program in the fourth quarter of 2022.

PR300 Overview – GPCR Modulator Small Molecule

Our PR300 program targets an orphan G-protein coupled receptor (GPCR) expressed predominantly in the GI tract that we believe has important functions underlying intestinal epithelial integrity and innate immune cell function. We have identified a coding single nucleotide polymorphism (SNP) in the gene of this target that represents a very strong genetic association with UC. Through further datamining, we have also identified multiple additional genetic variants that are associated with both UC and CD. These variants are linked to hard-to-treat clinical patient subpopulations, including those with medically refractory UC and perianal CD. We expect to submit an IND for a therapeutic candidate from the PR300 program by the end of 2023.

Other Development Programs and Takeda-Partnered Program

We have five other unpartnered programs with different mechanisms of action targeting UC and/or CD that are in the discovery stage of development. In addition, we are collaborating with Millennium Pharmaceuticals, Inc., a wholly owned subsidiary of Takeda Pharmaceutical Company Limited (Takeda), on the development of a preclinical program (TPR15) and related companion diagnostic for the treatment of UC and CD. Takeda has an option to collaborate with us on an additional target and its companion diagnostic.
Our Diagnostic Franchise

Our diagnostic franchise is comprised of laboratory developed tests (LDTs) we commercialize and our companion diagnostic tests in development. In June 2019, we acquired Prometheus Laboratories, Inc. (PLI) from Nestlé Health Sciences US Holdings, Inc. (Nestlé). Through this business, we market and conduct several LDTs used by gastroenterologists to monitor their IBD patients’ disease state and inform their therapeutic decisions, and have a Clinical Laboratory Improvement Amendments (CLIA)-certified laboratory located in San Diego, California. In addition, we plan to develop companion diagnostic tests in parallel with each of our therapeutic product candidates. Our commercial diagnostic products enable us to gain additional insight from gastroenterologists as we develop our therapeutic candidates and prioritize new targets.

Our Team

Our team is comprised of leaders and scientists with significant experience in IBD and other GI diseases, data analytics, biology and drug development. Mark McKenna, our President and Chief Executive Officer, was previously President at Salix Pharmaceuticals, Inc., a wholly owned subsidiary of Bausch Health Companies Inc., where he was responsible for the company’s GI franchise and launched several new products. Other members of our management team have served in senior positions at AbbVie Inc., Bristol-Myers Squibb Company, GlaxoSmithKline plc, Pfizer Inc. and Takeda. We are also guided by our board of directors, led by Chairman Tadataka (Tachi) Yamada, M.D., and a scientific advisory board composed of key opinion leaders in IBD, including Stephan Targan, M.D., William Sandborn, M.D. and Dermot P. McGovern, M.D., Ph.D.

Our Strengths

We believe that our company has the following key differentiating competitive strengths:

- We use a novel precision medicine approach to target the IBD market, which is primed for disruption.
- Our proprietary Prometheus 360 platform is a discovery engine for novel precision therapeutics and companion diagnostics.
- Our lead product candidate, PRA023, targets a clinically-validated TL1A pathway and has the potential to be a differentiated treatment with improved patient outcomes.
- Our platform has attracted partnerships with leading global pharmaceutical companies in the field of IBD.
- We have an established GI-focused commercial diagnostic franchise, which helps enable our precision medicine approach.
- We have assembled an experienced team comprised of industry leaders with drug discovery, development and commercialization expertise.

Our Strategy

Our goal is to revolutionize the treatment of IBD with a precision medicine approach for patients with significant unmet medical needs. The key elements of our strategy to achieve this goal are:

- Maximize the value of our Prometheus 360 precision medicine platform for the treatment of IBD.
- Rapidly advance PRA023 into the clinic and potentially accelerate its development by utilizing our companion diagnostic to identify patients who we expect to benefit from treatment.
- Advance our other programs, including PR600, into and through the clinic.
• Continue leveraging Prometheus 360 to expand our pipeline to address additional patient subpopulations.
• Selectively enter into strategic collaborations to maximize the value of our therapeutic pipeline.

Risks Related to Our Business

Our ability to execute our business strategy is subject to numerous risks, as more fully described in the section titled “Risk Factors” immediately following this Prospectus Summary. These risks include, among others:

• We have a limited operating history, have incurred significant operating losses since our inception and expect to incur significant losses for the foreseeable future. We may not be able to generate sufficient revenue to achieve and maintain profitability.
• In the near term, our ability to generate revenue will depend primarily on sales of our testing products and collaboration revenue.
• We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our development programs, commercialization efforts or other operations.
• Our approach to the discovery and development of precision medicines based on our Prometheus 360 platform is unproven, and we do not know whether we will be able to develop any therapeutics or diagnostic products of commercial value, or if competing technological approaches will limit the commercial value of our product candidates and companion diagnostics or render Prometheus 360 obsolete.
• We are early in our development efforts and all of our development programs are in the preclinical or discovery stage. If we are unable to successfully develop, obtain regulatory approval and ultimately commercialize product candidates and related companion diagnostics, or experience significant delays in doing so, our business will be materially harmed.
• Preclinical and clinical development involves a lengthy and expensive process with an uncertain outcome, and the results of preclinical studies and early clinical trials are not necessarily predictive of future results. We have not tested any of our product candidates in clinical trials and our product candidates may not have favorable results in clinical trials, if any, or receive regulatory approval on a timely basis, if at all.
• Any difficulties or delays in the commencement or completion, or termination or suspension, of our planned clinical trials could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.
• We have entered, and may in the future seek to enter into, collaborations, licenses and other similar arrangements and may not be successful in doing so, and even if we are, we may relinquish valuable rights and may not realize the benefits of such relationships.
• We rely on third parties to conduct many of our preclinical studies and clinical trials and to manufacture our product candidates, and these third parties may not perform satisfactorily.
• We face significant competition, and if our competitors develop technologies or product candidates more rapidly than we do or their technologies are more effective, our ability to develop and successfully commercialize products may be adversely affected.
• If we are unable to obtain and maintain patent protection for our therapeutic and diagnostic programs and other proprietary technologies we may develop, or if the scope of the patent protection obtained is
not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize our therapeutic and diagnostic programs and other proprietary technologies we may develop may be adversely affected.

- We may not be able to protect our intellectual property and proprietary rights throughout the world.
- We depend on intellectual property licensed from third parties, and our licensors may not always act in our best interest. If we fail to comply with our obligations under our intellectual property licenses, if the licenses are terminated or if disputes regarding these licenses arise, we could lose significant rights that are important to our business.

Corporate Information

We were originally founded as a Delaware corporation on October 26, 2016, under the name Precision IBD, Inc. On October 3, 2019, we changed our name to Prometheus Biosciences, Inc. Our principal executive offices are located at 9410 Carroll Park Drive, San Diego, California 92121, and our telephone number is 858-824-0895. Our website address is www.prometheusbiosciences.com. The information contained in, or accessible through, our website does not constitute part of this prospectus. We have included our website address as an inactive textual reference only.

Implications of Being an Emerging Growth Company and a Smaller Reporting Company

As a company with less than $1.07 billion in revenue during our last fiscal year, we qualify as an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012 (the JOBS Act). An emerging growth company may take advantage of reduced reporting requirements that are otherwise applicable to public companies. These provisions include, but are not limited to:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced “Management’s Discussion and Analysis of Financial Condition and Results of Operations” disclosure;
- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or Sarbanes-Oxley Act;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements, unless the SEC determines the new rules are necessary for protecting the public;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We may take advantage of these provisions until the last day of our fiscal year following the fifth anniversary of the date of the first sale of our common equity securities pursuant to an effective registration statement under the Securities Act of 1933, as amended (the Securities Act), which such fifth anniversary will occur in 2025. However, if certain events occur prior to the end of such five-year period, including if we become
a “large accelerated filer” as defined in Rule 12b-2 under the Securities Exchange Act of 1934 (the Exchange Act), our annual gross revenues exceed $1.07 billion or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period.

We have elected to take advantage of certain of the reduced disclosure obligations in this prospectus and in the registration statement of which this prospectus is a part and may elect to take advantage of other reduced reporting requirements in future filings. As a result, the information in this prospectus and that we provide to our stockholders in the future may be different than what you might receive from other public reporting companies in which you hold equity interests.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. We have irrevocably elected to avail ourselves of this exemption and, therefore, we will not be subject to the same timing of adoption of new or revised accounting standards as other public companies that are not emerging growth companies.

We are also a smaller reporting company as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our voting and non-voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.
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<th><strong>The Offering</strong></th>
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<tr>
<td>Common stock offered by us</td>
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<tr>
<td>Option to purchase additional shares</td>
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<tr>
<td>Common stock to be outstanding immediately after this offering</td>
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<tr>
<td>Use of proceeds</td>
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<tr>
<td>Risk factors</td>
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<td>Proposed Nasdaq Global Market symbol</td>
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The number of shares of our common stock to be outstanding after this offering set forth above is based on 111,239,386 shares of our common stock outstanding as of June 30, 2020, including 1,764,870 shares subject to forfeiture or our right of repurchase, after giving effect to the automatic conversion of all outstanding shares of our convertible preferred stock into 94,709,367 shares of our common stock immediately prior to the closing of this offering, and excludes:

- 15,382,110 shares of common stock issuable upon the exercise of outstanding stock options as of June 30, 2020, at a weighted-average exercise price of $0.22 per share;
- 2,379,000 shares of common stock issuable upon the exercise of stock options granted after June 30, 2020, at a weighted-average exercise price of $0.31 per share;
- 112,500 shares of common stock issuable upon the exercise of outstanding warrants as of June 30, 2020, at a weighted-average exercise price of $1.00 per share;
- shares of common stock reserved for future issuance under our 2020 Incentive Plan (the 2020 Plan), which will become effective in connection with this offering (which number does not include any potential evergreen increases pursuant to the terms of the 2020 Plan); and
- shares of common stock reserved for future issuance under our 2020 Employee Stock Purchase Plan (the ESPP), which will become effective in connection with this offering (which number does not include any potential evergreen increases pursuant to the terms of the ESPP).

Unless otherwise indicated, all information contained in this prospectus assumes or gives effect to:

- the filing and effectiveness of our amended and restated certificate of incorporation and the adoption of our amended and restated bylaws, each of which will occur immediately prior to the closing of this offering;
- the automatic conversion of all outstanding shares of our convertible preferred stock into 94,709,367 shares of our common stock immediately prior to the closing of this offering;
the conversion of outstanding warrants to purchase 112,500 shares of our Series C convertible preferred stock into warrants to purchase 112,500 shares of our common stock immediately prior to the closing of this offering;

- for- reverse stock split of our common stock to be effected before the closing of this offering;

no exercise of the outstanding options or warrants described above; and

no exercise by the underwriters of their option to purchase additional shares of our common stock.
**Summary Financial Data**

The following tables set forth a summary of our historical financial data as of, and for the periods ended on, the dates indicated. We have derived the summary statements of operations data for the years ended December 31, 2018 and 2019 from our audited consolidated financial statements included elsewhere in this prospectus. You should read these data together with our consolidated financial statements and related notes included elsewhere in this prospectus and the sections titled “Selected Financial Data” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” Our historical results for any prior period are not necessarily indicative of our future results.

<table>
<thead>
<tr>
<th>(in thousands, except share and per share data)</th>
<th>Years Ended December 31,</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2018</td>
</tr>
<tr>
<td><strong>Statements of Operations Data:</strong></td>
<td></td>
</tr>
<tr>
<td>Revenues:</td>
<td></td>
</tr>
<tr>
<td>Diagnostic services revenue</td>
<td>$ —</td>
</tr>
<tr>
<td>Collaboration revenue</td>
<td>—</td>
</tr>
<tr>
<td>Total revenues</td>
<td>—</td>
</tr>
<tr>
<td>Operating costs and expenses:</td>
<td></td>
</tr>
<tr>
<td>Cost of revenues</td>
<td>—</td>
</tr>
<tr>
<td>Research and development</td>
<td>4,386</td>
</tr>
<tr>
<td>Sales and marketing expense</td>
<td>—</td>
</tr>
<tr>
<td>General and administrative</td>
<td>2,413</td>
</tr>
<tr>
<td>Amortization of intangibles</td>
<td>—</td>
</tr>
<tr>
<td>Restructuring</td>
<td>—</td>
</tr>
<tr>
<td>Total operating costs and expenses</td>
<td>6,799</td>
</tr>
<tr>
<td>Loss from operations</td>
<td>(6,799)</td>
</tr>
<tr>
<td>Other income (expense):</td>
<td></td>
</tr>
<tr>
<td>Interest income</td>
<td>5</td>
</tr>
<tr>
<td>Interest expense</td>
<td>—</td>
</tr>
<tr>
<td>Total other income (expense)</td>
<td>5</td>
</tr>
<tr>
<td>Loss before income taxes</td>
<td>(6,794)</td>
</tr>
<tr>
<td>Income tax expense (benefit)</td>
<td>1</td>
</tr>
<tr>
<td>Net loss</td>
<td>$ (6,795)</td>
</tr>
<tr>
<td>Net loss per share, basic and diluted(1)</td>
<td>$ (0.91)</td>
</tr>
<tr>
<td>Weighted-average shares of common stock outstanding, basic and diluted(1)</td>
<td>7,471,474</td>
</tr>
<tr>
<td>Pro forma net loss per share, basic and diluted (unaudited)(1)</td>
<td></td>
</tr>
<tr>
<td>Pro forma weighted-average shares of common stock outstanding, basic and diluted (unaudited)(1)</td>
<td></td>
</tr>
</tbody>
</table>

(1) See Note 2 to our consolidated financial statements included elsewhere in this prospectus for an explanation of the method used to calculate the historical and pro forma net loss per share, basic and diluted, and the number of shares used in the computation of the per share amounts.
### Balance Sheet Data:

<table>
<thead>
<tr>
<th></th>
<th>Actual</th>
<th>Pro Forma (1)</th>
<th>Pro Forma As Adjusted (2)(3)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(in thousands)</td>
<td>(unaudited)</td>
<td>(unaudited)</td>
</tr>
<tr>
<td>Cash and cash equivalents</td>
<td>$8,371</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Working capital (4)</td>
<td>5,658</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total assets</td>
<td>50,483</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amounts due to Nestlé – related party, non-current</td>
<td>8,335</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acquisition-related consideration held in escrow</td>
<td>3,500</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Convertible preferred stock</td>
<td>43,740</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Accumulated deficit</td>
<td>(37,451)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total stockholders’ (deficit) equity</td>
<td>(36,968)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(1) Gives effect to the automatic conversion of all outstanding shares of our convertible preferred stock into an aggregate of 94,709,367 shares of our common stock and the related reclassification of the carrying value of the convertible preferred stock to permanent equity immediately prior to the closing of this offering.

(2) Gives effect to (i) the pro forma adjustments set forth in footnote (1) above, and (ii) the issuance and sale of shares of our common stock in this offering at the assumed initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each $1.00 increase (decrease) in the assumed initial public offering price of $ per share would increase (decrease) the pro forma as adjusted amount of each of our cash and cash equivalents, working capital, total assets and total stockholders’ equity (deficit) by approximately $ , assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each increase (decrease) of 1.0 million shares in the number of shares offered by us at the assumed initial public offering price of $ per share would increase (decrease) the pro forma as adjusted amounts of each of our cash and cash equivalents, working capital, total assets and total stockholders’ equity (deficit) by approximately $ , after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

(3) The pro forma and pro forma as adjusted information discussed above is illustrative only and will be adjusted based on the actual initial public offering price and other terms of our initial public offering determined at pricing.

(4) We define working capital as total current assets less total current liabilities. See our consolidated financial statements included elsewhere in this prospectus for further details regarding our current assets and current liabilities.
RISK FACTORS

Investing in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information in this prospectus, including our consolidated financial statements and related notes included elsewhere in this prospectus and in “Management’s Discussion and Analysis of Financial Condition and Results of Operations”, before making an investment decision. If any of the following risks are realized, our business, financial condition, results of operations and prospects could be materially and adversely affected. In that event, the trading price of our common stock could decline and you could lose part or all of your investment.

Risks Related to Our Limited Operating History, Financial Position and Capital Requirements

We have a limited operating history, have incurred significant operating losses since our inception and expect to incur significant losses for the foreseeable future. We may not be able to generate sufficient revenue to achieve and maintain profitability.

The development of product candidates, including therapeutic product candidates and companion diagnostic tests, is a highly speculative undertaking and involves a substantial degree of risk. All of our development programs, including our lead product candidate, PRA023, are in preclinical development or in the discovery stage. We commenced operations in 2016, and to date, we have focused primarily on organizing and staffing our company, business planning, raising capital, developing Prometheus 360, discovering and identifying product candidates, acquiring and integrating our diagnostic services business, establishing our intellectual property portfolio and conducting research and preclinical studies. Our approach to the discovery and development of product candidates based on Prometheus 360 is unproven, and we do not know whether we will be able to develop any product candidates that succeed in clinical development or products of commercial value. As an organization, we have not yet completed any clinical trials, successfully developed and validated a companion diagnostic test, obtained regulatory approvals, manufactured a commercial-scale product, or arranged for a third party to do so on our behalf, or conducted sales and marketing activities necessary for successful product commercialization. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing therapeutic products and companion diagnostics.

To date, we have only generated revenue from our diagnostic services business, which we acquired from Nestlé on June 30, 2019, and our collaboration agreements with Takeda and Falk. We have incurred significant operating losses since our inception. We do not have any product candidates approved for sale, and we may never generate any significant revenue from product sales. Our net losses were $6.8 million and $29.7 million for the years ended December 31, 2018 and December 31, 2019, respectively, and $ for the six months ended June 30, 2020. As of June 30, 2020, we had an accumulated deficit of $ . Substantially all of our losses have resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations. All of our development programs will require substantial additional development time and resources before we would be able to apply for or receive regulatory approvals and begin generating revenue from product sales. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase substantially as we continue our development of, seek regulatory approval for, and potentially commercialize any of our therapeutic product candidates and companion diagnostics. Additionally, due to our short history of selling our laboratory developed tests (LDTs), any predictions about the future success, performance or viability of our diagnostic services business may not be as accurate as they could be if we had a longer history of selling such testing products.

To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials of our product candidates, identifying lead product candidates, discovering additional product candidates, obtaining regulatory approval for these product candidates and manufacturing, marketing and selling any products for which we may obtain regulatory approval. We are
only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability. In addition, we have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biotechnology industry. Because of the numerous risks and uncertainties associated with biopharmaceutical and companion diagnostic product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable may have an adverse effect on the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product candidates or even continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

In the near term, our ability to generate diagnostic services revenue will depend primarily on sales of our testing products and collaboration revenue.

In connection with our acquisition of PLI in June 2019, we began to generate revenue for the sale of commercially available LDTs. A significant part of this revenue has been derived from the sale of our lead diagnostic test, Anser, which accounted for 38% of our diagnostic service revenue in the year ended December 31, 2019. In the near term, we expect to continue to derive a significant portion of our revenue from sales of Anser, as well as our other LDTs and potential future revenue under our collaboration agreements. We are in various stages of research and development with respect to other testing products that we may offer, but there can be no assurance that we will be able to commercialize these testing products.

The demand for our testing products may decrease or may not continue to increase at historical rates for a number of reasons, including as a result of our taking over the diagnostic services business from Nestlé. In addition, at any point in time we may decide to no longer commercialize any of our testing products for any number of reasons and we may not be able to maintain existing revenue levels. Further, we cannot ensure the continued availability of our testing products in commercial quantities at acceptable costs. If we are unable to increase sales of our testing products, expand reimbursement for our testing products, or successfully develop and commercialize additional testing products, our revenue from our diagnostic services business and our ability to achieve and sustain profitability in that business would be impaired, and the market price of our common stock could decline.

In addition, our ability to generate revenue from our collaboration arrangements will depend, in part, on our collaborators’ willingness to successfully develop and commercialize the applicable development programs. Revenue from these collaborations will depend upon continuation of the collaborations, the achievement of development, regulatory, commercial and sales milestones and royalties, if any. If we and our collaborators are unable to successfully advance the applicable development programs or achieve milestones, we may never be able to generate significant collaboration revenue.

We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our development programs, commercialization efforts or other operations.

The development of therapeutic product candidates and companion diagnostics is capital-intensive. We expect our expenses to increase in connection with our ongoing activities, particularly as we conduct our ongoing and planned preclinical studies of our development programs, initiate clinical trials for our therapeutic product candidates and companion diagnostics, and seek regulatory approval for our current therapeutic product candidates and companion diagnostics and any future therapeutic product candidates and companion diagnostics we may develop. If we obtain regulatory approval for any of our therapeutic product candidates and companion diagnostics, we also expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. Because the outcome of any preclinical study or clinical trial is highly
uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our therapeutic product candidates or companion diagnostics. Furthermore, following the completion of this offering, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

We believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will enable us to fund our operations for at least the next months. In particular, we expect that the net proceeds from this offering and our existing cash and cash equivalents will allow us to . We have based these estimates on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Our operating plans and other demands on our cash resources may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings or other capital sources, including potentially additional collaborations, licenses and other similar arrangements. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. Attempting to secure additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop our product candidates.

Our future capital requirements will depend on many factors, including, but not limited to:

- the type, number, scope, progress, expansions, results, costs and timing of discovery, preclinical studies and clinical trials of our product candidates which we are pursuing or may choose to pursue in the future;
- the financial results of our diagnostic services business;
- the costs and timing of manufacturing for our product candidates and commercial manufacturing if any product candidate is approved;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs and timing of developing our companion diagnostics, and the outcome of regulatory review;
- the success of our current and any future collaborations, including the timing and amount of the milestone or other payments made to us under our companion diagnostics development and collaboration agreement with Takeda (the Takeda Agreement), our co-development and manufacturing agreement with Dr. Falk Pharma GmbH (the Falk Agreement) or any future collaboration agreements;
- the costs of obtaining, maintaining and enforcing patents and other intellectual property rights;
- the additional costs we may incur as a result of operating as a public company, including our efforts to enhance operational systems and hire additional personnel, including enhanced internal controls over financial reporting;
- the timing and amount of payments that we must make to the licensors and other third parties from whom we have in-licensed intellectual property rights related to Prometheus 360 and products and product candidates;
- the costs associated with hiring additional personnel and consultants as our preclinical and clinical activities increase;
- the costs and timing of maintaining our sales and marketing capabilities and any expansion thereof, including if any product candidate is approved;
- our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third-party payors and adequate market share and revenue for any approved products and companion diagnostics;
Identifying potential product candidates and conducting preclinical studies and clinical trials is a time consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and commercialize our therapeutic product candidates and companion diagnostics. In addition, our product candidates, if approved, may not achieve commercial success. Our therapeutic commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if at all.

Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

**Raising additional capital may cause dilution to our stockholders, including purchasers of common stock in this offering, restrict our operations or require us to relinquish rights to our technologies, product candidates or testing products.**

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through equity offerings, debt financings, or other capital sources, including potential additional collaborations, licenses and other similar arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Our loan and security agreement (the Loan Agreement) with Oxford Finance LLC (Oxford) involves, and any future debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, selling or licensing our assets, making capital expenditures, declaring dividends orencumbering our assets to secure future indebtedness. Such restrictions could adversely impact our ability to conduct our operations and execute our business plan.

If we raise additional funds through future collaborations, licenses and other similar arrangements, we may have to relinquish valuable rights to our future revenue streams, research programs, product candidates, Prometheus 360 or testing products, or grant licenses on terms that may not be favorable to us and/or that may reduce the value of our common stock. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed or on terms acceptable to us, we would be required to delay, limit, reduce, or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates or testing products that we would otherwise prefer to develop and market ourselves.

**Our independent registered public accounting firm has included an explanatory paragraph relating to our ability to continue as a going concern in its report on our audited financial statements included in this prospectus.**

The report of our independent registered public accounting firm on our consolidated financial statements as of and for the year ended December 31, 2019 includes an explanatory paragraph indicating that there is substantial doubt about our ability to continue as a going concern. If we are unable to raise sufficient capital when needed, our business, financial condition and results of operations will be materially and adversely affected, and we will need to significantly modify our operational plans to continue as a going concern. If we are unable to continue as a going concern, we might have to liquidate our assets and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our consolidated financial statements. The inclusion of a going concern explanatory paragraph by our auditors, our lack of cash resources and our potential inability to continue as a going concern may materially adversely affect our share price and our ability to raise new capital or to enter into critical contractual relations with third parties.
Risks Related to the Discovery, Development and Regulatory Approval of Our Product Candidates, including our Therapeutic Product Candidates and Companion Diagnostics

Our approach to the discovery and development of precision medicines based on Prometheus 360 is unproven, and we do not know whether we will be able to develop any therapeutics or diagnostic products of commercial value, or if competing technological approaches will limit the commercial value of our therapeutic product candidates and companion diagnostics or render Prometheus 360 obsolete.

We have concentrated our therapeutic product research and development efforts on the application of precision medicine to the treatment and diagnosis of IBD, and our future success depends on the successful development of products based on Prometheus 360 and the continued development of this platform. However, neither we nor any other company has received regulatory approval to market therapeutics targeting specific subpopulations of IBD patients. The success of our business depends primarily upon our ability to identify, develop and commercialize precision medicine products based on Prometheus 360, which leverages a novel and unproven approach of applying data analytics and machine learning to the thousands of samples available to us through the biobank we license from Cedars-Sinai Medical Center (Cedars-Sinai). While we have had favorable preclinical study results utilizing Prometheus 360, we have not yet succeeded and may not succeed in demonstrating efficacy and safety for any product candidates in clinical trials or in obtaining marketing approval thereafter. Our lead therapeutic product candidate, PRA023, is in late preclinical development and we have not yet completed any clinical trials for any product candidate. Our research methodology and novel approach to precision medicine for IBD may be unsuccessful in identifying additional therapeutic product candidates, and any therapeutic product candidates discovered using Prometheus 360 may be shown to have harmful side effects or may have other characteristics that may necessitate additional clinical testing, or make the therapeutic product candidates unmarketable or unlikely to receive marketing approval. Further, because all of our therapeutic product candidates and development programs utilize Prometheus 360, adverse developments with respect to one of our programs may have a significant adverse impact on the actual or perceived likelihood of success and value of our other programs.

In addition, the biotechnology and biopharmaceutical industries are characterized by rapidly advancing technologies. Our future success will depend in part on our ability to maintain a competitive position with Prometheus 360, which relies on our ability to access the biobank owned and controlled by Cedars-Sinai as well as to maintain our exclusive license with Cedars-Sinai. If access to the biobank is lost or limited, it may materially and adversely affect our ability to create and develop therapeutic product candidates and companion diagnostics, and compete effectively. Our competitors may render our approach obsolete, or limit the commercial value of our therapeutic product candidates and companion diagnostics, by advances in existing technological approaches or the development of new or different approaches, potentially eliminating the advantages in our drug discovery process that we believe we derive from our research approach and proprietary technologies. By contrast, adverse developments with respect to other companies that attempt to use a similar approach to our approach may adversely impact the actual or perceived value of Prometheus 360 and potential of our product candidates.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs, which would have a material adverse effect on our business and could potentially cause us to cease operations.

We are early in our development efforts and all of our development programs are in the preclinical or discovery stage. If we are unable to successfully develop, obtain regulatory approval for and ultimately commercialize therapeutic product candidates and related companion diagnostics, or experience significant delays in doing so, our business will be materially harmed.

We are in the early stages of our development efforts and all of our development programs, including PRA023, are in the preclinical or drug discovery stage. We have invested substantially all of our efforts in developing Prometheus 360, identifying potential therapeutic product candidates and conducting preclinical
studies. We will need to progress PRA023 and our other therapeutic product candidates through IND-enabling studies and receive authorization from the Food and Drug Administration (FDA) to proceed under an IND prior to initiating their clinical development. Our ability to generate therapeutic product revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our product candidates. In addition, our therapeutic development programs contemplate the development of companion diagnostics, which are assays or tests designed to identify an appropriate patient populations. Companion diagnostics are subject to regulation as medical devices and must themselves be approved for marketing by the FDA or certain other foreign regulatory agencies before we may commercialize our product candidates. The success of our product candidates will depend on several factors, including the following:

- successful completion of preclinical studies with favorable results, including those compliant with good laboratory practice (GLP) toxicology studies, biodistribution studies and minimum effective dose studies in animals;
- acceptance of INDs by the FDA, or similar regulatory filing by comparable foreign regulatory authorities for the conduct of clinical trials of PRA023 and our other therapeutic product candidates and our proposed design of future clinical trials;
- successful enrollment in clinical trials and completion of clinical trials with favorable results;
- demonstrating safety and efficacy, or in the case of our therapeutic product candidates regulated as biologics, safety, purity and potency, to the satisfaction of applicable regulatory authorities;
- successful development and validation of companion diagnostics for use with our product candidates, if required;
- the performance of our collaborators;
- receipt of marketing approvals from applicable regulatory authorities for our product candidates, including new drug applications (NDAs) or biologics license applications (BLAs) from the FDA, and the premarket approvals (PMAs) from the FDA for companion diagnostics required for our therapeutic product candidates, and maintaining such approvals;
- making arrangements with our third-party manufacturers for, or establishing, commercial manufacturing capabilities;
- establishing sales, marketing and distribution capabilities and launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- obtaining adequate coverage, reimbursement, and pricing policies for our products from governmental authorities and health insurers;
- the willingness of physicians and patients to utilize or adopt any of our product candidates or future product candidates over alternative or more conventional therapies;
- establishing, maintaining, defending and enforcing patent, trade secret and other intellectual property protection or regulatory exclusivity for our therapeutic product candidates;
- maintaining an acceptable safety profile of our products following approval; and
- maintaining and growing an organization of people who can develop and commercialize our products and technology.

If we are unable to develop, obtain regulatory approval for, or, if approved, successfully commercialize our therapeutic product candidates and companion diagnostics, we may not be able to generate sufficient revenue to continue our business.
Preclinical and clinical development involves a lengthy and expensive process with an uncertain outcome, and the results of preclinical studies and early clinical trials are not necessarily predictive of future results. We have not tested any of our product candidates in clinical trials and our product candidates may not have favorable results in clinical trials.

Preclinical and clinical development is expensive and can take many years to complete, and its outcome is inherently uncertain. We cannot guarantee that any preclinical studies or clinical trials will be conducted as planned or completed on schedule, if at all, and failure can occur at any time during the preclinical study or clinical trial process. Despite promising preclinical or clinical results, any product candidate can unexpectedly fail at any stage of preclinical or clinical development. The historical failure rate for product candidates in our industry is high.

The results from preclinical studies or clinical trials of a product candidate may not predict the results of later clinical trials of the product candidate, and interim, topline, or preliminary results of a clinical trial are not necessarily indicative of final results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy characteristics despite having progressed through preclinical studies and initial clinical trials. In particular, while we have conducted certain preclinical studies of PRA023 and other potential product candidates targeting IBD, we do not know whether PRA023 or the other potential product candidates will perform in future clinical trials as they have performed in these prior studies. The positive results we have observed for PRA023 in preclinical animal models may not be predictive of our future clinical trials in humans. It is not uncommon to observe results in clinical trials that are unexpected based on preclinical studies and early clinical trials, and many product candidates fail in clinical trials despite very promising early results. We are currently conducting IND-enabling studies for PRA023. If unexpected observations or toxicities are observed in these studies, or in IND-enabling studies for any of our other development programs, this will delay clinical trials for PRA023 or our other development programs. Moreover, preclinical and clinical data may be susceptible to varying interpretations and analyses. A number of companies in the biopharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving promising results in earlier studies.

For the foregoing reasons, we cannot be certain that our ongoing and planned preclinical studies and planned clinical trials will be successful.

Any difficulties or delays in the commencement or completion, or termination or suspension, of our planned clinical trials could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.

Before we can initiate clinical trials for our product candidates, we must submit the results of preclinical studies to the FDA or comparable foreign regulatory authorities along with other information, including information about product candidate chemistry, manufacturing and controls and our proposed clinical trial protocol, as part of an IND or, in the case of a companion diagnostic, an investigational device exemption (IDE) application or similar regulatory filing required for authorization to proceed with clinical development. The FDA or comparable foreign regulatory authorities may require us to conduct additional preclinical studies for any product candidate before it allows us to initiate clinical trials under any IND, IDE, or similar regulatory filing, which may lead to delays and increase the costs of our preclinical development programs. Any such delays in the commencement or completion of our planned clinical trials for PRA023 or any other product candidate could significantly affect our product development costs.

We do not know whether our planned trials will begin on time or be completed on schedule, if at all. The commencement and completion of clinical trials can be delayed for a number of reasons, including delays related to:

- obtaining regulatory authorizations to commence a trial or reaching a consensus with regulatory authorities on trial design;
the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical studies;

any failure or delay in reaching an agreement with contract research organizations (CROs) and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

obtaining approval from one or more institutional review boards (IRBs);

IRBs refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial;

changes to clinical trial protocol;

clinical sites deviating from trial protocol or dropping out of a trial;

manufacturing sufficient quantities of our product candidates for use in clinical trials;

subjects failing to enroll or remain in our trials at the rate we expect, or failing to return for post-treatment follow-up, including subjects failing to remain in our trials due to movement;

delays in developing and validating the companion diagnostic to be used in a clinical trial, if applicable;

we may be required to submit an IDE application to the FDA with respect to our companion diagnostic product candidates, which must become effective prior to commencing certain human clinical trials of medical devices, and the FDA may reject our IDE application and notify us that we may not begin clinical trials;

restrictions, health reasons or otherwise resulting from the novel strain of coronavirus, COVID-19;

subjects choosing an alternative treatment for the indication for which we are developing our therapeutic product candidates, or participating in competing clinical trials;

lack of adequate funding to continue the clinical trial;

subjects experiencing severe or unexpected drug-related adverse effects;

occurrence of serious adverse events in trials of the same class of agents conducted by other companies;

selection of clinical endpoints that require prolonged periods of clinical observation or analysis of the resulting data;

a facility manufacturing our product candidates or any of their components being ordered by the FDA or comparable foreign regulatory authorities to temporarily or permanently shut down due to violations of current good manufacturing practice (cGMP) regulations or other applicable requirements, or infections or cross-contaminations of product candidates in the manufacturing process;

any changes to our manufacturing process that may be necessary or desired;

third-party clinical investigators losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, good clinical practices (GCP) or other regulatory requirements;

third-party contractors not performing data collection or analysis in a timely or accurate manner; or

third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications.
In addition, disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned clinical trials. We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA or comparable foreign regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug or diagnostic, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

Further, conducting clinical trials in foreign countries, as we may do for our product candidates, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. Moreover, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues.

In addition, many of the factors that cause, or lead to, the termination or suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. We may make formulation or manufacturing changes to our product candidates, in which case we may need to conduct additional preclinical studies to bridge our modified product candidates to earlier versions. Any delays to our clinical trials that occur as a result could shorten any period during which we may have the exclusive right to commercialize our product candidates and our competitors may be able to bring products to market before we do, and the commercial viability of our product candidates could be significantly reduced. Any of these occurrences may harm our business, financial condition and prospects significantly.

**We may find it difficult to enroll patients in our clinical trials. If we encounter difficulties enrolling subjects in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.**

Patient enrollment is a significant factor in the timing of clinical trials, and the timing of our clinical trials depends, in part, on the speed at which we can recruit patients to participate in our trials, as well as completion of required follow-up periods. We may not be able to initiate or continue clinical trials for our product candidates if
we are unable to identify and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. Subject enrollment is affected by many factors including the size and nature of the patient population, the severity of the disease under investigation, the availability and efficacy of approved drugs and diagnostics for the disease under investigation, the proximity of patients to clinical sites, the eligibility and exclusion criteria for the trial, the design of the clinical trial, the risk that enrolled patients will not complete a clinical trial, our ability to recruit clinical trial investigators with the appropriate competencies and experience, patient referral practices of physicians, the ability to monitor patients adequately during and after treatment, competing clinical trials and clinicians’ and patients’ perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating as well as any product candidates under development.

We will be required to identify and enroll a sufficient number of subjects for each of our clinical trials. Utilizing our precision medicine approach, we plan to focus our development activities on genetically or biomarker defined patients that we believe will be most likely to respond to our therapeutic product candidates. As a result, the potential patient populations for our clinical trials are narrowed, and we may experience difficulties in identifying and enrolling a sufficient number of patients in our clinical trials. We may not be able to initiate or continue clinical trials if we are unable to locate a sufficient number of eligible subjects to participate in the clinical trials required by the FDA or comparable foreign regulatory authorities. In addition, the process of finding and diagnosing subjects may prove costly.

Our inability to enroll a sufficient number of subjects for any of our future clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. In addition, we expect to rely on CROs and clinical trial sites to ensure proper and timely conduct of our future clinical trials and, while we intend to enter into agreements governing their services, we will have limited influence over their actual performance.

We cannot assure you that our assumptions used in determining expected clinical trial timelines are correct or that we will not experience delays in enrollment, which would result in the delay of completion of such trials beyond our expected timelines.

**Use of our therapeutic product candidates could be associated with side effects, adverse events or other properties or safety risks, which could delay or preclude approval, cause us to suspend or discontinue clinical trials, abandon a therapeutic product candidate, limit the commercial profile of an approved label or result in other significant negative consequences that could severely harm our business, prospects, operating results and financial condition.**

We have not evaluated any product candidates in human clinical trials. As is the case with biopharmaceuticals generally, it is likely that there may be side effects and adverse events associated with our therapeutic product candidates’ use. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by our therapeutic product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Moreover, if our therapeutic product candidates are associated with undesirable side effects in clinical trials or have characteristics that are unexpected, we may elect to abandon their development or limit their development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective, which may limit the commercial expectations for the therapeutic product candidate, if approved. We may also be required to modify
our study plans based on findings after we commence our clinical trials. Many compounds that initially showed promise in early-stage testing have later been found to cause side effects that prevented further development of the compound. In addition, regulatory authorities may draw different conclusions or require additional testing to confirm these determinations.

It is possible that as we test our therapeutic product candidates in larger, longer and more extensive clinical trials, or as the use of these therapeutic product candidates becomes more widespread if they receive regulatory approval, illnesses, injuries, discomforts and other adverse events that were observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, may be reported by subjects. If such side effects become known later in development or upon approval, if any, such findings may harm our business, financial condition and prospects significantly.

Patients treated with our products, if approved, may experience previously unreported adverse reactions, and it is possible that the FDA or other regulatory authorities may ask for additional safety data as a condition of, or in connection with, our efforts to obtain approval of our therapeutic product candidates. If safety problems occur or are identified after our products, if any, reach the market, we may make the decision or be required by regulatory authorities to amend the labeling of our products, recall our products or even withdraw approval for our products.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular therapeutic product candidate, if approved, and could significantly harm our business, results of operations and prospects.

As an organization, we have never conducted any clinical trials or submitted an application for regulatory approval, and may be unable to do so for any of our product candidates.

We are early in our development efforts for our product candidates and we will need to successfully complete IND-enabling studies, Phase 1 clinical trials and later-stage and pivotal clinical trials, in order to obtain FDA or comparable foreign regulatory approval to market PRA023 or any other therapeutic product candidates. Carrying out clinical trials and the submission of a successful BLA or NDA is a complicated process. As an organization, we plan to commence our first Phase 1 clinical trial in the fourth quarter of 2020, subject to receiving authorization to proceed under an IND. We have not previously conducted any clinical trials, have limited experience as a company in preparing, submitting and prosecuting regulatory filings and have not previously submitted an IND or a BLA or NDA or other comparable foreign regulatory submission for any therapeutic product candidate. In addition, we have had limited interactions with the FDA and cannot be certain how many clinical trials of PRA023 or any other product candidates will be required or how such trials should be designed. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to regulatory submission and approval of any of our therapeutic product candidates. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of therapeutic product candidates that we develop. Failure to commence or complete, or delays in, our planned clinical trials, could prevent us from or delay us in submitting BLAs or NDAs for and commercializing our therapeutic product candidates.

Our product candidates are subject to extensive regulation and compliance, which is costly and time consuming, and such regulation may cause unanticipated delays or prevent the receipt of the required approvals to commercialize our product candidates.

The clinical development, manufacturing, labeling, packaging, storage, record-keeping, advertising, promotion, import, export, marketing, distribution and adverse event reporting, including the submission of safety and other information, of our product candidates are subject to extensive regulation by the FDA in the United States and by comparable foreign regulatory authorities in foreign markets. In the United States, we are not permitted to market our product candidates until we receive regulatory approval from the FDA. The process
of obtaining regulatory approval is expensive, often takes many years following the commencement of clinical trials and can vary substantially based upon the type, complexity and novelty of the product candidates involved, as well as the target indications and patient population. Approval policies or regulations may change, and the FDA has substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. Despite the time and expense invested in clinical development of product candidates, regulatory approval is never guaranteed. Neither we nor any current or future collaborator is permitted to market any of our product candidates in the United States until we receive approval from the FDA.

Prior to obtaining approval to commercialize a product candidate in the United States or abroad, we or our collaborators must demonstrate with substantial evidence from adequate and well-controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that such product candidates are safe and effective, or with respect to a biological product candidate, safe, pure and potent, for their intended uses. Results from preclinical studies and clinical trials can be interpreted in different ways. Even if we believe the preclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authorities, as the case may be, may also require us to conduct additional preclinical studies or clinical trials for our product candidates either prior to or post-approval, or may object to elements of our clinical development program.

The FDA or comparable foreign regulatory authorities can delay, limit or deny approval of a product candidate for many reasons, including:

- such authorities may disagree with the design or implementation of our or our current or future collaborators’ clinical trials;
- negative or ambiguous results from our clinical trials or results may not meet the level of statistical significance required by the FDA or comparable foreign regulatory agencies for approval;
- serious and unexpected drug-related side effects may be experienced by participants in our clinical trials or by individuals using drugs or biologics similar to our therapeutic product candidates;
- such authorities may not accept clinical data from trials which are conducted at clinical facilities or in countries where the standard of care is potentially different from that of the United States;
- we or any of our current or future collaborators may be unable to demonstrate that a product candidate is safe and effective, and that the therapeutic product candidate’s clinical and other benefits outweigh its safety risks;
- we may be unable to demonstrate to the satisfaction of such authorities that our companion diagnostics are suitable to identify appropriate patient populations;
- such authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- such authorities may not agree that the data collected from clinical trials of our product candidates are acceptable or sufficient to support the submission of a BLA, NDA, PMA or other submission or to obtain regulatory approval in the United States or elsewhere, and such authorities may impose requirements for additional preclinical studies or clinical trials;
- such authorities may disagree regarding the formulation, labeling and/or the specifications of our product candidates;
- approval may be granted only for indications that are significantly more limited than what we apply for and/or with other significant restrictions on distribution and use;
- such authorities may find deficiencies in the manufacturing processes, test procedures and specifications or facilities of our third-party manufacturers with which we or any of our current or future collaborators contract for clinical and commercial supplies;
regulations and approval policies of such authorities may significantly change in a manner rendering our or any of our potential future collaborators’ clinical data insufficient for approval; or

such authorities may not accept a submission due to, among other reasons, the content or formatting of the submission.

This lengthy approval process, as well as the unpredictability of the results of clinical trials, may result in our failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations and prospects. In addition, even if we obtain approval of our product candidates, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may impose significant limitations in the form of narrow indications, warnings, or a Risk Evaluation and Mitigation Strategy (REMS).

In addition, with respect to foreign markets, approval procedures vary among countries and, in addition to the foregoing risks, may involve additional product testing, administrative review periods and agreements with pricing authorities. In addition, events raising questions about the safety of certain marketed biopharmaceuticals may result in increased cautiousness by the FDA and comparable foreign regulatory authorities in reviewing new drugs or biologics based on safety, efficacy or other regulatory considerations and may result in significant delays in obtaining regulatory approvals. Any delay in obtaining, or inability to obtain, applicable regulatory approvals would prevent us or any of our potential future collaborators from commercializing our product candidates.

If we are unable to successfully develop companion diagnostics for our therapeutic product candidates, or experience significant delays in doing so, our therapeutic development strategy may be harmed and we may not realize the full commercial potential of our therapeutic product candidates.

Because we are focused on precision medicine, in which genetic alterations or predictive biomarkers will be used to identify the right patients for our product candidates, we believe that our success will depend, in part, on our ability to develop companion diagnostics, which are assays or tests to identify an appropriate patient population for these therapeutic product candidates. To achieve this, our development programs are dependent on the development and commercialization of a companion diagnostic by us. Companion diagnostics are developed in conjunction with clinical programs for the associated product and are subject to regulation as medical devices by the FDA and comparable regulatory authorities. In general, if the FDA determines that a companion diagnostic is essential to the safe and effective use of a novel therapeutic product or indication, the FDA will generally not approve the therapeutic product if the companion diagnostic is not also approved or cleared for that indication. Accordingly, the FDA expects to review and approve simultaneously the NDA or BLA and PMA submissions for a therapeutic and its companion diagnostic, respectively, so any delay in diagnostic approval could delay or prevent approval of the therapeutic product. The approval of a companion diagnostic as part of the product label will also limit the use of the therapeutic product candidate to only those patients who express the specific genetic alteration or biomarker it was developed to detect. Also, to the extent other approved diagnostics are able to broaden their labeling claims to include our approved therapeutic products, we may be forced to abandon our companion diagnostic development plans or we may not be able to compete effectively upon approval, which could adversely impact our ability to generate revenue from the sale of our approved products and our business operations.

In addition, it may be necessary to resolve issues such as selectivity/specificity, analytical validation, reproducibility, or clinical validation of companion diagnostics during the development and regulatory approval processes. Moreover, even if data from preclinical studies and early clinical trials appear to support development of a companion diagnostic for a therapeutic product candidate, data generated in later clinical trials may fail to support the analytical and clinical validation of the companion diagnostic. We may encounter difficulties in developing, obtaining regulatory approval for, manufacturing and commercializing companion diagnostics similar to those we face with respect to our therapeutic product candidates themselves, including issues with achieving regulatory clearance or approval, production of sufficient quantities at commercial scale and with appropriate quality standards, and in gaining market acceptance.
If we or any third parties we may engage are unable to successfully develop companion diagnostics for our therapeutic product candidates, or experience delays in doing so:

- we may be unable to identify appropriate patients for enrollment in our clinical trials, which may adversely affect the development of our therapeutic product candidates;
- our therapeutic product candidates may not receive marketing approval, if the FDA or other regulators determine that the safe and effective use of our therapeutic product candidates, if any, depends on the companion diagnostic; and
- we may not realize the full commercial potential of any therapeutics that receive marketing approval if, among other reasons, we are unable to appropriately select patients who are likely to benefit from therapy with our medicines, if any.

As a result of any of these events, our business, financial condition, results of operations and prospects could be materially and adversely affected.

We have limited experience in developing and commercializing companion diagnostics and have never applied for or obtained regulatory clearance or approval for any diagnostic tests.

To be successful in developing and commercializing therapeutic product candidates in combination with companion diagnostics, we will need to address a number of scientific, technical, regulatory and logistical challenges. We currently anticipate that we will need to obtain approval of PMA applications from the FDA in order to legally market companion diagnostics in the United States. As a company, while we currently market LDTs acquired from our PLI acquisition, we have little experience in the development of companion diagnostics and may not be successful in developing appropriate diagnostics to pair with any of our therapeutic product candidates that receive marketing approval, and have never applied for or obtained regulatory clearance or approval of any diagnostic tests. Given our limited experience in developing companion diagnostics, we may rely in part or in whole on third parties for their design, development and manufacture of such tests.

Before a new medical device, or a new intended use of, claim for, or significant modification to an existing device, can be marketed in the United States, a company must first submit an application for and receive 510(k) clearance pursuant to a premarket notification submitted under Section 510(k) of the Federal Food, Drug, and Cosmetic Act (FDCA), de-novo classification, or PMA approval from FDA, unless an exemption applies. The PMA approval pathway, which we expect to pursue for our companion diagnostic product candidates, requires an applicant to demonstrate the safety and effectiveness of the product based, in part, on valid scientific evidence, including, but not limited to, technical, preclinical, and clinical data. The 510(k) pathway requires a FDA finding that the test is substantially equivalent to a legally marketed predicate device. If no legally marketed predicate can be identified to enable use of the 510(k) pathway, the device is automatically classified under the FDCA into Class III, which generally requires PMA approval. However, for low- to moderate-risk novel devices, FDA allows for the possibility of marketing authorization through the “de novo classification” process rather than requiring the device to be subject to PMA approval. Products that are approved through a PMA application generally need prior FDA approval before modifications can be made that affect safety or effectiveness, and certain modifications to a 510(k)-cleared device may also require FDA premarket review before the modified product can be marketed. If we are unable to successfully develop, obtain regulatory clearance for and commercialize companion diagnostics to pair with our therapeutic product candidates, it could adversely impact our ability to develop and generate revenue from our product candidates.

We may expend our limited resources to pursue a particular product candidate and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on specific product candidates and specific indications. As a result, we may forgo or delay pursuit of opportunities with other product candidates.
that could have had greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaborations, licenses and other similar arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

We may conduct certain of our clinical trials for our product candidates outside of the United States. However, the FDA and other foreign equivalents may not accept data from such trials, in which case our development plans will be delayed, which could materially harm our business.

We may conduct one or more of our clinical trials for our product candidates outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of this data is subject to certain conditions imposed by the FDA. For example, to accept data from a clinical trial that was conducted only at sites outside of the United States and not subject to an IND, the FDA requires such clinical trial to have been conducted in accordance with GCPs, and the FDA must be able to validate the data from the clinical trial through an on-site inspection if the FDA deems such inspection necessary. For such studies not subject to an IND, the FDA generally does not review clinical protocols for the studies, and therefore there is an additional potential risk that the FDA could determine that the study design, protocol, or results from a non-U.S. clinical trial was inadequate for the purposes we intend, which could require us to conduct additional clinical trials. There can be no assurance the FDA will accept data from clinical trials conducted outside of the United States. If the FDA does not accept data from our clinical trials of our product candidates, it would likely result in the need for additional clinical trials, which would be costly and time consuming and delay or permanently halt our development of our therapeutic product candidates.

Conducting clinical trials outside the United States also exposes us to additional risks, including risks associated with:

• additional foreign regulatory requirements;
• foreign exchange fluctuations;
• compliance with foreign manufacturing, customs, shipment and storage requirements;
• cultural differences in medical practice and clinical research; and
• diminished protection of intellectual property in some countries.

Interim, topline and preliminary data from our preclinical studies and clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose interim, preliminary or topline data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the interim, preliminary or topline results that we report may differ from future results of the same trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline and preliminary data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our clinical studies. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially

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change as patient enrollment continues and more patient data become available or as patients from our clinical trials continue other treatments for their disease. Adverse differences between preliminary, topline or interim data and final data could significantly harm our business prospects. In addition, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock after this offering.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and the value of our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product, product candidate or our business. If the topline data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory and policy changes, the FDA’s ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA’s ability to perform routine functions. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs, biologics, and medical devices, or modifications to approved drugs, biologics, and medical devices to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the COVID-19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most inspections of foreign manufacturing facilities and products, and on March 18, 2020 the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, on July 10, 2020, the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.
Risks Related to Our Reliance on Third Parties

We are substantially dependent upon the Cedars-Sinai license agreement for access to the Cedars-Sinai database and biobank, which supports Prometheus 360.

We rely on access to the Cedars-Sinai database and biobank and its over 200,000 samples linked to extensive clinical data from patients in order to stratify patients and carry out our precision medicine approach. We exclusively license the rights to the database and biobank from Cedars-Sinai under our license agreement. Cedars-Sinai may terminate the license agreement under certain circumstances, including as a result of our uncured breach of the agreement. Cedars-Sinai stores its biobank samples in a single location in Southern California, and we therefore are exposed to the risk that such samples could be destroyed pursuant to a natural or man-made disaster or that they may otherwise become unavailable. Without access to this data and samples, our business would be materially and adversely affected because we may not be able to identify additional therapeutic targets and/or develop therapeutic and diagnostic product candidates for development. Additionally, any dispute with Cedars-Sinai may result in costly litigation that diverts our management’s attention and resources away from our day-to-day activities and which may adversely affect our business, financial condition, results of operation and prospects.

We have entered, and may in the future seek to enter into, collaborations, licenses and other similar arrangements and may not be successful in doing so, and even if we are, we may relinquish valuable rights and may not realize the benefits of such relationships.

We have entered into a collaboration agreement with Takeda pursuant to which Takeda will develop programs focused on the treatment of IBD, and we will develop and commercialize companion diagnostics for any resulting therapeutics. In addition, we have entered into a collaboration agreement with Falk pursuant to which we and Falk will share responsibility for the global development of our PR600 development program. With respect to Takeda and Falk, and what we expect will be the case with any future license or collaboration agreements, we have and would expect to have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend on our collaborators’ willingness to successfully develop and commercialize the applicable development programs. Takeda and Falk may terminate the respective collaboration agreements for convenience and under certain other circumstances, including as a result of our uncured material breach of the agreement. Any such termination may adversely affect our business, financial condition, results of operation and prospects.

We may seek to enter into additional collaborations, joint ventures, licenses and other similar arrangements for the development or commercialization of other product candidates due to capital costs required to develop or commercialize the product candidate. We may not be successful in our efforts to establish such collaborations for our product candidates because our research and development pipeline may be insufficient, our product candidates may be deemed to be at too early of a stage of development for collaborative effort or third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy or significant commercial opportunity. In addition, we face significant competition in seeking appropriate strategic partners, and the negotiation process can be time-consuming and complex. We may have to relinquish valuable rights to our future revenue streams, research programs, product candidates or Prometheus 360, or grant licenses on terms that may not be favorable to us, as part of any such arrangement, and such arrangements may restrict us from entering into additional agreements with other potential collaborators. We cannot be certain that, following a collaboration, license or strategic transaction, we will achieve an economic benefit that justifies such transaction.
The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators and partners. Collaborations are subject to numerous risks, which may include the following risks to us:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations and they may not devote the level of effort or resources we expect;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on preclinical or clinical trial results, changes in the collaborators’ strategic focus or available funding, or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates, particularly if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- collaborators with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of such product or products;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly maintain, defend or enforce our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to litigation or potential liability;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborators may not provide us with timely and accurate information regarding development, regulatory or commercialization status or results, which could adversely impact our ability to manage our own development efforts, accurately forecast financial results or provide timely information to our stockholders regarding our out-licensed product candidates; and
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates.

We rely on third parties to conduct our preclinical studies and will rely on third parties to conduct our future clinical trials. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements or meet expected deadlines, our development programs and our ability to seek or obtain regulatory approval for or commercialize our product candidates may be delayed.

We are dependent on third parties to conduct our preclinical studies and expect to rely on such third parties for our future clinical trials, including our planned Phase 1a clinical trial of PRA023. Specifically, we have used and relied on, and intend to use and rely on, medical institutions, clinical investigators, CROs and consultants to conduct our preclinical studies and planned clinical trials in accordance with our clinical protocols and regulatory requirements. These CROs, investigators and other third parties play a significant role in the conduct and timing of these trials and subsequent collection and analysis of data. While we have and will have agreements governing
the activities of our third-party contractors, we have limited influence over their actual performance. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on our CROs and other third parties does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for all of our product candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs or trial sites fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. In addition, our clinical trials must be conducted with products produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

There is no guarantee that any of our CROs, investigators or other third parties will devote adequate time and resources to such trials or perform as contractually required. If any of these third parties fail to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, or otherwise performs in a substandard manner, our clinical trials may be extended, delayed or terminated. In addition, many of the third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other development activities that could harm our competitive position. In addition, principal investigators for our clinical trials are expected to serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected the interpretation of the study, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection by the FDA of any BLA, NDA or PMA we submit. Any such delay or rejection could prevent us from commercializing our product candidates.

If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties on commercially reasonable terms or at all. Switching or adding additional CROs, investigators and other third parties involves additional cost and requires our management’s time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, investigators and other third parties, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

We rely on third parties for the manufacture of our product candidates for preclinical and clinical development. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not own or operate manufacturing facilities and have no plans to develop our own clinical or commercial-scale manufacturing capabilities. We rely and expect to continue to rely on third parties for the manufacture of our product candidates and related raw materials for preclinical and clinical development, as well as for commercial manufacture of any of our product candidates receive marketing approval. The facilities used by third-party manufacturers to manufacture our product candidates must be approved by the FDA and any comparable foreign regulatory authority pursuant to inspections that will be conducted after we submit a BLA, NDA or PMA to the FDA or any comparable filing to a foreign regulatory authority. We do not control the manufacturing process of, and are completely dependent on, third-party manufacturers for compliance with cGMP requirements for manufacture of products. If these third-party manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or any
comparable foreign regulatory authority, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of third-party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or any comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products.

Our or a third party’s failure to execute on our manufacturing requirements on commercially reasonable terms and in compliance with cGMP could adversely affect our business in a number of ways, including:

- an inability to initiate clinical trials of our product candidates under development;
- delay in submitting regulatory applications, or receiving marketing approvals, for our product candidates;
- subjecting third-party manufacturing facilities or our manufacturing facilities to additional inspections by regulatory authorities;
- requirements to cease development or to recall batches of our product candidates; and
- in the event of approval to market and commercialize our product candidates, an inability to meet commercial demands for our product candidates or any other future product candidates.

In addition, we may be unable to establish any agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- failure of third-party manufacturers to comply with regulatory requirements and maintain quality assurance;
- breach of the manufacturing agreement by the third party;
- failure to manufacture our product according to our specifications;
- failure to manufacture our product according to our schedule or at all;
- misappropriation of our proprietary information, including our trade secrets and know-how; and
- termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Our product candidates and any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval, and any related remedial measures may be costly or time consuming to implement. We do not currently have arrangements in place for redundant supply or a second source for all required raw materials used in the manufacture of our product candidates. If our existing or future third-party manufacturers cannot perform as agreed, we may be required to replace such manufacturers and we may be unable to replace them on a timely basis or at all.
Our current and anticipated future dependence upon others for the manufacture of our product candidates or products may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

We rely on sole suppliers for some of the reagents, equipment and other materials used in our testing products, and we may not be able to find replacements or transition to alternative suppliers.

We rely on sole suppliers for critical supply of reagents, equipment and other materials that we use to perform the LDTs that comprise our diagnostic services business. We also purchase components used in our testing product transportation kits from sole-source suppliers. Some of these items are unique to these suppliers and vendors. While we have developed alternate sourcing strategies for many of these materials and vendors, we cannot be certain whether these strategies will be effective or the alternative sources will be available when we need them. We are not a major customer of some of our suppliers, and these suppliers may therefore give other customers’ needs higher priority than ours. If our suppliers can no longer provide us with the materials we need to perform the tests that comprise our testing products, if the materials do not meet our quality specifications, or if we cannot obtain materials, an interruption in test processing could occur and, in certain circumstances, we may be required to amend or cancel test results we have issued.

In addition, if we should encounter delays or difficulties in securing the quality and quantity of equipment we require for our testing products, we may need to reconfigure our test processes, which could result in an interruption in sales. Any such interruption may significantly affect our future revenue and harm our customer relations and reputation. In addition, in order to mitigate these risks, we may need to maintain inventories of these supplies at higher levels than would be the case if multiple sources of supply were available.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we currently rely on third parties to manufacture our product candidates and to perform quality testing, we must, at times, share our proprietary technology and confidential information, including trade secrets, with them. We seek to protect our proprietary technology, in part, by entering into confidentiality agreements, and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are intentionally or inadvertently incorporated into the technology of others or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets and despite our efforts to protect our trade secrets, a competitor’s discovery of our proprietary technology and confidential information or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business, financial condition, results of operations and prospects.

Additional Risks Related to our CLIA-certified Laboratory and Diagnostic Services Business

If we fail to comply with laboratory licensing, certification or accreditation requirements, we could lose the ability to perform our tests or experience disruptions to our business.

Our laboratory is subject to CLIA, a federal law that regulates clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. CLIA regulations require clinical laboratories to obtain a certificate and mandate specific standards in the areas of personnel qualifications, administration, and participation in proficiency testing, patient test management and quality assurance. CLIA certification is also required in order for us to be eligible to bill state and federal healthcare programs, as well as many private third-party payors, for our tests. To renew these
certifications, we are subject to survey and inspection every two years. Moreover, CLIA inspectors may make random inspections of our clinical laboratory.

We are also required to maintain state licenses to conduct testing in our laboratory. In addition to our California state license, several other states require that we hold licenses to test samples from patients located in those states. We cannot provide assurance that state authorities will at all times in the future find us to be in compliance with all applicable laws. If a clinical laboratory is out of compliance, the state authority may suspend, restrict or revoke the license to operate the clinical laboratory, assess substantial civil money penalties, or impose specific corrective action plans. Any such actions could materially affect our business.

We have obtained licenses from states where we believe we are required to be licensed. From time to time, we may become aware of other states that require out-of-state laboratories to obtain licensure in order to accept specimens from the state, and it is possible that other states do have such requirements or will have such requirements in the future. If we identify any other state with such requirements or if we are contacted by any other state advising us of such requirements, we expect to seek to comply with such requirements. However, there is no assurance that we will be able to obtain any such required license for the particular state.

Any sanction imposed under CLIA, its implementing regulations, or state or foreign laws or regulations governing licensure, or our failure to renew a CLIA certificate, a state license or accreditation, could have a material and adverse effect on our business, operating results and financial condition. The Centers for Medicare & Medicaid Services (CMS) also has the authority to impose a wide range of sanctions, including revocation of the CLIA certification along with a bar on the ownership or operation of a CLIA-certified laboratory by any owners or operators of the deficient laboratory. If we were to lose our CLIA certification or required state licensure, we would not be able to operate our clinical laboratory and conduct our tests, in full or in particular states, which would adversely impact our business, operating results, and financial condition.

If our sole laboratory facility becomes damaged or inoperable, we are required to vacate our existing facility or we are unable to expand our existing facility as needed, we will be unable to perform our current and future planned testing services and our business will be harmed.

We currently perform all our IBD and GI testing services for our LDTs in a single laboratory facility located in San Diego California. We use this same facility in connection with our development of companion diagnostic tests and plan to use it to conduct the testing services for any companion diagnostics approved with any approved therapeutic product candidates. San Diego is situated on or near earthquake fault lines. Our facility and equipment could be harmed or rendered inoperable by natural or man-made disasters, including earthquake, fire, flood, power loss, communications failure or terrorism. The inability to perform the tests contained in our testing products or to reduce the backlog of analyses that could develop if our facility is inoperable, for even a short period of time, may result in the loss of customers or harm to our reputation, and we may be unable to regain those customers or repair our reputation in the future. Additionally, we store our bio-repository of specimens, used to develop or test products and companion diagnostics at this facility. If these specimens were destroyed pursuant to a natural or man-made disaster or otherwise become unavailable, our ability to develop new testing products or companion diagnostics may be delayed. Furthermore, our facility and the equipment we use to perform our research and development work could be unavailable or costly and time-consuming to repair or replace. It would be difficult, time-consuming and expensive to rebuild our facility or license or transfer our proprietary technology to a third-party, particularly in light of the licensure and accreditation requirements for a commercial laboratory like ours. Even in the unlikely event we are able to find a third party with such qualifications to enable us to conduct the tests contained in our testing products, we may be unable to negotiate commercially reasonable terms. Importantly, we plan to rely on our laboratory to enable an end-to-end commercial companion diagnostic solution without the need to partner with a clinical reference laboratory facility.

In order to rely on a third party to perform the tests contained in our testing products or any future companion diagnostics, we would need to engage another facility with established state licensure and CLIA.
accreditation under the scope of which tests could be performed following validation and other required procedures. We cannot assure you that we would be able to find another CLIA-certified facility willing to comply with the required procedures, that any such facility would be willing to perform the tests contained in our testing products for us on commercially reasonable terms, or that it would be able to meet our quality standards.

In order to establish an additional clinical reference laboratory facility, we would have to spend considerable time and money securing adequate space, constructing the facility, recruiting and training employees, and establishing the additional operational and administrative infrastructure necessary to support a second facility. We may not be able, or it may take considerable time, to replicate our testing processes or results in a new facility. Additionally, any new clinical reference laboratory facility opened by us would be subject to certification under CLIA and licensing by several states, including California and New York, which could take a significant amount of time and result in delays in our ability to begin operations.

We believe we have the capacity to meet our projected needs for at least the next 12 months, although we may grow at a rate that is faster than we expect. To the extent required, any future expansion could disrupt laboratory operations, resulting in an inability to meet customer turnaround time expectations, and could be delayed, resulting in slower realization of laboratory efficiencies anticipated from the use of the expanded facilities. Adverse consequences resulting from a delay in the laboratory expansion could harm our relationships with our customers and our reputation, and could affect our ability to generate revenue.

We carry insurance for damage to our property and the disruption of our business, but this insurance may not cover all of the risks associated with damage or disruption to our business, provide coverage in amounts sufficient to cover our potential losses or continue to be available to us on acceptable terms, if at all.

If we are unable to maintain or expand our sales and marketing force to adequately address our target market, our business may be adversely affected.

We sell our testing products through our own specialized salesforce targeting gastroenterologists in the United States. Our testing products compete in a concentrated specialty market, and utilizing a specialized salesforce is integral to our future plans to commercialize any approved therapeutic product candidates and companion diagnostics. As such, we believe it is necessary to maintain a salesforce that includes sales representatives with specific technical backgrounds and industry expertise. If any of our product candidates ultimately receives marketing approval, we may need to expand the size of our salesforce. Training of additional sales representatives can be costly and time consuming, particularly given the level of experience and sophistication we seek in our salesforce. If we are unable to effectively retain, train and integrate additional sales representatives, if required, it may adversely affect our ability to effectively market and sell any approved therapeutic product candidates and companion diagnostics. In addition, competition for highly specialized sales personnel is intense, and we may not be able to attract and retain personnel or be able to maintain an efficient and effective sales and marketing force.

Our near-term sales of testing services and future sales of any approved products will depend in large part on our ability to maintain an effective salesforce. If we are unsuccessful in this regard, it could negatively impact our revenue growth and potential profitability.

Performance issues, service interruptions or price increases by our shipping carrier could adversely affect our diagnostic services business, results of operations and financial condition, and harm our reputation and ability to provide testing services on a timely basis.

Expedited, reliable shipping is essential to our operations. We rely extensively on a single carrier, United Parcel Service, for reliable and secure point-to-point transport of patient specimens to our laboratory and enhanced tracking of these patient specimens. Should United Parcel Service, or any other carrier we may use in
the future, encounter delivery performance issues such as loss, damage or destruction of a specimen, it may be difficult to replace our patient specimens in a timely manner and such occurrences may damage our reputation and lead to decreased utilization from gastroenterologists for our testing services and increased cost and expense to our business. In addition, any significant increase in shipping time could adversely affect our ability to receive and process patient specimens on a timely basis.

If we or United Parcel Service were to terminate our relationship, we would be required to find another party to provide expedited, reliable point-to-point transport of our patient specimens. There are only a few other providers of such nationwide transport services, and there can be no assurance that we will be able to enter into arrangements with such other providers on acceptable terms, if at all. Finding a new provider of transport services would be time-consuming and costly and result in delays in our ability to provide our testing services. Even if we were to enter into an arrangement with any such provider, there can be no assurance that they will provide the same level of quality in transport services currently provided to us by United Parcel Services. If any new provider does not provide, or if United Parcel Services does not continue to provide, the required quality and reliability of transport services at the same or similar costs, it could adversely affect our business, reputation, results of operations and financial condition.

Healthcare policy changes may have a material adverse effect on our financial condition and results of operations.

Sales of our diagnostic test depend, in large part, upon the availability of reimbursement from third-party payors. These third-party payors include government healthcare programs such as Medicare, managed care providers, private health insurers, and other organizations. Physicians and patients may not order our diagnostic tests unless commercial third-party payors and government payors provide coverage and payment for our tests.

Reimbursement to healthcare providers, such as specialized diagnostic service providers like us, is subject to continuing change in policies by governmental payors, such as Medicare and Medicaid, private insurers, including managed care organizations, and other private payors, such as hospitals and private medical groups. Statutory and regulatory changes, retroactive rate adjustments and administrative rulings, and other policy changes may be implemented with little or no prior notice, all of which could materially decrease the range of services for which we are reimbursed or the reimbursement rates paid for our tests.

For example, on April 1, 2014, the Protecting Access to Medicare Act of 2014 (PAMA) was signed into law, which, among other things, significantly altered the payment methodology under the Medicare Clinical Laboratory Fee Schedule (CLFS). Under the law, starting January 1, 2016 and every three years thereafter (or annually in the case of advanced diagnostic lab tests), clinical laboratories must report laboratory test payment data for each Medicare-covered clinical diagnostic lab test that it furnishes during a time period to be defined by future regulations. Data for reporting for the new PAMA process began in 2017, and in 2018, the Medicare payment rate for each clinical diagnostic lab test, with some exceptions, equaled the weighted median of the reported private third-party payor payment for the test, as calculated using data collected by applicable laboratories during the data collection period and reported to CMS, during a specified data reporting period. These revisions to the CLFS have altered payment rates for clinical diagnostic lab tests under the CLFS. We cannot be sure how revisions to the CLFS will affect reimbursement rates in the future.

Government payments are significant to our business, not only because approximately 7% of the total payments we received from payors in 2019 were derived from programs administered by CMS, but also because other payors often use Medicare amounts as a benchmark to develop their payment rates. We cannot predict whether Medicare and other third-party payor reimbursement rates that mirror Medicare’s will be sufficient to make our tests commercially attractive. Moreover, some states have passed or proposed legislation that would revise reimbursement methodology for clinical laboratory payment rates under their respective Medicaid programs. Any changes to the valuation or payment for codes that describe our tests could materially affect our business.
We also cannot predict whether future healthcare initiatives will be implemented at the federal or state level or in countries outside of the United States in which we may do business in the future, or the effect any future legislation or regulation will have on us. Although we cannot predict the full effect of the recent legislative changes discussed above, such changes individually or in the aggregate may result in decreased profits to us and/or lower reimbursement by payors for tests, which may adversely affect our business, financial condition and results of operations.

Billing for our testing products is complex, and we must dedicate substantial time and resources to the billing process to be paid for our testing products.

Billing for our testing products is complex, time consuming and expensive. Depending on the billing arrangement and applicable law, we bill various third-party payors, including Medicare and private insurance companies, as well as patients, all of which have different billing requirements. We generally bill third-party payors for our testing products and pursue reimbursement on a case-by-case basis where pricing contracts are not in place. We may also face increased risk in our collection efforts, including long collection cycles and potential delays in claims processing, which could adversely affect our business, results of operations and financial condition.

Several factors contribute to the complexity of the billing process, including:

- differences between the list price for our testing products and the reimbursement rates of third-party payors;
- compliance with complex federal and state regulations related to billing Medicare;
- disputes among third-party payors as to which party is responsible for payment;
- differences in coverage among third-party payors;
- the effect of patient deductibles, co-payments or co-insurance;
- differences in information and billing requirements among third-party payors;
- changes to billing codes used for our testing products;
- risk of government audits related to billing;
- incorrect or missing billing information; and
- the resources required to manage the billing and claims appeals process.

We use standard industry billing codes, known as CPT codes, to bill for our testing products. If these codes were to change, there is a risk of an error being made in the claim adjudication process. Such errors can occur with claims submission, third-party transmission or in the processing of the claim by the payor. Claim adjudication errors may result in a delay in payment processing or a reduction in the amount of the payment received.

If we introduce new testing products, we will need to add new codes to our billing process as well as our financial reporting systems. Failure or delays in effecting these changes in external billing and internal systems and processes could negatively affect our collection rates, revenue and cost of collecting.

Our billing activities require us to implement compliance procedures and oversight, train and monitor our employees, and undertake internal audits to evaluate compliance with applicable laws and regulations as well as internal compliance policies and procedures. When payors deny our claims, in order to obtain reimbursement for services that we provide, we may challenge coverage and payment denials. Payors also conduct external audits to evaluate payments, which add further complexity to the billing process. If the payor makes an overpayment determination, there is a risk that we may be required to return all or some portion of prior payments we have
received. Additionally, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, collectively the Affordable Care Act (ACA) established a requirement for providers and suppliers to report and return any overpayments received from government payors under the Medicare and Medicaid programs within 60 days of identification. Failure to identify and return such overpayments exposes the provider or supplier to liability under federal false claims laws.

Additionally, from time to time, third-party payors change processes that may affect timely payment. These changes may result in uneven cash flow or impact the timing of revenue recognized with these payors. With respect to payments received from governmental programs, factors such as a prolonged government shutdown could cause significant regulatory delays or could result in attempts to reduce payments made to us by federal government healthcare programs. In addition, third-party payors may refuse to ultimately make payment if their processes and requirements have not been met on a timely basis. These billing complexities, and the related uncertainty in obtaining payment for our testing products could negatively affect our revenue and cash flow, our ability to achieve profitability, and the consistency and comparability of our results of operations.

We also rely on a third-party provider to provide revenue cycle management software systems for certain processing and collection functions. In the past, we have experienced delays in claims processing as a result of our third-party provider making changes to its invoicing system, as well as not submitting claims to payors within the timeframe required. If claims for our testing products are not submitted to payors on a timely basis, or if we are required to switch to a different systems provider, it could have an adverse effect on our revenue and our business.

There is currently no national coverage decision that determines whether and how our test is covered by Medicare. In the absence of a national coverage decision, local Medicare contractors that administer the Medicare program in various regions have some discretion in determining coverage and therefore payment for tests. Palmetto GBA, the Medicare Administrative Contractor (MAC) responsible for administering Medicare’s molecular diagnostic services program (MolDX Program), has adopted a non-coverage policy for the Prometheus IBD sgi Diagnostic test and parallel policies have been adopted by MACs in other jurisdictions.

In addition, we are currently considered a “non-contracting provider” by many commercial third-party payors because we have not entered into specific contracts to provide out diagnostic tests to their insured patients, and as a result we take on primary responsibility for obtaining reimbursement on behalf of patients. If we were to become a contracting provider in the future, the amount of overall reimbursement we receive may decrease if we were to be reimbursed less money per product performed at a contracted rate than at a non-contracted rate, which could have a negative impact on our revenue. Further, we may be unable to collect payments from patients beyond that which is paid by their insurance and will experience lost revenue as a result.

If the FDA ends or modifies its current policy of enforcement discretion on LDTs, or if Congress enacts legislation that changes the current requirements for LDTs, we may become subject to extensive regulatory requirements and may be required to conduct additional clinical trials prior to continuing to sell our existing tests or launching any other LDTs we may develop, which may increase the cost of conducting, or otherwise harm, our business.

The tests we offer in our laboratory are LDTs, which are a category of in vitro diagnostic tests that are intended for clinical use and are designed, manufactured, and used within a single laboratory. Although LDTs are classified as medical devices and the FDA has statutory authority to ensure that medical devices are safe and effective for their intended uses, the FDA has historically exercised enforcement discretion and has not enforced certain applicable FDA requirements, including premarket review, with respect to LDTs, though such practices may not continue in the future. Even under its current enforcement discretion policy, the FDA has issued warning letters to in vitro diagnostic device manufacturers for commercializing laboratory tests that were purported to be LDTs but that the FDA alleged failed to meet the definition of an LDT or otherwise were not subject to the FDA’s policy on enforcement discretion because they presented a potential safety risk.
Additionally, the FDA could modify its current approach to LDTs in a way that could subject our testing products to the enforcement of additional regulatory requirements. In recent years, the FDA has stated its intention to modify its enforcement discretion policy with respect to LDTs. For example, on July 31, 2014, the FDA notified Congress of its intent to modify, in a risk-based manner, its policy of enforcement discretion with respect to LDTs. On October 3, 2014, the FDA issued two draft guidance documents entitled “Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs),” or the Framework Guidance, and “FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs),” or the Reporting Guidance. The Framework Guidance stated that the FDA intended to modify its policy of enforcement discretion with respect to LDTs in a risk-based manner consistent with the classification of medical devices generally in Classes I through III. The Reporting Guidance would have further enabled the FDA to collect information regarding the LDTs currently being offered for clinical use through a notification process, as well as to enforce its regulations for reporting safety issues and collecting information on any known or suspected adverse events related to the use of an LDT. Although the FDA halted finalization of the guidance in November 2016 to allow for further public discussion on an appropriate oversight approach to LDTs and to give congressional authorizing committees the opportunity to develop a legislative solution, and the FDA issued a discussion paper on possible approaches to LDT regulation in January 2017.

In addition, Congress has considered a number of proposals to change the FDA's enforcement discretion policy for LDTs and subject LDTs to additional regulatory requirements. For example, Congress has recently been working on legislation to create an LDT and in vitro diagnostic regulatory framework for all in vitro clinical tests (IVCTs) that would be separate and distinct from the existing medical device regulatory framework. In March 2020, Members of Congress introduced the Verifying Accurate Leading-edge IVCT Development Act of 2020 (the VALID Act). If passed in its current form, the VALID Act would create a new category of medical products separate from medical devices for IVCTs. As proposed, the bill would establish a risk-based approach to imposing requirements related to premarket review, quality systems, and labeling requirements on all IVCTs, including LDTs, but would create exemptions for certain LDTs marketed before the effective date of the bill (though other regulation requirements may apply, for example, registration, adverse event reporting). It is unclear whether the VALID Act or any other legislative proposals (including any proposals to reduce FDA oversight of LDTs) would be passed by Congress or signed into law by the President. Depending on the approach adopted under any potential legislation, certain LDTs (likely those of higher risk) may be required to undergo some form of premarket review, potentially with a transition period for compliance and a grandfathering provision.

If Congress does not take action in connection with the VALID Act or other LDT legislation, the FDA could nevertheless modify its current approach to LDTs in a way that could require that our testing products that we market as LDTs comply with additional FDA requirements. Moreover, even if the FDA does not modify its policy of enforcement discretion, the FDA may disagree that we are marketing our testing products within the scope of its policy of enforcement discretion and may impose significant regulatory requirements or take enforcement actions. In addition, the FDA may choose not to exercise enforcement discretion with respect to any new testing products we may launch as LDTs. A delay in the launch of our testing products could negatively impact our financial condition and results of operations. If the FDA changes its policy of enforcement discretion for LDTs, we may be required to obtain premarket clearance or approval for our testing products from the FDA or do so earlier than anticipated. The process for submitting a premarket notification and receiving FDA clearance usually takes from three to twelve months, depending on the type of submission, but it can take significantly longer and clearance is never guaranteed. The process for submitting and obtaining FDA clearance or approval is costly and uncertain. Moreover, there can be no assurance that any cleared or approved labeling claims will be consistent with the claims we currently make about our testing products, or that such claims will be adequate to support continued adoption of and reimbursement for our testing products. If premarket review is required for some or all of our testing products, the FDA may require that we stop selling our testing products pending clearance or approval, which would negatively impact our business. Even if our testing products are allowed to remain on the market prior to required clearance or approval, demand or reimbursement for our testing products may decline if there is uncertainty about our products, if we are required to label our testing products as investigational by the FDA, or if the FDA limits the labeling claims we are permitted to make for our...
testing products. As a result, we could experience significantly increased development costs and a delay in generating additional revenue from our testing products, or from other testing products now in development.

If the FDA changes its enforcement discretion policy or imposes significant changes to the regulation of LDTs, either generally or to our testing products in particular, it could reduce our revenues or increase our costs and adversely affect our business, prospects, results of operations or financial condition.

Risks Related to Commercialization of Our Product Candidates and Testing Products

Even if we receive regulatory approval for any therapeutic product candidate or companion diagnostic, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, our therapeutic product candidates and companion diagnostics, if approved, could be subject to labeling and other restrictions on marketing or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our therapeutic product candidates and companion diagnostics, when and if any of them are approved.

Any regulatory approvals that we may receive for our product candidates, including any therapeutic product candidates or companion diagnostics, will require the submission of reports to regulatory authorities and surveillance to monitor the safety and efficacy of the product candidate, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements. For example, the FDA may require a REMS in order to approve our therapeutic product candidates, which could entail requirements for a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if one of our product candidates is approved, it will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies and submission of safety, efficacy, and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities.

Manufacturers and manufacturers’ facilities are required to comply with extensive FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any approved marketing application. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

If the FDA or another regulatory authority discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, such regulatory authorities may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory authority or enforcement authority may, among other things:

- refuse to approve pending applications or supplements to approved applications;
- require us to change the way a product is distributed, conduct additional clinical trials, change the labeling of a product or require us to conduct additional post-marketing studies or surveillance;
- restrict our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials;
- require additional warnings on the product label, such as a “black box” warning or a contraindication;
- impose restrictions on the products, manufacturers or manufacturing process;
require warning or untitled letters; 
seek injunctions or civil or criminal penalties; 
suspend or withdraw regulatory approvals; 
seize or detain products or implement import bans; 
impose voluntary or mandatory product recalls and publicity requirements; 
totally or partially suspend production; and 
impose restrictions on operations, including costly new manufacturing requirements.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, our business will be seriously harmed.

Moreover, the policies of the FDA and of other regulatory authorities may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

The commercial success of our product candidates will depend upon the degree of market acceptance of such product candidates by physicians, patients, healthcare payors and others in the medical community.

Our product candidates may not be commercially successful. Even if any of our product candidates receive regulatory approval, they may not gain market acceptance among physicians, patients, healthcare payors or the medical community. The commercial success of any of our current or future product candidates will depend significantly on the broad adoption and use of the resulting product by physicians and patients for approved indications. The degree of market acceptance of our products will depend on a number of factors, including:

- demonstration of clinical efficacy and safety compared to other more-established products;
- the approval, availability, market acceptance and reimbursement for the companion diagnostic;
- the indications for which our product candidates are approved;
- the limitation of our targeted patient population and other limitations or warnings contained in any FDA-approved labeling;
- acceptance of a new drug or biologic for the relevant indication by healthcare providers and their patients;
- the pricing and cost-effectiveness of our products, as well as the cost of treatment with our products in relation to alternative treatments and therapies;
- our ability to obtain and maintain sufficient third-party coverage and adequate reimbursement from government healthcare programs, including Medicare and Medicaid, private health insurers and other third-party payors;
- the willingness of patients to pay all, or a portion of, out-of-pocket costs associated with our products in the absence of sufficient third-party coverage and adequate reimbursement;
- any restrictions on the use of our products, and the prevalence and severity of any adverse effects;
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- potential product liability claims;
- the timing of market introduction of our products as well as competitive drugs;
- the effectiveness of our or any of our current or potential future collaborators’ sales and marketing strategies; and
- unfavorable publicity relating to the product.

If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors or patients, we may not generate sufficient revenue from that product and may not become or remain profitable. Our efforts to educate the medical community and third-party payors regarding the benefits of our products may require significant resources and may never be successful.

The commercial success of our diagnostic testing products depends upon attaining and maintaining significant market acceptance of such testing products by physicians, patients, third-party payors and others in the medical community.

The success of our diagnostic services business depends on our ability to continue to develop and market testing products that are recognized and accepted as safe, effective, reliable and cost effective, and any testing product that we offer may not gain or maintain market acceptance among gastroenterologists, third-party payors, patients and the medical community. Market acceptance of our testing products depends on a number of factors, including:

- the perceived accuracy of our test results by gastroenterologists and patients;
- the potential and perceived advantages of our testing products over alternative products
- the demonstration in clinical studies of the performance and clinical validity of our testing products, the results of which studies may not replicate the positive results from earlier studies;
- the introduction of new tests that compete with our testing products;
- the product cost in relation to alternative products;
- publicity concerning our testing products or competing products;
- the availability of coverage and adequate reimbursement by third-party payors, including government authorities;
- relative convenience and ease of administration; and
- the effectiveness of our sales and marketing efforts.

If our testing products and promoted therapeutics do not achieve an adequate level of acceptance by gastroenterologists, hospitals, third-party payors or patients, we may not generate sufficient revenue to make our diagnostic services business profitable.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. If we are found or alleged to have improperly promoted off-label uses, we may become subject to significant liability.

The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, as our product candidates would be, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product’s approved labeling. If we receive marketing approval for a product candidate, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. If we are found
to have promoted such off-label uses, we may become subject to significant liability. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also required companies to enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

**Our therapeutic product candidates for which we intend to seek approval as biologics may face competition sooner than anticipated.**

The ACA includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 (BPCIA), which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a highly similar or “biosimilar” product may not be submitted to the FDA until four years following the date that the reference product was first approved by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first approved. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor’s own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty.

We believe that any of our therapeutic product candidates approved as biologics under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our therapeutic product candidates to be reference products for competing products, potentially creating the opportunity for competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

**The successful commercialization of our product candidates, if approved, will depend in part on the extent to which governmental authorities and health insurers establish coverage, adequate reimbursement levels and favorable pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates could limit our ability to market those products and decrease our ability to generate revenue.**

The availability of coverage and the adequacy of reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford prescription medications such as our product candidates, if approved. Our ability to achieve coverage and acceptable levels of reimbursement for our products by third-party payors will have an effect on our ability to successfully commercialize those products. Even if we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the United States, the European Union or elsewhere will be available for any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

Third-party payors increasingly are challenging prices charged for biopharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs when an equivalent generic drug or a less expensive therapy is available. It is possible that a third-party payor may consider our product candidates as substitutable and only offer to reimburse patients for the less expensive
These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our products, if approved, and may not be able to obtain a satisfactory financial return on products that we may develop.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs will be covered. Some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our products.

Obtaining and maintaining reimbursement status is time consuming, costly and uncertain. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs. However, no uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases at short notice, and we believe that changes in these rules and regulations are likely.

In addition, companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or biological products. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or biological products, will apply to companion diagnostics. Additionally, if any companion diagnostic provider is unable to obtain reimbursement or is inadequately reimbursed, that may limit the availability of such companion diagnostic, which would negatively impact prescriptions for our product candidates, if approved.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe and other countries has and will continue to put pressure on the pricing and usage of our products. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates, if approved. Accordingly, in markets outside the United States, the reimbursement for our product candidates may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our products. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.
We face significant competition, and if our competitors develop technologies or product candidates more rapidly than we do or their technologies are more effective, our business and our ability to develop and successfully commercialize products may be adversely affected.

The biotechnology and biopharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary and novel products and product candidates. Our competitors have developed, are developing or may develop products, product candidates and processes competitive with our product candidates. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. We believe that a significant number of products are currently under development, and may become commercially available in the future, for the treatment of IBD. Our competitors include larger and better funded pharmaceutical, specialty pharmaceutical and biotechnology companies. Moreover, we may also compete with universities, governmental agencies and other research institutions who may be active in the indications we are targeting and could be in direct competition with us. We also compete with these organizations in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

We expect to face competition from existing products and products in development for each of our therapeutic product candidates. If approved for the treatment of patients with moderate-to-severe IBD, PRA023, would compete with Entyvio, which is an a4b7 integrin antibody marketed by Takeda, Humira, which is a TNF antibody marketed by Abbvie Inc., Stelara, which is an IL-12/IL-23 antibody marketed by Janssen Pharmaceuticals, Inc., Xeljanz, which is a JAK1 inhibitor marketed by Pfizer Inc., and Simponi, which is a TNF antibody marketed by Johnson & Johnson.

We are aware of several companies with product candidates for the treatment of patients with UC and/or CD, including Pfizer’s PF-06480605, which is a fully human anti-TL1A antibody being developed in Phase 2 trials for UC, Rinoq, which is a JAK1 inhibitor being developed in Phase 3 clinical trials by AbbVie, ozanimod, which is a S1P inhibitor being developed in Phase 3 clinical trials by Bristol-Myers Squibb Company, etrolizumab, which is a b7 integrin being developed in Phase 3 clinical trials by Roche, mirikizumab, which is an anti-IL-23 antibody being developed in Phase 3 clinical trials by Eli Lilly and filgotinib, a JAK1 inhibitor being developed in Phase 3 clinical trials by Gilead Sciences, Inc. We are also aware of additional product candidates in clinical trials by AbbVie Inc., Abivax SA, Amgen Inc., Arena Pharmaceuticals, Inc., C.H. Boehringer Ingelheim Sohn AG & Ko. KG, Bristol-Myers Squibb Company, Celgene Corporation, Gilead Sciences, Inc., GlaxoSmithKline plc, Gossamer Bio, Inc., Incyte Corp., Janssen Pharmaceutica N.V., Landos Biopharma, Inc., Protagonist Therapeutics, Inc., Theravance Biopharma, Inc., Applied Molecular Transport Inc., Pandion Therapeutics, Inc., RedHill Biopharma Ltd. and Seres Therapeutics, Inc.

Our principal competition for our LDTs is traditional methods used by gastroenterologists to assess and diagnose patients with IBD symptoms. Such traditional methods include endoscopy and testing of blood, serum and fecal samples. We face competition from commercial laboratories, such as Laboratory Corporation of America Holdings, Quest Diagnostics Incorporated, ARUP Laboratories, Inc. and Mayo Clinic, all of which have existing infrastructures to support the commercialization of diagnostic services. Large, multispecialty group medical clinics, health systems and academic medical university-based clinics may provide in-house clinical laboratories offering IBD-related disease testing.

Many of our competitors have significantly greater financial, technical, manufacturing, marketing, sales and supply resources or experience than we do. If we successfully obtain approval for any product candidate, we will face competition based on many different factors, including the safety and effectiveness of our products, the ease with which our products can be administered, the effectiveness of any related companion diagnostic tests, the timing and scope of regulatory approvals for these products, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position. Competing products could
present superior treatment alternatives, including by being more effective, safer, more convenient, less expensive or marketed and sold more effectively than any products we may develop. Competitive products or technological approaches may make any products we develop, or Prometheus 360, obsolete or noncompetitive before we recover the expense of developing and commercializing our product candidates. If we are unable to compete effectively, our opportunity to generate revenue from the sale of our products we may develop, if approved, could be adversely affected.

If the market opportunities for our products are smaller than we believe they are, our revenue may be adversely affected, and our business may suffer.

The precise incidence and prevalence for all the conditions we aim to address with our product candidates are unknown. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our therapeutic product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including the scientific literature, surveys of clinics, patient foundations or market research, and may prove to be incorrect. Further, new trials may change the estimated incidence or prevalence of these diseases. The total addressable market across all of our product candidates will ultimately depend upon, among other things, the diagnosis criteria included in the final label for each of our product candidates approved for sale for these indications, the availability of alternative treatments and the safety, convenience, cost and efficacy of our therapeutic product candidates relative to such alternative treatments, acceptance by the medical community and patient access, drug pricing and reimbursement. The number of patients in the United States and other major markets and elsewhere may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our products or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business. Further, even if we obtain significant market share for our product candidates, because some of our potential target populations are very small, we may never achieve profitability despite obtaining such significant market share.

Our future growth may depend, in part, on our ability to operate in foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future growth may depend, in part, on our ability to develop and commercialize our product candidates in foreign markets. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from applicable regulatory authorities in foreign markets, and we may never receive such regulatory approvals for any of our product candidates. To obtain separate regulatory approval in many other countries we must comply with numerous and varying regulatory requirements regarding safety and efficacy and governing, among other things, clinical trials, commercial sales, pricing and distribution of our product candidates. If we obtain regulatory approval of our product candidates and ultimately commercialize our products in foreign markets, we would be subject to additional risks and uncertainties, including:

- different regulatory requirements for approval of drugs in foreign countries;
- reduced protection for intellectual property rights;
- the existence of additional third-party patent and other intellectual property rights of potential relevance to our business;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
foreign reimbursement, pricing and insurance regimes;
• workforce uncertainty in countries where labor unrest is common;
• production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
• business interruptions resulting from geopolitical actions, including war and terrorism, medical epidemics or natural disasters including earthquakes, typhoons, floods and fires.

Risks Related to Our Business Operations and Industry

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or any guidance we may provide.

Our quarterly and annual operating results may fluctuate significantly, which makes it difficult for us to predict our future operating results. These fluctuations may occur due to a variety of factors, many of which are outside of our control, including, but not limited to:

• the timing and cost of, and level of investment in, research, development, regulatory approval and commercialization activities relating to our therapeutic product candidates, LDTs and companion diagnostics, which may change from time to time;
• the financial results of our diagnostic services business;
• coverage and reimbursement policies with respect to our therapeutic product candidates, LDTs and companion diagnostics, if approved, and potential future drugs that compete with our products;
• the cost of manufacturing our product candidates and testing products, which may vary depending on the quantity of production and the terms of our agreements with third-party manufacturers;
• the timing and amount of the milestone or other payments we may receive under collaboration agreements;
• expenditures that we may incur to acquire, develop or commercialize additional product candidates and technologies;
• the level of demand for any approved products, which may vary significantly;
• future accounting pronouncements or changes in our accounting policies; and
• the timing and success or failure of preclinical studies or clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance.

This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue or earnings guidance we may provide.

Our business is subject to risks arising from the recent global outbreak of COVID-19 and other epidemic diseases.

The current COVID-19 worldwide pandemic has presented substantial public health and economic challenges and is affecting our employees, patients, physicians and other healthcare providers, communities and
business operations, as well as the U.S. and global economies and financial markets. International and U.S. governmental authorities in impacted regions are taking actions in an effort to slow the spread of COVID-19, including issuing varying forms of “stay-at-home” orders, and restricting business functions outside of one’s home. In response, we have implemented a work-from-home policy for certain of our employees. With respect to our diagnostic services business, as a result of government measures and the reordering of priorities across the U.S. healthcare system, our test volumes experienced a temporary substantial reduction in April, but have since substantially recovered on a month-to-month basis. In March 2020, as a result of the impacts of the COVID-19 pandemic, we implemented a reduction in workforce which resulted in the recognition of a restructuring charge for termination benefits of $2.5 million, of which $2.3 million was paid as of June 30, 2020. In addition, we believe there are several other important factors that have impacted, and that we expect will impact our diagnostic services business, including potential shutdowns of our laboratory facilities and operations as well as those of our suppliers and courier services, disruptions to the supply chain of material needed for our tests, our sales and commercialization activities and our ability to receive specimens and perform or deliver the results from our tests, delays in reimbursement and coverage decisions from Medicare and third-party payors and in interactions with regulatory authorities, and absorb fixed laboratory expenses. To date, we have not experienced material disruptions in our business operations for our therapeutics business. However, while it is not possible at this time to estimate the impact that COVID-19 could have on our therapeutics business in the future, particularly as we advance our product candidates to clinical development, the continued spread of COVID-19 and the measures taken by the governmental authorities could: disrupt the supply chain and the manufacture or shipment of drug substances and finished drug products for our product candidates for use in our research, preclinical studies and clinical trials; delay, limit or prevent our employees and CROs from continuing research and development activities; impede our clinical trial initiation and recruitment and the ability of patients to continue in clinical trials, including the risk that participants enrolled in our clinical trials will contract COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events; and impede testing, monitoring, study procedures (such as endoscopies that are deemed non-essential), data collection and analysis and other related activities that may impact the integrity of subject data and clinical study endpoints; any of which could delay our preclinical studies and clinical trials and increase our development costs, and have a material adverse effect on our business, financial condition and results of operations. The COVID-19 outbreak could also potentially affect the business of the FDA, European Medicines Agency (EMA) or other regulatory authorities, which could result in delays in meetings related to planned clinical trials. The COVID-19 pandemic and mitigation measures have had and may continue to have an adverse impact on global economic conditions which could have an adverse effect on our business and financial condition, including impairing our ability to raise capital when needed. The extent to which the COVID-19 pandemic impacts our results, including financial results for our diagnostic services business, will depend on future developments that are highly uncertain and cannot be predicted, including new information that may emerge concerning the virus and the actions to contain its impact.

We are dependent on the services of our management and other clinical and scientific personnel, and if we are not able to retain these individuals or recruit additional management or clinical and scientific personnel, our business will suffer.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. We are highly dependent upon our senior management, as well as our senior scientists and other members of our management team. The loss of services of any of these individuals could delay or prevent the successful development of our product pipeline, initiation or completion of our preclinical studies and clinical trials or the commercialization of our product candidates. Although we have executed employment agreements or offer letters with each member of our senior management team, these agreements are terminable at will with or without notice and, therefore, we may not be able to retain their services as expected. We do not currently maintain “key person” life insurance on the lives of our executives or any of our employees. This lack of insurance means that we may not have adequate compensation for the loss of the services of these individuals.
We will need to expand and effectively manage our managerial, operational, financial and other resources in order to successfully pursue our clinical development and commercialization efforts. We may not be successful in maintaining our unique company culture and continuing to attract or retain qualified management and scientific and clinical personnel in the future due to the intense competition for qualified personnel among biopharmaceutical, biotechnology and other businesses, particularly in the San Diego area. Our industry has experienced a high rate of turnover of management personnel in recent years. If we are not able to attract, integrate, retain and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

We may encounter difficulties in managing our growth and expanding our operations successfully.

We had 115 full-time employees as of July 24, 2020. As we continue development and pursue the potential commercialization of our product candidates, as well as function as a public company, we will need to expand our financial, development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various strategic partners, suppliers and other third parties. Our future financial performance and our ability to develop and commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively.

The terms of our Loan Agreement place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.

As of June 30, 2020, we have an outstanding term loan in the principal amount of $7.5 million under our Loan Agreement with Oxford. The term loan is secured by a lien covering substantially all of our personal property, rights and assets, excluding intellectual property, which is subject to a negative pledge. The Loan Agreement contains customary affirmative and negative covenants and events of default applicable to us. The affirmative covenants include, among others, covenants requiring us to maintain governmental approvals, deliver certain financial reports, maintain insurance coverage and protect material intellectual property. The negative covenants include, among others, restrictions on transferring collateral, incurring additional indebtedness, engaging in mergers or acquisitions, paying cash dividends or making other distributions, making investments, creating liens, selling assets and making any payment on subordinated debt, in each case subject to certain exceptions. The restrictive covenants of the Loan Agreement could cause us to be unable to pursue business opportunities that we or our stockholders may consider beneficial. In addition, Oxford could declare a default upon the occurrence of any event that it interprets as a material adverse change as defined under the Loan Agreement. If we default under the Loan Agreement, Oxford may accelerate all of our repayment obligations and take control of our pledged assets, potentially requiring us to renegotiate our agreement on terms less favorable to us or to immediately cease operations. Further, if we are liquidated, Oxford’s right to repayment would be senior to the rights of the holders of our common stock to receive any proceeds from the liquidation. Any declaration by Oxford of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline. If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

We are subject to various federal, state and foreign healthcare fraud and abuse laws and regulations, which could increase compliance costs, and our failure to comply with these laws and regulations could harm our results of operations and financial condition.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors and customers expose us to broadly applicable foreign, federal and state fraud and abuse and other healthcare and privacy laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including our commercial laboratory
operations and how we research, market, sell and distribute any products for which we obtain marketing approval. Such laws include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing any remuneration (including any kickback, bribe or certain rebates), directly or indirectly, overtly or covertly, in cash or in kind, in return for, either the referral of an individual or the purchase, lease, or order, or arranging for or recommending the purchase, lease, or order of any good, facility, item or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation;

- the federal physician self-referral prohibitions, commonly known as the Stark Law, which generally prohibit entities from billing a patient or the Medicare or Medicaid programs for certain designated health services, including clinical laboratory services, when the physician ordering the service, or any member of such physician’s immediate family, has a financial interest, such as an ownership or investment interest in or compensation arrangement with us, unless the arrangement meets an exception to the prohibition. These prohibitions apply regardless of any intent by the parties to induce or reward referrals or the reasons for the financial relationship and the referral;

- the federal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making or causing to be made a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute of Stark Law constitutes a false or fraudulent claim for purposes of the civil False Claims Act;

- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) to report annually to the CMS, information related to payments and other “transfers of value” made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by such healthcare professionals and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report such information regarding payments and transfers of value provided, as well as ownership and investment interests held, during the previous year to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists and certified nurse-midwives; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; some state laws require biotechnology companies to comply with the biotechnology industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to
physicians and other healthcare providers or marketing expenditures; some state laws that require biotechnology companies to report information on the pricing of certain drug products; and some state and local laws require the registration or pharmaceutical sales representatives.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare and privacy laws and regulations will involve ongoing substantial costs. It is possible that governmental authorities will conclude that our business practices, including certain consulting agreements with physicians, some of whom are in a position to influence the order of or use of our tests and product candidates, if approved, and are compensated in the form of stock or stock options for services provided to us, may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare program.

Recently enacted legislation, future legislation and healthcare reform measures may increase the difficulty and cost for us to obtain marketing approval for and commercialize our product candidates and may affect the prices we may set.

In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system, including cost-containment measures that may reduce or limit coverage and reimbursement for newly approved drugs and affect our ability to profitably sell any product candidates for which we obtain marketing approval. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare.

For example, in March 2010, the ACA was enacted in the United States. Among the provisions of the Affordable Care Act of importance to our potential product candidates, the ACA: established an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents; extended manufacturers’ Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations; expands eligibility criteria for Medicaid programs; expands the entities eligible for discounts under the Public Health program; increases the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program; creates a new Medicare Part D coverage gap discount program; establishes a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research; and establishes a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

There remain judicial and Congressional challenges to certain aspects of the ACA, as well as efforts by the current U.S. administration to repeal or replace certain aspects of the ACA. For example, H.R. 1, “An Act to provide for reconciliation pursuant to titles II and V of the concurrent resolution on the budget for fiscal year 2018”, informally titled the Tax Cuts and Jobs Act (the Tax Act), includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year (commonly referred to as the individual mandate.). On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas ruled that the
individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit affirmed the District Court’s decision that the individual mandate was unconstitutional but remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case, although it remains unclear when or how the Supreme Court will rule. It is also unclear how other efforts to challenge, repeal or replace the ACA will impact the ACA or our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, resulted in reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through December 31, 2020, unless additional Congressional action is taken. In addition, on January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Further, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the current U.S. administration’s budget proposal for the fiscal year 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients and increase patient access to lower-cost generic and biosimilar drugs. In addition, in July 2020, President Trump signed four executive orders that attempt to implement several of the Administration’s proposals, including: (1) a policy that would tie Medicare Part B drug prices to international drug prices; (2) an order that directs the U.S. Department of Health and Human Services (HHS) to finalize the Canadian drug importation proposed rule previously issued by HHS allowing states to submit importation program proposals to the FDA for review and authorization and makes other changes allowing for the facilitation of grants to individuals of waivers of the prohibition of importation of prescription drugs, provided such importation poses no additional risk to public safety; (3) one that reduces costs of insulin and epipens to patients of federally qualified health centers; and (4) an order that directs HHS to finalize the rulemaking process on modifying the safe harbors under the federal Anti-Kickback Statute regarding the rebates paid by manufacturers to Medicare Part D plans and Medicaid managed care organizations, either directly or through pharmacy benefit managers under contract with such sponsors or organizations, if HHS confirms that the action is not projected to increase federal spending, Medicare beneficiary premiums, or patients’ total out-of-pocket costs. Although a number of these and other measures may require additional authorization to become effective, Congress and the current U.S. administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our therapeutic product candidates, if approved, or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.
We expect that the ACA, these new laws and other healthcare reform measures that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates, if approved.

We and any of our third-party manufacturers or suppliers may use potent chemical agents and hazardous materials, and any claims relating to improper handling, storage or disposal of these materials could be time consuming or costly.

We and any of our third-party manufacturers or suppliers and current or potential future collaborators will use biological materials, potent chemical agents and may use hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety of the environment. Our operations and the operations of our third-party manufacturers and suppliers also produce hazardous waste products. Federal, state and local laws and regulations govern the use, generation, manufacture, storage, handling and disposal of these materials and wastes. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our product development efforts. In addition, we cannot eliminate the risk of accidental injury or contamination from these materials or wastes. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. In the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended. Although we maintain workers’ compensation insurance for certain costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for toxic tort claims that may be asserted against us in connection with our storage or disposal of biologic, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations, which have tended to become more stringent over time. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions or liabilities, which could materially adversely affect our business, financial condition, results of operations and prospects.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our products.

We face an inherent risk of product liability as a result of the clinical trials of our product candidates and will face an even greater risk if we commercialize our product candidates. For example, we may be sued if our product candidates allegedly cause injury or are found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product candidate, negligence, strict liability and a breach of warranties. Claims may be brought against us by clinical trial participants, patients or others using, administering or selling products that may be approved in the future. Claims could also be asserted under state consumer protection acts.

If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit or cease the commercialization of our products. Even a successful defense would...
require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our products;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- a diversion of our management’s time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- significant negative financial impact;
- the inability to commercialize our product candidates; and
- a decline in our stock price.

We currently do not hold product liability insurance coverage, but will need to obtain this insurance coverage prior to commencing clinical trials of our product candidates. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of our product candidates. Although we will maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies will also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

Our insurance policies are expensive and only protect us from some business risks, which will leave us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include property, general liability, employment benefits liability, business automobile, workers’ compensation, products liability, malicious invasion of our electronic systems, and clinical trials, and directors’ and officers’, employment practices and fiduciary liability insurance. We do not know, however, if we will be able to maintain insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our financial position and results of operations.

We and any of our current and potential future collaborators will be required to report to regulatory authorities if any of our approved products cause or contribute to adverse medical events, and any failure to do so would result in sanctions that would materially harm our business.

If we or any of our current and potential future collaborators are successful in commercializing our products, the FDA and foreign regulatory authorities would require that we and such collaborators report certain information about adverse medical events if those products may have caused or contributed to those adverse events. The timing of our obligation to report would be triggered by the date we become aware of the adverse event as well as the nature of the event. We and any of our current or potential future collaborators or CROs may fail to report adverse events within the prescribed timeframe. If we or any of our current or potential future
collaborators or CROs fail to comply with such reporting obligations, the FDA or a foreign regulatory authority could take action, including criminal prosecution, the imposition of civil monetary penalties, seizure of our products or delay in approval or clearance of future products.

Our internal computer systems, or those of any of our CROs, manufacturers, other contractors or consultants or current or potential future collaborators, may fail or experience security breaches or other unauthorized or improper access, which could result in a material disruption of our product development programs.

In the ordinary course of business, we collect, store, transmit and otherwise process large amounts of data including, without limitation, proprietary business information and personal information. Despite the implementation of security measures, our internal technology systems (including infrastructure) and those of our current and any future CROs and other contractors, consultants and collaborators are vulnerable to privacy and information security incidents, such as data breaches, damage from computer viruses, cybersecurity threats (such as denial-of-service attacks, cyber-attacks or cyber-intrusions over the Internet, hacking, phishing and other social engineering attacks), unauthorized access or use, natural disasters, terrorism, war and telecommunication and electrical failures. As we become more dependent on information technologies to conduct our operations, such incidents, including deliberate attacks and attempts to gain unauthorized access to computer systems and networks, may increase in frequency and sophistication. If such an event were to occur and cause interruptions in our operations or result in the unauthorized disclosure of or access to personally identifiable information or protected health information (violating certain privacy laws such as HIPAA or the European General Data Protection Regulation (the GDPR)), it could result in a material disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other similar disruptions. Some of the federal, state and foreign government requirements include obligations of companies to notify individuals of security breaches involving particular personally identifiable information, which could result from breaches experienced by us or by our vendors, contractors, or organizations with which we have formed strategic relationships.

Because the techniques used to obtain unauthorized access, disable or degrade service or sabotage systems change frequently and often are not recognized until launched against a target, we and our partners may be unable to anticipate these techniques or to implement adequate preventative measures. Further, we do not have any control over the operations of the facilities or technology of our cloud and service providers, including any third-party vendors that collect, process and store personal information on our behalf. Our systems, servers and platforms and those of our service providers may be vulnerable to computer viruses or physical or electronic break-ins that our or their security measures may not detect. Individuals able to circumvent such security measures may misappropriate our confidential or proprietary information, disrupt our operations, damage our computers or otherwise impair our reputation and business. We may need to expend significant resources and make significant capital investment to protect against security breaches or to mitigate the impact of any such breaches. There can be no assurance that we or our third-party providers will be successful in preventing security breaches or successfully mitigating their effects.

Any security breach or other incident, whether real or perceived, that results in a loss of or accidental, unlawful or unauthorized access to, use of, release of, or other processing of personal, proprietary or other sensitive information could impact our reputation, cause us to incur significant liability and costs, including legal expenses, fines and penalties for any noncompliance with any privacy and security laws, harm customer confidence, hurt our expansion into new markets, cause us to incur remediation costs, or cause us to lose existing customers. For example, the loss of clinical trial data from clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. We also rely on third parties to manufacture our product candidates, and similar events relating to their computer systems could also have a material adverse effect on our business. Any insurance we maintain against the risk of this type of loss may not be sufficient to cover actual losses, or may not apply to the circumstances relating to any particular loss.
Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or manmade disasters or business interruptions, for which we are predominantly self-insured. We rely on third-party manufacturers to produce our product candidates. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers were affected by a man-made or natural disaster or other business interruption. In addition, our corporate headquarters is located in San Diego, California near major earthquake faults and fire zones, and the ultimate impact on us of being located near major earthquake faults and fire zones and being consolidated in a certain geographical area is unknown. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

Our business could be affected by litigation, government investigations and enforcement actions.

We currently operate in a number of jurisdictions in a highly regulated industry and we could be subject to litigation, government investigation and enforcement actions on a variety of matters in the United States, or foreign jurisdictions, including, without limitation, intellectual property, regulatory, product liability, environmental, whistleblower, false claims, privacy, anti-kickback, anti-bribery, securities, commercial, employment and other claims and legal proceedings which may arise from conducting our business. Any determination that our operations or activities are not in compliance with existing laws or regulations could result in the imposition of fines, civil and criminal penalties, equitable remedies, including disgorgement, injunctive relief and/or other sanctions against us, and remediation of any such findings could have an adverse effect on our business operations.

Legal proceedings, government investigations and enforcement actions can be expensive and time consuming. An adverse outcome resulting from any such proceeding, investigations or enforcement actions could result in significant damages awards, fines, penalties, exclusion from the federal healthcare programs, healthcare debarment, injunctive relief, product recalls, reputational damage and modifications of our business practices, which could have a material adverse effect on our business and results of operations.

Our employees and independent contractors, including principal investigators, CROs, consultants and vendors, may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees and independent contractors, including principal investigators, CROs, consultants and vendors may engage in misconduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violate: (i) the laws and regulations of the FDA and other similar regulatory requirements, including those laws that require the reporting of true, complete and accurate information to such authorities, (ii) manufacturing standards, including cGMP requirements, (iii) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the United States and abroad or (iv) laws that require the true, complete and accurate reporting of financial information or data. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, the creation of fraudulent data in our preclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. In addition, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful...
in defending ourselves or asserting our rights, those actions could have a significant impact on our business and financial results, including, without limitation, the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, imprisonment, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We could face criminal liability and other serious consequences for violations, which could harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, and various economic and trade sanctions regulations administered by the U.S. Treasury Department’s Office of Foreign Assets Controls and anti-corruption and anti-money laundering laws and regulations, including the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, CROs, contractors and other collaborators and partners from authorizing, promising, offering, providing, soliciting or receiving, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties for clinical trials outside of the United States, to sell our products abroad once we enter a commercialization phase, and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, CROs, contractors and other collaborators and partners, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

We may engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.

From time to time, we may consider strategic transactions, including acquisitions of companies, such as our acquisition of PLI in June 2019, asset purchases and out-licensing or in-licensing of intellectual property, products or technologies. Additional potential transactions that we may consider in the future include a variety of business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any future transactions could increase our near and long-term expenditures, result in potentially dilutive issuances of our equity securities, including our common stock, or the incurrence of debt, contingent liabilities, amortization expenses or acquired in-process research and development expenses, any of which could affect our financial condition, liquidity and results of operations. Future acquisitions may also require us to obtain additional financing, which may not be available on favorable terms or at all. These transactions may never be successful and may require significant time and attention of our management. In addition, the integration of any business that we may acquire in the future may disrupt our existing business and may be a complex, risky and costly endeavor for which we may never realize the full benefits of the acquisition. Accordingly, although there can be no assurance that we will undertake or successfully complete any additional transactions of the nature described above, any additional transactions that we do complete could have a material adverse effect on our business, results of operations, financial condition and prospects.
Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.

The global credit and financial markets have recently experienced extreme volatility and disruptions (including as a result of the ongoing COVID-19 pandemic), which has included severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive an economic downturn, which could directly affect our ability to attain our operating goals on schedule and on budget.

Changes in U.S. tax law may materially adversely affect our financial condition, results of operations and cash flows.

The Tax Act significantly changed the U.S. federal income taxation of U.S. corporations. The Tax Act remains unclear in many respects and has been, and may continue to be, the subject of amendments and technical corrections, as well as interpretations and implementing regulations by the Treasury and Internal Revenue Service (IRS), which have lessened or increased certain adverse impacts of the Tax Act and may continue to do so in the future. In addition, it is unclear how these U.S. federal income tax changes will affect state and local taxation, which often uses federal taxable income as a starting point for computing state and local tax liabilities. On March 27, 2020, the CARES Act was signed into law to address the COVID-19 crisis. The CARES Act is an approximately $2 trillion emergency economic stimulus package that includes numerous U.S. federal income tax provisions, including the modification of: (i) net operating loss (NOL) rules (as discussed below), (ii) the alternative minimum tax refund and (iii) business interest deduction limitations under Section 163(j) of the Internal Revenue Code of 1986, as amended (the Code). We continue to work with our tax advisors and auditors to determine the full impact the Tax Act and the CARES Act will have on us. We urge our investors to consult with their legal and tax advisors with respect to both the Tax Act and the CARES Act and the potential tax consequences of investing in our common stock.

Our ability to use net operating loss carryforwards and other tax attributes is likely to be limited in connection with this offering or other ownership changes.

We have incurred substantial losses during our history, do not expect to become profitable in the near future and may never achieve profitability. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire (if at all). At December 31, 2019, we had federal and state NOL carryforwards of approximately $27.7 million and $36.1 million, respectively.

Under the Tax Act, federal NOL carryforwards arising in tax years beginning after December 31, 2017, may be carried forward indefinitely. Under the CARES Act, federal NOL carryforwards arising in tax years beginning after December 31, 2017 and before January 1, 2021 may be carried back to each of the five tax years preceding the tax year of such loss. The deductibility of federal NOL carryforwards, particularly for tax years beginning after December 31, 2020, may be limited. It is uncertain if and to what extent various states will conform to the Tax Act or the CARES Act. In addition, our NOL carryforwards are subject to review and possible adjustment by the IRS and state tax authorities. Under Section 382 of the Code, our federal NOL carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership of our company. An "ownership change" pursuant to Section 382 of the Code generally occurs if one or more stockholders or groups
of stockholders who own at least 5% of a company’s stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. Similar rules may apply under state tax laws. We have not yet formally determined the amount of the cumulative change in our ownership resulting from this offering or other transactions, or any resulting limitations on our ability to utilize our NOL carryforwards and other tax attributes. However, we believe that our ability to utilize our NOL carryforwards and other tax attributes to offset future taxable income or tax liabilities is likely to be limited as a result of ownership changes, including potential changes in connection with this offering. If we earn taxable income, such limitations could result in increased future income tax liability to us and our future cash flows could be adversely affected. We have recorded a full valuation allowance related to our NOL carryforwards and other deferred tax assets due to the uncertainty of the ultimate realization of the future benefits of those assets.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection for our therapeutic and diagnostic programs and other proprietary technologies we may develop, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize our therapeutic and diagnostic programs and other proprietary technologies we may develop may be adversely affected.

Our success depends in large part on our ability and the ability of our licensors and collaborators to obtain and maintain patent protection in the United States and other countries with respect to our therapeutic and diagnostic programs and other proprietary technologies we may develop. We seek to protect our proprietary position, in part, by filing patent applications in the United States and abroad relating to our therapeutic and diagnostic programs and other proprietary technologies we may develop. If we or our licensors are unable to obtain or maintain patent protection with respect to our therapeutic programs and other proprietary technologies we may develop, our business, financial condition, results of operations and prospects could be materially harmed.

Our current patent portfolio contains a limited number of patents and patent applications, some of which are in-licensed from third parties, related to various aspects of our therapeutic and diagnostic programs. We do not currently own or license any issued composition of matter patents or patent applications covering our PR600 product candidate, and we cannot be certain that any patent applications we or our licensors may file will result in issued patent claims covering the composition of matter of PR600. Composition-of-matter patents on the active pharmaceutical ingredient, or API, in prescription drug products are generally considered to be the strongest form of intellectual property protection for drug products because those types of patents provide protection without regard to any particular method of use or manufacture or formulation of the API used. Method-of-use patents protect the use of a product for the specified method and formulation patents cover formulations of the API. These types of patents do not prevent a competitor or other third party from developing or marketing an identical product for an indication that is outside the scope of the patented method or from developing a different formulation that is outside the scope of the patented formulation. Moreover, with respect to method-of-use patents, even if competitors or other third parties do not actively promote their product for our targeted indications or uses for which we may obtain patents, physicians may recommend that patients use these products off-label, or patients may do so themselves. Although off-label use may infringe or contribute to the infringement of method-of-use patents, the practice is common, and this type of infringement is difficult to prevent or prosecute. Accordingly, there can be no assurance that our patent portfolio will provide us with any competitive advantage.

Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our inventions, obtain, maintain and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our protection. We cannot predict whether the patent applications we or our licensors are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection against competitors or other third parties.
The patent prosecution process is expensive, time-consuming, and complex, and we may not be able to file, prosecute, maintain, defend, enforce, or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Moreover, in some circumstances, we do not have the right to control the preparation, filing and prosecution of patent applications, or to maintain and defend the patents, directed to technology that we license from third parties. We may also require the cooperation of our licensor in order to enforce the licensed patent rights, and such cooperation may not be provided. Therefore, these patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. We cannot be certain that patent prosecution and maintenance activities by our licensors have been or will be conducted in compliance with applicable laws and regulations, which may affect the validity and enforceability of such patents or any patents that may issue from such patent applications. If our licensors fail to do so, this could cause us to lose rights in any applicable intellectual property that we in-license, and as a result, our ability to develop and commercialize products or product candidates may be adversely affected and we may be unable to prevent competitors from making, using and selling competing products.

In addition, although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to obtain or maintain valid and enforceable patent protection. Furthermore, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or until issuance, or in some cases not at all. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in any of our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions.

The patent position of biotechnology and pharmaceutical companies is highly uncertain in general, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our owned or in-licensed patent applications may not result in patents being issued which protect our therapeutic and diagnostic programs and other proprietary technologies we may develop or which effectively prevent others from commercializing competitive technologies and products.

Moreover, the claim coverage in a patent application can be significantly reduced before a corresponding patent issues. Even if our owned or in-licensed patent applications issue as patents, they may not issue in a form that will provide us with meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents issuing from our owned or in-licensed patent applications may be challenged, narrowed, circumvented or invalidated by third parties. Consequently, we do not know whether our therapeutic and diagnostic programs and other proprietary technology will be protectable or remain protected by valid and enforceable patents. Even if a patent issues, our competitors or other third parties may be able to circumvent the patent by developing similar or alternative technologies or products in a non-infringing manner which could materially adversely affect our business, financial condition, results of operations and prospects. In addition, given the amount of time required for the development, testing and regulatory review of our therapeutic and diagnostic programs and eventual product candidates, patents protecting our product candidates might expire before or shortly after such product candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

The issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability and our patent rights may be challenged in the courts or patent offices in the United States and abroad. We or any of our licensors may be subject to a third-party pre-issuance submission of prior art to the United States Patent and Trademark Office (USPTO) or become involved in opposition, derivation, revocation, reexamination, post-grant
and inter partes review, or other similar proceedings challenging our patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our patent rights, allow third parties to commercialize our therapeutic and diagnostic programs and other proprietary technologies we may develop and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us.

Moreover, some of our owned and in-licensed patent rights are, and may in the future be, co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners’ interest in such patent rights, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of such patent rights in order to enforce such patent rights against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Furthermore, our owned and in-licensed patent rights may be subject to a reservation of rights by one or more third parties. For example, the research resulting in certain of our patent rights and technology was funded in part by the U.S. government. As a result, the government may have certain rights, or march-in rights, to such patent rights and technology. When new technologies are developed with government funding, the government generally obtains certain rights in any resulting patents, including a non-exclusive license authorizing the government to use the invention for non-commercial purposes. These rights may permit the government to disclose our confidential information to third parties and to exercise march-in rights to use or allow third parties to use our licensed technology. The government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the U.S. Any exercise by the government of such rights could harm our competitive position, business, financial condition, results of operations and prospects.

We may not be able to protect our intellectual property and proprietary rights throughout the world.

Filing, prosecuting, maintaining and defending patents on our therapeutic and diagnostic programs and other proprietary technologies we may develop in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but enforcement is not as strong as that in the United States. These products may compete with our products, and our patent rights or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, such as certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patent rights or marketing of competing products in violation of our intellectual property and proprietary rights generally. In addition, some jurisdictions, such as Europe, Japan and China, may have a higher standard for patentability than in the United States, including, for example, the requirement of claims having literal support in the original patent filing and the limitation on using supporting data that is not in the original patent filing. Under those heightened patentability requirements, we may not be able to obtain sufficient patent protection in certain jurisdictions even though the same or similar patent protection can be secured in the U.S. and other jurisdictions.
Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patent rights at risk of being invalidated or interpreted narrowly, could put our owned or in-licensed patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees, and various other government fees on patents and patent applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned or licensed patents and patent applications. In certain circumstances, we rely on our licensing partners to pay these fees due to U.S. and non-U.S. patent agencies. The USPTO and various non-U.S. government agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. We are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. In some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

The COVID-19 pandemic may impair our and our licensors’ ability to comply with these procedural, document submission, fee payment, and other requirements imposed by government patent agencies, which may materially and adversely affect our ability to obtain or maintain patent protection for our products and product candidates. This highly contagious disease has spread to most of the countries in the world and throughout the United States, creating a serious impact on patent offices worldwide and patent office personnel, as well as our employees and agents working directly with the patent offices to obtain and maintain patent protection in impacted countries. There may be situations in which a delay in, or failure to, file a patent application pertaining to certain subject matter will result in a lack of patent protection of that subject matter. Similarly, there may be situations in which a delay in, or failure to, respond to a patent office communication, pay a requisite fee, or otherwise maintain a patent application will result in loss of patent rights to that subject matter. In such an event, potential competitors might be able to enter the market with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of
issued patents. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act (the America Invents Act) enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are typically not published until 18 months after filing or until issuance, or in some cases not at all, we cannot be certain that we were the first to either (i) file any patent application related to our therapeutic and diagnostic programs and other proprietary technologies we may develop or (ii) invent any of the inventions claimed in our owned or in-licensed patent applications.

The America Invents Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, inter partes review and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our owned or in-licensed patent applications and the enforcement or defense of patents issuing from those patent applications, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals, as well as diagnostic methods, are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. For example, U.S. Supreme Court rulings, such as Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66 (2012) and Alice Corp. Pty. Ltd. v. CLS Bank Int’l, 573 U.S. 208 (2014), have created judicial exceptions to patentability of diagnostic methods in the U.S. that are directed to laws of nature or natural phenomena. As such, we cannot guarantee that we will be able to obtain patents covering our diagnostic products, including our companion diagnostic products. These cases and others like them have created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways. In addition, the complexity and uncertainty of European patent laws have also increased in recent years. Any of the foregoing could have a material adverse effect on our owned and in-licensed patent portfolio and our ability to protect and enforce our intellectual property in the future.

Issued patents covering our therapeutic or diagnostic programs or other proprietary technologies we may develop could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad.

If we or one of our licensors initiated legal proceedings against a third party to enforce a patent covering our therapeutic or diagnostic programs or other proprietary technologies we may develop, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be
an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may raise claims challenging the validity or enforceability of a patent before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, inter partes review, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in the revocation of, cancellation of or amendment to our patent rights in such a way that they no longer cover our therapeutic and diagnostic programs and other proprietary technologies we may develop. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we or our licensing partners and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our therapeutic and diagnostic programs and other proprietary technologies we may develop. Such a loss of patent protection would have a material adverse impact on our business, financial condition, results of operations and prospects.

Patent terms may be inadequate to protect our competitive position on products and product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional or international patent application filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent has expired, we may be vulnerable to competition from competitive products, including generics or biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. For example, certain patents related to certain of our LDT diagnostic products expired in 2020 and certain other patents related to such products are due to expire between 2021 and 2025. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If we do not obtain patent term extension for our product candidate, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of any of our product candidates, one or more of our issued U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984 (Hatch-Waxman Amendments). The Hatch-Waxman Amendments permit a patent extension term (PTE) of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. Similar patent term restoration provisions to compensate for commercialization delay caused by regulatory review are also available in certain foreign jurisdictions, such as in Europe under Supplemental Protection Certificate (SPC). However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations and prospects could be materially harmed.
We may be subject to claims challenging the inventorship of our owned or in-licensed patent rights and other intellectual property.

We may be subject to claims that former employees, collaborators or other third parties have an interest in our patent rights, trade secrets, or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our therapeutic and diagnostic programs and other proprietary technologies we may develop. Litigation may be necessary to defend against these and other claims challenging inventorship or our patent rights, trade secrets or other intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our therapeutic and diagnostic programs and other proprietary technologies we may develop. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patent protection for our therapeutic and diagnostic programs and other proprietary technologies we may develop, we also rely on trade secrets and confidentiality agreements to protect our unpatented know-how, technology, and other proprietary information and to maintain our competitive position. With respect to Prometheus 360 and our development programs, we consider trade secrets and know-how to be one of our important sources of intellectual property. Trade secrets and know-how can be difficult to protect. In particular, the trade secrets and know-how in connection with Prometheus 360, development programs and other proprietary technology we may develop may over time be disseminated within the industry through independent development, the publication of journal articles describing the methodology and the movement of personnel with scientific positions in academia and industry.

We seek to protect these trade secrets and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be materially and adversely harmed.

We may be subject to claims that third parties have an ownership interest in our trade secrets. For example, we may have disputes arise from conflicting obligations of our employees, consultants or others who are involved in developing our product candidate. Litigation may be necessary to defend against these and other claims challenging ownership of our trade secrets. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable trade secret rights, such as exclusive ownership of, or right to use, trade secrets that are important to our therapeutic and diagnostic programs and other proprietary technologies we may develop. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.
We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect our ability to develop and market our products and product candidates.

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending patent application in the United States and abroad that is relevant to or necessary for the commercialization of our current and future products and product candidates in any jurisdiction. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent’s prosecution history. Our interpretation of the relevance or the scope of a patent or a pending patent application may be incorrect, which may negatively impact our ability to market our products. We may incorrectly determine that our products or product candidates are not covered by a third-party patent or may incorrectly predict whether a third party’s pending patent application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, and our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may be subject to claims that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Some of our employees, consultants and advisors are currently or were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual’s current or former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations and prospects.

Third-party claims of intellectual property infringement, misappropriation or other violations against us or our collaborators may prevent or delay the development and commercialization of our therapeutic and diagnostic programs and other proprietary technologies we may develop.

Our commercial success depends in part on our ability, and the ability of our collaborators, to avoid infringing, misappropriating and otherwise violating the patents and other intellectual property rights of third parties. There is a substantial amount of complex litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, derivation and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. As discussed above, recently, due to changes in U.S. law, new procedures including inter partes review and post-grant review have also been implemented. As stated above, these changes add uncertainty to the possibility of challenges to our patent rights in the future.
Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist in the fields in which we are commercializing or plan to commercialize our therapeutic and diagnostic programs and in which we are developing other proprietary technologies. As the biotechnology and pharmaceutical industries expand and more patents are issued, and as we gain greater visibility and market exposure as a public company, the risk that our therapeutic and diagnostic programs and commercializing activities may give rise to claims of infringement of the patent rights of others increases. We cannot assure you that our therapeutic and diagnostic programs and other proprietary technologies we may develop will not infringe existing or future patents owned by third parties. We may not be aware of patents that have already been issued and that a third party, including a competitor in the fields in which we are developing our therapeutic and diagnostic programs, might assert as infringed by us. It is also possible that patents owned by third parties of which we are aware, but which we do not believe we infringe or that we believe we have valid defenses to any claims of patent infringement, could be found to be infringed by us. It is not unusual that corresponding patents issued in different countries have different scopes of coverage, such that in one country a third-party patent does not pose a material risk, but in another country, the corresponding third-party patent may pose a material risk to our products or product candidates. As such, we monitor third-party patents in the relevant pharmaceutical markets. In addition, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that we may infringe.

In the event that any third party claims that we infringe their patents or that we are otherwise employing their proprietary technology without authorization and initiates litigation against us, even if we believe such claims are without merit, a court of competent jurisdiction could hold that such patents are valid, enforceable and infringed by us. Defense of infringement claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from our business, and may impact our reputation. In the event of a successful claim of infringement against us, we may be enjoined from further developing or commercializing the infringing products or technologies. In addition, we may have to pay substantial damages, including treble damages and attorneys’ fees for willful infringement, obtain one or more licenses from third parties, pay royalties and/or redesign our infringing products or technologies, which may be impossible or require substantial time and monetary expenditure. Such licenses may not be available on commercially reasonable terms or at all. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, we may be unable to commercialize the infringing products or technologies or such commercialization efforts may be significantly delayed, which could in turn significantly harm our business. In addition, we may in the future pursue patent challenges with respect to third-party patents, including as a defense against the foregoing infringement claims. The outcome of such challenges is unpredictable.

Even if resolved in our favor, the foregoing proceedings could be very expensive, particularly for a company of our size, and time-consuming. Such proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such proceedings adequately. Some of our competitors may be able to sustain the costs of litigation or administrative proceedings more effectively than we can because of greater financial resources. Such legal proceedings may also absorb significant time of our technical and management personnel and distract them from their normal responsibilities. Uncertainties resulting from such proceedings could impair our ability to compete in the marketplace. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition or results of operations.
We may become involved in lawsuits to protect or enforce our patent rights and other intellectual property rights, which could be expensive, time consuming and unsuccessful.

Third parties, such as a competitor, may infringe our patent rights. In an infringement proceeding, a court may decide that a patent owned by or licensed to us is invalid or unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that the patent does not cover such technology. In addition, our patent rights may become involved in inventorship, priority or validity disputes. To counter or defend against such claims can be expensive and time consuming. An adverse result in any litigation proceeding could put our patent rights at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation and proceedings, there is a risk that some of our confidential information could be compromised by disclosure during such litigation and proceedings.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition or results of operations.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we are given an opportunity to respond to such rejections, we may be unable to overcome them. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, which may not survive such proceedings. Moreover, any name we have proposed to use with our product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA or an equivalent administrative body in a foreign jurisdiction objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark.

We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impairing our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations.
of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, domain name or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations and prospects.

**Intellectual property rights do not necessarily address all potential threats.**

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products that are similar to our products and product candidates or utilize similar technology but that are not covered by the claims of the patents that we own or license;
- we, or our licensing partners or collaborators, might not have been the first to make the inventions covered by our owned or licensed current or future patent applications;
- we, or our licensing partners or collaborators, might not have been the first to file patent applications covering our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing, misappropriating or otherwise violating our intellectual property rights;
- it is possible that our owned or licensed current or future patent applications will not lead to issued patents;
- any patent issuing from our owned or licensed current or future patent applications may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties, or may not provide us with any competitive advantages;
- our competitors or other third parties might conduct research and development activities in countries where we do not have patent or other intellectual property rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- it is possible that there are prior public disclosures that could invalidate our or our licensors’ patents;
- we may not develop additional proprietary technologies that are patentable;
- the patents or pending or future patent applications of others, if issued, may harm our business; and
- we may choose not to file for patent protection in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent application covering such intellectual property.

Should any of the foregoing occur, it could adversely affect our business, financial condition, results of operations and prospects.

**We depend on intellectual property licensed from third parties, and our licensors may not always act in our best interest. If we fail to comply with our obligations under our intellectual property licenses, if the licenses are terminated or if disputes regarding these licenses arise, we could lose significant rights that are important to our business.**

We are dependent, in part, on patents, know-how and other intellectual property and proprietary technology licensed from others. We are a party to a number of license agreements under which we are granted rights to intellectual property that are important to our business and we may enter into additional license agreements in the
future. For example, in September 2017, we entered into an exclusive license agreement with Cedars-Sinai that grants us an exclusive license from Cedars-Sinai under certain patent rights, information and materials related to novel therapeutic targets and diagnostic products for our therapeutic programs that are important to our business. This agreement and our other existing license agreements impose, and we expect that any future license agreements where we in-license intellectual property, will impose on us, various development, regulatory and/or commercial diligence obligations, payment of milestones and/or royalties and other obligations. If we fail to comply with our obligations under these agreements, or we are subject to bankruptcy-related proceedings, the licensor may have the right to terminate the license, in which event we would not be able to develop or market products covered by the license.

If we or our licensors fail to adequately protect our licensed intellectual property, our ability to commercialize product candidates could suffer. We do not have complete control over the maintenance, prosecution and litigation of our in-licensed patents, patent applications and other intellectual property and may have limited control over future intellectual property that may be in-licensed. For example, we cannot be certain that activities such as the maintenance and prosecution by our licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. It is possible that our licensors’ conduct of intellectual property enforcement or defense proceedings may be less vigorous than had we conducted them ourselves, or may not be conducted in accordance with our best interests.

In addition, the agreements under which we license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant patents, know-how and other intellectual property and proprietary technology, or increase what we believe to be our financial or other obligations under the relevant agreement. Disputes that may arise between us and our licensors regarding intellectual property subject to a license agreement could include disputes regarding:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe, misappropriate or otherwise violate intellectual property of the licensor that is not subject to the license agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our products and product candidates and what activities satisfy those diligence obligations;
- our right to transfer or assign the license agreement; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected technology, products or product candidates. As a result, any termination of or disputes over our intellectual property license agreements could result in the loss of our ability to develop and commercialize Prometheus 360, or our therapeutic and diagnostic products or product candidates, or we could lose other significant rights, any of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

For example, our agreements with certain of our third-party research partners provide that improvements developed in the course of our relationship may be owned solely by either us or our third-party research partner,
or jointly between us and the third party. If we determine that rights to such improvements owned solely by a research partner or other third party with whom we collaborate are necessary to commercialize our product candidates or maintain our competitive advantage, we may need to obtain a license from such third party in order to use the improvements and continue developing, manufacturing or marketing our products or product candidates. We may not be able to obtain such a license on an exclusive basis, on commercially reasonable terms, or at all, which could prevent us from commercializing our products or product candidates or allow our competitors or others the chance to access technology that is important to our business. We also may need the cooperation of any co-owners of our intellectual property in order to prosecute, maintain, defend and enforce such intellectual property against third parties, and such cooperation may not be provided to us.

We may not be successful in obtaining or maintaining necessary rights to product components and processes for our development pipeline through acquisitions and in-licenses.

The growth of our business may depend in part on our ability to acquire, in-license or use third-party intellectual property and proprietary rights. Other pharmaceutical companies and academic institutions may own patents or may have filed, or be planning to file, patent applications potentially relevant to our business. In order to avoid infringing such patent rights, we may find it necessary or prudent to obtain licenses to such patent rights from such third-parties. For example, our product candidates may require specific formulations to work effectively and efficiently, we may develop product candidates containing our compounds and pre-existing pharmaceutical compounds, or we may be required by the FDA or comparable foreign regulatory authorities to provide a companion diagnostic test or tests with our product candidates, any of which could require us to obtain rights to use intellectual property held by third parties. In addition, with respect to any patent or other intellectual property rights we may co-own with third parties, we may require licenses to such co-owners’ interest to such patent or other intellectual property rights. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary or important to our business operations. In addition, we may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. Were that to happen, we may need to cease use of the compositions or methods covered by those third-party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe, misappropriate or otherwise violate those intellectual property rights, which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license, it may be non-exclusive, which means that our competitors may also receive access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology.

Additionally, we sometimes collaborate with academic institutions to accelerate our preclinical research or development under written agreements with these institutions. In certain cases, these institutions provide us with an option to negotiate a license to any of the institution’s rights in technology resulting from the collaboration. Even if we hold such an option, we may be unable to negotiate a license from the institution within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to others, potentially blocking our ability to pursue our program.

The licensing and acquisition of third-party intellectual property rights is a competitive area, and companies that may be more established or have greater resources than we do may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their size, resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. There can be no assurance that we will be able to successfully complete these types of negotiations and ultimately acquire the rights to the intellectual property related to the products or product candidates that we may seek to develop or market. If we are unable to successfully obtain rights to required third-party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of certain programs and our business, financial condition, results of operations and prospects could suffer.
We, our collaborators and our service providers may be subject to a variety of data privacy and security laws, regulations, contractual obligations and industry standards, which could increase compliance costs and our failure to comply with them could subject us to potentially significant liability, fines or penalties and otherwise harm our business.

We maintain a large quantity of sensitive information, including confidential business information, protected health information and other personal information, and are subject to laws and regulations governing the privacy and security of such information. The global data protection landscape is rapidly evolving, and we and our collaborators and service providers may be affected by or subject to new, amended or existing laws and regulations in the future, including as our operations continue to expand or if we operate in foreign jurisdictions. These laws and regulations may be subject to differing interpretations, which adds to the complexity of processing personal data. Guidance on implementation and compliance practices are often updated or otherwise revised.

In the United States, there are numerous federal and state data privacy and security laws and regulations governing the collection, use, disclosure and protection of personal information, including federal and state health information privacy laws, federal and state security breach notification laws and federal and state consumer protection laws. Each of these laws is subject to varying interpretations and constantly evolving. By way of example, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and the regulations promulgated thereunder, imposes privacy and security requirements and breach reporting obligations with respect to individually identifiable health information upon “covered entities” (health plans, health care clearinghouses and certain health care providers), and their respective business associates, individuals or entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HIPAA mandates the reporting of certain breaches of health information to the HHS, affected individuals and if the breach is large enough, the media. Entities that are found to be in violation of HIPAA as the result of a breach of unsecured protected health information, a complaint about privacy practices or an audit by HHS, may be subject to significant civil, criminal and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance. Even when HIPAA does not apply, according to the Federal Trade Commission (FTC), violating consumers’ privacy rights or failing to take appropriate steps to keep consumers’ personal information secure may constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act. The FTC expects a company’s data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards.

In addition, certain state laws govern the privacy and security of health information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. By way of example, the California Consumer Privacy Act (CCPA), which went into effect on January 1, 2020, gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability. Although there are limited exemptions for certain health-related information, including certain clinical trial data, the precise application and scope of these exemptions as well as how they would apply to our business is not yet clear. As currently written, the CCPA may impact our business activities and exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information. Accordingly, based on the applicability of the CCA to our business, we may need to update our data privacy and security policies and procedures to comply with the CCPA. Some observers have noted that the CCPA could mark the beginning of a trend toward more stringent privacy legislation in the United States, which could increase our potential liability and adversely affect our business.
In Europe, the GDPR went into effect in May 2018. The GDPR governs the collection, use, disclosure, transfer or other processing of personal data of individuals within the European Economic Area (EEA). Among other things, the GDPR requires the establishment of a lawful basis for the processing of data, imposes requirements relating to the consent of the individuals to whom the personal data relates, including detailed notices for clinical trial subjects and investigators, as well as requirements regarding the security of personal data and notification of data processing obligations to the competent national data processing authorities. In addition, the GDPR increases the scrutiny of transfers of personal data from clinical trial sites located in the EEA to the United States and other jurisdictions that the European Commission does not recognize as having “adequate” data protection laws. Recent legal developments in Europe have created complexity and uncertainty regarding transfers of personal data from the EEA to the United States. For example, on July 16, 2020, the Court of Justice of the European Union (CJEU) invalidated the EU-US Privacy Shield Framework (Privacy Shield) under which personal data could be transferred from the EEA to United States entities that had self-certified under the Privacy Shield scheme. While the CJEU upheld the adequacy of the standard contractual clauses (a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism, and potential alternative to the Privacy Shield), it made clear that reliance on them alone may not necessarily be sufficient in all circumstances. Use of the standard contractual clauses must now be assessed on a case-by-case basis taking into account the legal regime applicable in the destination country, in particular applicable surveillance laws and rights of individuals and additional measures and/or contractual provisions may need to be put in place, however, the nature of these additional measures is currently uncertain. The GDPR imposes substantial fines for breaches and violations (up to the greater of €20 million or 4% of consolidated annual worldwide gross revenue). The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies and obtain compensation for damages resulting from violations of the GDPR. Further, following the withdrawal of the United Kingdom from the EU and the EEA on January 31, 2020 and the end of the transition period, we will have to comply with the GDPR and separately the GDPR as implemented in the United Kingdom, each regime having the ability to fine up to the greater of €20 million/£17 million or 4% of global turnover. The relationship between the United Kingdom and the EU and the EEA in relation to certain aspects of data protection law remains unclear, including how data transfers between EU and EEA member states and the United Kingdom will be treated.

In many jurisdictions, enforcement actions and consequences for noncompliance are rising. In the United States, these include enforcement actions in response to rules and regulations promulgated under the authority of federal agencies and state attorneys general and legislatures and consumer protection agencies. In addition, privacy advocates and industry groups have regularly proposed, and may propose in the future, self-regulatory standards that may legally or contractually apply to us. If we fail to follow these security standards, even if no personal information is compromised, we may incur significant fines or experience a significant increase in costs. Many state legislatures have adopted legislation that regulates how businesses operate online, including measures relating to privacy, data security and data breaches. Laws in all U.S. states require businesses to provide notice to customers whose personally identifiable information has been disclosed as a result of a data breach. The laws are not consistent, and compliance in the event of a widespread data breach is costly.

Compliance with U.S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, update our data privacy and security policies and procedures, or in some cases, impact our ability to operate in certain jurisdictions. Failure by us or our collaborators and service providers to comply with U.S. and international data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals’ privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend, could result in adverse publicity and could have a material adverse effect on our business, financial condition, results of operations and prospects.
Risks Related to Our Common Stock and This Offering

There has been no public market for our common stock and an active, liquid and orderly market for our common stock may not develop, and you may not be able to resell your common stock at or above the public offering price.

Prior to this offering, there has been no public market for our common stock. Although our common stock has been approved for listing on the Nasdaq Global Market (Nasdaq), an active trading market for our common stock may never develop or be sustained following this offering. We and the representatives of the underwriters will determine the initial public offering price of our common stock through negotiation. This price will not necessarily reflect the price at which investors in the market will be willing to buy and sell our shares following this offering. In addition, an active trading market may not develop following the consummation of this offering or, if it is developed, may not be sustained. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other businesses or technologies using our shares as consideration, which, in turn, could materially adversely affect our business.

The trading price of the shares of our common stock could be highly volatile, and purchasers of our common stock could incur substantial losses.

Our stock price is likely to be volatile. The stock market in general and the market for stock of biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the initial public offering price. The market price for our common stock may be influenced by those factors discussed in this “Risk Factors” section and many others, including:

- results of our preclinical studies and clinical trials, and the results of trials of our competitors or those of other companies in our market sector;
- our ability to enroll subjects in our future clinical trials;
- regulatory approval of our product candidates, or limitations to specific label indications or patient populations for its use, or changes or delays in the regulatory review process;
- regulatory developments in the United States and foreign countries;
- changes in the structure of healthcare payment systems;
- the success or failure of our efforts to develop, acquire or license additional product candidates;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- manufacturing, supply or distribution delays or shortages;
- any changes to our relationship with any manufacturers, suppliers, collaborators or other strategic partners;
- achievement of expected product sales and profitability;
- variations in our financial results or those of companies that are perceived to be similar to us;
- market conditions in the biopharmaceutical sector and issuance of securities analysts’ reports or recommendations;
- trading volume of our common stock;
- an inability to obtain additional funding;
sales of our stock by insiders and stockholders;

• general economic, industry and market conditions other events or factors, many of which are beyond our control;

• additions or departures of key personnel; and

• intellectual property, product liability or other litigation against us.

In addition, in the past, stockholders have initiated class action lawsuits against biopharmaceutical companies following periods of volatility in the market prices of these companies’ stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert our management’s attention and resources, which could have a material adverse effect on our business, financial condition and results of operations.

We may allocate the net proceeds from this offering in ways that you and other stockholders may not approve.

Our management will have broad discretion in the application of the net proceeds from this offering, including for any of the purposes described in “Use of Proceeds.” Because of the number and variability of factors that will determine our use of the net proceeds from this offering, their ultimate use may vary substantially from their currently intended use. Our management might not apply our net proceeds in ways that ultimately increase the value of your investment, and the failure by our management to apply these funds effectively could harm our business. Pending their use, we may invest the net proceeds from this offering in short- and intermediate-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government. These investments may not yield a favorable return to our stockholders. If we do not invest or apply the net proceeds from this offering in ways that enhance stockholder value, we may fail to achieve expected results, which could cause our stock price to decline.

You will suffer immediate and substantial dilution in the net tangible book value of the common stock you purchase.

The initial public offering price of our common stock is substantially higher than the pro forma as adjusted net tangible book value per share of our outstanding common stock immediately after the completion of this offering. Purchasers of common stock in this offering will experience immediate dilution of approximately $ per share, assuming an initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover of this prospectus. In the past, we issued options to acquire common stock at prices significantly below the initial public offering price. To the extent these outstanding options are ultimately exercised, investors purchasing common stock in this offering will sustain further dilution. For a further description of the dilution that you will experience immediately after this offering, see “Dilution.”

After this offering, our executive officers, directors and principal stockholders, if they choose to act together, will continue to have the ability to significantly influence all matters submitted to stockholders for approval.

Following the completion of this offering, our executive officers, directors and greater than 5% stockholders, in the aggregate, will own approximately 34.0% of our outstanding common stock (assuming no exercise of the underwriters’ option to purchase additional shares and no exercise of outstanding options or warrants). As a result, such persons, acting together, will have the ability to significantly influence all matters submitted to our board of directors or stockholders for approval, including the appointment of our management, the election and removal of directors and approval of any significant transaction, as well as our management and business affairs. This concentration of ownership may have the effect of delaying, deferring or preventing a change in control, impeding a merger, consolidation, takeover or other business combination involving us, or discouraging a potential acquiror from making a tender offer or otherwise attempting to obtain control of our business, even if such a transaction would benefit other stockholders.
We do not currently intend to pay dividends on our common stock, and, consequently, your ability to achieve a return on your investment will depend on appreciation, if any, in the price of our common stock.

We have never declared or paid any cash dividend on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, under the terms of our Loan Agreement, we are prohibited from paying any cash dividends without the consent of the lenders and any future debt agreements may preclude us from paying dividends. Any return to stockholders will therefore be limited to the appreciation of their stock. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which stockholders have purchased their shares.

Sales of a substantial number of shares of our common stock by our existing stockholders in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur could significantly reduce the market price of our common stock and impair our ability to raise adequate capital through the sale of additional equity securities.

Based on shares of common stock outstanding as of June 30, 2020, upon the closing of this offering, we will have outstanding a total of __ shares of common stock, assuming no exercise of the underwriters’ option to purchase additional shares and no exercise of outstanding options or warrants. Of these shares, only the __ shares of common stock sold in this offering by us, plus any shares sold upon exercise of the underwriters’ option to purchase additional shares, will be freely tradable, without restriction, in the public market immediately following this offering, unless they are purchased by one of our affiliates.

Our directors and executive officers and holders of substantially all of our outstanding securities have entered into lock-up agreements with the underwriters pursuant to which they may not, with limited exceptions, for a period of 180 days from the date of this prospectus, offer, sell or otherwise transfer or dispose of any of our securities, without the prior written consent of SVB Leerink LLC and Credit Suisse Securities (USA) LLC. The underwriters may permit our officers, directors and other securityholders who are subject to the lock-up agreements to sell shares prior to the expiration of the lock-up agreements at any time in their sole discretion. See “Underwriting.” Sales of these shares, or perceptions that they will be sold, could cause the trading price of our common stock to decline. After the lock-up agreements expire, up to an additional __ shares of common stock will be eligible for sale in the public market, of which shares are held by directors, executive officers and other affiliates and will be subject to volume limitations under Rule 144 under the Securities Act.

In addition, as of June 30, 2020, __ shares of common stock that are subject to outstanding options under our employee benefit plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

After this offering, the holders of __ shares of our outstanding common stock, or approximately % of our total outstanding common stock based on shares outstanding as of June 30, 2020, will be entitled to rights with respect to the registration of their shares under the Securities Act, subject to vesting and the 180-day lock-up agreements described above. See “Description of Capital Stock—Registration Rights.” Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.
We are an emerging growth company and a smaller reporting company, and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors.

We are an emerging growth company, as defined in the JOBS Act, and may remain an emerging growth company until the last day of the fiscal year following the fifth anniversary of the completion of this offering. However, if certain events occur prior to the end of such five-year period, including if we become a “large accelerated filer,” our annual gross revenues exceed $1.07 billion or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced “Management’s Discussion and Analysis of Financial Condition and Results of Operations” disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting pursuant to Sarbanes-Oxley;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements, unless the SEC determines the new rules are necessary for protecting the public;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We have taken advantage of reduced reporting burdens in this prospectus. In particular, in this prospectus, we have provided only two years of audited financial statements and have not included all of the executive compensation related information that would be required if we were not an emerging growth company. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be reduced or more volatile. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies. We have elected to avail ourselves of this exemption and, therefore, we will not be subject to the same timing of adoption of new or revised accounting standards as other public companies that are not emerging growth companies.

We are also a smaller reporting company as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our voting and non-voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year.

We will incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. We will be subject to the reporting requirements of the Exchange Act, which will require,
among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition. In addition, Sarbanes-Oxley, as well as rules subsequently adopted by the SEC and Nasdaq to implement provisions of Sarbanes-Oxley, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, the SEC has adopted additional rules and regulations in these areas, such as mandatory “say on pay” voting requirements that will apply to us when we cease to be an emerging growth company. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition and results of operations. The increased costs will decrease our net income or increase our net loss, and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

If securities or industry analysts do not publish research or reports or publish unfavorable research or reports about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us, our business, our market or our competitors. We do not currently have and may never obtain research coverage by securities and industry analysts. If no securities or industry analysts commence coverage of our company, the trading price for our stock would be negatively impacted. In the event we obtain securities or industry analyst coverage, if one or more of the analysts who covers us downgrades our stock, our stock price would likely decline. If one or more of these analysts ceases to cover us or fails to regularly publish reports on us, interest in our stock could decrease, which could cause our stock price or trading volume to decline.

We have identified a material weakness in our internal control over financial reporting. If we fail to remediate one or more of our material weaknesses, our ability to accurately and timely report our financial results could be adversely affected.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with U.S. generally accepted accounting principles (GAAP). A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our consolidated financial statements will not be prevented or detected on a timely basis.

Prior to the completion of this offering, we have been a private company with limited accounting personnel and other resources to address our internal control over financial reporting. In connection with the audit of our 2018 and 2019 annual consolidated financial statements, we and our independent registered public accounting firm identified a material weakness in our internal controls due to a lack of controls in the financial closing and reporting process, including a lack of segregation of duties and the documentation and design of formalized
processes and procedures in the revenue cycle. Beginning in the third quarter of 2020, we began to take steps to address the material weakness through our remediation plan, which included the hiring of a Chief Financial Officer and the engagement of external advisors to provide financial accounting assistance in the short term. We have plans to hire additional personnel to improve the segregation of duties in our financial closing and reporting process. In addition, we plan to engage external advisors to evaluate and document the design and operating effectiveness of our internal controls and assist with the remediation and implementation of our internal controls as required. For a discussion of our remediation plan, see “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Internal Control Over Financial Reporting.” The actions we have taken are subject to continued review, supported by confirmation and testing by management as well as audit committee oversight. While we have implemented a plan to remediate this weakness we cannot assure you that we will be able to remediate this weakness, which could impair our ability to accurately and timely report our financial position, results of operations or cash flows. Moreover, our failure to remediate the material weakness identified above or the identification of additional material weaknesses, could adversely affect our stock price and we may be unable to maintain compliance with exchange listing requirements.

If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely financial statements could be impaired, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

Pursuant to Section 404 of Sarbanes-Oxley, our management will be required to report upon the effectiveness of our internal control over financial reporting beginning with the annual report for our fiscal year ending December 31, 2021. When we lose our status as an "emerging growth company" and reach an accelerated filer threshold, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for our management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the requirements of being a reporting company under the Exchange Act, we will need to upgrade our information technology systems; implement additional financial and management controls, reporting systems and procedures; and hire additional accounting and finance staff. If we or, if required, our auditors are unable to conclude that our internal control over financial reporting is effective, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting once that firm begin its Section 404 reviews, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

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Provisions in our charter documents and under Delaware law could discourage a takeover that stockholders may consider favorable and may lead to entrenchment of management.

Our amended and restated certificate of incorporation and amended and restated bylaws that will be in effect immediately prior to the consummation of this offering will contain provisions that could significantly reduce the value of our shares to a potential acquiror or delay or prevent changes in control or changes in our management without the consent of our board of directors. The provisions in our charter documents will include the following:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our board of directors, unless the board of directors grants such right to the stockholders, to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- the required approval of at least 66-2/3% of the shares entitled to vote to remove a director for cause, and the prohibition on removal of directors without cause;
- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror;
- the ability of our board of directors to alter our amended and restated bylaws without obtaining stockholder approval;
- the required approval of at least 66-2/3% of the shares entitled to vote to adopt, amend or repeal our amended and restated bylaws or repeal the provisions of our amended and restated certificate of incorporation regarding the election and removal of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- an exclusive forum provision providing that the Court of Chancery of the State of Delaware will be the exclusive forum for certain actions and proceedings;
- the requirement that a special meeting of stockholders may be called only by the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders’ meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror’s own slate of directors or otherwise attempting to obtain control of us.

We are also subject to the anti-takeover provisions contained in Section 203 of the Delaware General Corporation Law. Under Section 203, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other exceptions, the board of directors has approved the transaction.

Our amended and restated certificate of incorporation and amended and restated bylaws will provide that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders’ ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation and amended and restated bylaws will provide that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding.
brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General
Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws, or any action asserting a claim against us
that is governed by the internal affairs doctrine; provided, that, this provision would not apply to suits brought to enforce a duty or liability created by
the Exchange Act. Furthermore, our amended and restated certificate of incorporation will also provide that unless we consent in writing to the selection
of an alternative forum, the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause
of action arising under the Securities Act. These choice of forum provisions may limit a stockholder’s ability to bring a claim in a judicial forum that it
finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors,
officers and other employees. By agreeing to this provision, however, stockholders will not be deemed to have waived our compliance with the federal
securities laws and the rules and regulations thereunder. Furthermore, the enforceability of similar choice of forum provisions in other companies’
certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be
inapplicable or unenforceable. If a court were to find the choice of forum provisions in our amended and restated certificate of incorporation to be
inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could
adversely affect our business and financial condition.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This
risk is especially relevant for us, because biotechnology and biopharmaceutical companies have experienced significant stock price volatility in recent
years. If we face such litigation, it could result in substantial costs and a diversion of our management’s attention and resources, which could harm our
business.
SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements. All statements other than statements of historical facts contained in this prospectus, including statements regarding our future results of operations and financial position, business strategy, research and development plans, the anticipated timing, costs, design and conduct of our ongoing and planned preclinical studies and planned clinical trials for our product candidates, our plans to use our Prometheus 360 product platform to expand our pipeline of product candidates and develop marketable products, the anticipated timing and costs of our development of companion diagnostics, the potential benefits from our collaboration arrangements with third parties and our plans to enter into additional arrangements, the timing and likelihood of regulatory filings and approvals for our product candidates and companion diagnostics, our ability to commercialize our product candidates, if approved, the impact of COVID-19 on our business, the pricing and reimbursement of our product candidates, if approved, and testing products, the potential to develop future product candidates, the timing and likelihood of success, plans and objectives of management for future operations, and future results of anticipated product development efforts, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplates,” “believes,” “estimates,” “predicts,” “potential” or “continue” or the negative of these terms or other similar expressions. The forward-looking statements in this prospectus are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this prospectus and are subject to a number of risks, uncertainties and assumptions described in “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this prospectus. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. Except as required by applicable law, we undertake no obligation to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. You should, however, review the factors and risks we describe in the reports we will file from time to time with the SEC after the date of this prospectus. See the section titled “Where You Can Find More Information.”

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this prospectus, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and you are cautioned not to rely unduly upon them.
MARKET AND INDUSTRY DATA

We obtained the industry, market and competitive position data used throughout this prospectus from our own internal estimates and research, as well as from independent market research, industry and general publications and surveys, governmental agencies and publicly available information in addition to research, surveys and studies conducted by third parties. Internal estimates are derived from publicly available information released by industry analysts and third-party sources, our internal research and our industry experience, and are based on assumptions made by us based on such data and our knowledge of our industry and market, which we believe to be reasonable. In some cases, we do not expressly refer to the sources from which this data is derived. In that regard, when we refer to one or more sources of this type of data in any paragraph, you should assume that other data of this type appearing in the same paragraph is derived from the same sources, unless otherwise expressly stated or the context otherwise requires. In addition, while we believe the industry, market and competitive position data included in this prospectus is reliable and based on reasonable assumptions, such data involve risks and uncertainties and are subject to change based on various factors, including those discussed in “Risk Factors.” These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties or by us.
USE OF PROCEEDS

We estimate that the net proceeds to us from the sale of the common stock that we are offering will be approximately $\text{<number>} million (or $\text{<number>} million if the underwriters exercise their option to purchase additional shares in full), assuming an initial public offering price of $\text{<number>} per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Each $1.00 increase (decrease) in the assumed initial public offering price of $\text{<number>} per share, which is the midpoint of the estimated price range set forth on the cover page of this prospectus, would increase (decrease) the net proceeds to us from this offering by approximately $\text{<number>} million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each increase (decrease) of 1.0 million shares in the number of shares offered by us would increase (decrease) the net proceeds to us from this offering, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, by approximately $\text{<number>} million, assuming the assumed initial public offering price stays the same.

The principal purposes of this offering are to obtain additional capital to support our operations, to create a public market for our common stock and to facilitate our future access to the public equity markets. We intend to use net proceeds from this offering to fund the research and development of our product candidates and companion diagnostics, and the remainder for working capital and general corporate purposes.

We may also use a portion of the net proceeds to in-license, acquire, or invest in complementary businesses, technologies, products or assets. However, we have no current commitments or obligations to do so.

We believe, based on our current operating plan, that the net proceeds from this offering together with our existing cash and cash equivalents, will be sufficient to fund our operations for at least the next $\text{<number>} months from the date of this prospectus. In particular, we expect that the net proceeds from this offering, together with our existing cash and cash equivalents, will allow us to $\text{<number>} . We have based these estimates on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. However, our expected use of proceeds from this offering described above represents our current intentions based on our present plans and business condition. We cannot predict with certainty all of the particular uses of the net proceeds from this offering or the actual amounts that we will spend on the uses set forth above. The net proceeds from this offering, together with our cash and cash equivalents, will not be sufficient for us to fund all of our product candidates through regulatory approval, and we will need to raise additional capital to complete the development and commercialization of each of our product candidates.

The amounts and timing of our actual expenditures will depend on numerous factors, including the time and cost necessary to conduct our ongoing and planned preclinical studies and planned clinical trials, the results of such studies and trials, the financial results of our diagnostic services business, and other factors described in “Risk Factors,” as well as the amount of cash used in our operations and any unforeseen cash needs. Therefore, our actual expenditures may differ materially from the estimates described above. We may find it necessary or advisable to use the net proceeds for other purposes, and we will have broad discretion in the application of the net proceeds.

Pending the uses described above, we plan to invest the net proceeds from this offering in short- and intermediate-term, investment grade interest-bearing instruments.
DIVIDEND POLICY

We have never declared or paid any cash dividends on our capital stock. We intend to retain future earnings, if any, to finance the operation of our business and do not anticipate paying any cash dividends in the foreseeable future. Any future determination related to dividend policy will be made at the discretion of our board of directors after considering our financial condition, results of operations, capital requirements, business prospects and other factors the board of directors deems relevant, and subject to the restrictions contained in any future financing instruments. In addition, under the terms of our loan and security agreement, we are prohibited from paying any cash dividends without the consent of Oxford Finance LLC.
The following table sets forth our cash and cash equivalents and capitalization as of June 30, 2020:

- on an actual basis;
- on a pro forma basis to reflect (i) the automatic conversion of all outstanding shares of our convertible preferred stock into 94,709,367 shares of our common stock and the related reclassification of the carrying value of the convertible preferred stock and preferred stock warrant liabilities to permanent equity immediately prior to the closing of this offering, and (ii) the filing and effectiveness of our amended and restated certificate of incorporation immediately prior to the closing of this offering; and
- on a pro forma as adjusted basis to give further effect to our issuance and sale of shares of our common stock in this offering at an assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The pro forma as adjusted information below is illustrative only, and our cash and cash equivalents and capitalization following the closing of this offering will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing. You should read this information in conjunction with our consolidated financial statements and related notes included in this prospectus and in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and other financial information contained in this prospectus.

<table>
<thead>
<tr>
<th>(in thousands, except share and par value data)</th>
<th>Actual</th>
<th>Pro Forma (unaudited)</th>
<th>Pro Forma As Adjusted (unaudited)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cash and cash equivalents</td>
<td>$</td>
<td>$</td>
<td>$</td>
</tr>
<tr>
<td>Capitalization:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amounts due to Nestlé – related party, including current portion</td>
<td>$</td>
<td>$</td>
<td>$</td>
</tr>
<tr>
<td>Bank borrowings, including current portion</td>
<td>$</td>
<td>$</td>
<td>$</td>
</tr>
<tr>
<td>Convertible preferred stock, $0.0001 par value; 101,645,867 shares authorized, 94,709,367 shares issued and outstanding, actual; no shares authorized, issued and outstanding, pro forma and pro forma as adjusted</td>
<td>$</td>
<td>$</td>
<td>$</td>
</tr>
<tr>
<td>Stockholders’ equity (deficit):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preferred stock, $0.0001 par value; no shares authorized, issued and outstanding, actual; no shares issued and no shares outstanding, pro forma and pro forma as adjusted</td>
<td>$</td>
<td>$</td>
<td>$</td>
</tr>
<tr>
<td>Common stock, $0.0001 par value; 138,630,900 shares authorized, 31,500,644 shares issued and 16,530,019 outstanding, excluding 1,764,870 shares subject to forfeiture or a right of repurchase, actual; shares authorized, shares issued and shares outstanding, excluding 1,764,870 shares subject to forfeiture or a right of repurchase, pro forma; shares authorized, shares issued and shares outstanding, excluding 1,764,870 shares subject to forfeiture or a right of repurchase, pro forma as adjusted</td>
<td>$</td>
<td>$</td>
<td>$</td>
</tr>
<tr>
<td>Additional paid-in capital</td>
<td>$</td>
<td>$</td>
<td>$</td>
</tr>
<tr>
<td>Accumulated deficit</td>
<td>$</td>
<td>$</td>
<td>$</td>
</tr>
<tr>
<td>Total stockholders’ equity (deficit)</td>
<td>$</td>
<td>$</td>
<td>$</td>
</tr>
<tr>
<td>Total capitalization</td>
<td>$</td>
<td>$</td>
<td>$</td>
</tr>
</tbody>
</table>
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(1) Each $1.00 increase (decrease) in the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of our cash and cash equivalents, additional paid-in capital, total stockholders’ equity (deficit) and total capitalization by approximately $, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each increase (decrease) of 1.0 million shares in the number of shares offered by us at the assumed initial public offering price of $ per share would increase (decrease) the pro forma as adjusted amount of each of our cash and cash equivalents, additional paid-in capital, total stockholders’ equity (deficit) and total capitalization by approximately $, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The number of shares of our common stock to be outstanding after this offering set forth above is based on 111,239,386 shares of our common stock outstanding as of June 30, 2020, including 1,764,870 shares subject to forfeiture or our right of repurchase, after giving effect to the automatic conversion of all outstanding shares of our convertible preferred stock into 94,709,367 shares of our common stock immediately prior to the closing of this offering, and excludes:

- 15,382,110 shares of common stock issuable upon the exercise of outstanding stock options as of June 30, 2020, at a weighted-average exercise price of $0.22 per share;
- 2,379,000 shares of common stock issuable upon the exercise of stock options granted after June 30, 2020, at a weighted-average exercise price of $0.31 per share;
- 112,500 shares of common stock issuable upon the exercise of outstanding warrants as of June 30, 2020 at a weighted-average exercise price of $1.00 per share;
- shares of common stock reserved for future issuance under our 2020 Plan, which will become effective in connection with this offering (which number does not include any potential evergreen increases pursuant to the terms of the 2020 Plan); and
- shares of common stock reserved for future issuance under our ESPP, which will become effective in connection with this offering (which number does not include any potential evergreen increases pursuant to the terms of the ESPP).
DILUTION

If you invest in our common stock in this offering, your ownership interest will be immediately diluted to the extent of the difference between the initial public offering price per share and the pro forma as adjusted net tangible book value per share of our common stock after this offering.

As of June 30, 2020, our historical net tangible book value (deficit) was $ million, or $ per share of our common stock, based on shares of common stock issued and outstanding as of such date, including shares subject to forfeiture or our right of repurchase as of such date. Our historical net tangible book value per share represents total tangible assets less total liabilities and convertible preferred stock, divided by the number of shares of common stock outstanding at June 30, 2020.

On a pro forma basis, after giving effect to (i) the automatic conversion of all outstanding shares of our convertible preferred stock into 94,709,367 shares of our common stock and (ii) the related reclassification of the carrying value of the convertible preferred stock and preferred stock warrant liabilities to permanent equity immediately prior to the closing of this offering, our pro forma net tangible book value as of June 30, 2020 would have been approximately $ million, or approximately $ per share of our common stock.

After giving further effect to the sale of shares of common stock in this offering at an assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value per share as of June 30, 2020 would have been approximately $ per share to our existing stockholders and an immediate dilution in pro forma net tangible book value of approximately $ per share to new investors purchasing shares of common stock in this offering.

Dilution per share to new investors is determined by subtracting pro forma as adjusted net tangible book value per share after this offering from the initial public offering price per share paid by new investors. The following table illustrates this dilution (without giving effect to any exercise by the underwriters of their option to purchase additional shares):

| Assumed initial public offering price per share | $ |
| Historical net tangible book value (deficit) per share as of June 30, 2020 | $ |
| Pro forma increase in historical net tangible book value per share as of June 30, 2020 attributable to the pro forma adjustments described above | $ |
| Pro forma net tangible book value per share as of June 30, 2020 | $ |
| Increase in pro forma net tangible book value per share attributable to new investors participating in this offering | $ |
| Pro forma as adjusted net tangible book value per share after this offering | $ |
| Dilution per share to new investors participating in this offering | $ |

Each $1.00 increase (decrease) in the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted net tangible book value per share after this offering by approximately $, and dilution in pro forma as adjusted net tangible book value per share to new investors by approximately $, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and the estimated offering expenses payable by us. Each increase (decrease) of 1.0 million shares in the number of shares offered by us would increase (decrease) our pro forma as adjusted net tangible book value per share after this offering by approximately $.
$ per share and decrease (increase) the dilution to investors participating in this offering by approximately $ per share, assuming that the assumed initial public offering price of $ per share remains the same, and after deducting the estimated underwriting discounts and commissions and the estimated offering expenses payable by us.

If the underwriters exercise their option to purchase additional shares of our common stock in full in this offering, the pro forma as adjusted net tangible book value after the offering would be approximately $ per share, the increase in pro forma as adjusted net tangible book value per share to existing stockholders would be approximately $ per share and the dilution per share to new investors would be $ per share, in each case assuming an initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus.

The following table summarizes on the pro forma as adjusted basis described above, as of June 30, 2020, the differences between the number of shares purchased from us, the total consideration paid to us in cash and the average price per share paid by existing stockholders for shares issued prior to this offering and the price to be paid by new investors in this offering. The calculations below are based on an assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of the prospectus, before deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

<table>
<thead>
<tr>
<th>Shares Purchased</th>
<th>Total Consideration</th>
<th>Weighted-Average Price Per Share</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
<td>Percent</td>
</tr>
<tr>
<td>Existing stockholders before this offering</td>
<td></td>
<td></td>
</tr>
<tr>
<td>New investors participating in this offering</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

|                  | 100% | 100% | $      |

If the underwriters exercise their option to purchase additional shares of our common stock in full:

- the percentage of shares of common stock held by existing stockholders before this offering will decrease to approximately % of the total number of shares of our common stock outstanding after this offering; and
- the number of shares held by new investors participating in this offering will increase to , or approximately % of the total number of shares of our common stock outstanding after this offering.

The foregoing tables and calculations on a pro forma and pro forma as adjusted basis are based on 111,239,386 shares of our common stock outstanding as of June 30, 2020, including 1,764,870 shares subject to forfeiture or our right of repurchase, after giving effect to the automatic conversion of all outstanding shares of our preferred stock into 94,709,367 shares of our common stock immediately prior to the closing of this offering, and exclude:

- 15,382,110 shares of common stock issuable upon the exercise of outstanding stock options as of June 30, 2020, at a weighted-average exercise price of $0.22 per share;
- 2,379,000 shares of common stock issuable upon the exercise of stock options granted after June 30, 2020, at a weighted-average exercise price of $0.31 per share;
- 112,500 shares of common stock issuable upon the exercise of outstanding warrants as of June 30, 2020, at a weighted-average exercise price of $1.00 per share;
- shares of common stock reserved for future issuance under our 2020 Plan, which will become effective in connection with this offering (which number does not include any potential evergreen increases pursuant to the terms of the 2020 Plan); and
shares of common stock reserved for future issuance under our ESPP, which will become effective in connection with this offering (which number does not include any potential evergreen increases pursuant to the terms of the ESPP).

To the extent any outstanding options, warrants or other rights are exercised, or we issue additional equity or convertible securities in the future, there will be further dilution to new investors.
SELECTED FINANCIAL DATA

The following tables set forth our selected historical financial data as of, and for the periods ended on, the dates indicated. We have derived the selected statements of operations data for the years ended December 31, 2018 and 2019 and the selected balance sheet data as of December 31, 2018 and 2019 from our audited consolidated financial statements included elsewhere in this prospectus. You should read these data together with our audited consolidated financial statements and related notes included elsewhere in this prospectus and in “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” Our historical results for any prior period are not necessarily indicative of our future results.

<table>
<thead>
<tr>
<th>Statements of Operations Data:</th>
<th>Years Ended December 31, 2018</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Revenue:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diagnostic services revenue</td>
<td>$ —</td>
<td>$ 22,674</td>
</tr>
<tr>
<td>Collaboration revenue</td>
<td>—</td>
<td>1,118</td>
</tr>
<tr>
<td><strong>Total revenue</strong></td>
<td>—</td>
<td>23,792</td>
</tr>
<tr>
<td><strong>Operating expenses:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cost of diagnostic services revenue</td>
<td>—</td>
<td>8,864</td>
</tr>
<tr>
<td>Research and development</td>
<td>4,386</td>
<td>14,436</td>
</tr>
<tr>
<td>Sales and marketing</td>
<td>—</td>
<td>10,036</td>
</tr>
<tr>
<td>General and administrative</td>
<td>2,413</td>
<td>13,976</td>
</tr>
<tr>
<td>Amortization of intangibles</td>
<td>—</td>
<td>488</td>
</tr>
<tr>
<td>Restructuring</td>
<td>—</td>
<td>5,484</td>
</tr>
<tr>
<td><strong>Total operating expenses</strong></td>
<td>6,799</td>
<td>53,284</td>
</tr>
<tr>
<td><strong>Loss from operations</strong></td>
<td>(6,799)</td>
<td>(29,492)</td>
</tr>
<tr>
<td><strong>Other income (expense):</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interest income</td>
<td>5</td>
<td>38</td>
</tr>
<tr>
<td>Interest expense</td>
<td>—</td>
<td>(770)</td>
</tr>
<tr>
<td><strong>Total other income (expense)</strong></td>
<td>5</td>
<td>(732)</td>
</tr>
<tr>
<td><strong>Loss before income taxes</strong></td>
<td>$ (6,794)</td>
<td>$ (30,224)</td>
</tr>
<tr>
<td>Income tax expense (benefit)</td>
<td>1</td>
<td>(501)</td>
</tr>
<tr>
<td><strong>Net loss</strong></td>
<td>$ (6,795)</td>
<td>$ (29,723)</td>
</tr>
<tr>
<td>Net loss per share, basic and diluted(1)</td>
<td>$ (0.91)</td>
<td>$ (2.65)</td>
</tr>
<tr>
<td>Weighted-average shares of common stock outstanding, basic and diluted(1)</td>
<td>7,471,474</td>
<td>11,227,009</td>
</tr>
<tr>
<td>Pro forma net loss per share, basic and diluted (unaudited)(1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pro forma weighted-average shares of common stock outstanding, basic and diluted (unaudited)(1)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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See Note 2 to our consolidated financial statements included elsewhere in this prospectus for an explanation of the method used to calculate the historical and pro forma net loss per share, basic and diluted, and the number of shares used in the computation of the per share amounts.

<table>
<thead>
<tr>
<th>(in thousands)</th>
<th>Years Ended December 31,</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2018</td>
</tr>
<tr>
<td>Cash and cash equivalents</td>
<td>$10,880</td>
</tr>
<tr>
<td>Working capital(1)</td>
<td>9,785</td>
</tr>
<tr>
<td>Total assets</td>
<td>11,107</td>
</tr>
<tr>
<td>Amounts due to Nestlé – related party,</td>
<td></td>
</tr>
<tr>
<td>non-current</td>
<td>—</td>
</tr>
<tr>
<td>Acquisition-related consideration held</td>
<td>—</td>
</tr>
<tr>
<td>in escrow</td>
<td></td>
</tr>
<tr>
<td>Convertible preferred stock</td>
<td>17,500</td>
</tr>
<tr>
<td>Accumulated deficit</td>
<td>(7,728)</td>
</tr>
<tr>
<td>Total stockholders’ (deficit) equity</td>
<td>(7,638)</td>
</tr>
</tbody>
</table>

We define working capital as total current assets less total current liabilities. See our consolidated financial statements included elsewhere in this prospectus for further details regarding our current assets and current liabilities.
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MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and related notes included elsewhere in this prospectus. Some of the information contained in this discussion and analysis are set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business and related financing, and includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in “Risk Factors,” our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a biotechnology company pioneering a precision medicine approach to the discovery, development, and commercialization of novel therapeutic and companion diagnostic products for the treatment and diagnosis of IBD. We leverage our proprietary precision medicine platform, Prometheus 360, which includes one of the world’s largest GI bioinformatics databases, to identify novel therapeutic targets and develop therapeutic candidates to engage those targets. In parallel, we are developing companion diagnostic tests designed to identify patients more likely to respond to our therapeutic candidates.

Our lead product candidate, PRA023, is an IgG1 humanized mAb that has been shown to block TL1A, a target associated with both intestinal inflammation and fibrosis that was clinically-validated in a third-party Phase 2a clinical trial in UC. PRA023 has the potential to substantially improve outcomes for moderate-to-severe IBD patients predisposed to increased TL1A expression. We are developing PRA023 for the treatment of UC and CD, and expect to initiate a Phase 1a clinical trial in normal healthy volunteers in the fourth quarter of 2020. Our goal is to revolutionize the treatment of IBD with a precision medicine approach for patients with significant unmet medical needs. We have generated a robust initial pipeline of therapeutic development programs for the treatment of IBD, and plan to develop a companion diagnostic for each program. The research and development of therapeutic product candidates and companion diagnostics comprises our therapeutics business segment. The following table summarizes our key current internal and partnered programs.

<table>
<thead>
<tr>
<th>PROGRAM</th>
<th>DISCOVERY</th>
<th>LEAD OPTIMIZATION</th>
<th>IND.ENABLED</th>
<th>PHASE 1</th>
<th>PHASE 2</th>
<th>PHASE 3</th>
<th>PARTNER</th>
</tr>
</thead>
<tbody>
<tr>
<td>PRA023</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anti-TL1A mAb</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PR000</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Takeda</td>
</tr>
<tr>
<td>Anti-TNF Super Family Monoclonal mAb</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(a) Europe Partner</td>
</tr>
<tr>
<td>PR000</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GPCR Modulator Small Molecule</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TPR15</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Takeda</td>
</tr>
<tr>
<td>mAb</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(b) Takeda</td>
</tr>
</tbody>
</table>

(1) We retain all commercialization rights to PR600 outside of Europe, Australia and New Zealand.
(2) We are developing a companion diagnostic in tandem with Takeda’s drug discovery and development efforts. Takeda has an option to collaborate on an additional program.

In addition, we have five other programs with different mechanisms of action targeting UC and/or CD that are in the discovery stage of development.

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On June 30, 2019, we acquired PLI from Nestlé. As a result of this acquisition, we have a commercial stage diagnostic franchise that operates out of a 36,000 square foot CLIA and College of American Pathologists (CAP) certified clinical laboratory in San Diego, California. Through this business, we market and conduct several LDTs that are used by gastroenterologists in monitoring their IBD patients’ disease state and informing their therapeutic decisions. While the commercial LDT business enables us to gain additional insight from gastroenterologists as we develop PRA023 and prioritize new drug targets, we believe the addition of our CLIA-certified laboratory from the PLI acquisition will provide us a competitive advantage by allowing for an end-to-end commercial companion diagnostic solution without the need to partner with the general reference laboratories. The marketing and conduct of the LDTs comprise our diagnostic services business.

Prior to our acquisition of PLI in June 2019, we had devoted substantially all of our resources to organizing and staffing our company, business planning, raising capital, developing our Prometheus 360 platform, discovering and identifying potential product candidates, establishing our intellectual property portfolio and conducting research and preclinical studies, and providing other general and administrative support for these operations. Following the PLI acquisition, we conducted 79,915 diagnostic tests and generated revenue of $22.7 million for the year ended December 31, 2019. Additionally, during the year ended December 31, 2019, we generated $1.1 million in revenue from our collaboration with Takeda as described below.

While we expect to continue to generate revenue from our diagnostic services business and potentially under our current and/or future collaboration agreements, we do not expect to generate any revenue from therapeutic product sales until we successfully complete development and obtain regulatory approval for one or more of our therapeutic product candidates and companion diagnostics, which we expect will take a number of years and may never occur.

We have incurred operating losses in each year since inception. Our net losses were $6.8 million and $29.7 million for the years ended December 31, 2018 and 2019, respectively. As of December 31, 2019, we had an accumulated deficit of $37.5 million. We expect our expenses and operating losses will increase substantially as we conduct our ongoing and planned preclinical studies and clinical trials, continue our research and development activities, develop and validate companion diagnostics, utilize third parties to manufacture our product candidates and related raw materials, hire additional personnel, protect our intellectual property and incur additional costs associated with being a public company, including audit, legal, regulatory, and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance premiums, and investor relations costs. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our preclinical studies and clinical trials and our expenditures on other research and development activities, as well as the generation of any services and collaboration revenue.

As of December 31, 2019, we had raised a total of $27.5 million to fund our operations from gross proceeds from the sale and issuance of convertible preferred stock. As of December 31, 2019, we had cash and cash equivalents of $8.4 million. In the first quarter of 2020, we raised an additional $28.1 million from the sale and issuance of additional convertible preferred stock and $7.5 million from the issuance of commercial debt.

If we obtain regulatory approval for any of our therapeutic product candidates and companion diagnostics, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. As we continue to advance our pipeline of diagnostic products, we expect to incur additional costs associated with conducting clinical studies to demonstrate the utility of our products and support reimbursement efforts. Accordingly, until such time as we can generate significant revenue from sales of our therapeutic product candidates and expanded diagnostic portfolio, if ever, we expect to finance our cash needs through equity offerings, debt financings or other capital sources, including potential additional collaborations, licenses and other similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements when needed would have a negative impact on our financial condition and could force us to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates or testing products that we would otherwise prefer to develop and market ourselves.
Our history of recurring losses and anticipated expenditures raise substantial doubt about our ability to continue as a going concern. See Note 1 to our consolidated financial statements included elsewhere in this prospectus for additional information on our assessment. Similarly, the report of our independent registered public accounting firm on our consolidated financial statements as of and for the year ended December 31, 2019 includes an explanatory paragraph indicating that there is substantial doubt about our ability to continue as a going concern. The accompanying consolidated financial statements have been prepared assuming we will continue to operate as a going concern, which contemplates the realization of assets and settlement of liabilities in the normal course of business, and does not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from uncertainty related to our ability to continue as a going concern.

COVID-19

The current COVID-19 worldwide pandemic has presented substantial public health and economic challenges and is affecting our employees, patients, physicians and other healthcare providers, communities and business operations, as well as the U.S. and global economies and financial markets. International and U.S. governmental authorities in impacted regions are taking actions in an effort to slow the spread of COVID-19, including issuing varying forms of “stay-at-home” orders, and restricting business functions outside of one’s home. In response, we have implemented a work-from-home policy for certain of our employees. With respect to our diagnostic services business, as a result of government measures and the reordering of priorities across the U.S. healthcare system, our test volumes experienced a temporary substantial reduction in April, but have since substantially recovered on a month-to-month basis. In March 2020, as a result of the impacts of the COVID-19 pandemic, we implemented a reduction in workforce which resulted in the recognition of a restructuring charge for termination benefits of $2.5 million, of which $2.3 million was paid as of June 30, 2020.

License and Collaboration Agreements

Our Collaboration with Cedars-Sinai Medical Center

We entered into an exclusive license agreement (the Cedars-Sinai License Agreement) with Cedars-Sinai in September 2017, pursuant to which Cedars-Sinai granted us an exclusive, worldwide license with respect to certain patents, information and materials related to therapeutic targets and companion diagnostic products, to conduct research, develop, and commercialize therapeutic and diagnostic products for the diagnosis and treatment of IBD. The licensed technology includes information and materials arising out of Cedars-Sinai’s database and biobank, as well as exclusive access to this database and biobank to develop diagnostic and
therapeutic products for human use, which biobank is an integral part of our Prometheus 360 platform. As upfront consideration for the license agreement, we issued to Cedars-Sinai 2,575,000 shares of fully vested common stock and 3,350,000 shares of restricted common stock, which shares will fully vest in September 2020. We are obligated to pay Cedars-Sinai low- to mid-single digit percentage royalties on net sales of therapeutic and diagnostic products covered under the agreement, including, PRA023 and our PR600 and PR300 development programs and any related companion diagnostic products, as well any diagnostic products we develop under the Takeda collaboration agreement discussed below, in each case to the to the extent such products are covered by the licensed patents or developed through the licensed rights.

Our Collaboration with Takeda

In March 2019, we entered into a companion diagnostics development and collaboration agreement (the Takeda Agreement) with Millennium Pharmaceuticals, Inc., a wholly owned subsidiary of Takeda. Pursuant to this agreement, we established a strategic collaboration under which we will develop a companion diagnostic product (Diagnostic Product) for one selected drug target, with the option for Takeda to select an additional drug target (each, a Collaboration Target), in support of development and potential commercialization by Takeda of any therapeutic clinical candidates that it develops in connection with the agreement directed against a Collaboration Target for the treatment of IBD (Takeda Drugs). We will be responsible for development and commercialization of the Diagnostic Product(s) pursuant to the terms and conditions of the agreement, while Takeda will be responsible for all future clinical development and commercialization of the Takeda Drug(s). Under the Takeda Agreement, we received an upfront payment of $1.5 million. We are also eligible to receive development, regulatory, commercial and sales milestone payments, and low-single digit royalties on net sales of Takeda Drugs.

Separately, we also provide services to Takeda to develop and perform a prognostic test under a services agreement we entered into with Takeda in December 2019.

Our Collaboration with Dr. Falk Pharma

We entered into a co-development and manufacturing agreement (the Falk Agreement) with Falk in July 2020, pursuant to which we will co-develop and commercialize, exclusively in our respective territories, therapeutic product candidates targeting members of the TNF super family for the treatment of UC and CD under our PR600 development program. We will be responsible for regulatory approvals and commercialization of any products in the United States and the rest of the world, other than the Falk territory. Falk is responsible for regulatory approvals and commercialization of any products in the European Union, United Kingdom, Switzerland, the countries of the European Economic Area (excluding Malta and the Republic of Cyprus), Australia and New Zealand (Falk territory). Under the agreement, Falk agreed to fund 25% of our third party development costs set forth in a mutually agreed upon development plan. In addition, Falk is obligated to make future development milestone payments, and a mid-single digit to low-double digit royalty on net sales of all products incorporating antibodies covered by the agreement in the Falk territory. We agreed to pay Falk a low-single digit royalty on net sales for such products in our territory.

For additional information regarding the Cedars-Sinai License Agreement, Takeda Agreement and Falk Agreement, as well as other agreements pursuant to which we in-license certain intellectual property rights, see “Business—License and Collaboration Agreements.”

Components of Results of Operations

We operate our business through the following two reportable segments; the diagnostic services and therapeutics businesses. The diagnostic services business derives all of its diagnostic services revenue in the IBD space generated from the conduct of LDTs we acquired as part of the PLI acquisition. Our therapeutics business currently derives all of its revenue from collaboration agreements and devotes all of its efforts to development of therapeutic product candidates and companion diagnostics in the IBD space.
We evaluate segment performance based on operating income (loss) of each segment. Operating income (loss) of each segment represents revenues less directly identifiable expenses to arrive at operating income (loss) for the segment. We do not allocate all general and administrative expenses by segment, and such expenses are included in Corporate in our financial statements.

**Revenue**

**Diagnostic services segment revenue**

Our diagnostic services revenue is generated from the sale of our testing products, a large portion of which is attributable to our Anser® test. We primarily market our testing products to gastroenterologists in the United States. The healthcare professionals who order our testing products and to whom test results are reported are generally not responsible for payment for these products. The parties that pay for these services consist of client payors (i.e., hospitals and other laboratories), healthcare insurers, government payors (primarily Medicare and Medicaid), and patient self-pay. Our service is completed upon the delivery of test results to the prescribing physicians which triggers billing for the service.

We recognize revenue in accordance with the provisions of ASC Topic 606, Revenue from Contracts with Customers. We record revenue on an accrual basis based on our estimate of the amount that will be ultimately realized for each test upon delivery based on a historical analysis of amounts collected by test and by payor. These assessments require significant judgment by management.

Our ability to increase our revenue will depend on our ability to further penetrate the market for our current and future testing products and increase our reimbursement and collection rates for tests delivered.

**Therapeutics segment (Collaboration) revenue**

Our Therapeutics segment currently derives all of its revenue from our collaboration agreements. For the foreseeable future, we expect to generate revenue from services performed under the Takeda Agreement and Falk Agreement. We may receive a combination of upfront payments and milestone payments under our current and/or future collaboration agreements.

We do not expect to generate any revenue from the sale of therapeutic products unless and until such time that our therapeutic product candidates and companion diagnostics have advanced through clinical development and regulatory approval, if ever. We expect that any revenue we generate, if at all, will fluctuate from quarter-to-quarter as a result of the timing and amount of payments relating to such services and milestones and the extent to which any of our therapeutic product candidates are approved and successfully commercialized. If we fail to complete preclinical and clinical development of therapeutic product candidates or obtain regulatory approval for them, our ability to generate future revenues, and our results of operations and financial position would be adversely affected.

**Operating Expenses**

**Cost of Diagnostic Services Revenue**

Cost of diagnostic services revenue consists principally of costs for obtaining, transporting and testing specimens. The components of our costs of revenue include materials costs, direct labor, equipment and infrastructure expenses associated with testing specimens, shipping charges to transport specimens, blood specimen collections fees, royalties, depreciation and allocated overhead, including rent and utilities.

Each payor, healthcare insurers, government, client or individual, reimburses us at different amounts. These differences can be significant. As a result, our costs of revenue as a percentage of revenue may vary significantly from period to period due to the composition of payors for each month’s billings.
We expect that our costs of revenue will increase in absolute dollars as the number of tests we perform increases. However, we expect that the cost per test will decrease over time due to volume discounts on materials and shipping costs and other volume efficiencies we may gain as the number of tests we perform increases.

**Research and Development**

Research and development expenses consist of external and internal costs associated with our research and development activities, including our discovery and research efforts, the preclinical and clinical development of our product candidates and the development and validation of our companion diagnostics. Our research and development expenses include:

- external costs, including expenses incurred under arrangements with third parties, such as CROs, contract manufacturers, consultants and our scientific advisors; and
- internal costs, including:
  - employee-related expenses, including salaries, benefits, and stock-based compensation; the costs of laboratory supplies and acquiring, developing and manufacturing preclinical study materials; and
  - facilities, information technology and depreciation, which include direct and allocated expenses for rent and maintenance of facilities and depreciation of leasehold improvements and equipment.

The following table summarizes our research and development expenses by product candidate and for our diagnostic services for the periods indicated (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>December 31,</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2018</td>
</tr>
<tr>
<td>PRA023</td>
<td>$1,705</td>
</tr>
<tr>
<td>PR300</td>
<td>1,929</td>
</tr>
<tr>
<td>PR600</td>
<td>388</td>
</tr>
<tr>
<td>Diagnostic services</td>
<td>—</td>
</tr>
<tr>
<td>research and development</td>
<td></td>
</tr>
<tr>
<td>Other preclinical</td>
<td>364</td>
</tr>
<tr>
<td>programs</td>
<td></td>
</tr>
<tr>
<td>Total research and</td>
<td>$4,386</td>
</tr>
<tr>
<td>development</td>
<td></td>
</tr>
</tbody>
</table>

We expect our research and development expenses to increase for the foreseeable future as we continue to conduct our ongoing research and development activities, advance our preclinical research programs toward clinical development, including conducting IND-enabling studies, develop companion diagnostics, and conduct clinical trials. The process of conducting preclinical studies and clinical trials necessary to obtain regulatory approval is costly and time consuming. We may never succeed in achieving marketing approval for any of our product candidates.

The timelines and costs with research and development activities are uncertain and can vary significantly for each product candidate and development program and are difficult to predict. We anticipate we will make determinations as to which programs to pursue and how much funding to direct to each program on an ongoing basis in response to preclinical and clinical results, regulatory developments, ongoing assessments as to each program’s commercial potential, and our ability to maintain or enter into new collaborations, to the extent we determine the resources or expertise of a collaborator would be beneficial for a given program. We will need to raise substantial additional capital in the future. In addition, we cannot forecast which development programs may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

Our development costs may vary significantly based on factors such as:

- the number and scope of preclinical and IND-enabling studies;
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- per patient trial costs;
- the number of trials required for approval;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of patients that participate in the trials;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- the number, costs and timing of developing companion diagnostics and scope of validation studies;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of patient participation in the trials and follow-up;
- the cost and timing of manufacturing our product candidates;
- the phase of development of our product candidates;
- the efficacy and safety profile of our product candidates and effectiveness of our companion diagnostics; and
- the costs associated with conducting clinical studies to demonstrate the utility of our diagnostic products and support reimbursement efforts.

Sales and Marketing

Sales and marketing expense consist principally of the costs associated with our sales and marketing efforts, billing operations, and general sales management and administrative support of our diagnostic services business.

We expect that our selling and marketing expenses will remain consistent in absolute dollars as we continue to optimize our sales and sales support functions.

General and Administrative

General and administrative expenses consist primarily of employee-related expenses, including salaries, benefits and stock-based compensation, for employees in our finance, accounting, legal, business development and support functions. Other general and administrative expenses include allocated facility, information technology and depreciation related costs not otherwise included in research and development expenses and professional fees for auditing, tax, intellectual property and legal services. Costs related to filing and pursuing patent applications are recognized as general and administrative expenses as incurred since recoverability of such expenditures is uncertain.

We expect our general and administrative expenses will increase for the foreseeable future to support our increased research and development activities and increased costs of operating as a public company. These increased costs will likely include increased expenses related to audit, legal, regulatory and tax services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance premiums and investor relations costs associated with operating as a public company.

Amortization of Intangible Assets

Amortization of intangible assets represents the total amortization expense for intangible assets acquired in the PLI acquisition.
We expect our amortization of intangible assets to increase for 2020 as we will record a full year of amortization expense.

**Interest and Other Income (Expense)**

**Interest income**

Interest income consists primarily of interest earned on our cash and cash equivalents.

**Interest expense**

Interest expense consists of non-cash interest expense associated with the deferred purchase payments for PLI.

We expect our interest expense to increase in the future as a result of borrowings made in early 2020 under our Loan Agreement with Oxford Finance.

**Results of Operations**

**Comparison of the Years Ended December 31, 2018 and 2019**

The following table summarizes our results of operations for the years ended December 31, 2018 and 2019 (in thousands):

<table>
<thead>
<tr>
<th>Years Ended December 31</th>
<th>2018</th>
<th>2019</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revenue</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diagnostic services revenue</td>
<td>$0</td>
<td>$22,674</td>
<td>$22,674</td>
</tr>
<tr>
<td>Collaboration revenue</td>
<td>—</td>
<td>1,118</td>
<td>1,118</td>
</tr>
<tr>
<td></td>
<td>—</td>
<td>23,792</td>
<td>23,792</td>
</tr>
<tr>
<td>Operating expenses:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cost of diagnostic services revenue</td>
<td>—</td>
<td>8,864</td>
<td>8,864</td>
</tr>
<tr>
<td>Research and development</td>
<td>4,386</td>
<td>14,436</td>
<td>10,050</td>
</tr>
<tr>
<td>Sales and marketing</td>
<td>—</td>
<td>10,036</td>
<td>10,036</td>
</tr>
<tr>
<td>General and administrative</td>
<td>2,413</td>
<td>13,976</td>
<td>11,563</td>
</tr>
<tr>
<td>Amortization of intangible assets</td>
<td>—</td>
<td>488</td>
<td>488</td>
</tr>
<tr>
<td>Restructuring</td>
<td>—</td>
<td>5,484</td>
<td>5,484</td>
</tr>
<tr>
<td>Total operating expenses</td>
<td>6,799</td>
<td>53,284</td>
<td>46,485</td>
</tr>
<tr>
<td>Loss from operations</td>
<td>(6,799)</td>
<td>(29,492)</td>
<td>(22,693)</td>
</tr>
<tr>
<td>Other income (expense), net</td>
<td>5</td>
<td>(732)</td>
<td>(727)</td>
</tr>
<tr>
<td>Loss before income taxes</td>
<td>(6,794)</td>
<td>(30,224)</td>
<td>(23,430)</td>
</tr>
<tr>
<td>Income tax expense (benefit)</td>
<td>1</td>
<td>(501)</td>
<td>(502)</td>
</tr>
<tr>
<td>Net loss</td>
<td>$(6,795)</td>
<td>$(29,723)</td>
<td>$(22,928)</td>
</tr>
</tbody>
</table>

**Revenue**

Revenue was $0 for the year ended December 31, 2018 compared to $23.8 million for the year ended December 31, 2019. Diagnostic services revenue resulted from the PLI acquisition in June 2019. Collaboration revenue during the year ended December 31, 2019 was derived from services performed under the Takeda Agreement, which was entered into in March 2019.
Costs of Diagnostic Services Revenue

Costs of diagnostic services revenue increased in the year ended December 31, 2019 compared to the year ended December 31, 2018 as a result of the PLI acquisition. Costs of diagnostic services revenue as a percentage of diagnostic services revenue was 39% in 2019.

Research and Development Expenses

Research and development expenses were $4.4 million for the year ended December 31, 2018 compared to $14.4 million for the year ended December 31, 2019. The increase of $10.0 million was primarily driven by a $6.4 million increase in expenses related to research and development expenses for our lead product candidate, PRA023, and a $3.5 million increase in diagnostic services business research and development expenses resulting from the PLI acquisition.

Sales and Marketing Expenses

Sales and marketing expenses were $0 million for the year ended December 31, 2018 compared to $10.0 million for the year ended December 31, 2019. The increase of $10.0 million was primarily driven by an increase of $10.0 million incurred by the diagnostic services business resulting from the PLI acquisition for which no comparable expense existed in 2018.

General and Administrative Expenses

General and administrative expenses were $2.4 million for the year ended December 31, 2018 compared to $14.0 million for the year ended December 31, 2019. The increase of $11.6 million in 2019 was primarily driven by increases of $5.2 million in corporate personnel costs due to the expansion of our executive team and personnel additions resulting from the PLI acquisition. The rest of the increase is due to increased facility and other general and administrative expenses resulting from the PLI acquisition, and a $2.1 million increase in legal and patent costs associated with the therapeutics business.

Amortization of Intangible Assets

Amortization of intangible assets was $0 for the year ended December 31, 2018 compared to $0.5 million for the year ended December 31, 2019. The increase of $0.5 million was driven by the amortization of intangible assets acquired in the PLI acquisition in June 2019.

Restructuring Expenses

Restructuring charges were $0 for the year ended December 31, 2018 compared to $5.5 million for the year ended December 31, 2019 and were primarily for severance and other personnel costs resulting from workforce reduction initiatives associated with our integration and restructuring activities of PLI subsequent to the acquisition.

Other Income (Expense), Net

Interest and other income, net was $5,000 for the year ended December 31, 2018 compared to interest and other expense, net of $0.7 million for the year ended December 31, 2019. The increase of $0.7 million was primarily related to non-cash interest expense incurred in 2019 in connection with the deferred purchase price of PLI.

Liquidity and Capital Resources

Sources of Liquidity

From our inception through December 31, 2019, we have received aggregate gross proceeds of $27.5 million from the sale of convertible preferred stock and $2.7 million from amounts received under the
Takeda Agreement. In the first quarter of 2020, we raised an additional $28.1 million from the sale and issuance of Series C convertible preferred stock.

Oxford Loan and Security Agreement

In January 2020, we entered into a Loan and Security Agreement (the Loan Agreement) with Oxford Finance LLC and its affiliates (Oxford) which provides for total borrowings of up to $25.0 million, of which $7.5 million was drawn upon execution of the agreement. The Oxford Loan provides for an additional minimum of $5.0 million and up to $17.5 million to be drawn down at our option beginning upon the receipt of a Series C financing of at least $30.0 million (Equity Event) and ending on the earliest of (i) 90 days after the occurrence of the Equity Event; (ii) September 30, 2020; or (iii) upon an event of default. Interest accrues at an annual rate equal to the sum of (I) the greater of (a) the 30-day U.S. LIBOR rate reported the last business day of the month that immediately precedes the month in which the interest will accrue, and (b) 2.01%, plus (II) 5.98%. Notwithstanding the foregoing, the rate from the period of the effective date of the Loan Agreement through and including January 31, 2020, shall be 7.99% and the annual rate shall at no time be less than 7.99%. From March 1, 2020, through February 28, 2022, we are required to make interest only payments. Beginning March 1, 2023, in addition to interest payments, the monthly payments will include an amount equal to the outstanding principal amount divided by 24 months. At maturity (or earlier prepayment), we are also required to make a final payment equal to 4.0% of the original principal amount borrowed and 3% of the future amount to be funded.

The Loan Agreement is collateralized by substantially all of our assets, excluding intellectual property, which is subject to a negative pledge. The Loan Agreement contains customary affirmative and negative covenants and events of default applicable to us. The affirmative covenants include, among others, covenants requiring us to maintain governmental approvals, deliver certain financial reports, maintain insurance coverage and protect material intellectual property. The negative covenants include, among others, restrictions on us transferring collateral, incurring additional indebtedness, engaging in mergers or acquisitions, paying cash dividends or making other distributions, making investments, creating liens, selling assets and making any payment on subordinated debt, in each case subject to certain exceptions.

In connection with execution of the Loan Agreement, we issued Oxford a warrant to purchase 112,500 shares of our Series C convertible preferred stock at an exercise price of $1.00 per share, exercisable at any time following issuance. The preferred stock warrant has a term of ten years. The warrant will become exercisable for an aggregate of 112,500 shares of our common stock upon the completion of this offering at an exercise price of $1.00 per share.

Future Capital Requirements

As of December 31, 2019, we had cash and cash equivalents in the amount of $8.4 million. Based upon our current operating plans, we believe that the estimated net proceeds from this offering, together with our existing cash and cash equivalents, will be sufficient to fund our operations for at least the next months from the date of this prospectus. In particular, we expect that the net proceeds from this offering and our existing cash and cash equivalents will allow us to support our operations for months. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward looking statement that involves risks and uncertainties, and actual results could vary materially. We have based this estimate on assumptions that may prove to be wrong, and we could deplete our capital resources sooner than we expect. Additionally, the process of conducting preclinical studies and testing product candidates in clinical trials is costly, and the timing of progress and expenses in these studies and trials is uncertain.

Our future capital requirements are difficult to forecast and will depend on many factors, including but not limited to:

• the type, number, scope, progress, expansions, results, costs and timing of, discovery, preclinical studies and clinical trials of our product candidates which we are pursuing or may choose to pursue in the future;
Other than our collaboration agreements, we have no other committed sources of capital. Until we can generate a sufficient amount of product revenue to finance our cash requirements, if ever, we expect to finance our future cash needs primarily through equity offerings, debt financings or other capital sources, including potential collaborations, licenses and other similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Our Loan Agreement with Oxford involves, and any future debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through other collaborations or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required
to delay, limit, reduce or terminate our product development or commercialization efforts or grant rights to develop and market product candidates or testing products to third parties that we would otherwise prefer to develop and market ourselves.

**Cash Flows**

The following table shows a summary of our cash flows for the periods presented (in thousands):

<table>
<thead>
<tr>
<th>Net cash provided by (used in)</th>
<th>Years Ended December 31,</th>
<th>2018</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating activities</td>
<td></td>
<td>$ (6,099)</td>
<td>$(20,197)</td>
</tr>
<tr>
<td>Investing activities</td>
<td></td>
<td>(82)</td>
<td>7,933</td>
</tr>
<tr>
<td>Financing activities</td>
<td></td>
<td>10,141</td>
<td>9,755</td>
</tr>
<tr>
<td>Net increase (decrease) in cash and cash equivalents</td>
<td></td>
<td>$ 3,960</td>
<td>$(2,509)</td>
</tr>
</tbody>
</table>

**Operating Activities**

Cash used by operating activities was $20.2 million during the year ended December 31, 2019 as compared to cash used in operating activities of $6.1 million during the year ended December 31, 2018. The increase of $14.1 million was the result of an increase in deferred revenue of $1.9 million, partially offset by a $22.9 million increase in net loss adjusted for increases in non-cash items totaling $2.3 million and a decrease in the net changes in working capital totaling $4.6 million. The overall increase in cash used in operating activities is mainly due to the PLI acquisition and related restructuring charges of $5.5 million, as well as an increase in the development activities for our lead product candidate, PRA023.

**Investing Activities**

Net cash provided by investing activities was $7.9 million during the year ended December 31, 2019 as compared to net cash used in investing activities $0.1 million during the year ended December 31, 2018. This change primarily was the result of $8.9 million cash acquired in PLI acquisition.

**Financing Activities**

Net cash provided by financing activities was $9.8 million during the year ended December 31, 2019 as compared to $10.1 million during the year ended December 31, 2018. During 2019, we received $9.8 million from the sale of shares of our Series B convertible preferred stock, net of issuance costs. During 2018, we received $10.1 million from the issuance of our Series B convertible preferred stock, net of issuance costs.

**Contractual Obligations and Commitments**

The following table summarizes our contractual obligations and commitments at December 31, 2019 (in thousands):

<table>
<thead>
<tr>
<th>Payments Due by Period</th>
<th>Total</th>
<th>Less than 1 Year</th>
<th>1-3 Years</th>
<th>3-5 Years</th>
<th>More than 5 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating lease obligations(1)</td>
<td>$6,338</td>
<td>$2,020</td>
<td>$4,318</td>
<td>$—</td>
<td>$—</td>
</tr>
<tr>
<td>Non-cancellable purchase obligations(2)</td>
<td>872</td>
<td>872</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Total</td>
<td>$7,210</td>
<td>$2,892</td>
<td>$4,318</td>
<td>$—</td>
<td>$—</td>
</tr>
</tbody>
</table>
(1) Represents monthly payments under our operating lease obligations which relate to our corporate headquarters in San Diego, California. We lease 110,041 square feet of office and laboratory space under an operating lease that expires in December 2022.

(2) Represents non-cancellable purchase commitments related to diagnostic supplies purchases and therapeutics commitments with one contract manufacturing organization for the manufacture of materials used in our preclinical and planned clinical trials and one contract research organization conducting our pre-IND toxicity studies.

We enter into contracts in the normal course of business for contract research services, contract manufacturing services, professional services and other services and products for operating purposes. These contracts generally provide for termination after a notice period, and, therefore, are cancellable contracts and not included in the table above.

In 2020, we borrowed $7.5 million under the Oxford Loan Agreement, and such payments, including final payment of 4% of the principal amount, are not included in the above table.

The table above does not include any additional potential royalty payments we may be required to make under license agreements we have entered into pursuant to which we have in-licensed certain intellectual property. See the section entitled “Business—License and Collaboration Agreements” for additional information. The timing of when these additional payments will actually be made is uncertain and the payments are contingent upon the completion of future activities.

Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements as defined under rules and regulations of the SEC.

Critical Accounting Policies and Estimates

This management discussion and analysis of financial condition and results of operations is based on our financial statements, which have been prepared in accordance with GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities revenue and expenses.

On an ongoing basis, we evaluate these estimates and judgments. We base our estimates on historical experience and on various assumptions that we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities and the recording of revenue and expenses that are not readily apparent from other sources. Actual results may differ materially from these estimates.

While our significant accounting policies are described in more detail in Note 2 to our financial statements included elsewhere in this prospectus, we believe that the following accounting policies are the most critical to understanding and evaluating our historical and future performance.

Revenue Recognition

We recognize revenue in accordance with Accounting Standards Update (ASU) No. 2014-09, Revenue from Contracts with Customers (ASC 606). In accordance with ASC 606, we perform the following steps in determining the appropriate amount of revenue to be recognized as we fulfill our obligations under each of these agreements: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration;
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(iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when, or as satisfy each performance obligation. At contract inception, once the contract is determined to be within the scope of ASC 606, we assess the goods or services promised within each contract and determine those that are performance obligations and assesses whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

For collaboration arrangements, we consider a variety of factors in determining the appropriate estimates and assumptions under these arrangements, such as whether the elements are distinct performance obligations, whether there are observable stand-alone prices, and whether any licenses are functional or symbolic. We evaluate each performance obligation to determine if it can be satisfied and recognized as revenue at a point in time or over time. Typically, license fees, non-refundable upfront fees, and funding of research activities are considered fixed, while milestone payments are identified as variable consideration which must be evaluated to determine if it is constrained and, therefore, excluded from the transaction price. We estimate the amount of variable consideration using the most likely amount, as milestone payments typically only have two possible outcomes. We recognize revenue for sales-based royalty promised in exchange for the license of intellectual property only when the subsequent sale occurs.

We may allocate transaction price using a number of methods including estimating standalone selling price of performance obligations and using the residual approach when the standalone selling price of the license is highly variable or uncertain, and observable standalone selling prices exist for the other goods or services promised in the contract.

With respect to our assessment of the Takeda Agreement, we identified one performance obligation for all the deliverables under the agreement since the delivered elements are not distinct within the context of the contract. Accordingly, we will recognize revenue for the transaction price in an amount proportional to the collaboration expenses incurred and the total estimated collaboration expenses over the three-year period over which it expects to deliver its performance obligations. We included two milestones in the transaction price as they were deemed not probable of significant reversal at the inception of the agreement. Due to the uncertainty in the achievement of the developmental and commercial milestones, the variable consideration associated with these future milestone payments has been fully constrained (excluded) from the transaction price until such time that we conclude that it is probable that a significant reversal of previously recognized revenue will not occur.

Amounts received prior to satisfying the above revenue recognition criteria were recognized as deferred revenue until all applicable revenue recognition criteria were met. Deferred revenue represented the portion of payments received that have not been earned.

Stock-Based Compensation

Stock-based compensation expense represents the cost of the grant date fair value of equity awards recognized over the requisite service period of the awards (usually the vesting period) on a straight-line basis. We estimate the fair value of stock option awards using the Black-Scholes option pricing model and recognize forfeitures as they occur.

The Black-Scholes option pricing model requires the use of subjective assumptions, including the risk-free interest rate, the expected stock price volatility, the expected term of stock options, the expected dividend yield and the fair value of the underlying common stock on the date of grant. Changes in the assumptions can materially affect the fair value and ultimately how much stock-based compensation expense is recognized. These inputs are subjective and generally require judgment to develop. See Note 8 to our financial statements included elsewhere in this prospectus for information concerning certain of the specific assumptions we used in applying the Black-Scholes option pricing model to determine the estimated fair value of our stock options granted in the years ended December 31, 2018 and 2019. Stock-based compensation totaled approximately $42,000 and $0.2 million for the years ended December 31, 2018 and 2019, respectively.

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As of December 31, 2019, the unrecognized stock-based compensation expense related to stock options was $1.6 million which is expected to be recognized as expense over a weighted-average period of approximately 3.4 years. The intrinsic value of all outstanding stock options as of December 31, 2019 was approximately $ , based on the assumed public offering price of $ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, of which approximately $ million related to vested options and approximately $ million related to unvested options.

Common Stock Valuations

We are required to estimate the fair value of the common stock underlying our equity awards when performing fair value calculations. The fair value of the common stock underlying our equity awards was determined on each grant date by our board of directors, taking into account input from management and independent third-party valuation analyses. All options to purchase shares of our common stock are intended to be granted with an exercise price per share no less than the fair value per share of our common stock underlying those options on the date of grant, based on the information known to us on the date of grant. In the absence of a public trading market for our common stock, on each grant date we develop an estimate of the fair value of our common stock in order to determine an exercise price for the option grants. Our determinations of the fair value of our common stock were made using methodologies, approaches and assumptions consistent with the American Institute of Certified Public Accountants Accounting and Valuation Guide: Valuation of Privately Held Company Equity Securities Issued as Compensation (the Practice Aid).

Our board of directors considered various objective and subjective factors, along with input from management, to determine the fair value of our common stock, including:

- valuations of our common stock performed with the assistance of independent third-party valuation specialists;
- our stage of development and business strategy, including the status of research and development efforts of our product candidates, and the material risks related to our business and industry;
- our results of operations and financial position, including our levels of available capital resources;
- the valuation of publicly traded companies in the life sciences and biotechnology sectors, as well as recently completed mergers and acquisitions of peer companies;
- the lack of marketability of our common stock as a private company;
- the prices of our convertible preferred stock sold to investors in arm’s length transactions and the rights, preferences and privileges of our convertible preferred stock relative to those of our common stock;
- the likelihood of achieving a liquidity event for the holders of our common stock, such as an initial public offering or a sale of our company, given prevailing market conditions;
- trends and developments in our industry; and
- external market conditions affecting the life sciences and biotechnology industry sectors.

The Practice Aid prescribes several valuation approaches for setting the value of an enterprise, such as the cost, income and market approaches, and various methodologies for allocating the value of an enterprise to its common stock. The cost approach establishes the value of an enterprise based on the cost of reproducing or replacing the property less depreciation and functional or economic obsolescence, if present. The income approach establishes the value of an enterprise based on the present value of future cash flows that are reasonably reflective of our future operations, discounting to the present value with an appropriate risk adjusted discount rate or capitalization rate. The market approach is based on the assumption that the value of an asset is equal to the
value of a substitute asset with the same characteristics. Each valuation methodology was considered in our valuations.

Historically, we estimated the enterprise value of our business and underlying stock option grants using the back-solve method, the income and market approach, and used the Option Pricing Method (OPM) to allocate enterprise value. The back-solve method is a market approach that assigns an implied enterprise value based on the most recent round of funding or investment and allows for the incorporation of the implied future benefits and risks of the investment decision assigned by an outside investor. Under OPM, shares are valued by creating a series of call options with exercise prices based on the liquidation preferences and conversion terms of each equity class. The values of the preferred and common stock are inferred by analyzing these options. We believed the OPM was the most appropriate method at that time given the expectation of various potential liquidity outcomes and the difficulty of selecting and supporting appropriate enterprise values given our early stage of development. In August 2020, we changed to a hybrid of the OPM and Probability-Weighted Expected Return Method (PWERM). The PWERM is a scenario-based analysis that estimates the value per share based on the probability-weighted present value of expected future investment returns, considering each of the possible outcomes available to us, as well as the economic and control rights of each share class. Under this hybrid method, we considered the expected initial public offering liquidity scenario, but also used the OPM to capture all other scenarios in the event a near-term initial public offering does not occur.

There are significant judgments and estimates inherent in the determination of the fair value of our common stock. These judgments and estimates include assumptions regarding our future operating performance, the time to complete an initial public offering or other liquidity event and the determination of the appropriate valuation methods. If we had made different assumptions, our stock-based compensation expense, net loss and net loss per common share could have been significantly different.

Following the completion of this offering, the fair value of our common stock will be based on the closing price as reported on the date of grant on the primary stock exchange on which our common stock is traded.

Accrued Research and Development Costs

We are required to make estimates of our accrued expenses resulting from our obligations under contracts with CROs, manufacturers, vendors and consultants, in connection with conducting research and development activities. The financial terms of these contracts vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided under such contracts. We reflect research and development expenses in our financial statements by matching those expenses with the period in which services and efforts are expended.

We account for these expenses according to the progress of the preclinical study as measured by the timing of various aspects of the study or related activities. In accruing for these activities, we obtain information from various sources and estimates level of effort or expense allocated to each period. Although we do not expect our estimates to be materially different from amounts actually incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, it could result in us reporting amounts that are too high or too low in any particular period. To date, there have been no material differences between our estimates of such expenses and the amounts actually incurred.

Long-lived Assets and Goodwill

Our long-lived assets are comprised principally of our property and equipment, finite lived intangible assets, and goodwill.

We amortize all finite lived intangible assets over their respective estimated useful lives. In considering whether intangible assets are impaired, we combine our intangible assets and other long-lived assets (excluding
Goodwill is reviewed for impairment annually (during the fourth quarter) or more frequently if indications of impairment exist.

The judgments and estimates involved in identifying and quantifying the impairment of long-lived assets or goodwill involve inherent uncertainties, and the measurement of the fair value is dependent on the accuracy of the assumptions used in making the estimates and how those estimates compare to our future operating performance.

No goodwill impairments were recorded during the years ended December 31, 2018 and 2019.

Following the completion of this offering, our stock price and associated market capitalization will also be considered in the determination of reporting unit fair value. A prolonged or significant decline in our share price could provide evidence of a need to record a material impairment of goodwill.

Other Company Information

Net Operating Loss and Research and Development Carryforwards and Other Income Tax Information

As of December 31, 2019, we had federal and state net operating loss (NOL) carryforwards of $27.7 million and $36.1 million, respectively. The net operating losses generated subsequent to 2017 will carryforward indefinitely and may generally be used to offset up to 80% of future taxable income. The state NOL carryforwards will begin to expire in 2036, unless previously utilized.

As of December 31, 2019, we also had federal and state research credit carryforwards of $0.9 million each. The federal research and development tax credit carryforwards expire beginning in 2037 unless previously utilized, and the state research and development tax credit carryforwards do not expire. We have not completed a Section 382 study to assess whether an ownership change has occurred or whether there have been multiple ownership changes since our formation due to the complexity and cost associated with such a study and the fact that there may be additional such ownership changes in the future. Pursuant to Sections 382 and 383 of the Code, annual use of our NOL and research and development tax credit carryforwards may be limited in the event a cumulative change in ownership of more than 50% occurs within a three-year period.

New Accounting Pronouncements Not Yet Adopted

See Note 2 to our financial statements included elsewhere in this prospectus for accounting pronouncements not yet adopted.

Quantitative and Qualitative Disclosures About Market Risk

Our cash and cash equivalents consist of cash in readily available checking accounts and money market accounts. We do not hold any short-term investments. As a result, the fair value of our portfolio is relatively insensitive to interest rate changes. Due to the nature of our cash and cash equivalents, an immediate hypothetical 10% change in interest rates would not have a material effect on the fair value of our cash and cash equivalents. Our long-term debt bears interest at a fixed rate.
JOBS Act

As an emerging growth company under the JOBS Act, we can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption from new or revised accounting standards and, therefore, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates. We also intend to rely on other exemptions provided by the JOBS Act, including without limitation, not being required to comply with the auditor attestation requirements of Section 404(b) of Sarbanes-Oxley.

We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year following the fifth anniversary of the consummation of this offering; (ii) the last day of the fiscal year in which we have total annual gross revenue of at least $1.07 billion; (iii) the last day of the fiscal year in which we are deemed to be a “large accelerated filer” as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common stock held by non-affiliates exceeded $700.0 million as of the last business day of the second fiscal quarter of such year; or (iv) the date on which we have issued more than $1.0 billion in nonconvertible debt securities during the prior three year period.

Internal Control Over Financial Reporting

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our consolidated financial statements will not be prevented or detected on a timely basis. In connection with the audit of our 2018 and 2019 annual consolidated financial statements, we and our independent registered public accounting firm identified a material weakness in our internal controls due to a lack of controls in the financial closing and reporting process, including a lack of segregation of duties and for 2019, documentation and design of formalized processes and procedures in the revenue cycle. Beginning in the third quarter of 2020, we began to take steps to address the material weakness through our remediation plan, which included the hiring of a Chief Financial Officer and the engagement of external advisors to provide financial accounting assistance in the short term. We have plans to hire additional personnel to improve the segregation of duties in our financial closing and reporting process. In addition, we plan to engage external advisors to evaluate and document the design and operating effectiveness of our internal controls and assist with the remediation and implementation of our internal controls as required. We are evaluating the longer-term resource needs of our various financial functions. See the section titled “Risk Factors—Risks Related to Our Common Stock and This Offering—We have identified a material weakness in our internal control over financial reporting. If we fail to remediate one or more of our material weaknesses, our ability to accurately and timely report our financial results could be adversely affected.”
Overview
We are a biotechnology company pioneering a precision medicine approach to the discovery, development, and commercialization of novel therapeutic and companion diagnostic products for the treatment and diagnosis of inflammatory bowel disease (IBD). We leverage our proprietary precision medicine platform, Prometheus 360, which includes one of the world’s largest gastrointestinal (GI) bioinformatics databases, to identify novel therapeutic targets and develop therapeutic candidates to engage those targets. In parallel, we are developing companion diagnostic tests designed to identify patients more likely to respond to our therapeutic candidates. We have generated a robust pipeline of therapeutic development programs for the treatment of IBD. Our lead product candidate, PRA023, is an IgG1 humanized monoclonal antibody (mAb) that has been shown to block the tumor necrosis factor (TNF)-like ligand 1A (TL1A), a target associated with both intestinal inflammation and fibrosis that was clinically-validated in a third-party Phase 2a clinical trial in ulcerative colitis (UC). PRA023 has the potential to substantially improve outcomes for moderate-to-severe IBD patients predisposed to increased TL1A expression. We are developing PRA023 for the treatment of UC and Crohn’s disease (CD), and we expect to initiate a Phase 1a clinical trial in normal healthy volunteers in the fourth quarter of 2020. Our goal is to revolutionize the treatment of IBD with a precision medicine approach for patients with significant unmet medical needs.

Inflammatory Bowel Disease
IBD is a complex disease with many contributing factors, including genetic, environmental and immunologic. UC and CD are two of the most common forms of IBD. Both UC and CD are chronic, relapsing, remitting, inflammatory conditions of the GI tract that begin most commonly during adolescence and young adulthood. UC involves the innermost lining of the large intestine, and symptoms include abdominal pain and diarrhea, frequently with blood and mucus. CD can affect the entire thickness of the bowel wall and all parts of the GI tract from mouth to anus. CD symptoms include abdominal pain, diarrhea, and other more systemic symptoms such as weight loss, nutritional deficiencies, and fever.

The current standard of care for the treatment of patients with moderate-to-severe IBD is typically anti-inflammatory agents; however, none of these therapies address fibrosis, or scarring, in IBD. Since the approval of the first anti-TNF agent for the treatment of CD in 1998, the availability of JAK inhibitors and newer biological agents, including anti-integrin and anti-IL12/23, has improved the care of moderate-to-severe IBD (JAK inhibitors in UC only). However, these subsequently approved therapies have generally failed to demonstrate a clinical remission effect size of more than 15% relative to placebo. Moreover, among those patients who do respond to therapy, up to 45% will lose response over time. Current therapies used for the treatment of UC and CD apply a one-size-fits-all approach without regard to biologic variations amongst patients, and substantial unmet need remains.

IBD is estimated to affect over 2,000,000 people in the United States and over 5,000,000 people globally. The IBD market was approximately $12.5 billion in the United States and $18.4 billion globally in 2019 and is expected to grow to approximately $14.2 billion in the United States and $21.4 billion globally by 2024.

Our Precision Medicine Approach
Precision medicine involves the discovery and development of therapies that integrate clinical and molecular information based on the biological basis of disease to improve clinical decision-making and patient outcomes. We are pioneering the application of precision medicine in IBD because we believe that by leveraging Prometheus 360 we can identify novel therapeutic targets impacting the underlying pathways involved in IBD and the patient subgroups that will be responsive to a particular therapy.

We believe we have the potential to transform the entire IBD pharmaceutical value chain from discovery to commercialization with our precision medicine approach. Our Prometheus 360 platform includes our extensive - 110 -
clinical database and associated biobank, which is one of the world’s largest collections of biospecimens from patients suffering from IBD and other GI disorders. This database and biobank, which we exclusively license from Cedars-Sinai Medical Center (Cedars-Sinai), includes more than 200,000 samples linked to extensive clinical data from over 20,000 patients collected over more than 20 years. This, in combination with our state-of-the-art machine-learning methodologies, make Prometheus 360 a discovery engine for novel precision therapeutics and companion diagnostics. IBD development programs can take seven to ten years to complete and physicians are often challenged with the task of enrolling patients from a limited pool of qualified candidates into a large number of trials with undifferentiated mechanisms of action. By using companion diagnostics to target a specific subset of the IBD population, we expect to reduce overall development time and cost through smaller trials and faster enrollment rates. We believe our precision medicine approach will result in a greater likelihood of identifying and developing the right drug for the right patient, help to maximize patient and trial outcomes, improve label claims, accelerate adoption of targeted therapeutics for addressable patients and provide attractive treatment options from a cost-benefit perspective for payors.

**Our Portfolio**

We have a robust pipeline of therapeutic development programs to address several clinical IBD patient subpopulations, and plan to develop a companion diagnostic for each program. The following table summarizes our key current internal and partnered programs.

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<tr>
<th>PROGRAM</th>
<th>DISCOVERY</th>
<th>LEAD OPTIMIZATION</th>
<th>IND-ENABLING</th>
<th>PHASE 1</th>
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<td>PRA023 Anti-TL1A mAb</td>
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<td>TPR15 mAb</td>
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(1) We retain all commercialization rights to PR600 outside of Europe, Australia and New Zealand.
(2) We are developing a companion diagnostic in tandem with Takeda’s drug discovery and development efforts. Takeda has an option to collaborate on an additional program.

In addition, we have five other programs with different mechanisms of action targeting UC and/or CD that are in the discovery stage of development.

**PRA023 Overview—anti-TL1A mAb**

Our lead product candidate, PRA023, is an IgG1 humanized mAb that has been shown to block TL1A. Third-party antibody programs against this target have been shown to reduce both intestinal inflammation and fibrosis in preclinical studies, and this target has been clinically-validated in a third-party Phase 2a clinical trial in UC. PRA023 binds both soluble and membrane-associated human TL1A with high affinity and specificity and has the potential to substantially improve outcomes for moderate-to-severe IBD patients predisposed to increased TL1A expression. We are developing PRA023 for the treatment of UC and CD, and expect to initiate a Phase 1a clinical trial in normal healthy volunteers in the fourth quarter of 2020. Assuming favorable safety results in this trial, we expect to commence in parallel in 2021 a Phase 1b/2a randomized placebo-controlled clinical trial in patients with moderate-to-severe UC and an open-label Phase 1b clinical trial in patients with moderate-to-severe
CD, with data expected in the second quarter of 2022 for both indications. We are also developing a genetic-based companion diagnostic to identify patients who are predisposed to increased expression of TL1A and therefore potentially more likely to respond to PRA023. We intend to evaluate and use this companion diagnostic starting with the Phase 1b/2a UC trial and the Phase 1b CD trial.

**PR600 Overview—Anti-TNF Super Family Member mAb**

Our PR600 program targets a member of the TNF super family, whose expression is limited to immune cells. It has been shown that blocking this target inhibits disease in multiple third-party IBD animal models. We believe that a therapeutic developed against this target is likely to impede both the reactivation and propagation of the pathogenic immune response in IBD. We have identified multiple genetic variants linked to patient subpopulations with a complicated course of disease. We have conducted functional genetic studies in patient samples and have identified genetic variations associated with an increase in target expressing immune cells in CD peripheral blood and an increased capacity to produce inflammatory cytokines. We intend to leverage Prometheus 360 in combination with functional assays to identify patients with these genetic variants. We entered into a co-development and manufacturing agreement (the Falk Agreement) with Dr. Falk Pharma GmbH (Falk) for our PR600 program, in order to leverage Falk’s experience in GI drug development and commercialization in Europe. Under this agreement, we granted to Falk exclusive commercialization rights in Europe, Australia and New Zealand, while we retained commercialization rights in the United States and the rest of the world for therapeutics developed from our PR600 program. We expect to submit an IND for a therapeutic candidate from the PR600 program in the fourth quarter of 2022.

**PR300 Overview—GPCR Modulator Small Molecule**

Our PR300 program targets an orphan G-protein coupled receptor (GPCR) expressed predominantly in the GI tract that we believe has important functions underlying intestinal epithelial integrity and innate immune cell function. We have identified a coding single nucleotide polymorphism (SNP) in the gene of this target that represents a very strong genetic association with UC. Through further datamining, we have also identified multiple additional genetic variants that are associated with both UC and CD. These variants are linked to hard-to-treat clinical patient subpopulations, including those with medically refractory UC and perianal CD. We expect to submit an IND for a therapeutic candidate from the PR300 program by the end of 2023.

**Other Development Programs and Takeda-Partnered Program**

We have five other unpartnered programs with different mechanisms of action targeting UC and/or CD that are in the discovery stage of development. In addition, we are collaborating with Millennium Pharmaceuticals, Inc., a wholly owned subsidiary of Takeda Pharmaceutical Company Limited (Takeda), on the development of a preclinical program (TPR15) and related companion diagnostic for the treatment of UC and CD. Takeda has an option to collaborate with us on an additional target and its companion diagnostic.

**Our Diagnostic Franchise**

Our diagnostic franchise is comprised of laboratory developed tests (LDTs) we commercialize and our companion diagnostic tests in development. In June 2019, we acquired Prometheus Laboratories, Inc. (PLI) from Nestlé Health Sciences US Holdings, Inc. (Nestlé). Through this business, we market and conduct several LDTs used by gastroenterologists to monitor their IBD patients’ disease state and inform their therapeutic decisions, and have a Clinical Laboratory Improvement Amendments (CLIA)-certified laboratory located in San Diego, California. In addition, we plan to develop companion diagnostic tests in parallel with each of our therapeutic product candidates. Our commercial diagnostic products enable us to gain additional insight from gastroenterologists as we develop our therapeutic candidates and prioritize new targets.

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Our Team

Our team is comprised of leaders and scientists with significant experience in IBD and other GI diseases, data analytics, biology and drug development. Mark McKenna, our President and Chief Executive Officer, was previously President at Salix Pharmaceuticals, Inc., a wholly owned subsidiary of Bausch Health Companies Inc., where he was responsible for the company’s GI franchise and launched several new products. Other members of our management team have served in senior positions at AbbVie Inc., Bristol-Myers Squibb Company, GlaxoSmithKline plc, Pfizer Inc. and Takeda. We are also guided by our board of directors, led by Chairman Tadataka (Tachi) Yamada, M.D., and a scientific advisory board composed of key opinion leaders in IBD, including Stephan Targan, M.D., William Sandborn, M.D. and Dermot P. McGovern, M.D., Ph.D.

Our Strengths

We believe that our company has the following key differentiating competitive strengths:

• **We use a novel precision medicine approach to target the IBD market, which is primed for disruption.** Current therapies used for the treatment of IBD apply a one-size-fits-all approach without regard to biologic variations amongst patients. We, on the other hand, apply a novel precision medicine approach by analyzing genetics and functional genomics to discover novel targets in order to address the heterogeneity of the IBD population and potentially improve patient outcomes substantially. Our approach builds on the recent successes of companies that employ precision medicine approaches in other therapeutic areas such as oncology. The global IBD market is projected to be over $21 billion by 2024, but there still exists a significant unmet medical need due to the heterogeneous nature of the IBD patient population.

• **Our proprietary Prometheus 360 platform is a discovery engine for novel precision therapeutics and companion diagnostics.** A central pillar of Prometheus 360 is our extensive clinical database and associated biobank, one of the world’s largest collections of biospecimens from patients suffering from IBD and other GI disorders. This database and biobank, which we exclusively license from Cedars-Sinai, includes more than 200,000 samples linked to extensive clinical data from over 20,000 patients collected over more than 20 years. This, in combination with our state-of-the-art machine-learning methodologies, makes Prometheus 360 a discovery engine for novel precision therapeutics and companion diagnostics. Furthermore, we believe that our companion diagnostics approach differentiates us from our competitors by potentially improving patient outcomes and reducing overall development time and cost by identifying the right patient for the right therapy.

• **Our lead product candidate, PRA023, targets a clinically-validated TL1A pathway and has the potential to be a differentiated treatment with improved patient outcomes.** PRA023 is an anti-TL1A mAb that targets both inflammation and fibrosis in IBD, whereas currently approved therapies only directly target inflammation. Using our precision medicine approach with a companion diagnostic, PRA023 has the potential to substantially improve patient outcomes by combining a clinically-validated pathway with the ability to identify patients more likely to respond favorably to the treatment.

• **Our platform has attracted partnerships with leading global pharmaceutical companies in the field of IBD.** The strength of Prometheus 360 has already led to collaborations with Takeda and Falk. We intend to leverage these global pharmaceutical organizations to expand the reach of our Prometheus 360 platform and potentially accelerate the clinical development of precision medicine in IBD for patients with significant unmet medical need.

• **We have an established GI-focused commercial diagnostic franchise, which helps enable our precision medicine approach.** Our marketed diagnostic testing products share a common gastroenterologist prescriber base with our precision medicine therapeutic product candidates. We are focused on changing the IBD disease management paradigm through the use of our tests to help gastroenterologists inform their therapeutic decisions and monitor their GI patients’ disease state over time. Our existing strong relationships with gastroenterologist prescribers will continue to allow us to
educate physicians and prepare the GI marketplace for a precision medicine approach. Additionally, our commercial diagnostics infrastructure enables the continued collection of patient samples, which strengthens our proprietary databases that we utilize to discover novel therapeutic targets for the treatment of IBD.

- **We have assembled an experienced team comprised of industry leaders with drug discovery, development, and commercialization expertise.** Our team is comprised of leaders and scientists with significant experience in IBD and other GI diseases, data analytics, biology and drug development.

Our Strategy

Our goal is to revolutionize the treatment of IBD with a precision medicine approach for patients with significant unmet medical needs. The key elements of our strategy to achieve this goal are:

- **Maximize the value of our Prometheus 360 precision medicine platform for the treatment of IBD.** Prometheus 360 serves as our drug discovery and development engine. We have generated a robust pipeline of therapeutic development programs for the treatment of IBD in a capital and time efficient manner and are designing and developing companion diagnostics. We intend to continue leveraging our platform to generate additional new targets, novel therapeutics and companion diagnostics, and to further advance our pipeline of precision therapeutic candidates.

- **Rapidly advance PRA023 into the clinic and potentially accelerate its development by utilizing our companion diagnostic to identify patients who we expect to benefit from treatment.** PRA023 targets the TL1A pathway, which was clinically-validated in a third-party Phase 2a clinical trial in UC, and has the potential to significantly improve the quality of life of IBD patients by targeting both inflammation and fibrosis. By developing a companion diagnostic in parallel, we expect to be able to identify patients who may specifically benefit from PRA023. Through this patient identification, we believe PRA023 has the potential to lead to improved patient outcomes. We are developing PRA023 for the treatment of UC and CD, and expect to initiate a Phase 1a clinical trial in normal healthy volunteers in the fourth quarter of 2020. Assuming favorable safety results in this trial, we expect to commence in parallel in 2021 a Phase 1b/2a randomized placebo-controlled clinical trial in patients with moderate-to-severe UC and an open-label Phase 1b clinical trial in patients with moderate-to-severe CD, with data expected in the second quarter of 2022 for both indications.

- **Advance our other programs, including PR600, into and through the clinic.** We have a robust pipeline of additional programs for the treatment of IBD, including PR600, which we believe can address additional unmet medical need. By utilizing Prometheus 360, we believe we will be able to identify subsets of IBD patients who will differentially benefit from our product candidates. We intend to submit an IND for a therapeutic candidate from the PR600 program in the fourth quarter of 2022.

- **Continue leveraging Prometheus 360 to expand our pipeline to address additional patient subpopulations.** We continue to identify and stratify IBD patients into disease subpopulations with our Prometheus 360 platform and companion diagnostics. This will provide us the opportunity to develop additional product candidates designed to address the unmet need of additional patient subpopulations. We will continue to strengthen our datamining and machine-learning capabilities to further enhance our platform.

- **Selectively enter into strategic collaborations to maximize the value of our therapeutic pipeline.** For our PRA023 program, we intend to retain worldwide development and commercialization rights. We will continue to explore business development opportunities to maximize the value of the novel targets and therapeutic candidates developed through our Prometheus 360 platform. For example, in 2019 we entered into a companion diagnostics and development collaboration with Takeda to use Prometheus 360 to develop companion diagnostics in tandem with Takeda’s therapeutic discovery efforts. Additionally, in 2020 we entered into the Falk Agreement in order to leverage Falk’s experience in GI drug development and commercialization in Europe for our PR600 program.
Limitations of Current IBD Drug Development

Despite the increasing global burden of IBD, the lack of evolution and innovation in drug development has left many patients with suboptimal outcomes. While there are many programs and mechanisms of action in development for IBD, nearly all are primarily focused on inflammation, and multiple programs are pursuing the same well-established targets and pathways. Efficacy of approved treatments and therapies in development has remained undifferentiated since the approval of the first anti-TNF product for use in IBD. With the large number of therapies in clinical development and the undifferentiated landscape, there is intense competition for the limited pool of qualified patients for clinical trials, leading to very slow recruitment. As a consequence of the slow recruitment rate and the large studies required due to small treatment effect, clinical development in IBD has become costly and slow. We believe our ability to select patients with a higher probability of response to a specific therapy will enable smaller, faster, and less costly studies and allow for targeted recruitment in this crowded IBD development landscape.

Given the heterogeneous nature of IBD, there is a growing need for the development of predictive biomarkers and companion diagnostics that can be used to identify those patients more likely to benefit from a specific therapeutic. Although there are product candidates with predictive biomarkers in development for IBD, there is no therapy approved with a companion diagnostic that predicts whether an IBD patient will respond to a specific therapeutic.

Attempts to identify new, targeted therapeutics for IBD through the use of publicly available clinical datasets have been hampered by the significant challenges associated with generating high-volume and high-quality data in a standardized manner from these datasets. Furthermore, while post-hoc analysis of clinical trial data can be helpful to retrospectively understand patient responses to particular therapeutics, the ability to use these data for understanding pathway pathogenesis in IBD or target discovery for IBD, is limited.
We believe we have overcome these challenges by utilizing Prometheus 360 to identify potential targeted treatments for IBD patients. We deploy the following three main components of Prometheus 360 to stratify the overall, heterogeneous IBD patient population into biologically homogeneous subgroups: (1) our high-density clinical data; (2) our large collection of GI biospecimens; and (3) our advanced data analytics capabilities. We believe this allows us to identify novel drug targets which can be used to develop product candidates designed to be effective in the specific IBD patient subpopulations we have identified.

Prometheus 360 includes our extensive clinical database and associated biobank, which is one of the world’s largest collections of biospecimens from patients suffering from IBD and other GI disorders. This database and biobank, which we exclusively license from Cedars-Sinai, includes more than 200,000 samples linked to extensive clinical data from over 20,000 patients collected over more than 20 years. Clinical data sources included in Prometheus 360 include electronic medical records, imaging data, clinical chemistry, pathology records and serologies. As such, clinical history, response to therapy and longitudinal data are available to us for analysis. In addition to clinical data, we have access to relevant, well-annotated patient samples for translational validation of therapeutic targets to help guide therapeutic development. Stored biorepository patient samples available to us include tissue biopsies (either from endoscopy or from surgery), serum/plasma, DNA, RNA, peripheral blood mononuclear cells (PBMC), lamina propria mononuclear cells (LPMC), stool and mesenteric adipose tissue. For many patients, we have multiple types of samples collected over multiple years. Samples from Prometheus 360 are routinely interrogated by deep molecular profiling including SNP genotyping, whole exome sequencing, RNA sequencing, metabolomics and microbiomics. In addition to this large, well-annotated IBD cohort of data and biosamples, Prometheus 360 also contains samples derived from independent cohorts and samples received through our commercial diagnostics business, which we believe gives us a competitive advantage in the discovery and development of our novel drug targets, therapeutic candidates and companion diagnostics.

Prometheus 360 incorporates advanced datamining and bio-analytical capabilities that we employ to uncover insights about immunological pathways that drive IBD, while providing a holistic view of the biology surrounding potential targets. We apply machine-learning algorithms to our clinical data and molecular profiling data to reveal disease-related trends, patterns and associations that are more reflective of what happens at a molecular level in a complex disease like IBD. Unlike traditionally employed strategies such as relying on genome-wide association studies (GWAS) alone, our bioinformatics approach allows us to discover and examine...
genome-wide association studies (GWAS) alone, our bioinformatics approach allows us to discover and examine the joint effects of multiple genetic variants in key inflammatory pathways that contribute to the development and progression of IBD. As a consequence, our approach allows us to create complex algorithm-based and proprietary companion diagnostic products that we use to identify patients likely to benefit from our product candidates.

Altogether, Prometheus 360 provides what we believe to be a unique ability to discover and develop novel precision medicine therapeutics that have the potential to lead to substantially improved patient outcomes in IBD.

Advantages of Our Prometheus 360 Precision Medicine Platform

We believe Prometheus 360 can potentially revolutionize the drug development and treatment paradigm for IBD patients by identifying patients more likely to respond favorably to treatment. We believe our platform has several key advantages, including:

• **Potential to offer improved patient outcomes.** IBD treatments approved and in development are largely undifferentiated and primarily target inflammation, resulting in a suboptimal clinical remission rate. We believe the ability to combine new mechanisms of action discovered through our platform and a novel patient selection approach utilizing companion diagnostics will allow for better patient outcomes. To realize this advantage, we are developing precision therapeutic candidates with companion diagnostics to address multiple targets and pathways in IBD.

• **Reduced trial costs and development timelines.** IBD development programs can take seven to ten years to complete and physicians are often challenged with the task of enrolling patients from a limited pool of qualified candidates into a large number of trials with undifferentiated mechanisms of action. We believe Prometheus 360 has the potential to significantly reduce development time and cost and improve traditionally slow enrollment rates by allowing for the design of smaller clinical trials through the targeting of pre-identified patients more likely to respond to a therapeutic candidate. We believe our approach will motivate investigators to prioritize enrolling eligible patients in a trial with a therapy that addresses a target patient subpopulation, thereby also improving traditionally slow enrollment rates.

• **Potential to drive physician and payor adoption of our therapeutic product candidates.** Given the success of precision medicine in oncology, gastroenterologists are eager to implement a similar approach to the treatment of IBD. Our platform and approach will potentially offer physicians the ability to prescribe specific treatments for each individual, which we believe will lead to improved patient outcomes. We believe this will help drive physician adoption of our therapeutic product candidates. In addition, we believe our approach will be attractive to payors seeking to maximize overall cost-benefit and enhance our ability to more rapidly and effectively obtain payor coverage for any approved product we develop.

IBD and Market Opportunity Overview

IBD is a chronic relapsing and remitting inflammatory disease of the GI tract. It is a complex disease with many contributing factors, including genetic, environmental and immunologic. IBD typically onsets during adolescence and young adulthood and is diagnosed based on clinical, laboratory, endoscopy and histopathology and/or imaging findings. The IBD market was approximately $12.5 billion in the United States and $18.4 billion globally in 2019 and is expected to grow to approximately $14.2 billion in the United States and $21.4 billion globally by 2024.

UC and CD are the two most common types of IBD. UC causes long-lasting inflammation and ulcers in the digestive tract and affects the innermost lining of the large intestine (colon) and rectum. UC is debilitating and can lead to life-threatening complications. There are no treatments that cure UC and patients often require life-long treatment. Symptoms include diarrhea, bloody stools, abdominal pain and cramping, urgency to defecate,
inability to defecate despite urgency, weight loss, fatigue, and fever. Chronic inflammation associated with UC puts a patient at increased risk of developing colon cancer. UC affects an estimated 926,000 people in the United States and 2,750,000 people globally. The UC market was approximately $4.2 billion in the United States and $6.2 billion globally in 2019 and is expected to grow to approximately $5.4 billion in the United States and $8.3 billion globally by 2024.

CD also causes long-lasting inflammation and ulcers in the digestive tract. It differs from UC in that it affects the entire thickness of the bowel wall and all parts of the digestive tract from mouth to anus. There are no treatments that cure the disease and patients often require life-long treatment. Symptoms include diarrhea, fever, fatigue, abdominal pain and cramping, bloody stools, mouth sores, reduced appetite and weight loss, and pain or drainage near or around the anus due to development of fistula from the inflammation. CD affects an estimated 1,157,000 people in the United States, and 2,446,000 people globally. The development of abnormal narrowing of the digestive tract, known as strictures is common and is the leading indication requiring surgical intervention. Up to 70% of CD patients develop a stricturing or perforating complication. The CD market was approximately $8.4 billion in the United States and $12.2 billion globally in 2019 and is expected to grow to approximately $8.8 billion in the United States and $13.1 billion globally by 2024.

IBD Current Treatments and Limitations

Medical treatment of IBD is typically divided into two types of therapy: induction and maintenance. Induction therapy is used to reduce inflammation quickly (in three months or less) and maintenance therapy is used to sustain that reduction after three months. Patients with IBD are classified as mild, moderate or severe, based on the level of symptoms experienced, inflammatory biomarkers, and severity of disease on endoscopy. The current standard of care for the treatment of patients with moderate-to-severe IBD is typically anti-inflammatory agents.

Aminosalicylates (5-ASAs) are used as a first-line therapy in mild-to-moderate UC. Corticosteroids are used primarily during induction therapy and are effective for reducing symptoms but not for mucosal healing. There are serious side effects with extended corticosteroid use, including lowered quality of life, bone loss, weight gain and cardiovascular complications. Because of these serious long-term safety concerns, corticosteroids are used primarily as a bridge to manage symptoms until immunomodulators or biologic agents become effective and enable mucosal healing. Oral immunosuppressants (e.g. azathioprine and 6-mercaptopurine) have not been effective as induction agents and are generally used for steroid-sparing or as an adjunctive therapy for reducing immunogenicity against biologic agents. Oral immunosuppressants are also associated with known toxicities such as drops in white blood cell counts and increased risk for infection.

Since the approval of the first anti-TNF agent for the treatment of CD in 1998, the availability of JAK inhibitors and newer biological agents, including anti-integrin and anti-IL12/23, has improved the care of moderate-to-severe IBD (JAK inhibitors in UC only), but these agents have safety and tolerability concerns, including increased risks for cancers, infections and blood clots due to their systemic impact and resulting effects on the immune system outside of the GI tract. More importantly, these subsequently approved therapies have generally failed to demonstrate a clinical remission effect size of more than 15% relative to placebo. Moreover, among those patients who do respond to therapy, up to 45% will lose response over time. As a consequence, despite the advances in approved therapies over the past two decades, more than 15% of UC and 50% of CD patients require surgery within 10 years of diagnosis. The most common cause of surgery in UC is progressive disease not responsive to medical therapy and in CD it is development of strictures and/or perforation, requiring surgical resection of the intestine. The only novel mechanism of action that is currently in late stage clinical development is oral S1P modulators.

While fibrosis and stricturing are common in CD, clinically observable colonic strictures have also been reported in up to 11% of patients with UC, and we believe microscopic submucosal fibrosis is actually much more prevalent in UC patients than reported. In a study that examined 89 consecutive UC colectomy specimens
from Cleveland Clinic, submucosal fibrosis was detected in 100% of the specimen. Microscopic evidence of fibrosis in the colonic wall may have significant clinical implications such as motility abnormalities leading to symptoms such as diarrhea, abdominal pain, urgency and incontinence. It has long been speculated that intestinal fibrosis may be the underlying cause of persistent UC symptoms, after the resolution of inflammation, that is commonly misclassified as irritable bowel syndrome.

Current treatment of IBD applies a one-size-fits-all approach without regard to genetic or biological variations in patients. We believe there must be a paradigm shift towards developing specific therapies for patients whose disease is driven by a specific biology. To date, we believe there are no clinical stage programs focused on integrating precision therapeutics with companion diagnostics to overcome the limitations of a one-size-fits-all treatment approach for IBD. Additionally, despite the advances in anti-inflammatory therapeutics for the treatment of UC and CD over the past two decades, fibrosis in these patients has largely not been addressed by therapy, representing an area of high unmet need. There is currently no approved therapy that directly targets the reversal of fibrosis in IBD.

Our Solutions for the Treatment of IBD

**PRA023 (anti-TL1A mAb) + Companion Diagnostic**

Utilizing our precision medicine approach, we have developed our lead product candidate, PRA023, which is an investigational, IgG1 humanized mAb that has been shown to block TL1A. Third-party antibody programs against this target have been shown to reduce both intestinal inflammation and fibrosis in preclinical studies, and this target has been clinically-validated in a third-party Phase 2a clinical trial in UC. PRA023 binds both soluble and membrane-associated human TL1A with high affinity and specificity and has the potential to substantially improve outcomes for moderate-to-severe IBD patients predisposed to increased TL1A expression. PRA023 binds to a novel epitope that differentiates it from other anti-TL1A mAbs in clinical development. We are developing PRA023 for the treatment of UC and CD, and expect to initiate a Phase 1a clinical trial in normal healthy volunteers in the fourth quarter of 2020. Assuming favorable safety results in this trial, we expect to commence in parallel in 2021 a Phase 1b/2a randomized placebo-controlled clinical trial in patients with moderate-to-severe UC and an open-label Phase 1b clinical trial in patients with moderate-to-severe CD, with data expected in the second quarter of 2022 for both indications.

We are developing a genetic-based companion diagnostic to identify patients who are predisposed to increased expression of TL1A and therefore potentially more likely to respond to PRA023. We intend to evaluate and use this companion diagnostic starting with the Phase 1b/2a UC trial and the Phase 1b CD trial. We believe this approach will lead to reduced development costs and timelines, and ultimately lead to improved patient outcomes.
TL1A as an IBD drug target—potential to address not only inflammation but also fibrosis

Much of the early research and development on anti-TL1A therapy has focused on the TL1A-DR3 pathway with regards to regulation of inflammation. More recently, however, the potential for TL1A as a therapeutic target in intestinal fibrosis was demonstrated in a study conducted by Cedars-Sinai evaluating the effect of anti-TL1A antibodies in mouse models of IBD. In these studies, treatment with a neutralizing TL1A mAb attenuated disease and reversed colonic fibrosis. We believe there is currently no other anti-fibrotic therapy approved for CD. Thus, intestinal fibrosis mediated by increased levels of TL1A in the gut, continues to remain an area of high unmet medical need in IBD and differentiates the TL1A pathway mechanism of action from other approved therapies.

TL1A—a clinically-validated drug target in UC

Pfizer’s TL1A compound (PF-06480605) was studied in a Phase 2a 14-week open-label study in patients with moderate-to-severe UC, with inclusion criteria that did not stratify patients. The study observed a high proportion of patients (38%) achieving endoscopic improvement with endoscopies read at an independent reading center. In addition, 24% of subjects achieved clinical remission, compared to the historic placebo remission rate of 8%. Lastly, substantial decreases in disease biomarkers were observed with early onset of action at weeks 2 to 4. Treatment was generally safe and well-tolerated. We believe these results clinically validate TL1A as a target in UC.

Preclinical Studies of PRA023

PRA023 is an investigational, humanized IgG1 mAb that potently binds human and cynomolgus monkey TL1A. PRA023 has sub-nanomolar binding affinity to soluble TL1A and nanomolar affinity to membrane-associated TL1A. In *in vitro* studies, PRA023 blocked TL1A’s ability to bind and activate its receptor, DR3. In whole blood, PRA023 inhibited the TL1A-dependent IFN-γ response following the *ex vivo* exposure to immune-complex and a combination of IL-12 and IL-18. Additionally, PRA023 was observed to be highly selective for TL1A with no detectable binding to related TNF super family members FAS, LIGHT, or TRAIL.

We assessed the potential toxicity of PRA023 in a series of nonclinical *in vitro* assays and *in vivo* studies in cynomolgus monkeys. The monkey was selected as a pharmacologically relevant nonclinical species because of similar TL1A protein sequence homology and nearly equivalent binding affinity of PRA023 to monkey TL1A, as compared to human. PRA023 is similarly active in monkey and human *in vitro* cell-based assays.

PRA023 has been engineered to remove the potential for the mAb to induce an immune response. In non-good laboratory practice (GLP) cell-based *in vitro* assays, PRA023 treatment did not lead to antibody-
cell-mediated cytotoxicity or cytokine release from peripheral blood cells thus indicating that it was not provoking an undesired immune response.

In a non-GLP tolerability and pharmacokinetic (PK) study, cynomolgus monkeys (1/sex/group) were administered PRA023 intravenous (IV) at 30, 100 and 243 mg/kg/week on Days 1 and 8 and subsequently followed for approximately 11 weeks to assess systemic exposure of PRA023. There were no PRA023-related clinical observations or changes in body weight, clinical chemistry, or hematology parameters. PK measurements suggested that PRA023 has a long half-life of 5 to 11 days, which is consistent with human IgG1 in monkeys.

An ongoing GLP study is being performed to evaluate the potential toxicity, including immunotoxicity, of PRA023 and associated systemic exposure after six weeks of once-weekly dosing (7 total doses) in cynomolgus monkeys. PRA023 was administered IV (bolus) to male and female monkeys (3/sex/group) at doses of 0 (vehicle control), 30, 100, or 300 mg/kg/week. Recovery animals (2/sex/group) were administered 0 or 300 mg/kg/week of PRA023. A single death occurred in the 30 mg/kg group, which was likely not PRA023-related. No PRA023-related mortality occurred, and no PRA023-related changes in clinical signs, body weights, clinical pathology (clinical chemistry, coagulation, hematology and urinalysis), macroscopic observations, electrocardiogram, cytokine analysis, T-cell dependent antibody response, and immunophenotyping profiles were observed. Blood samples have been collected for an evaluation of systemic exposure to PRA023 and potential for anti-drug antibody development and microscopic evaluations are pending.

A six-month repeat-dose monkey toxicity study using mature animals is also planned to support clinical studies longer than six weeks in duration.

**Our Companion Diagnostic Product Candidate for PRA023**

TL1A was one of the first targets shown by GWAS to be genetically associated with risk of developing IBD in a diverse patient population. Peripheral blood cells from patients carrying the TNFSF15 polymorphism risk SNPs produce higher levels of TL1A than those without the risk-associated polymorphism, suggesting this polymorphism may provide a means to identify patients with TL1A-driven disease and who are thus more likely to respond to anti-TL1A therapy. We are developing a genetic-based, 3-SNP polymerase chain reaction assay as a companion diagnostic for PRA023. In establishing our 3-SNP genomic biomarker set, we utilized machine-learning algorithms that, in contrast to traditional GWAS methodologies, allow us to take into account complex, non-linear genomic interactions that drive complex biology such as IBD. Our approach also prioritizes combinations that correlate with high TL1A pathway activity and not merely all patients with an observed set of symptoms. Across multiple patient cohorts, our companion diagnostic captured approximately 30% of the IBD population and showed about a 4-times greater probability of identifying patients predisposed to increased TL1A expression over IBD patients predisposed to lowered TL1A expression.

**Clinical Development Plan for PRA023**

We are developing PRA023 for the treatment of UC and CD, and expect to initiate a Phase 1a clinical trial in normal healthy volunteers in the fourth quarter of 2020. Assuming favorable safety results in this trial, we expect to commence in parallel in 2021 a Phase 1b/2a randomized placebo-controlled clinical trial in patients with moderate-to-severe UC and an open label Phase 1b clinical trial in patients with moderate-to-severe CD, with data expected in the second quarter of 2022 for both indications.

The Phase 1a clinical trial will be a single-center, double-blind, placebo-controlled safety, tolerability and PK study in normal healthy volunteers receiving IV administration of PRA023. The single ascending dose (SAD) phase of the trial will consist of 8 subjects (6 active and 2 placebo) per cohort with up to 6 dose levels. The multiple ascending dose (MAD) phase of the trial will commence after an equal or higher SAD dose has been studied and acceptable safety and tolerability has been observed. The MAD phase will consist of 8 subjects (6 active and 2 placebo) per cohort with up to 5 dose levels. The trial will evaluate the safety and tolerability of...
single and multiple doses of PRA023 via IV administration as well as the PK of PRA023 after single and multiple doses in healthy, ambulatory, non-smoking, male or female volunteers aged 18 to 60 years. In addition, the trial will determine the effects of PRA023 on pharmacodynamic (PD) markers as well as the exposure-response relationship of PRA023 on PD markers.

**PR600 Program**

Our PR600 program targets a member of the TNF super family, whose expression is limited to immune cells. It has been shown that blocking this target inhibits disease in multiple third-party IBD animal models. We believe that a therapeutic developed against this target is likely to impede both the reactivation and propagation of the pathogenic immune response in IBD. We have identified multiple genetic variants linked to patient subpopulations with a complicated course of disease. We have conducted functional genetic studies in patient samples and have identified genetic variations associated with an increase in target expressing immune cells in CD peripheral blood and an increased capacity to produce inflammatory cytokines. We intend to leverage Prometheus 360 in combination with functional assays to identify patients with these genetic variants. We entered into the Falk Agreement in order to leverage Falk’s experience in GI drug development and commercialization in Europe. Under this agreement, we granted to Falk exclusive commercialization rights in Europe, Australia and New Zealand, while we retained commercialization rights in the United States and the rest of the world for therapeutics developed from our PR600 program. We expect to submit an IND for a therapeutic candidate from the PR600 program in the fourth quarter of 2022.

**PR300 Program**

Our PR300 program targets an orphan GPCR expressed predominantly in the GI tract that we believe has important functions underlying intestinal epithelial integrity and innate immune cell function. We have identified a coding SNP in the gene of this target that represents a very strong genetic association with UC. Through further datamining, we have also identified multiple additional genetic variants that are associated with both UC and CD. These variants are linked to hard-to-treat clinical patient subpopulations, including those with medically refractory UC and perianal CD. We expect to submit an IND for a therapeutic candidate from the PR300 program by the end of 2023.

**Our Diagnostic Franchise**

Our diagnostic franchise, comprised of LDTs we commercialize and our companion diagnostic tests in development, supports our therapeutics strategy. Companion diagnostics are a critical component of our precision medicine approach. In parallel to each of our therapeutic product candidates, we plan to develop companion diagnostic tests. We believe pairing therapeutics with diagnostic tests designed to identify patients more likely to respond to our therapeutic candidates improves the drug development process and enables better patient outcomes. Our companion diagnostics strategy has the potential to decrease trial size and reduce enrollment time, thereby reducing clinical development costs and time. We believe this approach will result in a greater likelihood of identifying and developing the right drug for the right patient, help to maximize patient and trial outcomes, improve label claims, accelerate adoption of targeted therapeutics for addressable patients and provide attractive treatment options from a cost-benefit perspective for payors. We also believe our companion diagnostics strategy will advance the adoption of our therapeutic product candidates and position them as frontline treatment options ahead of current standard of care.

As a result of our June 2019 acquisition of PLI from Nestlé, we acquired our CLIA-certified laboratory and also market several LDTs, including those useful to gastroenterologists to inform their therapeutic decisions and monitor their GI patients’ disease state over time. The acquisition provided us with several advantages which enable our therapeutic pipeline. First, the acquisition will allow us to shift development of our companion
diagnostics in-house over time providing an efficient co-development model with our therapeutic business. Second, the CLIA-certified laboratory we acquired in this acquisition receives approximately 150,000 samples annually, providing a wealth of information as a second platform validation source which can potentially accelerate development of our therapeutic targets and product candidates. Finally, the commercial diagnostic products we acquired enable us to prepare the GI marketplace for a precision medicine approach consisting of our therapeutic and companion diagnostic products.

Our diagnostic franchise also has the potential to grow as we develop and commercialize new testing solutions designed to help gastroenterologists achieve better outcomes for their patients. Proactively testing IBD patients can be clinically valuable in areas such as therapeutic selection, biologic dose optimization and non-invasive monitoring of disease status over time.

**Our Marketed Products**

We commercialize a group of LDTs and solutions to facilitate the diagnosis, prognosis and monitoring of IBD and GI autoimmune diseases, all conducted in our CLIA-certified laboratory located in San Diego, California. Our dedicated team of field sales representatives and account managers market these products to prescribers across the United States.

**Disease Diagnosis Solutions**

The IBD sgi Diagnostic® test uniquely combines serologic, genetic and inflammatory biomarkers, five of which are exclusive to Prometheus, into a proprietary pattern recognition Smart Diagnostic Algorithm to provide added diagnostic accuracy and prognostic insights. The diagnosis and differentiation of UC and CD from other GI disorders can be challenging in the clinical setting. We believe IBD sgi is the most comprehensive blood test currently available in the field of IBD diagnostic testing. Each test report provides a diagnostic prediction as well as individual marker findings which may also provide physicians with risk stratification for potential course of disease. We believe offering both diagnostic and prognostic information in a single test provides additional advantages over other existing IBD tests in the marketplace.

**Celiac Testing**

We offer three comprehensive celiac disease tests, Celiac Serology, Celiac Genetics and Celiac PLUS as well as individual biomarkers used for celiac disease assessment. Our comprehensive celiac testing panel was designed to help physicians assess the risk and make a more accurate diagnosis of the disease.

**7C4 Testing**

The PROMETHEUS 7C4 Diagnostic Test measures 7α-hydroxy-4-cholesten-3-one (7C4) levels in patients to determine if bile acid malabsorption may be the underlying cause of gastrointestinal-related symptoms in patients with IBD.

**LactoTYPE Testing**

Prometheus LactoTYPE® assists physicians with stratifying patients with suspected lactose intolerance.

**FIBROspect®**

The FIBROspect test, validated for use in patients with hepatitis C and nonalcoholic steatohepatitis, helps detect, stage and monitor liver fibrosis. The test is a non-invasive, serum diagnostic that provides a quantitative fibrosis score to help physicians risk stratify and monitor patients based on three clinically relevant biomarkers.
**Disease Prognosis Solutions**

**Crohn’s Prognostic**

The Crohn’s Prognostic test is the first test to uniquely combine proprietary serologic and genetic markers to provide an individualized CD patient’s probability for developing disease complications. This test allows physicians to stratify their CD patients according to their risks of developing complications over time and thereby personalize their disease treatment plan.

**Disease Monitoring Solutions**

**Anser**

Our leading diagnostic product, Anser, is a therapeutic drug monitoring solution which leverages our proprietary homogeneous mobility shift assay (HMSA) technology platform to accurately measure and monitor both drug and antidrug antibody levels. Our Anser tests are validated to provide objective and actionable measurements that can help a gastroenterologist optimize the use of leading biologics used to treat IBD: infliximab and infliximab biosimilars (Remicade®, Inflectra® and Renflexis®); adalimumab (Humira®); ustekinumab (Stelara®); and vedolizumab (Entyvio®). The clinical utility of therapeutic drug monitoring can help inform treatment decisions and achieve and maintain therapeutic drug levels, which are associated with improved clinical outcomes for patients with IBD. Anser provides high assay accuracy in identifying antidrug antibodies in the presence of circulating drug, a key limitation of other testing methods. This offers the additional advantage of performing the test at almost any time during treatment.

**Monitr™**

The Monitr CD test is the first-of-its-kind disease monitoring tool designed specifically to aid in the assessment of a CD patient’s endoscopic disease activity through a noninvasive blood test. Validated against endoscopy, the standard protocol for the objective assessment of disease activity, Monitr employs a proprietary algorithm analyzing the concentrations of 13 serum-proteins associated with CD pathophysiology and mucosal inflammation to produce a unique Endoscopic Healing Index (EHI) score to help distinguish patients in endoscopic remission from those with active disease. Treating patients to achieve endoscopic healing, beyond symptom improvement alone, is associated with improved treatment outcomes and reduced complications. We believe Monitr provides clinical utility as an objective and actionable tool to help gastroenterologists optimize their treatment management decisions by tracking over time, either as an adjunct to or between colonoscopies, the patient’s disease progress and response to therapy. We believe Monitr has advantages over other commonly used tests that are less sensitive or specific for assessing disease activity.

**Thiopurine Testing**

We offer three distinct thiopurine management testing solutions, TPMT Enzyme, Thiopurine Metabolites and TPMT Genetics that help physicians better manage therapeutic treatment when prescribing thiopurine drugs such as azathioprine and 6-mercaptopurine, either alone or in combination with anti-TNF therapy to mitigate the risk for immunogenicity. Because each patient metabolizes thiopurines differently, the efficacy and toxicity of thiopurines can vary widely from patient to patient. Knowledge provided by our thiopurine tests aid the physician in individualizing patient dosing for both efficacious and safe use as well as in identifying patients in whom thiopurine therapy should be avoided or modified.

**Intellectual Property**

Our commercial success depends in part on our ability to obtain, maintain and protect intellectual property and other proprietary rights for our current and future product candidates and marketed products, novel discoveries, product development technologies, patient enrichment strategies and companion diagnostics, and
know-how, to operate without infringing, misappropriating or otherwise violating the intellectual property and proprietary rights of others, and to prevent others from infringing, misappropriating or otherwise violating our intellectual property and proprietary rights. We seek to protect our proprietary position by, among other methods, filing or exclusively in-licensing U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development and implementation of our business. We also rely on trade secrets, know-how, continuing technological innovation and potential in-licensing of intellectual property to develop and maintain our proprietary position.

As for the therapeutic product candidates we are developing and seeking to commercialize, we intend to pursue composition and therapeutic method of use patents, dosage formulation patents, and therapeutic use patents on novel indications. For our therapeutic product candidates that are biologics, and more particularly monoclonal antibodies, we also intend to seek protection for epitopes, amino acid and nucleotide sequences, and other claims conventionally used to protect aspects of therapeutic biological agents. As for diagnostic and prognostic products and product candidates, we intend to pursue methods of use patents on novel patient selection methods for our therapeutic candidates and known compounds, and novel patient stratification criteria useful in the prognosis or diagnosis of disease. We may also pursue patents with respect to our proprietary screening and drug development processes and technology. We may also seek patent protection, either alone or jointly with our collaborators, as our collaboration agreements may dictate.

Our patent portfolio as of August 11, 2020 includes approximately 86 issued or allowed U.S. patents, 19 pending U.S. non-provisional patent applications and 15 pending U.S. provisional patent applications with claims relating to all of our product candidates or marketed products, all of which are exclusively owned or in-licensed by us. Our patent portfolio as of August 11, 2020 also includes approximately 14 pending Patent Cooperation Treaty (PCT) applications and certain foreign counterparts of a subset of the aforementioned U.S. patents and U.S. patent applications in foreign countries, including Argentina, Australia, Canada, China, Japan, South Korea, Taiwan and countries within the European Patent Convention, with claims relating to all of our product candidates or marketed products. With respect to our lead therapeutic product candidate, PRA023, we exclusively own or license two issued U.S. patents and four pending U.S. patent applications in three different patent families relating to the composition of PRA023 and its therapeutic use, as well as one pending U.S. non-provisional patent application related to the companion diagnostic for PRA023. In addition, our non-U.S. patent portfolio covering the composition of PRA023 and its companion diagnostic includes two pending PCT applications as well as foreign counterparts in foreign countries, including Argentina, Taiwan, Japan, Laos, Malaysia, Philippines, Singapore, Thailand, Brunei, Cambodia, Hong Kong, Korea, China, Indonesia, Venezuela, as well as countries within the European Patent Convention. As of August 11, 2020, we expect the expiry dates for the issued U.S. patents for the composition of PRA023 to be no earlier than 2037. Regarding our PR600 program, we co-own and exclusively license one pending PCT patent application related to patient selection. We do not currently own or license any issued composition of matter patents or patent applications covering PR600. Regarding our PR300 program, we exclusively own four pending U.S. patent applications, and co-own and exclusively license from Cedars-Sinai one pending PCT patent application related to patient selection for PR300.

Provisional patent applications are not eligible to become issued patents until, among other things, we file a non-provisional patent application within 12 months of filing of one or more of our related provisional patent applications. Moreover, PCT patent applications are not eligible to become an issued patent until, among other things, we file one or more national stage patent applications within, depending on the country, 30 to 32 months of the PCT application’s priority date in the countries in which we seek patent protection. If we do not timely file any non-provisional patent applications or national stage patent applications, we may lose our priority date with respect to our provisional patent applications or PCT patent applications and any patent protection on the inventions disclosed in our provisional patent applications. While we intend to timely file non-provisional patent applications relating to our provisional patent applications and national stage patent applications relating to our PCT patent applications, we cannot predict whether any such patent applications will result in the issuance of patents that provide us with any competitive advantage.
Individual issued patents extend for varying periods depending on the date of filing of the patent application or the date of patent issuance and the legal term of patents in the countries in which they are obtained. Generally, utility patents issued for applications filed in the United States are granted a term of 20 years from the earliest effective filing date of a non-provisional patent application. The term of a patent, and the protection it affords, is therefore limited and once the patent term of our issued patents have expired, we may face competition, including from other competing technologies. Because of the extensive time required for clinical development and regulatory review of a drug we may develop, it is possible that, before any of our product candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of any such patent. For example, certain patents related to certain of our LDT diagnostic products expired in 2020 and certain other patents related to such products are due to expire between 2021 and 2025.

In addition, in certain instances, a U.S. patent term can be extended to recapture a portion of the term effectively lost as a result of the Food and Drug Administration (FDA) regulatory review period or delay by the USPTO in issuing the patent. However, with respect to patent term extensions granted as a result of the FDA regulatory review period, the restoration period cannot be longer than five years, the total patent term including the restoration period must not exceed 14 years following FDA approval, only one patent applicable to each regulatory review period may be extended and only those claims covering the approved drug or a method for using it may be extended. We may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. There can be no assurance that we will benefit from any patent term extension or favorable adjustment to the term of any of our patents.

The duration of foreign patents varies in accordance with provisions of applicable local law, but typically is also 20 years from the earliest effective filing date. However, the actual protection afforded by a patent varies on a product by product basis, from country to country, and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If we do not adequately protect our intellectual property, third parties, including our competitors, may be able to use our technologies to produce and market drugs or diagnostic and/or prognostic products in direct competition with us and erode our competitive advantage. The patent positions of biotechnology and pharmaceutical products and processes like those we may develop and commercialize are generally uncertain and involve complex legal and factual questions that may diminish our ability to protect our intellectual property. For more information regarding risks related to our intellectual property, see “Risk Factors—Risks Related to Our Intellectual Property.”

Rapidly evolving patent laws in the United States and elsewhere make it difficult to predict the breadth of claims that may be allowed or enforced in our patents. Moreover, patent offices in general can require that patent applications concerning pharmaceutical and/or biotechnology-related inventions be limited or narrowed substantially to cover only the specific innovations exemplified in the patent application, thereby limiting the scope of protection against competitive challenges. Thus, even if we are able to obtain patents, the patents may be substantially narrower than anticipated.

Our ability to maintain and defend our intellectual property and proprietary position for our products, product candidates and other technologies will depend on our success in obtaining effective claims and enforcing those claims once granted. We do not know whether any of the patent applications that we may file or license from third parties will result in the issuance of any patents. The issued patents that we own, may receive in the future, or license from third parties may be challenged, invalidated, held unenforceable, narrowed or circumvented, and the rights granted under any issued patents may not provide us with proprietary protection or
competitive advantages against third parties, including our competitors, with similar technology. Furthermore, third parties, including our competitors, may be able to independently develop and commercialize similar drugs or products, or duplicate our technology, business model or strategy without infringing our patents.

**Trade Secrets**

We also rely upon unpatented trade secrets and know-how and continuing technological innovation to develop, protect and maintain our competitive position and aspects of our business that are not amenable to, or that we do not presently consider appropriate for, patent protection and prevent competitors from reverse engineering or copying our technologies. However, the foregoing rights are difficult to protect. We seek to protect our proprietary information, in part, using confidentiality agreements with our commercial partners, collaborators, employees and consultants and invention assignment agreements with our employees. We also have confidentiality agreements or invention assignment agreements with our commercial partners and selected consultants. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed through a relationship with a third party. These agreements may be breached, and we may not have adequate remedies for any breach. There can be no assurance that these agreements will be self-executing or otherwise provide meaningful protection for our trade secrets or other intellectual property or proprietary information. In addition, our trade secrets may otherwise become known or be independently discovered by third parties, including our competitors. To the extent that our commercial partners, collaborators, employees and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. For more information regarding risks related to our trade secrets, see “Risk Factors—Risks Related to Our Intellectual Property.”

**Collaboration and License Agreement Overview**

**Our Collaboration with Cedars-Sinai Medical Center**

In September 2017, we entered into an exclusive license agreement with Cedars-Sinai that grants us an exclusive, worldwide license from Cedars-Sinai with respect to certain patent rights, information and materials related to therapeutic targets and companion diagnostic products for the diagnosis and treatment of IBD, in each case to conduct research and development, as well as to commercialize diagnostic or therapeutic products (Cedars-Sinai Products) that are covered by the patents or that are developed through use of the licensed rights. The technology subject to the foregoing license includes information and materials arising out of the Cedars-Sinai database and biobank, as well as exclusive access to this database and biobank to develop diagnostic and therapeutic products for human use, which biobank is an integral part of our Prometheus 360 platform. PRA023 and our PR600 and PR300 development programs and any related companion diagnostics, as well as any diagnostic products we develop under the Takeda collaboration agreement discussed below, are all covered as Cedars-Sinai Products under the agreement, to the extent covered by the licensed patents or developed through the licensed rights. We were also granted an exclusive first right to negotiate with Cedars-Sinai to obtain exclusive licenses to future patent rights claiming inventions invented by certain Cedars-Sinai employees after the effective date of the agreement through any use of the patent rights and technology initially licensed to us by Cedars-Sinai. We have the right to sublicense our rights under the license agreement, subject to certain conditions. We are required to use commercially reasonable efforts to develop and commercialize Cedars-Sinai Products and to achieve certain development and regulatory milestones.

As upfront consideration for the license agreement, we issued to Cedars-Sinai 2,575,000 shares of fully vested common stock and 3,350,000 shares of restricted common stock, which shares will fully vest in September 2020. We are obligated to pay Cedars-Sinai low- to mid-single digit percentage royalties on net sales of therapeutic and diagnostic Cedars-Sinai Products.

The term of, and our royalty obligations under, the license agreement expires on a licensed Cedars-Sinai Product-by-Cedars-Sinai Product and country-by-country basis on the later of ten years from the date of first
commercial sale or when there is no longer a valid patent claim covering such licensed Cedars-Sinai Product in such country. We may terminate the agreement in the event that we determine that it would not be commercially reasonable to continue to develop and/or commercialize Cedars-Sinai Products. Cedars-Sinai may terminate the agreement if the performance by either party would jeopardize Cedars-Sinai’s legal status or is illegal or unethical. In addition, either party may terminate the agreement in the event of an uncured material breach by the other party. The agreement will terminate automatically in the event of our bankruptcy. Upon termination of the agreement for any reason all rights and licenses granted to us under the agreement will terminate.

In March 2019, we entered into two additional exclusive license agreements with Cedars-Sinai, pursuant to which Cedars-Sinai granted us an exclusive license in certain additional patent rights related to the treatment of UC and CD, respectively. In consideration for each such license, we paid Cedars-Sinai an upfront license fee. Each agreement will terminate automatically in the event of our bankruptcy. Cedars-Sinai may terminate either agreement if the performance by either party would jeopardize Cedars-Sinai’s legal status or is illegal or unethical. In addition, either party may terminate either agreement in the event of an uncured material breach by the other party.

Our Collaboration with Takeda

In March 2019, we entered into the Takeda Agreement with Millennium Pharmaceuticals, Inc., a wholly owned subsidiary of Takeda. Pursuant to this agreement, we established a strategic collaboration under which we will develop a companion diagnostic product (Diagnostic Product) for one selected drug target, with the option for Takeda to select an additional drug target (each, a Collaboration Target), in support of development and potential commercialization by Takeda of any therapeutic clinical candidates that it develops in connection with the agreement directed against a Collaboration Target for the treatment of IBD (Takeda Drugs). The parties are obligated to use diligent efforts (as defined in the agreement) to perform their respective obligations under the agreement. With respect to each Collaboration Target, the parties have agreed to work exclusively with each other on the development and commercialization of the Diagnostic Product(s) for use with a specific Takeda Drug during the term of the agreement. We will be responsible for development and commercialization of the Diagnostic Product(s) pursuant to the terms and conditions of the agreement, while Takeda will be responsible for all future clinical development and commercialization of the Takeda Drug(s).

We own all right, title and interest in and to intellectual property arising out of the collaboration that relates to (i) methods of selecting patients for treatment, (ii) methods of treating those patients generally, and (iii) any assays or tests, including compositions used in, and methods of manufacturing, such assays or tests. Takeda owns all right, title and interest in and to intellectual property arising out of the collaboration that relates to a compound or the chemical genus thereof owned or controlled by Takeda, as well as formulations and methods of therapeutic use of such compound. We granted Takeda a non-exclusive, worldwide license under our relevant background intellectual property and certain intellectual property arising under the agreement as necessary to exploit Takeda Drugs for use with Diagnostic Products and to perform its obligations under the agreement. In addition, we granted Takeda an exclusive, worldwide license under certain intellectual property arising from the agreement that primarily relates to the Diagnostic Products to exploit the Takeda Drugs with the Diagnostic Products. Takeda granted us a worldwide, royalty-free license under Takeda’s background intellectual property and intellectual property arising under the agreement to develop and commercialize Diagnostic Products for use with Takeda Drugs, which license is non-exclusive other than with respect to certain arising intellectual property related to the Takeda Drugs and their use for this purpose, in which case it is exclusive.

Takeda paid us an upfront technology access fee of $1.5 million under the agreement, and is obligated to pay us a pre-specified amount to cover our internal development expenses for activities undertaken pursuant to a mutually agreed upon work plan under the agreement. Takeda is obligated to make future development and regulatory milestone payments to us of up to $47.9 million for each Collaboration Target, commercial milestone payments of up to $25 million in connection with each Collaboration Target for successful commercialization of the applicable Takeda Drug and the associated Diagnostic Product, and sales milestone payments of up to
$75 million in connection with each Collaboration Target, provided that regulatory approval for the applicable Takeda Drug includes use of the associated Diagnostic Product. In addition, Takeda is obligated to pay us a low-single digit percentage royalty on net sales of all Takeda Drugs, which are subject to certain reductions, including in the case that the regulatory approval for the applicable Takeda Drug does not require use of the associated Diagnostic Product.

The term of, and royalty obligations under, the Takeda Agreement expires on a Takeda Drug-by-Takeda Drug and country-by-country basis on the later of (i) ten years from the date of first commercial sale, (ii) when there is no longer a valid patent claim covering a Takeda Drug in such country, and (iii) expiration of any applicable regulatory exclusivity for such Takeda Drug. Takeda may terminate the agreement, in whole or with respect to a given Collaboration Target, at any time with or without cause. We may terminate the agreement on a diagnostic product-by-diagnostic product or Target-by-Target basis in the case of lack of scientific merits or insurmountable technical challenges in developing such diagnostic products, or diagnostic products specific for such Collaboration Target generally, despite using diligent efforts (as defined in the agreement). In addition, either party may terminate the agreement in the event of an uncured material breach by, or bankruptcy of, the other party. Upon termination of the agreement, the licenses granted to each party by the other party under the agreement will terminate; except that if we terminate the agreement due to scientific or technical challenges, or Takeda terminates the agreement due to an uncured material breach by us, or bankruptcy of ours and Takeda opts to continue the development and commercialization of any Takeda Drug for use with the associated Diagnostic Product then if Takeda proceeds to commercialize any Takeda Drug for use with the associated Diagnostic Product after the termination of the agreement, any remaining Takeda payment obligations in connection with the associated Collaboration Target will be reduced by a specified percent.

If Takeda opts to commercialize a Takeda Drug independent of the associated Diagnostic Product(s), Takeda may request a target license that survives termination of this agreement. Under such target license, we will grant Takeda an exclusive, worldwide license to use the information with respect to the applicable target to develop, manufacture and commercialize such Takeda Drugs. Takeda is obligated to pay a low single-digit percentage royalty on sales of such Takeda Drug pursuant to such target license.

Our Collaboration with Falk

In July 2020, we entered into a co-development and manufacturing agreement (the Falk Agreement) with Dr. Falk Pharma GmbH (Falk), pursuant to which we will co-develop and commercialize, exclusively in our respective territories, therapeutic product candidates targeting members of the TNF super family for the treatment of UC and CD under our PR600 program. We will mutually agree with Falk on a development plan with respect to such products, and each party agreed to use commercially reasonable efforts to conduct such development activities. We will be responsible for regulatory approvals and commercialization of any products in the United States and the rest of the world, other than the Falk territory. Falk is responsible for regulatory approvals and commercialization of any products in the European Union, United Kingdom, Switzerland, the countries of the European Economic Area (excluding Malta and the Republic of Cyprus), Australia and New Zealand (Falk territory). Under the agreement, Falk agreed to fund 25% of our third party development costs set forth in the mutually agreed upon development plan.

Falk paid us an upfront payment in the low seven figures under the Falk Agreement, and is required to make a second cash payment in a similar amount to us following our mutual agreement on the development plan. In addition, Falk is obligated to make future development milestone payments to us of up to $15 million, and to pay us a mid-single to low-double digit royalty on net sales of all products incorporating antibodies covered by the agreement in the Falk territory. We agreed to pay Falk a low single digit royalty on net sales for such products in our territory. Any intellectual property, including know-how, owned by us, Falk, or our respective affiliates that existed prior to the effective date of the agreement or is generated during the term of the agreement, that is also necessary or useful to develop, manufacture, or commercialize the compounds and/or products that result from the collaboration, are jointly owned by us and Falk at a share of 75% for us and a 25% for Falk.
The term of, and our respective royalty obligations under, the agreement expires on a product-by-product and country-by-country basis on the later of (i) ten years from the date of first commercial sale, (ii) when there is no longer a valid patent claim covering a product in such country, or (iii) expiration of any applicable regulatory exclusivity for such product. Falk may terminate the agreement without cause, and either party may terminate the agreement for regulatory or scientific reasons. In the event of such termination, all licenses granted to the terminating party will cease and be transferred to the non-terminating party, and such non-terminating party will have access to the terminating party’s technology, subject to the obligation to pay the applicable royalties to the terminating party. In addition, either party may terminate the agreement in the event of an uncured material breach by, or bankruptcy of, the other party. In the event of such termination, the terminating party has the option to purchase the non-terminating party’s ownership share of any jointly-owned intellectual property at a fair market price. Additionally, in the event of such termination for uncured material breach or bankruptcy: all rights of the terminating party granted under the agreement will be maintained and extended as required to develop, manufacture and commercialize the compounds and/or products that result from the collaboration for the remainder of the term, while any licenses granted to the non-terminating party shall terminate upon the effective date of termination and the obligation of each party to co-fund development will remain unaffected.

Our License Agreement with Alloy Therapeutics, LLC

In March 2020, we entered into a license agreement with Alloy Therapeutics, LLC (Alloy), pursuant to which Alloy granted us a non-exclusive license under Alloy’s patent and other intellectual property rights to use Alloy’s platform technology solely for antibody discovery, and to exploit products incorporating such antibodies discovered using Alloy’s platform technology (Alloy Products). In return, we granted to Alloy a non-exclusive license to certain data we generate under this agreement, solely for marketing Alloy’s platform technology and developing improvements to the same. We are using Alloy’s technology in connection with our PR600 development program. We paid Alloy a five-digit upfront fee, and the license is subject to an annual maintenance fee. In addition, we are obligated to make future milestone payments of up to $15.6 million per product. We have the right to sublicense our rights under the license agreement, subject to a one-time fee. The term of our access to the Alloy technology for new antibody discovery purposes expires two years from the effective date of the agreement. We may terminate the agreement for any or no reason. In addition, either party may terminate the agreement in the event of an uncured material breach by or bankruptcy of the other party. Our right to use and license to antibodies selected by us under the agreement survive any termination of the agreement, subject to the foregoing payment obligations.

Manufacturing

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We rely, and expect to continue to rely on third parties for the manufacture of our product candidates and related raw materials for preclinical and clinical development, as well as for commercial manufacture of any of our product candidates that receive marketing approval. We believe there are multiple sources for all of the materials required for the manufacture of our product candidates and development programs. As our product candidates advance through development, we expect to enter into longer-term commercial supply agreements with key suppliers and manufacturers to fulfill and secure our production needs.

Laboratory Operations

We are a College of American Pathologists (CAP) accredited (6805501), CLIA-certified (05D0917432) clinical laboratory. All of our high complexity LDTs are performed in our 36,000 square foot facility, located in San Diego, California. Our laboratory is regulated by the Centers for Medicare and Medicaid Services (CMS) through CLIA. The laboratory is approved for clinical testing in all 50 states. We believe that our existing laboratory facilities are adequate to meet our business needs for at least the next 12 months and that additional laboratory space will be available on commercially reasonable terms, if required.
Sales and Marketing

We believe that we can maximize the value of our products by retaining substantial commercialization rights to our product candidates and companion diagnostics, and, where appropriate, entering into collaborations for specific therapeutic indications or geographic territories.

We sell our LDTs, including Anser and Monitr, through our dedicated team of field sales representatives and account managers, targeting gastroenterologists in the United States. As we progress PRA023 and other development programs through clinical development, we will leverage the knowledge and experience of our sales team and company brand awareness to prepare for and implement a potential product launch. Furthermore, we plan to leverage our commercial diagnostic franchise, which shares a common gastroenterologist prescriber base with our precision medicine therapeutic product candidates to prepare the GI marketplace for a precision medicine treatment approach.

We have global commercial rights to PRA023 and its companion diagnostic. Our current commercial strategy is to market PRA023 and its companion diagnostics using a dedicated sales force focused on selected gastroenterologists in the United States. These target prescribers are typically affiliated with leading hospitals and medical centers and tend to have well-established referral networks. We expect to benefit from preexisting relationships with many of these gastroenterologist prescribers and believe that we can appropriately manage outreach and effectively commercialize PRA023 through a specialty care sales model.

We retain rights similar to those for PRA023 for each of our unpartnered programs. For PR600, which is subject to the Falk collaboration, we have exclusively outlicensed commercialization rights to Falk in Europe, Australia and New Zealand. However, we retain commercial rights to our PR600 program in the United States and the rest of the world and plan to take a similar commercialization approach as with PRA023, if approved.

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our scientific knowledge, technology and development experience, our Prometheus 360 platform and our pioneering culture provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions. Any therapeutic candidates and companion diagnostics that we successfully develop and commercialize will compete with existing products and new products that may become available in the future.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industry may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize therapeutic products that are safer, more effective, have fewer or less severe side effects, or companion diagnostics that are more effective, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than
we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products. If our product candidates achieve marketing approval, we expect that they will be priced at a significant premium over competitive products.

The key competitive factors affecting the success of all of our therapeutic product candidates if approved, are likely to be efficacy, safety, convenience, price, the level competition, intellectual property protection and the availability of reimbursement from government and other third-party payors. The key competitive factors affecting the success of our LDTs include quality and strength of clinical and analytical validation data, confidence in diagnostic results, sales and marketing capabilities, the extent of reimbursement, inclusion in clinical guidelines, cost-effectiveness, and ease of use.

If approved for the treatment of patients with moderate-to-severe IBD, PRA023 and our other development programs would compete with Entyvio, which is an a4b7 integrin antibody marketed by Takeda, Humira, which is a TNF antibody marketed by AbbVie Inc., Stelara, which is an IL-12/IL-23 antibody marketed by Johnson & Johnson, Xeljanz, which is a JAK1 inhibitor marketed by Pfizer Inc., and Simponi, which is a TNF antibody marketed by Johnson & Johnson.

We are aware of several companies with product candidates in development for the treatment of patients with UC and/or CD, including Pfizer Inc.’s PF-06480605, Rinvoq, which is a JAK1 inhibitor being developed in Phase 3 clinical trials by AbbVie Inc., ozanimod, which is a S1P inhibitor being developed in Phase 3 clinical trials by Bristol-Myers Squibb Company, etrolizumab, which is a b7 integrin being developed in Phase 3 clinical trials by F. Hoffman-La Roche AG, mirikizumab, which is an anti-IL-23 antibody being developed in Phase 3 clinical trials by Eli Lilly and Company, and filgotinib, a JAK1 inhibitor being developed in Phase 3 clinical trials by Gilead Sciences, Inc. We are also aware of additional product candidates in clinical trials by AbbVie Inc., Abivax SA, Amgen Inc., Arena Pharmaceuticals, Inc., C.H. Boehringer Sohn AG & Ko. KG, Bristol-Myers Squibb Company, Celgene Corporation, Gilead Sciences, Inc., GlaxoSmithKline plc, Gossamer Bio, Inc., Incyte Corp., Janssen Pharmaceutica N.V., Landos Biopharma, Inc., Protagonist Therapeutics, Inc., Theravance Biopharma, Inc., Applied Molecular Transport Inc., Pandion Therapeutics, Inc., RedHill Biopharma Ltd. and Seres Therapeutics, Inc.

Our principal competition for our LDTs is traditional methods used by gastroenterologists to assess and diagnose patients with IBD symptoms. Such traditional methods include endoscopy and testing of blood, serum and fecal samples. We face competition from commercial laboratories, such as Laboratory Corporation of America Holdings, Quest Diagnostics Incorporated, ARUP Laboratories, Inc. and Mayo Clinic, all of which have existing infrastructures to support the commercialization of diagnostic services. Large, multispecialty group medical clinics, health systems and academic medical university-based clinics may provide in-house clinical laboratories offering IBD-related disease testing.

**U.S. Regulation of Diagnostic Tests and other Medical Devices**

In the United States, the laws and regulations governing the marketing of diagnostic products are evolving, extremely complex, and in many instances, there are no significant regulatory or judicial interpretations of these
laws and regulations. Clinical laboratory tests are regulated under CLIA, as well as by applicable state laws. In addition, the Federal Food, Drug and Cosmetic Act (FDCA) defines a medical device to include any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory, intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals. The tests we currently market and are developing are considered by the FDA to be subject to regulation as medical devices. Among other things, pursuant to the FDCA and its implementing regulations, the FDA regulates the research, testing, manufacturing, safety, labeling, storage, recordkeeping, premarket clearance or approval, marketing and promotion and sales and distribution of medical devices in the United States to ensure that medical products distributed domestically are safe and effective for their intended uses. Although the FDA has statutory authority to assure that medical devices are safe and effective for their intended uses, the FDA has historically exercised its enforcement discretion and not enforced certain applicable provisions of the FDCA and regulations with respect to LDTs.

**Clinical Laboratory Improvement Amendments of 1988**

As a clinical reference laboratory, we are required to hold certain federal, state and local licenses, certifications and permits to conduct our business. Under CLIA, we are required to hold a certificate applicable to the type of laboratory tests we perform and to comply with standards applicable to our operations, including test processes, personnel, facilities administration, equipment maintenance, recordkeeping, quality systems and proficiency testing. We must maintain CLIA compliance and certification to be eligible to bill for diagnostic services provided to federal health care program beneficiaries.

We have current certification under CLIA to perform testing at our San Diego facility. To renew our CLIA certificate, we are subject to survey and inspection every two years to assess compliance with program standards. The regulatory and compliance standards applicable to the testing we perform may change over time, and any such changes could have a material effect on our business.

Penalties for non-compliance with CLIA requirements include suspension, limitation or revocation of the laboratory’s CLIA certificate, as well as a directed plan of correction, state on-site monitoring, civil money penalties, civil injunctive suit or criminal penalties.

**State Laboratory Licensing**

In addition to federal certification requirements of laboratories under CLIA, licensure is required and maintained for our clinical reference laboratory under California law. Such laws establish standards for the day-to-day operation of a clinical reference laboratory, including the training and skills required of personnel and quality control. In addition, California laws mandate proficiency testing, which involves testing of specimens that have been specifically prepared for the laboratory.

Because we receive specimens from New York, our clinical reference laboratory is required to be licensed by New York, under New York laws and regulations, which establish standards for day-to-day operation of a clinical laboratory, including training and skill levels required of laboratory personnel, physical requirements of a facility, equipment and validation and quality control.

New York law also mandates proficiency testing for laboratories licensed under New York state law, regardless of whether such laboratories are located in New York. If a laboratory is out of compliance with New York statutory or regulatory standards, the New York Department of Health (NYDOH) may suspend, limit, revoke or annul the laboratory’s New York license, censure the holder of the license or assess civil money penalties. Statutory or regulatory noncompliance may result in a laboratory’s operator being found guilty of a misdemeanor under New York law. NYDOH also must approve an LDT before the test is offered in New York. We have received written approval from NYDOH to offer our products in New York.
In addition to New York and California, other states, including Maryland, Pennsylvania and Rhode Island, require licensing of out-of-state laboratories under certain circumstances.

**Billing, Coverage and Reimbursement for Clinical Laboratory Services**

Medicare coverage is limited to items and services that are within the scope of a Medicare benefit category that are reasonable and necessary for the diagnosis or treatment of an illness or injury. With respect to Medicare coverage for clinical laboratory services Medicare Administrative Contractors (MACs) may develop and implement policies that stipulate the conditions under which items and services may be covered by the Medicare program. Additionally, Palmetto GBA, the MAC responsible for administering Medicare’s molecular diagnostic services (MolDX Program) has the purview to develop coverage policies specific to laboratory services that, in some instance, are adopted by MACs in other jurisdictions.

Under Medicare, payment for our laboratory tests are generally made under the Clinical Laboratory Fee Schedule (CLFS) with payment amounts assigned to specific procedure billing codes. In April 2014, Congress passed the Protecting Access to Medicare Act (PAMA) which included substantial changes to the way in which clinical laboratory services will be paid under Medicare. Under PAMA, laboratories that receive the majority of their Medicare revenue from payments made under the CLFS or the Physician Fee Schedule are required to report to CMS, beginning in 2017 and every three years thereafter (or annually for “advanced diagnostic laboratory tests”), private payor payment rates and volumes for their tests. Laboratories that fail to report the required payment information may be subject to substantial civil monetary penalties. As required under PAMA, CMS uses the rates and volumes reported by laboratories to develop Medicare payment rates for laboratory tests equal to the volume-weighted median of the private payor payment rates for the tests.

On June 23, 2016, CMS published the final rule implementing the reporting and rate-setting requirements under PAMA. For tests furnished on or after January 1, 2018, Medicare payments for clinical diagnostic laboratory tests are based upon these reported private payor rates. For clinical diagnostic laboratory tests that are assigned a new or substantially revised CPT code, initial payment rates will be assigned by the gap-fill methodology, as under prior law. Initial payment rates for new advanced diagnostic laboratory tests will be based on the actual list charge for the laboratory test. Any reductions to payment rates resulting from the new methodology are limited to 10% per test per year in each of the years 2018 through 2020 and to 15% per test per year in each of the years 2021 through 2023.

PAMA also authorizes the adoption of new, temporary billing codes and unique test identifiers for FDA-cleared or approved tests, as well as advanced diagnostic laboratory tests. The AMA's CPT Editorial Panel has approved a proposal to create a new section of billing codes to facilitate implementation of this section of PAMA. These proprietary laboratory analyses (PLA) codes may be requested by a clinical laboratory or manufacturer to specifically identify their test. If approved, the codes are issued by the AMA on a quarterly basis. While our testing products are not presently identified by any PLA codes, we may seek a specific PLA code or codes to describe some of our testing products in the future.

Billing for diagnostic testing can be complicated. Depending on the billing arrangement and applicable law, we must bill various payors, such as insurance companies, Medicare, Medicaid, physicians, hospitals, employer groups and patients, all of which have different billing requirements. Additionally, compliance with applicable laws and regulations as well as internal compliance policies and procedures adds further complexity to the billing process. Changes in laws and regulations could negatively impact our ability to bill our clients or increase our costs. CMS also establishes new procedures and continuously evaluates and implements changes to the reimbursement process for billing government programs. Missing or incorrect information on test requisitions adds complexity to and slows the billing process, creates backlogs of unbilled tests, and generally increases the aging of accounts receivable and bad debt expense. Failure to timely or correctly bill may lead to our not being reimbursed for our services or an increase in the aging of our accounts receivable, which could adversely affect...
our results of operations and cash flows. Failure to comply with applicable laws relating to billing federal healthcare programs could also lead to various penalties, including:

- overpayments and recoupments of reimbursement received;
- exclusion from participation in Medicare/Medicaid programs;
- asset forfeitures;
- civil and criminal fines and penalties; and
- the loss of various licenses, certificates and authorizations necessary to operate our business.

Any of these penalties or sanctions could have a material adverse effect on our results of operations or cash flows.

Federal Oversight of Laboratory Developed Tests

In the United States, the diagnostic products we currently market are subject to regulation by the FDA under the FDCA and its implementing regulations, and other federal and state statutes and regulations. Under FDA’s regulatory framework, in vitro diagnostic devices (IVDs) such as our currently marketed diagnostic products, are a type of medical device that can be used in the diagnosis or detection of diseases, such as cancer, or other conditions. The FDA considers LDTs to be a subset of IVDs that are intended for clinical use and are designed, manufactured, and used within a single laboratory. Although the FDA has statutory authority to assure that medical devices, including IVDs, are safe and effective for their intended uses, the FDA has historically exercised its enforcement discretion and not enforced certain applicable provisions of the FDCA and regulations with respect to LDTs.

Even under its current enforcement discretion policy, the FDA has issued warning letters to IVD manufacturers for commercializing laboratory tests that were purported to be LDTs but that the FDA alleged failed to meet the definition of an LDT or otherwise were not subject to the FDA’s policy on enforcement discretion because they presented a potential safety risk. Additionally, the FDA could change its policy of enforcement discretion for LDTs, even without legislation. For example, in recent years, the FDA has stated its intention to modify its enforcement discretion policy with respect to LDTs. Specifically, on July 31, 2014, the FDA notified Congress of its intent to modify, in a risk-based manner, its policy of enforcement discretion with respect to LDTs. On October 3, 2014, the FDA issued two draft guidance documents entitled “Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs),” or the Framework Guidance, and “FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs),” or the Reporting Guidance. The Framework Guidance stated that FDA intended to modify its policy of enforcement discretion with respect to LDTs in a risk-based manner consistent with the classification of medical devices generally in Classes I through III. The Reporting Guidance would have further enabled the FDA to collect information regarding the LDTs currently being offered for clinical use through a notification process, as well as to enforce its regulations for reporting safety issues and collecting information on any known or suspected adverse events related to the use of an LDT.

The FDA halted finalization of this guidance in November 2016 to allow for further public discussion on an appropriate oversight approach for LDTs and to give congressional authorizing committees the opportunity to develop a legislative solution. In January 2017, the FDA issued a discussion paper on possible approaches to LDT regulation.

Legislative and administrative proposals proposing to amend the FDA’s oversight of LDTs have been introduced in recent years and we expect that new legislative and administrative proposals will continue to be introduced from time to time. It is possible that legislation could be enacted into law or regulations or guidance could be issued by the FDA that may result in new or increased regulatory requirements for us to continue to
offer our LDTs or to develop and introduce new tests as LDTs. For example, key congressional committees with jurisdiction over FDA matters have indicated an interest in continuing negotiations on potential legislation regarding LDTs. In March 2020, the VALID Act was introduced in the U.S. Senate. If passed in its current form, the VALID Act would create a new category of medical products separate from medical devices called “in vitro clinical tests,” (IVCTs). As proposed, the bill would establish a risk-based approach to imposing requirements related to premarket review, quality systems, and labeling requirements on all IVCTs, including LDTs, but would create exemptions for certain LDTs marketed before the effective date of the bill (though other regulatory requirements may apply, such as registration and adverse event reporting). It is unclear whether the VALID Act or any other legislative proposals (including any proposals to reduce FDA oversight of LDTs) would be passed by Congress or signed into law by the President. Depending on the approach adopted under any potential legislation, certain LDTs (likely those of higher risk) could become subject to some form of premarket review, potentially with a transition period for compliance and a grandfathering provision.

If Congress does not take action in connection with the VALID Act or other LDT legislation, it is possible that the FDA could change its regulatory policy governing LDTs in a way that could require that our currently marketed diagnostic tests, and any future products that we anticipate marketing as LDTs, comply with certain additional FDA requirements.

PMA Pathway

In addition to the diagnostics that we currently market as LDTs, we are developing companion diagnostics to be used in connection with our therapeutic product candidates, if approved. These companion diagnostics are also regulated as medical devices, and unlike our LDTs, they are not subject to FDA’s enforcement discretion policy. Rather, they will be subject to the direct oversight of the FDA as regulated medical devices. The FDA categorizes medical devices into one of three classes—Class I, II, or III—based on the risks presented by the device and the regulatory controls necessary to provide a reasonable assurance of the device’s safety and effectiveness. Class I includes devices with the lowest risk to the patient and are those for which safety and effectiveness can be assured by adherence to the FDA’s General Controls for medical devices, which include compliance with the applicable portions of the Quality System Regulation (QSR) facility registration and product listing, reporting of adverse medical events, and truthful and non-misleading labeling, advertising, and promotional materials. Class II devices are subject to the FDA’s General Controls, and special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. Special controls are established by the FDA for a specific device type and often include specific labeling provisions, performance metrics, and other types of controls that mitigate risks of the device (usually incorrect results for an IVD). Devices deemed by the FDA to pose the greatest risks, such as life sustaining, life supporting or some implantable devices, or devices that have a new intended use, or use advanced technology that is not substantially equivalent to that of a legally marketed device, are placed in Class III, requiring approval of an application for premarket approval (PMA). Some pre-amendment devices are unclassified, but are subject to the FDA’s premarket notification and clearance process in order to be commercially distributed.

Class III devices, including most companion diagnostics, generally require PMA approval before they can be marketed. Obtaining PMA approval requires the submission of “valid scientific evidence” to the FDA to support a finding of a reasonable assurance of the safety and effectiveness of the device. A PMA must provide complete analytical and clinical performance data and also information about the device and its components regarding, among other things, device design, manufacturing and labeling. Following receipt of a PMA, the FDA determines whether the application is sufficiently complete to permit a substantive review. If the FDA accepts the application for review, it has 180 days under the FDCA to complete its review of a PMA, although in practice, FDA’s review often takes significantly longer, and can take up to several years. An advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. The FDA may or may not accept the panel’s recommendation. As part of the FDA’s review of a PMA, the FDA will typically inspect the manufacturer’s
facilities for compliance with QSR requirements, which impose requirements related to design controls, manufacturing controls, documentation and other quality assurance procedures. The user fee costs and the length of FDA review time for obtaining PMA approval are significantly higher than for a 510(k) notification or a de novo classification.

The FDA will approve the new device for commercial distribution if it determines that the data and information in the PMA constitute valid scientific evidence and that there is reasonable assurance that the device is safe and effective for its intended use(s). The FDA may approve a PMA with post-approval conditions intended to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution, and collection of long-term follow-up data from patients in the clinical study that supported PMA approval or requirements to conduct additional clinical studies post-approval. The FDA may condition PMA approval on some form of post-market surveillance when deemed necessary to provide additional safety and efficacy data for the device in a larger population or for a longer period of use. In such cases, the manufacturer might be required to follow certain patient groups for a number of years and to make periodic reports to the FDA on the clinical status of those patients. Failure to comply with the conditions of approval can result in material adverse enforcement action, including withdrawal of the approval.

Certain changes to an approved device, such as changes in manufacturing facilities, methods, or quality control procedures, or changes in the design performance specifications, which affect the safety or effectiveness of the device, require submission of a PMA supplement. PMA supplements often require submission of the same type of information as a PMA, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA and may not require as extensive clinical data or the convening of an advisory panel. Certain other changes to an approved device require the submission of a new PMA, such as when the design change causes a different intended use, mode of operation, and technical basis of operation, or when the design change is so significant that a new generation of the device will be developed, and the data that were submitted with the original PMA are not applicable for the change in demonstrating a reasonable assurance of safety and effectiveness.

We expect that any companion diagnostics we develop will require approval of a PMA before they can be marketed for use with a therapeutic product.

510(k) Notification Pathway.

To obtain 510(k) clearance, a manufacturer must submit a premarket notification demonstrating to the FDA's satisfaction that the proposed device is “substantially equivalent” to another legally marketed device that itself does not require PMA approval (a predicate device). A predicate device is a legally marketed device that is not subject to premarket approval, i.e., a device that was legally marketed prior to May 28, 1976 (pre-amendments device) and for which a PMA is not required, a device that has been reclassified from Class III to Class II or I, or a device that was found substantially equivalent through the 510(k) process. The FDA's 510(k) clearance process usually takes from three to twelve months, but often takes longer. FDA may require additional information, including clinical data, to make a determination regarding substantial equivalence. In addition, the FDA collects user fees for certain medical device submissions and annual fees and for medical device establishments.

If the FDA agrees that the device is substantially equivalent to a lawfully marketed predicate device, it will grant 510(k) clearance to authorize the device for commercialization. If the FDA determines that the device is “not substantially equivalent” to a previously cleared device, the device is automatically designated as a Class III device. The device sponsor must then fulfill more rigorous PMA requirements, or can request a risk-based classification determination for the device in accordance with the de novo process, which is a route to market for novel medical devices that are low to moderate risk and are not substantially equivalent to a predicate device, discussed below.
After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change or modification in its intended use, will require a new 510(k) clearance or, depending on the modification, PMA approval. The FDA requires each manufacturer to determine whether the proposed change requires submission of a 510(k) or a PMA in the first instance, but the FDA can review any such decision and disagree with a manufacturer’s determination. Many minor modifications are accomplished by a “letter to file” in which the manufacturer documents the rationale for the change and why a new 510(k) is not required. However, if the FDA disagrees with a manufacturer’s determination, the FDA can require the manufacturer to cease marketing and/or request the recall of the modified device until 510(k) marketing clearance or PMA approval is obtained. Also, in these circumstances, the manufacturer may be subject to significant regulatory fines or penalties.

Over the last several years, the FDA has proposed reforms to its 510(k) clearance process, and such proposals could include increased requirements for clinical data and a longer review period, or could make it more difficult for manufacturers to utilize the 510(k) clearance process for their products. For example, in November 2018, FDA officials announced forthcoming steps that the FDA intends to take to modernize the premarket notification pathway under Section 510(k) of the FDCA. Among other things, the FDA announced that it planned to develop proposals to drive manufacturers utilizing the 510(k) pathway toward the use of newer predicates. These proposals included plans to potentially sunset certain older devices that were used as predicates under the 510(k) clearance pathway, and to potentially publish a list of devices that have been cleared on the basis of demonstrated substantial equivalence to predicate devices that are more than 10 years old.

In May 2019, the FDA solicited public feedback on its plans to develop proposals to drive manufacturers utilizing the 510(k) pathway toward the use of newer predicates, including whether the FDA should publish a list of devices that have been cleared on the basis of demonstrated substantial equivalence to predicate devices that are more than 10 years old. The FDA requested public feedback on whether it should consider certain actions that might require new authority, such as whether to sunset certain older devices that were used as predicates under the 510(k) clearance pathway. These proposals have not yet been finalized or adopted, and the FDA may work with Congress to implement such proposals through legislation. More recently, in September 2019, the FDA published revised final guidance outlining an optional “safety and performance based” premarket review pathway for manufacturers of “well-understood device types” to demonstrate substantial equivalence under the 510(k) clearance pathway, by demonstrating that such device meets objective safety and performance criteria established by the FDA, obviating the need for manufacturers to compare the safety and performance of their medical devices to specific predicate devices in the clearance process. The FDA intends to maintain a list of device types appropriate for the “safety and performance based pathway” and to continue developing product-specific guidance documents that identify the performance criteria for each such device type, as well as the testing methods recommended in the guidance documents, where feasible.

If no legally marketed predicate can be identified for a new device to enable use of the 510(k) pathway, the device is automatically classified under the FDCA into Class III, which generally requires PMA approval. However, the FDA can reclassify or seek de novo classification for a device that meets the FDCA standards for a Class I or Class II device, permitting the device to be marketed without PMA approval. To grant such a reclassification, the FDA must determine that the FDCA’s general controls alone, or general controls and special controls together, are sufficient to provide a reasonable assurance of the device’s safety and effectiveness. The de novo classification route is generally less burdensome than the PMA approval process.

De Novo Classification

Medical device types that the FDA has not previously classified as Class I, II or III are automatically classified under the FDCA into Class III regardless of the level of risk they pose. The Food and Drug Administration Modernization Act of 1997 established a route to market for low to moderate risk medical devices that are automatically placed into Class III due to the absence of a predicate device, called the “Request for Evaluation of Automatic Class III Designation,” or the de novo classification procedure. This procedure
allows a manufacturer whose novel device is automatically classified into Class III to request down-classification of its medical device into Class I or Class II on the basis that the device presents low or moderate risk, rather than requiring the submission and approval of a PMA application. Prior to the enactment of the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA) a medical device could be eligible for de novo classification only if the manufacturer first submitted a 510(k) premarket notification and received a determination from the FDA that the device was not substantially equivalent to a legally marketed predicate device. FDASIA streamlined the de novo classification pathway by permitting manufacturers to request de novo classification directly without first submitting a 510(k) premarket notification to the FDA and receiving a not substantially equivalent determination. If the manufacturer seeks reclassification into Class II, the manufacturer must include a draft proposal for special controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the medical device. In addition, the FDA may reject the request if it identifies a legally marketed predicate device that would be appropriate for a 510(k) notification, determines that the device is not low to moderate risk, or that general controls would be inadequate to control the risks and special controls cannot be developed. After a device receives de novo classification, any modification that could significantly affect its safety or efficacy, or that would constitute a major change or modification in its intended use, will require a new 510(k) clearance or, depending on the modification, another de novo request or even PMA approval.

Investigational Device Exemption Process.

Clinical trials are almost always required to support a PMA and are sometimes required to support a 510(k) submission. All clinical investigations of investigational devices to determine safety and effectiveness must be conducted in accordance with the FDA's investigational device exemption (IDE) regulations which govern investigational device labeling, prohibit promotion of the investigational device, and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. If the device presents a “significant risk” to human health, the FDA requires the device sponsor to submit an IDE application to the FDA, which must become effective prior to commencing human clinical trials. A significant risk device is one that presents a potential for serious risk to the health, safety or welfare of a patient and either is implanted, used in supporting or sustaining human life, substantially important in diagnosing, curing, mitigating or treating disease or otherwise preventing impairment of human health, or otherwise presents a potential for serious risk to a subject. An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE will automatically become effective 30 days after receipt by the FDA, unless the FDA notifies the company that the investigation may not begin. If the FDA determines that there are deficiencies or other concerns with an IDE for which it requires modification, the FDA may permit a clinical trial to proceed under a conditional approval.

In addition, the study must be approved by, and conducted under the oversight of, an Institutional Review Board (IRB) for each clinical site. The IRB is responsible for the initial and continuing review of the IDE, and may pose additional requirements for the conduct of the study. If an IDE application is approved by the FDA and one or more IRBs, human clinical trials may begin at a specific number of investigational sites with a specific number of patients, as approved by the FDA. If the device presents a non-significant risk to the patient, a sponsor may begin the clinical trial after obtaining approval for the trial by one or more IRBs without separate approval from the FDA, but must still follow abbreviated IDE requirements, such as monitoring the investigation, ensuring that the investigators obtain informed consent, and labeling and record-keeping requirements. Acceptance of an IDE application for review does not guarantee that the FDA will allow the IDE to become effective and, if it does become effective, the FDA may or may not determine that the data derived from the trials support the safety and effectiveness of the device or warrant the continuation of clinical trials. An IDE supplement must be submitted to, and approved by, the FDA before a sponsor or investigator may make a change to the investigational plan that may affect its scientific soundness, study plan or the rights, safety or welfare of human subjects.

During a study, the sponsor is required to comply with the applicable FDA requirements, including, for example, trial monitoring, selecting clinical investigators and providing them with the investigational plan,
ensuring IRB review, adverse event reporting, record keeping, and prohibitions on the promotion of investigational devices or on making safety or effectiveness claims for them. The clinical investigators in the clinical study are also subject to FDA regulations and must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of the investigational device, and comply with all reporting and recordkeeping requirements. Additionally, after a trial begins, we, the FDA or the IRB could suspend or terminate a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits.

**Expeditied Development and Review Programs for Medical Devices**

Through recent federal legislation, the FDA has implemented a Breakthrough Devices Program, which is a voluntary program offering manufacturers of certain devices an opportunity to interact with the FDA more frequently and efficiently as they develop their products with the goal of expediting commercialization of such products to help patients have more timely access. The program is available to medical devices that meet certain eligibility criteria, including that the device provides more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions, and constitutes a device (i) that represents a breakthrough technology, (ii) for which no approved or cleared alternatives exist, (iii) that offer significant advantages over existing approved or cleared alternatives, or (iv) the availability of which is in the best interest of patients. Devices granted Breakthrough Device designation are eligible to rely on certain features of the Breakthrough Device Program, including interactive and timely communications with FDA staff, use of post-market data collection, when scientifically appropriate, to facilitate expedited and efficient development and review of the device, opportunities for efficient and flexible clinical study design and priority review of premarket submissions.

**Postmarket Regulation of Medical Devices**

After a device is cleared or approved by the FDA for marketing, numerous and pervasive regulatory requirements continue to apply. These include:

- establishment registration and device listing with the FDA;
- QSR requirements, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of “off-label” uses of cleared or approved products;
- requirements related to promotional activities;
- clearance or approval of product modifications to 510(k)-cleared devices that could significantly affect safety or effectiveness or that would constitute a major change in intended use of cleared devices, or approval of certain modifications to PMA-approved devices;
- medical device reporting regulations, which require that a manufacturer report to the FDA if a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur;
- correction, removal and recall reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health;
- The FDA's recall authority, whereby the agency can order device manufacturers to recall from the market a product that is in violation of governing laws and regulations; and
post-market surveillance activities and regulations, which apply when deemed by the FDA to be necessary to protect the public health or to provide additional safety and effectiveness data for the device.

Device manufacturing processes subject to FDA oversight are required to comply with the applicable portions of the QSR, which cover the methods and the facilities and controls for the design, manufacture, testing, production, processes, controls, quality assurance, labeling, packaging, distribution, installation and servicing of finished devices intended for human use. The QSR also requires, among other things, maintenance of a device master file, device history file, and complaint files. Manufacturers are subject to periodic scheduled or unscheduled inspections by the FDA. A failure to maintain compliance with the QSR requirements could result in the shut-down of, or restrictions on, manufacturing operations and the recall or seizure of products. The discovery of previously unknown problems with products, including unanticipated adverse events or adverse events of increasing severity or frequency, whether resulting from the use of the device within the scope of its clearance or off-label by a physician in the practice of medicine, could result in restrictions on the device, including the removal of the product from the market or voluntary or mandatory device recalls.

The FDA has broad regulatory compliance and enforcement powers. If the FDA determines that a manufacturer has failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, including the following:

- issuance of warning letters, untitled letters, fines, injunctions, consent decrees and civil penalties;
- requesting or requiring recalls, withdrawals, or administrative detention or seizure of our products;
- imposing operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying requests for 510(k) marketing clearance or PMA approvals of new products or modified products;
- withdrawing 510(k) clearances or PMA approvals that have already been granted;
- refusal to grant export approvals for our products; or
- criminal prosecution.

FDA Approval and Regulation of Companion Diagnostics

If safe and effective use of a therapeutic depends on an IVD, then the FDA generally will require approval or clearance of that diagnostic, known as a companion diagnostic, at the same time that the FDA approves the therapeutic product. In August 2014, the FDA issued final guidance clarifying the requirements that will apply to approval of therapeutic products and in vitro companion diagnostics. According to the guidance, if the FDA determines that a companion diagnostic device is essential to the safe and effective use of a novel therapeutic product or indication, FDA generally will not approve the therapeutic product or new therapeutic product indication if the companion diagnostic device is not approved or cleared for that indication. Approval or clearance of the companion diagnostic device will ensure that the device has been adequately evaluated and has adequate performance characteristics in the intended population. The review of in vitro companion diagnostics in conjunction with the review of our therapeutic product candidates will, therefore, likely involve coordination of review by the FDA’s Center for Drug Evaluation and Research and the FDA’s Center for Devices and Radiological Health Office of In Vitro Diagnostics and Radiological Health.

We currently anticipate that each of our therapeutic product candidates will require us to develop and obtain FDA approval of a companion diagnostic for such therapeutic product candidates.

U.S. Regulation of Drugs and Biologics

In the United States, the FDA regulates drugs under the FDCA, and its implementing regulations, and biologics under the FDCA and the Public Health Service Act and its implementing regulations. FDA approval is
required before any new unapproved drug or dosage form, including a new use of a previously approved drug, can be marketed in the United States. Drugs and biologics are also subject to other federal, state, and local statutes and regulations. The process required by the FDA before product candidates may be marketed in the United States generally involves the following:

- completion of extensive preclinical laboratory tests and preclinical animal studies, all performed in accordance with the GLP regulations;
- submission to the FDA of an IND, which must become effective before human clinical studies may begin and must be updated annually;
- approval by an independent IRB or ethics committee representing each clinical site before each clinical study may be initiated;
- performance of adequate and well-controlled human clinical studies in accordance with GCP requirements to establish the safety and efficacy, or with respect to biologics, the safety, purity and potency of the product candidate for each proposed indication;
- preparation of and submission to the FDA of a new drug application (NDA) or biologics license application (BLA) after completion of all pivotal clinical studies;
- potential review of the product application by an FDA advisory committee, where appropriate and if applicable;
- a determination by the FDA within 60 days of its receipt of an NDA or BLA to file the application for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities where the proposed product drug substance is produced to assess compliance with current Good Manufacturing Practices (cGMP) and audits of selected clinical trial sites to ensure compliance with GCP; and
- FDA review and approval of an NDA or BLA prior to any commercial marketing or sale of the drug in the United States.

An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol or protocols for preclinical studies and clinical trials. The IND also includes results of animal and in vitro studies assessing the toxicology, PK, pharmacology and PD characteristics of the product, chemistry, manufacturing and controls (CMC) information, and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCP, which includes the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site, and must monitor the study until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include
oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing preclinical studies and clinical trials and clinical study results to public registries.

The clinical investigation of a drug is generally divided into three phases. Although the phases are usually conducted sequentially, they may overlap or be combined.

- **Phase 1.** The investigational product is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.

- **Phase 2.** The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.

- **Phase 3.** The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

In some cases, the FDA may condition approval of an NDA or BLA for a product candidate on the sponsor’s agreement to conduct additional clinical studies after approval. In other cases, a sponsor may voluntarily conduct additional clinical studies after approval to gain more information about the drug. Such post-approval studies are typically referred to as Phase 4 clinical studies. Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the biological characteristics of the product candidate, and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product, or for biologics, the safety, purity and potency.

**NDA and BLA Review Process**

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of an NDA or BLA requesting approval to market the product for one or more indications. The NDA or BLA must include all relevant data available from pertinent preclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product’s CMC and proposed labeling, among other things. Data can come from company-sponsored clinical studies intended to test the safety and effectiveness of the product, or from a number of alternative sources, including studies initiated and sponsored by investigators. The submission of an NDA or BLA requires payment of a substantial application user fee to the FDA, unless a waiver or exemption applies.

In addition, under the Pediatric Research Equity Act (PREA) a NDA or BLA or supplement to an NDA or BLA must contain data to assess the safety and effectiveness of the biological product candidate for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDASIA requires that a sponsor who is planning to submit a marketing application for a drug or biological product that includes a new active ingredient, new
indication, new dosage form, new dosing regimen or new route of administration submit an initial pediatric study plan within sixty days after an
day of Phase 2 meeting or as may be agreed between the sponsor and FDA. Unless otherwise required by regulation, PREA does not apply to any
biological product for an indication for which orphan designation has been granted.

Within 60 days following submission of the application, the FDA reviews the submitted BLA or NDA to determine if the application is
substantially complete before the agency accepts it for filing. The FDA may refuse to file any NDA or BLA that it deems incomplete or not properly
reviewable at the time of submission and may request additional information. In this event, the NDA or BLA must be resubmitted with the additional
information. Once an NDA or BLA has been accepted for filing, the FDA's goal is to review standard applications within ten months after the filing
date, or, if the application qualifies for priority review, six months after the FDA accepts the application for filing. In both standard and priority reviews,
the review process may also be extended by FDA requests for additional information or clarification. The FDA reviews an NDA to determine, among
other things, whether a product is safe and effective for its intended use and whether its manufacturing is sufficient to assure and preserve the product’s
identity, strength, quality and purity. The FDA reviews a BLA to determine, among other things, whether a product is safe, pure and potent and the
facility in which it is manufactured, processed, packed or held meets standards designed to assure the product’s continued safety, purity and potency.
When reviewing an NDA or BLA, the FDA may convene an advisory committee to provide clinical insight on application review questions. The FDA is
not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA or BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not
approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to
assure consistent production of the product within required specifications. Additionally, before approving an NDA or BLA, the FDA will typically
inspect one or more clinical sites to assure compliance with GCP. If the FDA determines that the application, manufacturing process or manufacturing
facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding
the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for
approval.

After the FDA evaluates the NDA or BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug
substance will be produced, the FDA may issue an approval letter or a Complete Response letter. An approval letter authorizes commercial marketing of
the product with specific prescribing information for specific indications. A Complete Response letter will describe all of the deficiencies that the FDA
has identified in the NDA or BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the
FDA may issue the Complete Response letter without first conducting required inspections, testing submitted product lots and/or reviewing proposed
labeling. In issuing the Complete Response letter, the FDA may recommend actions that the applicant might take to place the NDA or BLA in condition
for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of an NDA or BLA if applicable
regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or
efficacy of a product.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated
uses for which such product may be marketed. For example, the FDA may approve the NDA or BLA with a Risk Evaluation and Mitigation Strategy
(REMS) to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated
with a product and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides,
physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization
tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and
specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-

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marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product’s safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies.

Expedited Development and Review Programs for Drugs and Biologics

The FDA offers a number of expedited development and review programs for qualifying product candidates. The fast track program is intended to expedite or facilitate the process for reviewing new products that meet certain criteria. Specifically, new products are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a fast track product has opportunities for more frequent interactions with the review team during product development and, once an NDA or BLA is submitted, the product may be eligible for priority review. A fast track product may also be eligible for rolling review, where the FDA may consider for review sections of the NDA or BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA or BLA, the FDA agrees to accept sections of the NDA or BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA or BLA.

A product intended to treat a serious or life-threatening disease or condition may also be eligible for breakthrough therapy designation to expedite its development and review. A product can receive breakthrough therapy designation if preliminary clinical evidence indicates that the product, alone or in combination with one or more other drugs or biologics, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the fast track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product, including involvement of senior managers.

Any marketing application for a biologic submitted to the FDA for approval, including a product with a fast track designation and/or breakthrough therapy designation, may be eligible for other types of FDA programs intended to expedite the FDA review and approval process, such as priority review and accelerated approval. A product is eligible for priority review if it has the potential to provide a significant improvement in the treatment, diagnosis or prevention of a serious disease or condition. For new-molecular-entity NDAs and original BLAs, priority review designation means the FDA’s goal is to take action on the marketing application within six months of the 60-day filing date (as compared to ten months under standard review).

Additionally, products studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may receive accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled post-marketing clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. Products receiving accelerated approval may be subject to expedited withdrawal procedures if the sponsor fails to conduct the required post-marketing studies or if such studies fail to verify the predicted clinical benefit. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

Fast track designation, breakthrough therapy designation, priority review, and accelerated approval do not change the standards for approval but may expedite the development or approval process. Even if a product
qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. We may explore some of these opportunities for our product candidates as appropriate.

**Orphan Drug Designation**

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States for which there is no reasonable expectation that the cost of developing and making available in the United States a drug or biologic for this type of disease or condition will be recovered from sales in the United States for that drug or biologic. Orphan drug designation must be requested before submitting an NDA or BLA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. The orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusive approval (or exclusivity), which means that the FDA may not approve any other applications, including a full NDA or BLA, to market the same drug or biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug or biologic was designated. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the NDA or BLA application user fee.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

**Post-Approval Requirements for Drugs and Biologics**

Any products manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing user fee requirements, under which the FDA assesses an annual program fee for each product identified in an approved NDA or BLA. Drug and biologic manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMPs, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMPs and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMPs and other aspects of regulatory compliance.
The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of a product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;
- product seizure or detention, or refusal of the FDA to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of biologics. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product’s labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer’s communications on the subject of off-label use of their products.

Drug Product Marketing Exclusivity

Market exclusivity provisions authorized under the FDCA can delay the submission or the approval of certain marketing applications. For example, the FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not approve or even accept for review an abbreviated new drug application (ANDA) or an NDA submitted under Section 505(b)(2), or 505(b)(2) NDA, submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovative drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder.

The FDCA alternatively provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored
by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for drugs containing the active agent for the original indication or condition of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to any preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Pediatric exclusivity is another type of marketing exclusivity available in the United States. Pediatric exclusivity provides for an additional six months of marketing exclusivity attached to another period of exclusivity if a sponsor conducts clinical trials in children in response to a written request from the FDA. The issuance of a written request does not require the sponsor to undertake the described clinical trials. In addition, orphan drug exclusivity, as described above, may offer a seven-year period of marketing exclusivity, except in certain circumstances.

**Biosimilars and Reference Product Exclusivity**

The Biologics Price Competition and Innovation Act of 2009 (BPCIA) created an abbreviated approval pathway for biological products that are highly similar, or “biosimilar,” to or interchangeable with an FDA-approved reference biological product. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars. Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, is generally shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. A product shown to be biosimilar or interchangeable with an FDA-approved reference biological product may rely in part on the FDA’s previous determination of safety and effectiveness for the reference product for approval, which can potentially reduce the cost and time required to obtain approval to market the product. Complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant’s own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed “interchangeable” by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

A biological product can also obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued “Written Request” for such a study.

The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of
the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact, implementation, and impact of the BPCIA is subject to significant uncertainty.

U.S. Healthcare Fraud and Abuse Laws and Compliance Requirements

In addition to FDA regulation of pharmaceutical products and diagnostic tests, U.S. federal and state healthcare laws and regulations restrict business practices in the pharmaceutical and clinical laboratory industries. These laws may impact, among other things, our current and future business operations, including our clinical research activities, and constrain the business or financial arrangements and relationships with healthcare providers and other parties. These laws include anti-kickback, self-referral and false claims laws, civil monetary penalties laws, data privacy and security laws, and physician payment transparency laws. In addition to the federal laws summarized below, we may also be subject to similar state and local laws and regulations that may apply to business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, or by patients themselves.

The federal Anti-Kickback Statute prohibits, among other things, individuals or entities from knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, overtly or covertly, in cash or in kind to induce or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation.

The federal physician self-referral prohibitions, commonly known as the Stark Law, generally prohibit entities from billing a patient or the Medicare or Medicaid programs for certain designated health services, including clinical laboratory services, when the physician ordering the service, or any member of such physician’s immediate family, has a financial interest, such as an ownership or investment interest in or compensation arrangement with us, unless the arrangement meets an exception to the prohibition. These prohibitions apply regardless of any intent by the parties to induce or reward referrals or the reasons for the financial relationship and the referral. In addition, knowing violations of the Stark Law may also serve as the basis for liability under the Federal False Claims Act, which can result in additional civil and criminal penalties.

The federal civil and criminal false claims laws, including the civil False Claims Act, and civil monetary penalties laws prohibit, among other things, any individual or entity from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act.

The federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) created additional federal criminal statutes that prohibit, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the healthcare fraud statute implemented under HIPAA or specific intent to violate it in order to have committed a violation.

The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health

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Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services (CMS) information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare providers beginning in 2022 and teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by physicians (as defined under the statute) and their immediate family members.

Similar state and local laws and regulations may also restrict business practices in the pharmaceutical and clinical laboratory industries, such as state anti-kickback and false claims laws, which may apply to business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, or by patients themselves; state laws that require pharmaceutical and diagnostic companies to comply with the industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information or which require tracking gifts and other remuneration and items of value provided to physicians, other healthcare providers and entities; and state and local laws that require the registration of pharmaceutical sales representatives.

Violation of any of such laws or any other governmental regulations that apply may result in significant criminal, civil and administrative penalties including damages, fines, imprisonment, disgorgement, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm, diminished profits and future earnings, disgorgement, exclusion from participation in government healthcare programs and the curtailment or restructuring of our operations.

U.S. Coverage and Reimbursement of Drugs

Significant uncertainty exists as to the coverage and reimbursement status of any product candidate for which we may seek regulatory approval. Sales in the United States will depend, in part, on the availability of sufficient coverage and adequate reimbursement from third-party payors, which include government health programs such as Medicare, Medicaid, TRICARE and the Veterans Administration, as well as managed care organizations and private health insurers. Prices at which we or our customers seek reimbursement for our product candidates can be subject to challenge, reduction or denial by third-party payors.

The process for determining whether a third-party payor will provide coverage for a product is typically separate from the process for setting the reimbursement rate that the payor will pay for the product. In the United States, there is no uniform policy among payors for coverage or reimbursement. Decisions regarding whether to cover any of a product, the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies, but also have their own methods and approval processes. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that can require manufacturers to provide scientific and clinical support for the use of a product to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product that receives approval. Third-party payors may not consider our product candidates to be medically necessary or cost-effective compared to other available therapies, or the rebate percentages required to secure favorable coverage may not yield an adequate margin over
cost or may not enable us to maintain price levels sufficient to realize an appropriate return on our investment in drug development. Additionally, decreases in third-party reimbursement for any product or a decision by a third-party payor not to cover a product could reduce physician usage and patient demand for the product.

**U.S. Healthcare Reform**

In the United States, there has been, and continues to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect the profitable sale of product candidates.

Among policy makers and payors in the United States, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In March 2010, the Patient Protection and Affordable Care Act (Affordable Care Act) was passed, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly affected the pharmaceutical, medical device and clinical laboratory industries. The Affordable Care Act increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1%; required collection of rebates for drugs paid by Medicaid managed care organizations; required manufacturers to participate in a coverage gap discount program, in which manufacturers must agree to offer point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer’s outpatient drugs to be covered under Medicare Part D; imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell certain “branded prescription drugs” to specified federal government programs, implemented a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected; expanded eligibility criteria for Medicaid programs; creates a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare Innovation at the CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been judicial and political challenges to certain aspects of the Affordable Care Act. For example, the Tax Cuts and Jobs Act of 2017, or Tax Act, includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate.” On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas (the Texas District Court Judge) ruled that the individual mandate is a critical and inseverable feature of the Affordable Care Act, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the Affordable Care Act are invalid as well. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit ruled that that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the Affordable Care Act are invalid as well. On March 2, 2020, the U.S. Supreme Court granted the petitions for writs of certiorari to review this case, although it is unclear when or how the Supreme Court will rule. It is also unclear how other efforts to challenge, repeal or replace the Affordable Care Act will impact the law.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. These changes included aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2020, with the exception of a temporary suspension from May 1, 2020 through December 31, 2020, unless additional Congressional action is taken. In addition, on January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.
Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for pharmaceutical products. In addition, on March 10, 2020, the Trump administration sent “principles” for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Individual states in the United States have also become increasingly active in implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine which drugs and suppliers will be included in their healthcare programs. Furthermore, there has been increased interest by third-party payors and governmental authorities in reference pricing systems and publication of discounts and list prices.

**Foreign Regulation**

In order to market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we would need to obtain the necessary approvals by the comparable foreign regulatory authorities before we can commence clinical trials or marketing of the product in foreign countries and jurisdictions. Although many of the issues discussed above with respect to the United States apply similarly in the context of the European Union, or EU, the approval process varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

To market a medicinal product in the European Economic Area (EEA) (which is comprised of the 28 Member States of the EU plus Norway, Iceland and Liechtenstein), we must obtain a Marketing Authorization (MA). There are two types of marketing authorizations:

- the Community MA, which is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use of the EMA and which is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, advanced therapy products, and medicinal products containing a new active substance indicated for the treatment certain diseases, such as AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU; and

- National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in another Member State through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure.
Under the above described procedures, before granting the MA, the EMA or the competent authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

**Data and marketing exclusivity**

In the EEA, new products authorized for marketing, or reference products, qualify for eight years of data exclusivity and an additional two years of market exclusivity upon marketing authorization. The data exclusivity period prevents generic or biosimilar applicants from relying on the pre-clinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar marketing authorization in the EU during a period of eight years from the date on which the reference product was first authorized in the EU. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until 10 years have elapsed from the initial authorization of the reference product in the EU. The 10-year market exclusivity period can be extended to a maximum of 11 years if, during the first eight years of those 10 years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies.

**Pediatric investigation plan**

In the EEA, marketing authorization applications for new medicinal products not authorized have to include the results of studies conducted in the pediatric population, in compliance with a pediatric investigation plan (PIP) agreed with the EMA's Pediatric Committee (PDCO). The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the drug for which marketing authorization is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures of the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data is not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the marketing authorization is obtained in all Member States of the EU and study results are included in the product information, even when negative, the product is eligible for six months’ supplementary protection certificate extension.

**Clinical trials**

Clinical trials of medicinal products in the European Union must be conducted in accordance with European Union and national regulations and the International Conference on Harmonization guidelines on GCPs. Additional GCP guidelines from the European Commission, focusing in particular on traceability, apply to clinical trials of advanced therapy medicinal products. If the sponsor of the clinical trial is not established within the European Union, it must appoint an entity within the European Union to act as its legal representative. The sponsor must take out a clinical trial insurance policy, and in most EU countries, the sponsor is liable to provide ‘no fault’ compensation to any study subject injured in the clinical trial.

Prior to commencing a clinical trial, the sponsor must obtain a clinical trial authorization from the competent authority, and a positive opinion from an independent ethics committee. The application for a clinical trial authorization must include, among other things, a copy of the trial protocol and an investigational medicinal product dossier containing information about the manufacture and quality of the medicinal product under investigation. Currently, clinical trial authorization applications must be submitted to the competent authority in each EU Member State in which the trial will be conducted. Under the new Regulation on Clinical Trials, which is currently expected to take effect in 2019, there will be a centralized application procedure where one national authority takes the lead in reviewing the application and the other national authorities have only a limited involvement. Any substantial changes to the trial protocol or other information submitted with the clinical trial
applications must be notified to or approved by the relevant competent authorities and ethics committees. Medicines used in clinical trials must be manufactured in accordance with cGMP. Other national and European Union-wide regulatory requirements also apply.

Privacy and data protection laws

Numerous state, federal and foreign laws, including consumer protection laws and regulations, govern the collection, dissemination, use, access to, confidentiality and security of personal information, including health-related information. In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws and regulations (e.g., Section 5 of the FTC Act), that govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our partners. For example, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and their respective implementing regulations, imposes privacy, security and breach notification obligations on certain health care providers, health plans, and health care clearinghouses, known as covered entities, as well as their business associates that perform certain services that involve creating, receiving, maintaining or transmitting individually identifiable health information for or on behalf of such covered entities. Entities that are found to be in violation of HIPAA as the result of a breach of unsecured protected health information, a complaint about privacy practices or an audit by HHS, may be subject to significant civil, criminal and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance. Further, entities that knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA covered entity in a manner that is not authorized or permitted by HIPAA may be subject to criminal penalties.

Even when HIPAA does not apply, according to the FTC, violating consumers’ privacy rights or failing to take appropriate steps to keep consumers’ personal information secure may constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act. The FTC expects a company’s data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards.

Further, certain state laws govern the privacy and security of health-related information or other personal information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. For example, California recently enacted legislation, the California Consumer Privacy Act (CCPA) which went into effect January 1, 2020. The CCPA, among other things, creates new data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to opt out of certain disclosures of their information. The CCPA also creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach.

In addition, we are also subject to laws and regulations in non-U.S. countries covering data privacy and the protection of health-related and other personal information. EU member states and other jurisdictions have adopted data protection laws and regulations, which impose significant compliance obligations. Laws and regulations in these jurisdictions apply broadly to the collection, use, storage, disclosure, processing and security of personal information that identifies or may be used to identify an individual, such as names, contact information, and sensitive personal data such as health data. These laws and regulations are subject to frequent revisions and differing interpretations, and have generally become more stringent over time.
For example, the General Data Protection Regulation (GDPR) which is in effect across the EEA, imposes several stringent requirements for controllers and processors of personal data, and has increased our obligations, for example, by imposing higher standards for obtaining consent from individuals to process their personal data, requiring more robust disclosures to individuals, strengthening individual data rights, shortening timelines for data breach notifications, limiting retention periods and secondary use of information, increasing requirements pertaining to health data and pseudonymised (i.e., key-coded) data and imposing additional obligations when we contract third-party processors in connection with the processing of the personal data. The GDPR allows EU and EEA member states to make additional laws and regulations further limiting the processing of genetic, biometric or health data.

Further, the GDPR prohibits, without an appropriate legal basis, the transfer of personal data to countries outside of the EEA, such as the United States, which are not considered by the European Commission to provide an adequate level of data protection. Recent legal developments in Europe have created complexity and uncertainty regarding transfers of personal data from the EEA to the United States. For example, on July 16, 2020, the Court of Justice of the European Union (the CJEU) invalidated the EU-US Privacy Shield Framework (Privacy Shield) under which personal data could be transferred from the EEA to United States entities that had self-certified under the Privacy Shield scheme. While the CJEU upheld the adequacy of the standard contractual clauses (a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism, and potential alternative to the Privacy Shield), it made clear that reliance on them alone may not necessarily be sufficient in all circumstances. Use of the standard contractual clauses must now be assessed on a case-by-case basis taking into account the legal regime applicable in the destination country, in particular applicable surveillance laws and rights of individuals and additional measures and/or contractual provisions may need to be put in place, however, the nature of these additional measures is currently uncertain. As we expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business.

Failure to comply with the requirements of GDPR and the applicable national data protection laws of the EU and EEA member states may result in fines of up to €20,000,000 or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, and other administrative penalties. Additionally, following the United Kingdom’s withdrawal from the EU and the EEA, companies have to comply with the GDPR and the GDPR as incorporated into United Kingdom national law, the latter regime having the ability to separately fine up to the greater of £17.5 million or 4% of global turnover. The relationship between the United Kingdom and the EU in relation to certain aspects of data protection law remains unclear, for example around how data can lawfully be transferred between each jurisdiction, which exposes us to further compliance risk.

Employees

As of July 24, 2020, we had 115 full-time employees and 12 part-time employees. Of these employees, 25 are engaged in research and development. We consider our relationship with our employees to be good.

Facilities

We lease approximately 110,000 square feet of office and laboratory space in San Diego, California under a lease agreement that expires in December 2022. We believe that our existing facility will meet our current and near-term needs and that suitable additional space will be available as and when needed.

Legal Proceedings

From time to time, we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. Regardless of outcome, legal proceedings or claims can have an adverse impact on the company because of defense and settlement costs, diversion of resources and other factors, and there can be no assurances that favorable outcomes will be obtained. We are currently a party to the following legal
proceedings, each arising out of PLI and from alleged conduct occurring prior to our acquisition of PLI on June 30, 2019.

Between July 2019 and August 2019, PLI was served with six lawsuits by individual plaintiffs alleging that they suffered injuries caused by the ingestion of generic allopurinol and asserting claims against PLI under an innovator liability theory. The plaintiffs allege tort claims, including negligence, negligent misrepresentation, and concealment, and seek compensatory and punitive damages. Plaintiffs’ claims are based on alleged ingestion of allopurinol during the period March 2016 to March 2017, after PLI’s December 2015 sale of the NDA relating to the innovator product (Zyloprim) to Sebela Pharmaceuticals, Inc. Consistent with indemnity agreements which require Sebela to defend and indemnify such matters, Sebela has assumed the defense of these cases.

In March 2018, PLI received a demand letter from James Pepio, a former employee who had been terminated as part of a reduction in force. The demand letter sought to resolve potential claims relating to alleged off-label promotion of PROLEUKIN and wrongful termination, and was rejected by Prometheus. In August 2019, Prometheus received a copy of an amended complaint in a qui tam action that had been filed under seal by Mr. Pepio in U.S. District Court for the Middle District of Florida, styled United States ex rel. James Pepio v. Prometheus Laboratories, Inc. The amended complaint brought claims on behalf of the United States and the state of Florida and alleged that PLI violated the Federal and Florida False Claims Acts and related laws through the promotion and marketing of PROLEUKIN. The amended complaint seeks, among other things, treble damages, civil penalties for each alleged false claim, and attorneys’ fees and costs. In March 2020, the United States and the State of Florida declined to intervene in this matter and the amended complaint was subsequently unsealed. The decision not to intervene does not prevent Mr. Pepio from litigating this matter, and the United States and Florida may later seek to intervene in it. Prometheus accepted service of the amended complaint and intends to defend these claims vigorously. Our defense of this matter is subject to its indemnification agreement with Nestlé.
MANAGEMENT

Executive Officers and Directors

The following table sets forth the name, age and position of each of our executive officers and directors as of August 30, 2020.

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<tr>
<th>Name</th>
<th>Age</th>
<th>Position</th>
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<tr>
<td>Executive Officers</td>
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<tr>
<td>Mark C. McKenna</td>
<td>40</td>
<td>President and Chief Executive Officer</td>
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<tr>
<td>Keith W. Marshall, Ph.D.</td>
<td>52</td>
<td>Chief Financial Officer and Treasurer</td>
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<tr>
<td>Laurens Kruidenier, Ph.D.</td>
<td>51</td>
<td>Chief Scientific Officer</td>
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<tr>
<td>Allison Luo, M.D.</td>
<td>47</td>
<td>Chief Medical Officer</td>
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<tr>
<td>Lauren G. Otsuki</td>
<td>67</td>
<td>Chief Operating Officer</td>
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<td>Non-Employee Directors</td>
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<td>Tadatada Yamada, M.D.(1)</td>
<td>75</td>
<td>Chairman of the Board of Directors</td>
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<tr>
<td>Grégory Behar</td>
<td>51</td>
<td>Director</td>
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<tr>
<td>Scott L. Glenn</td>
<td>70</td>
<td>Director</td>
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<tr>
<td>James Laur</td>
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<td>Director</td>
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<tr>
<td>Shlomo Melmed, M.D.</td>
<td>72</td>
<td>Director</td>
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<tr>
<td>Joseph C. Papa(1)</td>
<td>64</td>
<td>Director</td>
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<tr>
<td>William Sandborn, M.D.</td>
<td>57</td>
<td>Director</td>
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<tr>
<td>Mark Stenhouse(1)</td>
<td>53</td>
<td>Director</td>
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<tr>
<td>Douglas F. Wall(2)</td>
<td>62</td>
<td>Director</td>
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<tr>
<td>Shierley Widjaja</td>
<td>36</td>
<td>Director</td>
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</tbody>
</table>

(1) Member of the compensation committee
(2) Member of the audit committee
(3) Member of the nominating and corporate governance committee

Executive Officers

Mark C. McKenna has served as our President and Chief Executive Officer and as a member of our board of directors since September 2019. Prior to joining us, he served as President and Chief Executive Officer of Salix Pharmaceuticals, Inc. (Salix), a wholly-owned subsidiary of Bausch Health Companies, Inc. (Bausch), from March 2016 through August 2019. Prior to Salix, Mr. McKenna spent more than a decade in various roles with Bausch + Lomb, also a division of Bausch, most recently as Senior Vice President and General Manager of its U.S. Vision Care business. Before joining Bausch + Lomb, he held several positions with Johnson & Johnson. Mr. McKenna holds a B.S. in Marketing from Arizona State University and an M.B.A. from Azusa Pacific University. Mr. McKenna’s knowledge of our business, as well as his significant development, commercial and executive management experience, contributed to our board of directors’ conclusion that he should serve as a director of the company.

Keith W. Marshall, Ph.D. has served as our Chief Financial Officer served since August 2020. Previously, he served as Executive Vice President, Chief Operating Officer, and Chief Financial Officer of Conatus Pharmaceuticals Inc., now Histogen, Inc., from August 2017 to May 2020. Dr. Marshall served as Chief Financial Officer and Head of Corporate Development at Torque Therapeutics Inc. from 2015 to 2017, where his responsibilities included finance, operations, human resources, corporate strategy and business development. He served as Managing Director and Advisor in Healthcare Investment Banking from 2012 to 2014 at GCA Savvian Advisors, where he provided strategic counsel to healthcare companies, and continued from 2014 to 2015 at TAG Healthcare Advisors under an alliance with GCA Savvian. Previously, Dr. Marshall was Managing Director from 2011 to 2012 at Sagent Advisors and Managing Director, Co-founder, and Chief Financial Officer from
2008 to 2011 at Montgomery, Marshall Healthcare Partners. He holds an A.B. in Biology from Washington University in St. Louis, a Ph.D. in Pharmaceutical Chemistry from the University of California, San Francisco, and an M.B.A. with concentrations in Finance, Strategy, and Entrepreneurship from the University of Chicago Booth School of Business.

Laurens Kruidenier, Ph.D. has served as our Chief Scientific Officer since May 2019, and previously served as our SVP of Research from July 2018 to May 2019. He has over 25 years of experience in IBD discovery research, both in academic settings as well as in the life sciences industry. Most recently, Dr. Kruidenier was Vice President of Discovery at Second Genome Inc. from July 2017 to July 2018, where he was responsible for a portfolio of microbiome programs. Previously, Dr. Kruidenier served as Head of GI Immunology Research at Takeda Pharmaceuticals from January 2015 to June 2017. Dr. Kruidenier also held various positions at GlaxoSmithKline plc. starting in April 2006, including most recently as Head of Biology of the Protein Degradation Unit from January 2013 to January 2015. Dr. Kruidenier holds a M.Sc. in Medical Biology from Utrecht University in the Netherlands and a Ph.D. in Experimental Gastroenterology from Leiden University in the Netherlands.

Allison Luo, M.D., has served as our Chief Medical Officer since August 2018. Prior to that, Dr. Luo concurrently served as Chief Medical Officer at Oppilan Pharma and Escalier Pharma since March 2017, and as Senior Vice President of Clinical Development for Gastroenterology at Progenity Inc. since June 2017. Before that, Dr. Luo was Vice President of Clinical Development at Ophthotech Corp., now Iveric bio, Inc., since September 2015. She was an Executive Director at Bristol-Myers Squibb Company from September 2006 to October 2014, where she was responsible for inflammatory bowel disease and led the Phase 3 program for Oencia (abatacept) and the Phase 2 programs for edelumab (anti-IP10 antibody) for ulcerative colitis and Crohn’s disease. Earlier in her career, Dr. Luo was a Medical Director at Abbott Laboratories, where she submitted the Japanese NDA for Humira in rheumatoid arthritis and developed the clinical trial protocols for Humira in ulcerative colitis. Dr. Luo holds a B.S. in Biochemistry and an M.D. from Northwestern University.

Lauren G. Otsuki has served as our Chief Operating Officer since May 2018 and has over twenty-five years of experience in biotechnology product development and commercialization with specific expertise in preclinical programs. Over the past fifteen years, Ms. Otsuki has founded and managed six successful biotechnology firms including Oncternal Therapeutics, Inc., Selexagen Therapeutics, Inc., Kanisa Pharmaceuticals Inc., Alastin Skincare, Inc., NovaCardia, Inc. and Dexcom, Inc.. Most recently, she served as Chief Operating Officer of Oncternal Therapeutics, Inc. from 2014 to 2018. Previously, she was Chief Executive Officer at Selexagen Therapeutics, Inc. from 2009 to 2012. Earlier in her career, Ms. Otsuki held a number of positions, including VP of Operations, VP of International, Director of Business Development, Director of Manufacturing and Director of Process Development, at Quidel Corporation, an in vitro diagnostics company. She holds a B.S. in Biochemistry from the University of California at Davis.

Non-Employee Directors

Tadatsuka Yamada, M.D. has served as Chairman of our board of directors since June 2018 and as a Venture Partner at Frazier Life Sciences since June 2015. From June 2011 to June 2015, Dr. Yamada served as the Chief Medical and Scientific Officer of Takeda Pharmaceutical Company Ltd. From 2006 to 2011, Dr. Yamada served as President of the Global Health Program of the Bill & Melinda Gates Foundation. Previously, he was the Chairman of Research and Development of GlaxoSmithKline Inc. and held research and development positions at SmithKline Beecham. Prior to that, Dr. Yamada served as Chairman of the Department of Internal Medicine at the University of Michigan Medical School and Physician-in-Chief of the University of Michigan Medical Center. Dr. Yamada is a member of the National Academy of Medicine, a Fellow of the Imperial College of Medicine, a Master of the American College of Physicians, a Fellow of the Royal College of Physicians, a Member of the American Academy of Arts and Sciences and a past-President of the American Gastroenterological Association and the Association of American Physicians. Dr. Yamada has served as the Chairman of the boards of directors of Phathom Pharmaceuticals, Inc. and Passage Bio, Inc. since March 2019.
and July 2017, respectively. He has also served since 2011 as a member of the board of directors of Agilent Technologies, Inc. and previously served on the boards of directors of Takeda Pharmaceutical Company Ltd, GlaxoSmithKline Inc. and CSL Limited. Dr. Yamada received a B.A. in History from Stanford University and his M.D. from New York University School of Medicine. Dr. Yamada’s extensive research and experience in product development, as well as his service as a director or officer of other healthcare companies, contributed to our board of directors’ conclusion that he should serve as Chairman of our board of directors.

Grégory Behar has served on our board of directors since July 2019. Mr. Behar currently serves as Chief Executive Officer of Nestlé Health Science, a global business of Nestlé S.A., which he joined in July 2014. Previously, Mr. Behar was President and Chief Executive Officer of Boehringer Ingelheim Pharmaceuticals Inc. (USA) from 2011 to June 2014 and Corporate Vice President Region NECAR (North European Union, Canada and Australasia) for Boehringer Ingelheim GmbH from 2010 to 2011. He also spent seven years in marketing and sales leadership in various roles at Novartis AG, following earlier work at Nestlé S.A. Mr. Behar currently serves on the boards of Aimmune Therapeutics, Inc., Seres Therapeutics, Inc., Cerecin, Inc., Axcella Health, Inc. and of Amazones SA. Mr. Behar received a B.S. in Mechanical Engineering from the University of California, Los Angeles, an M.S. in Mechanical Engineering from EPFL in Switzerland and an M.B.A. from INSEAD in France. Mr. Behar’s extensive global management and leadership experience in the life science industry contributed to our board of directors’ conclusion that he should serve as a director of our company.

Scott L. Glenn has served on our board of directors since August 2020, and was one of our founders, and currently serves as an employee Advisor, a role he has held since October 2019. From October 2016 to October 2019, Mr. Glenn served as our Chief Executive Officer. Mr. Glenn has served as the Managing Partner of Windamere Venture Partners, LLC since he founded it in 1999. In addition, Mr. Glenn is the founder of Evoke Pharma, Inc., Santarus, Inc., DexCom, Inc., Cadence Pharmaceuticals, NovaCardia Inc., Somaxon Pharmaceuticals, SpineWave, SkinMedica, Inc. and Conception Technologies, Inc. Mr. Glenn also serves on the board of directors of Glo Pharma, Inc. and served on the board of directors of Evoke Pharma, Inc. from June 2007 to May 2019. Before founding Windamere, Mr. Glenn was the President and Chief Executive Officer of Quidel Corporation. Prior to Quidel, Mr. Glenn has held various management positions, including Division General Manager with Allergan, Inc. Mr. Glenn holds a B.S. in Finance and Accounting from California State University at Fullerton. Mr. Glenn’s extensive knowledge of our business and history, experience as a board member of multiple publicly-traded companies, and experience in developing, financing and leading numerous biopharmaceutical companies contributed to our board of directors’ conclusion that he should serve as a director of our company.

James Laur has served on our board of directors since April 2020, and through his work leading Cedars-Sinai Medical Center’s Technology Transfer Office, Mr. Laur played a role in our founding. Mr. Laur currently serves as Vice President, Intellectual Property for Cedars-Sinai, and, in addition to his role with Cedars-Sinai’s Technology Transfer Office, Mr. Laur helps lead the Cedars-Sinai Accelerator program and Cedars-Sinai Health Ventures, Cedars-Sinai’s venture fund. Mr. Laur has served in a variety of business roles at Cedars-Sinai since originally joining its Legal Affairs Department in 1991. Mr. Laur is a member of the California State Bar and holds a dual degree B.A. in Political Science and Philosophy from the University of California, Los Angeles, as well as a J.D. from Boston College Law School. Mr. Laur’s extensive experience with early-stage life science companies, the healthcare sector, as well as his knowledge of intellectual property issues, technology ventures, innovation development and commercialization strategies contributed to our board of directors’ conclusion that he should serve as a director of our company.

Shlomo Melmed, M.D. has served on our board of directors since February 2019. Since 1980, Dr. Melmed has served in numerous roles at Cedars-Sinai Medical Center, where he currently serves as Executive Vice President of Academic Affairs, Dean of the Medical Faculty, and Professor of Medicine. As Professor of Medicine, Dr. Melmed holds the Helene A. and Philip E. Hixon Distinguished Chair in Investigative Medicine and is also an associate dean of the University of California, Los Angeles School of Medicine. Dr. Melmed is editor-in-chief of The Pituitary, editor of Williams Textbook of Endocrinology and is on the editorial board of the Journal of...
Clinical Investigation. In addition, Dr. Melmed is an elected member of the Association of American Physicians, the American Society of Clinical Investigation and the Endocrine Society Council, a fellow of the American College of Physicians and currently serves on the California Life Sciences Association Board. He has served as president of the International Society of Endocrinology, president and founding member of the Pituitary Society and as a member of the California Institute for Regenerative Medicine’s Independent Citizen’s Oversight Committee. Dr. Melmed holds an M.B. Ch.B. from the University of Cape Town, South Africa and is certified in endocrinology and metabolism by the American Board of Internal Medicine. Dr. Melmed’s significant experience in medical research and healthcare contributed to our board of directors’ conclusion that he should serve as a director of our company.

Joseph C. Papa has served on our board of directors since August 2020 and has been Chairman of the board of directors and Chief Executive Officer of Bausch Health Companies Inc. since May 2016. Mr. Papa has more than 35 years of experience in the pharmaceutical, healthcare and specialty pharmaceutical industries, including 20 years of branded prescription drug experience. He served as the CEO of Perrigo Company plc from 2006 to April 2016, where he also served as Chairman from 2007 to April 2016. Prior to joining Perrigo, Mr. Papa served from 2004 to 2006 as Chairman and CEO of the Pharmaceutical and Technologies Services segment of Cardinal Health, Inc. From 2001 to 2004, he served as President and Chief Operating Officer of Watson Pharmaceuticals, Inc. Prior to joining Watson, Mr. Papa held management positions at DuPont Pharmaceuticals, Pharmacia/Searle and Novartis AG. Mr. Papa served as a director of Smith & Nephew plc, a developer of advanced medical devices, from 2008 to April 2018. Mr. Papa’s extensive leadership experience in the pharmaceutical industry contributed to our board of directors’ conclusion that he should serve as a director of our company.

William Sandborn, M.D. has served on our board of directors since August 2017. Since January 2011, Dr. Sandborn has served as Director, Inflammatory Bowel Disease Center; Chief, Division of Gastroenterology; and Professor of Medicine for the University of California, San Diego Health System. Dr. Sandborn also serves as a member of UC San Diego Health’s Clinical Practice Operations Board. From April 1993 until December 2010, Dr. Sandborn was on the faculty of the Mayo Clinic, rising to Professor of Medicine, Vice Chairman of the Division of Gastroenterology and Hepatology and Associate Dean of Research for Intellectual Property and Industry Relations. Dr. Sandborn is also a member of the editorial board for the New England Journal of Medicine, and was a co-founder of Santarus, Inc. and Shoreline Biosciences. Dr. Sandborn holds a B.A. in Chemistry from Southern College and an M.D. from Loma Linda University. Dr. Sandborn’s significant experience with clinical trial design and clinical pharmacology related to inflammatory bowel disease contributed to our board of directors’ conclusion that he should serve as a director of our company.

Mark Stenhouse has served on our board of directors since April 2018. Mr. Stenhouse has served as General Manager, Screening at Exact Sciences Corporation since November 2019 and previously served as President, Cologuard from April 2018 until November 2019. From October 2016 until March 2018, Mr. Stenhouse served as Vice President, U.S. Immunology of AbbVie, Inc., where he oversaw U.S. expansion into the immunology marketplace. From April 2010 until September 2016, Mr. Stenhouse served as Vice President and Vice President/General Manager, U.S. Immunology—Gastroenterology Franchise at AbbVie. From September 2006 through March 2010, Mr. Stenhouse held various senior management, marketing and sales positions within Abbott Laboratories’ U.S. Immunology division. Mr. Stenhouse holds a B.B.A. from the College of Charleston. Mr. Stenhouse’s executive experience in the biopharmaceutical industry and knowledge of our business contributed to our board of directors’ conclusion that he should serve as a director of our company.

Douglas F. Wall has served on our board of directors since November 2017. Mr. Wall is currently the Managing Member and Managing Director of Life Ventures, where he has served since September 2015. Since August 2018, Mr. Wall has served as Chairman of the board of directors of Tech M3, Inc. dba PureForge. Mr. Wall has founded several companies, including PureForge, Genea Energy, San Diego Band of Angels and RCG Management. In his sixteen years leading RCG Management, the firm provided strategic advisory services to over 3,000 emerging growth companies. Prior to founding RCG Management, Mr. Wall practiced as an accountant at Ernst & Young LLP and Arthur Anderson LLP, where he rose to manager and senior, respectively.
Mr. Wall holds a B.S. in Business Administration from San Diego State University. Mr. Wall’s finance and accounting expertise and experience advising emerging companies contributed to our board of directors’ conclusion that he should serve as a director of our company.

Shierley Widjaja has served on our board of directors since June 2019. Ms. Widjaja has served as an Executive Director and Chief Investment Officer of SJE Investments since May 2019. Prior to founding SJE Investments, Ms. Widjaja was a Portfolio Manager at McKinley Capital Management from August 2010 to December 2018. Ms. Widjaja began her career in June 2006 as an analyst at UBS Investment Bank in Hong Kong. Ms. Widjaja holds a B.S. in Electrical Engineering from the University of California, Los Angeles and an M.B.A. from the University of Pennsylvania’s Wharton School with a Finance and Accounting concentration. Ms. Widjaja’s significant experience with financing early-stage companies contributed to our board of directors’ conclusion that she should serve as a director of our company.

**Family Relationships**

Dr. Sandborn, a member of our board of directors, is the spouse of Dr. Luo, our Chief Medical Officer. There are no other family relationships among our directors and executive officers.

**Board Composition and Election of Directors**

**Director Independence**

Our board of directors currently consists of eleven members. Our board of directors has determined that all of our directors, other than are independent directors in accordance with the listing requirements of the Nasdaq Global Market (Nasdaq). The Nasdaq independence definition includes a series of objective tests, including that the director is not, and has not been for at least three years, one of our employees and that neither the director nor any of his or her family members has engaged in various types of business dealings with us. In addition, as required by Nasdaq rules, our board of directors has made a subjective determination as to each independent director that no relationships exist, which, in the opinion of our board of directors, would interfere with the exercise of independent judgment in carrying out the responsibilities of the director. In making these determinations, our board of directors reviewed and discussed information provided by the directors and us with regard to each director’s business and personal activities and relationships as they may relate to us and our management. There are no family relationships among any of our directors or executive officers.

**Classified Board of Directors**

In accordance with the terms of our amended and restated certificate of incorporation that will go into effect immediately prior to the closing of this offering, our board of directors will be divided into three classes with staggered, three-year terms. At each annual meeting of stockholders, the directors whose terms then expire will be eligible for reelection until the third annual meeting following reelection. Effective upon the closing of this offering, our directors will be divided among the three classes as follows:

- the Class I directors will be , and their terms will expire at our first annual meeting of stockholders following this offering;
- the Class II directors will be , and their terms will expire at our second annual meeting of stockholders following this offering; and
- the Class III directors will be , and their terms will expire at our third annual meeting of stockholders following this offering.

Our amended and restated certificate of incorporation that will go into effect immediately prior to the closing of this offering will provide that the authorized number of directors may be changed only by resolution of the board of directors. Any additional directorships resulting from an increase in the number of directors will be
distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. The division of our board of directors into three classes with staggered three-year terms may delay or prevent a change of our board of directors or a change in control of our company. Our directors may be removed only for cause by the affirmative vote of the holders of at least two-thirds of our outstanding voting stock then entitled to vote in an election of directors.

**Board Leadership Structure**

Our board of directors is currently led by our Chairman, Dr. Yamada. Our board of directors recognizes that it is important to determine an optimal board leadership structure to ensure the independent oversight of management as the company continues to grow. We separate the roles of chief executive officer and chairman of the board of directors in recognition of the differences between the two roles. The chief executive officer is responsible for setting the strategic direction for our company and the day-to-day leadership and performance of our company, while the chairman of the board of directors provides guidance to the chief executive officer and presides over meetings of the full board of directors. We believe that this separation of responsibilities provides a balanced approach to managing the board of directors and overseeing our company.

Our board of directors has concluded that our current leadership structure is appropriate at this time. However, our board of directors will continue to periodically review our leadership structure and may make such changes in the future as it deems appropriate.

**Role of Board in Risk Oversight Process**

Our board of directors has responsibility for the oversight of our risk management processes and, either as a whole or through its committees, regularly discusses with management our major risk exposures, their potential impact on our business and the steps we take to manage them. The risk oversight process includes receiving regular reports from board committees and members of senior management to enable our board of directors to understand our risk identification, risk management and risk mitigation strategies with respect to areas of potential material risk, including operations, finance, legal, regulatory, strategic and reputational risk.

The audit committee reviews information regarding liquidity and operations, and oversees our management of financial risks. Periodically, the audit committee reviews our policies with respect to risk assessment, risk management, loss prevention and regulatory compliance. Oversight by the audit committee includes direct communication with our external auditors, and discussions with management regarding significant risk exposures and the actions management has taken to limit, monitor or control such exposures. The compensation committee is responsible for assessing whether any of our compensation policies or programs has the potential to encourage excessive risk-taking. The nominating and corporate governance committee manages risks associated with the independence of the board of directors, corporate disclosure practices and potential conflicts of interest. While each committee is responsible for evaluating certain risks and overseeing the management of such risks, the entire board of directors is regularly informed through committee reports about such risks. Matters of significant strategic risk are considered by our board of directors as a whole.

**Board Committees and Independence**

Our board of directors has established three standing committees—audit, compensation and nominating and corporate governance—each of which operates under a charter that has been approved by our board of directors.

**Audit Committee**

The audit committee’s main function is to oversee our accounting and financial reporting processes and the audits of our consolidated financial statements. This committee’s responsibilities include, among other things:

- appointing our independent registered public accounting firm;
• evaluating the qualifications, independence and performance of our independent registered public accounting firm;
• approving the audit and non-audit services to be performed by our independent registered public accounting firm;
• reviewing the design, implementation, adequacy and effectiveness of our internal accounting controls and our critical accounting policies;
• discussing with management and the independent registered public accounting firm the results of our annual audit and the review of our quarterly unaudited consolidated financial statements;
• reviewing, overseeing and monitoring the integrity of our consolidated financial statements and our compliance with legal and regulatory requirements as they relate to financial statements or accounting matters;
• reviewing on a periodic basis, or as appropriate, any investment policy and recommending to our board of directors any changes to such investment policy;
• reviewing with management and our auditors any earnings announcements and other public announcements regarding our results of operations;
• preparing the report that the SEC requires in our annual proxy statement;
• reviewing and approving any related party transactions and reviewing and monitoring compliance with our code of conduct and ethics; and
• reviewing and evaluating, at least annually, the performance of the audit committee and its members including compliance of the audit committee with its charter.

The members of our audit committee are , , and . serves as the chairperson of the committee. All members of our audit committee meet the requirements for financial literacy under the applicable rules and regulations of the SEC and Nasdaq. Our board of directors has determined that is an “audit committee financial expert” as defined by applicable SEC rules and has the requisite financial sophistication as defined under the applicable Nasdaq listing standards. Our board of directors has determined each of , , and is independent under the applicable rules of the SEC and Nasdaq. Upon the listing of our common stock on Nasdaq, the audit committee will operate under a written charter that satisfies the applicable standards of the SEC and Nasdaq.

Compensation Committee

Our compensation committee approves policies relating to compensation and benefits of our officers and employees. The compensation committee approves corporate goals and objectives relevant to the compensation of our Chief Executive Officer and other executive officers, evaluates the performance of these officers in light of those goals and objectives and approves the compensation of these officers based on such evaluations. The compensation committee also approves the issuance of stock options and other awards under our equity plans. The compensation committee will review and evaluate, at least annually, the performance of the compensation committee and its members, including compliance by the compensation committee with its charter.

The members of our compensation committee are Mr. Papa, Mr. Stenhouse and Dr. Yamada. Mr. Papa serves as the chairperson of the committee. Our board of directors has determined that each of , , and is independent under the applicable Nasdaq listing standards, is a “non-employee director” as defined in Rule 16b-3 promulgated under the Exchange Act. Upon the listing of our common stock on Nasdaq, the compensation committee will operate under a written charter, which the compensation committee will review and evaluate at least annually.
Nominating and Corporate Governance Committee

The nominating and corporate governance committee is responsible for assisting our board of directors in discharging the board of directors’ responsibilities regarding the identification of qualified candidates to become board members, the selection of nominees for election as directors at our annual meetings of stockholders (or special meetings of stockholders at which directors are to be elected), and the selection of candidates to fill any vacancies on our board of directors and any committees thereof. In addition, the nominating and corporate governance committee is responsible for overseeing our corporate governance policies, reporting and making recommendations to our board of directors concerning governance matters and oversight of the evaluation of our board of directors. The members of our nominating and corporate governance committee are , , and . serves as the chairperson of the committee. Our board of directors has determined that each of , , and is independent under the applicable Nasdaq listing standards. Upon the listing of our common stock on Nasdaq, the nominating and corporate governance committee will operate under a written charter, which the nominating and corporate governance committee will review and evaluate at least annually.

Compensation Committee Interlocks and Insider Participation

None of the members of our compensation committee is currently, or has at any time been, one of our officers or employees. None of our executive officers currently serves, or has served, as a member of the board of directors or compensation committee (or other board committee performing equivalent functions or, in the absence of any such committee, the entire board of directors) of any entity that has one or more executive officers serving as a member of our board of directors or compensation committee.

Board Diversity

Upon the closing of this offering, our nominating and corporate governance committee will be responsible for reviewing with the board of directors, on an annual basis, the appropriate characteristics, skills and experience required for the board of directors as a whole and its individual members. In evaluating the suitability of individual candidates (both new candidates and current members) for election or appointment, the nominating and corporate governance committee and the board of directors will take into account many factors, including the following:

- personal and professional integrity, ethics and values;
- experience in corporate management, such as serving as an officer or former officer of a publicly-held company;
- experience as a board member or executive officer of another publicly-held company;
- strong finance experience;
- diversity of expertise and experience in substantive matters pertaining to our business relative to other board members;
- diversity of background and perspective, including, but not limited to, with respect to age, gender, race, place of residence and specialized experience;
- experience relevant to our business industry and with relevant social policy concerns; and
- relevant academic expertise or other proficiency in an area of our business operations.

Currently, our board of directors evaluates, and following the closing of this offering will evaluate, each individual in the context of the board of directors as a whole, with the objective of assembling a group that can best maximize the success of the business and represent stockholder interests through the exercise of sound judgment using its diversity of experience in these various areas.
Code of Conduct and Ethics

We plan to adopt a written code of conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, which will be effective upon the closing of this offering. Upon the closing of this offering, our code of conduct and ethics will be available under the Corporate Governance section of our website at www.prometheusbiosciences.com. In addition, we intend to post on our website all disclosures that are required by law or the listing standards of Nasdaq concerning any amendments to, or waivers from, any provision of the code. The reference to our website address does not constitute incorporation by reference of the information contained at or available through our website, and you should not consider it to be a part of this prospectus.
EXECUTIVE AND DIRECTOR COMPENSATION

This section discusses the material components of the executive compensation program for our executive officers who are named in the “Summary Compensation Table” below, whom we refer to as our named executive officers or NEOs.

This discussion may contain forward-looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs. Actual compensation programs that we adopt following the closing of this offering may differ materially from the currently planned programs summarized in this discussion.

Summary Compensation Table

The following table presents summary information regarding the total compensation that was awarded to, earned by or paid to our NEOs for services rendered during the year ended December 31, 2019.

<table>
<thead>
<tr>
<th>Name and principal position</th>
<th>Year</th>
<th>Salary ($)</th>
<th>Bonus ($)</th>
<th>Stock awards ($)</th>
<th>Option awards ($)</th>
<th>Non-equity incentive plan compensation ($)</th>
<th>All other compensation ($)</th>
<th>Total ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mark C. McKenna</td>
<td>2019</td>
<td>156,891</td>
<td>—</td>
<td>—</td>
<td>635,857</td>
<td>—</td>
<td>183,102</td>
<td>975,850</td>
</tr>
<tr>
<td>President and Chief Executive Officer</td>
<td></td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>Scott L. Glenn</td>
<td>2019</td>
<td>500,641</td>
<td>250,000</td>
<td>—</td>
<td>160,000</td>
<td>—</td>
<td>172</td>
<td>910,813</td>
</tr>
<tr>
<td>Advisor and Former President and Chief Executive Officer</td>
<td></td>
<td></td>
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<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Lauren G. Otsuki</td>
<td>2019</td>
<td>375,481</td>
<td>150,000</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>172</td>
<td>525,653</td>
</tr>
<tr>
<td>Chief Operating Officer</td>
<td></td>
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</tr>
<tr>
<td>Allison Luo, M.D.</td>
<td>2019</td>
<td>293,077</td>
<td>83,333</td>
<td>—</td>
<td>42,500</td>
<td>—</td>
<td>2,839</td>
<td>421,749</td>
</tr>
<tr>
<td>Chief Medical Officer</td>
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</tr>
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</table>

(1) Mr. McKenna commenced employment with us on September 9, 2019, and was appointed as our President and Chief Executive Officer on October 1, 2019. Mr. Glenn ceased serving as our President and Chief Executive Officer on October 1, 2019, at which time he transitioned to the role of Advisor. Mr. Glenn’s salary reflects his salary as Chief Executive Officer from January 1, 2019 through October 1, 2019 and his salary as Advisor from October 1, 2019 through December 31, 2019.

(2) Represents the grant date fair value of stock options to purchase shares of common stock of Prometheus Biosciences, Inc. computed in accordance with FASB ASC 718. See Note 8 to the consolidated financial statements for the fiscal year ended December 31, 2019 included with this prospectus for a description of the assumptions used in valuing our stock options.

(3) Includes matching contributions made by us on behalf of the NEO under our 401(k) plan ($4,487 for Mr. McKenna and $2,667 for Dr. Luo) and life insurance premiums paid by us on behalf of the NEO. For Mr. McKenna, also includes $178,549 in relocation assistance provided by the company, of which $68,154 was a tax-gross up on such portion of the relocation benefits that were taxable to him.

(4) Represents a transaction bonus paid in consideration of the company’s acquisition of PLI in June 2019.

(5) Dr. Luo is married to William Sandborn, M.D., one of our non-employee directors. Dr. Sandborn’s compensation is described below under “Director Compensation.”

(6) Represents a transaction bonus of $25,000 paid to Dr. Luo in consideration of the company’s acquisition of PLI in June 2019 and a guaranteed annual bonus of $58,333 for 2019 pursuant to her employment letter.
Narrative Disclosure to Compensation Tables

The primary elements of compensation for our NEOs are base salary, annual performance bonuses and equity awards. The NEOs also participate in employee benefit plans and programs that we offer to our other employees, as described below.

Annual Base Salary

We pay our NEOs a base salary to compensate them for the performance of services rendered to us. The base salary payable to each NEO is intended to provide a fixed component of compensation reflecting the executive’s skill set, experience, role and responsibilities. Base salaries for our NEOs have generally been set at levels deemed necessary to attract and retain individuals with superior talent.

Mr. McKenna’s annual base salary of $500,000 was established in connection with his commencement of employment in September 2019.

Dr. Luo’s annual base salary was $200,000 prior to her conversion to full-time employment in July 2019, at which time her annual base salary increased to $400,000. In connection with our standard merit increase process, Dr. Luo’s annual base salary was increased to $410,000 in March 2020.

In March 2020, Ms. Otsuki’s annual base salary was increased from $375,000, the rate in effect during 2019, to $384,375 in connection with our standard merit increase process.

Bonus Compensation

From time to time, our board of directors or compensation committee may approve bonuses for our NEOs based on individual performance, company performance or as otherwise determined appropriate.

For 2019, we did not pay annual bonuses to the NEOs, with the exception of Dr. Luo, who was entitled to a guaranteed annual bonus of 20% of her base salary for 2019 pursuant to her employment letter. This bonus, in the amount of $58,333, was paid in February 2020.

Mr. Glenn, Ms. Otsuki and Dr. Luo were also paid transaction bonuses in the amount of $250,000, $150,000 and $25,000, respectively, in consideration of the company’s acquisition of PLI in June 2019. These bonuses were paid in February 2020.

Each NEO has an established target annual bonus amount. The 2020 target annual bonus amount for each NEO, expressed as a percentage of annual base salary, is 50% for Mr. McKenna, 50% for Mr. Glenn, 40% for Ms. Otsuki and 40% for Dr. Luo. We have not established a formal bonus program for 2020.

Equity-Based Incentive Awards

Our equity-based incentive awards are designed to align our interests and the interests of our stockholders with those of our employees and consultants, including our named executive officers. The board of directors or the compensation committee is responsible for approving equity grants. We typically grant equity awards to new hires upon their commencing employment with us. Generally, our equity awards vest over four years, subject to the employee’s continued employment with us on each vesting date.

In October 2019, in connection with her commencement of employment, we granted Dr. Luo an option to purchase 250,000 shares of our common stock under our 2017 Equity Incentive Plan, as amended, or the 2017 Plan. Twenty-five percent of the options vest on the 12-month anniversary of her employment commencement date and 1/48th of the options vest monthly thereafter, subject to Dr. Luo’s continuous service through each
vesting date. The options were granted at an exercise price of $0.29 per share, which our board of directors determined was equal to the fair market value per share of our common stock on the date of grant. The options are also eligible for accelerated vesting on the terms provided in her employment letter, as described below.

In November 2019, in connection with his commencement of employment, we granted Mr. McKenna an option to purchase 3,740,336 shares of our common stock. Twenty-five percent of the options vest on the 12-month anniversary of his employment commencement date and 1/48th of the options vest monthly thereafter, subject to Mr. McKenna’s continuous service through each vesting date. The options were granted at an exercise price of $0.29 per share, which our board of directors determined was equal to the fair market value per share of our common stock on the date of grant. The options are also eligible for accelerated vesting on the terms provided in his employment letter, as described below.

In November 2019, in connection with his transition to Advisor, we granted Mr. Glenn an option to purchase 1,000,000 shares of our common stock at an exercise price of $0.29 per share, which our board of directors determined was equal to the fair market value per share of our common stock on the date of grant. The options are eligible to vest in 14 equal installments on the last day of each month beginning with November 2019, subject to his continuous service through each vesting date. The options are also eligible for accelerated vesting on the terms provided in his employment letter, as described below.

Employment Letter Agreements with our NEOs

We have entered into employment agreements with each of our NEOs, the terms of which will be described in a subsequent filing.

Outstanding Equity Awards at Fiscal Year-End

The following table sets forth information with respect to outstanding equity awards for each of our NEOs as of December 31, 2019.

<table>
<thead>
<tr>
<th>Grant Date</th>
<th>Number of Securities Underlying Unexercised Options (#) Exercisable</th>
<th>Number of Securities Underlying Unexercised Options (#) Unexercisable</th>
<th>Option Exercise Price ($)</th>
<th>Option Expiration Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>11/7/2019</td>
<td>3,740,336</td>
<td>3,740,336</td>
<td>$0.29</td>
<td>11/6/2029</td>
</tr>
<tr>
<td>11/7/2019</td>
<td>142,857</td>
<td>857,143</td>
<td>$0.29</td>
<td>11/6/2029</td>
</tr>
<tr>
<td>10/1/2019</td>
<td>250,000</td>
<td>250,000</td>
<td>$0.29</td>
<td>9/30/2029</td>
</tr>
<tr>
<td>8/2/2018</td>
<td>261,459</td>
<td>261,459</td>
<td>$0.29</td>
<td>8/2/2018</td>
</tr>
</tbody>
</table>

(1) With the exception of the award to Mr. Glenn, stock option awards generally vest as to 25% of such grant on the one year anniversary of the vesting commencement date (September 9, 2019 for Mr. McKenna’s award and July 15, 2019 for Dr. Luo’s award) and monthly thereafter in equal installments until fully vested at the fourth anniversary of the vesting commencement date, subject to the recipient’s continued service through each vesting date, and subject to accelerated vesting in certain circumstances as described above under “Employment Letter Agreements with our NEOs.” Mr. Glenn’s award vests in 14 equal installments on the last day of each month beginning with November 2019, subject to his continuous service through each vesting date, and subject to accelerated vesting in certain circumstances as described above under “Employment Letter Agreements with our NEOs.”

(2) Represents restricted shares issued upon early exercise of stock options originally granted to Dr. Luo on August 2, 2018 at an exercise price of $0.05 per share, which option was subject to the standard vesting
schedule described in footnote (1) above commencing July 1, 2018. The remaining restricted shares will vest in equal monthly installments until fully vested on July 1, 2022, subject to accelerated vesting in certain circumstances as described above under “Employment Letter Agreements with our NEOs.”

(3) Represents the fair market value per share of our common stock as of December 31, 2019 of $0.29 per share, which our board of directors determined was the fair market value per share of our common stock on such date.

Other Elements of Compensation

Perquisites, Health, Welfare and Retirement Benefits

Our named executive officers are eligible to participate in our employee benefit plans, including our medical, dental, vision, group life, disability and accidental death and dismemberment insurance plans, in each case on the generally on same basis as all of our other employees. We offer a 401(k) plan to our employees, including our named executive officers, as discussed in the section below entitled “401(k) Plan.”

We generally do not provide perquisites or personal benefits to our named executive officers, except in limited circumstances. Our board of directors may elect to adopt qualified or non-qualified benefit plans in the future if it determines that doing so is in our best interests.

401(k) Plan

We maintain a defined contribution employee retirement plan, or 401(k) plan, for our employees. Our named executive officers are eligible to participate in the 401(k) plan on the same basis as our other employees. The 401(k) plan is intended to be a tax-qualified plan under Section 401(k) of the Internal Revenue Code. The 401(k) plan provides that each participant may make pre-tax deferrals from his or her compensation up to the statutory limit, which is $19,500 for calendar year 2020, and other testing limits. Participants who are age 50 or older can also make “catch-up” contributions, which in calendar year 2020 may be up to an additional $6,500 above the statutory limit. We currently match employee deferrals under the 401(k) plan at 100% of deferrals up to the first 3% of eligible compensation and 50% of deferrals up to the next 2% of eligible compensation. Participant contributions are held and invested, pursuant to the participant’s instructions, by the 401(k) plan’s trustee.

Nonqualified Deferred Compensation

We do not maintain nonqualified defined contribution plans or other nonqualified deferred compensation plans. Our board of directors may elect to provide our officers and other employees with non-qualified defined contribution or other nonqualified deferred compensation benefits in the future if it determines that doing so is in our best interests.

Termination or Change in Control Benefits

Our named executive officers may become entitled to certain benefits or enhanced benefits in connection with a change in control of our company. Each NEO’s employment letter agreement entitles him or her to certain benefits, including accelerated vesting of equity awards, upon a qualifying termination of employment and/or in connection with a change in control of our company. For additional discussion, please see the section titled “Employment Letter Agreements with our NEOs.”

Incentive Award Plans

2020 Incentive Award Plan

Prior to this offering, we intend to adopt and ask our stockholders to approve the 2020 Plan, which would become effective in connection with this offering. Under the 2020 Plan, we may grant cash and equity incentive
awards to eligible service providers in order to attract, motivate and retain the talent for which we compete. The material terms of the 2020 Plan, as it is currently contemplated, are summarized below. Our board of directors is still in the process of developing, approving and implementing the 2020 Plan and, accordingly, this summary is subject to change.

Eligibility and Administration

Our employees, consultants and directors, and employees and consultants of our subsidiaries, will be eligible to receive awards under the 2020 Plan. Following our initial public offering, the 2020 Plan will generally be administered by our board of directors with respect to awards to non-employee directors and by our compensation committee with respect to other participants, each of which may delegate its duties and responsibilities to committees of our directors and/or officers (referred to collectively as the plan administrator below), subject to certain limitations that may be imposed under the 2020 Plan, Section 16 of the Exchange Act and/or stock exchange rules, as applicable. The plan administrator will have the authority to make all determinations and interpretations under, prescribe all forms for use with, and adopt rules for the administration of, the 2020 Plan, subject to its express terms and conditions. The plan administrator will also set the terms and conditions of all awards under the 2020 Plan, including any vesting and vesting acceleration conditions.

Limitation on Awards and Shares Available

The number of shares initially available for issuance under awards granted pursuant to the 2020 Plan will be the sum of (1) shares of our common stock, plus (2) any shares subject to outstanding awards under the 2017 Plan as of the effective date of the 2020 Plan that become available for issuance under the 2020 Plan thereafter in accordance with its terms. The number of shares initially available for issuance will be increased on January 1 of each calendar year beginning in 2021 and ending in 2030, by an amount equal to the lesser of (a) % of the shares of common stock outstanding on the final day of the immediately preceding calendar year and (b) such smaller number of shares as determined by our board of directors. No more than shares of common stock may be issued upon the exercise of incentive stock options under the 2020 Plan. Shares issued under the 2020 Plan may be authorized but unissued shares, shares purchased in the open market or treasury shares.

If an award under the 2020 Plan or the 2017 Plan expires, lapses or is terminated, exchanged for cash, surrendered, repurchased, cancelled without having been fully exercised or forfeited, any shares subject to such award will, as applicable, become or again be available for new grants under the 2020 Plan. Awards granted under the 2020 Plan upon the assumption of, or in substitution for, awards authorized or outstanding under a qualifying equity plan maintained by an entity with which we enter into a merger or similar corporate transaction will not reduce the shares available for grant under the 2020 Plan.

Awards

The 2020 Plan provides for the grant of stock options, including incentive stock options, or ISOs, and nonqualified stock options, or NSOs; restricted stock; dividend equivalents; restricted stock units, or RSUs; stock appreciation rights, or SARs; and other stock or cash-based awards. Certain awards under the 2020 Plan may constitute or provide for a deferral of compensation, subject to Section 409A of the Internal Revenue Code, which may impose additional requirements on the terms and conditions of such awards. All awards under the 2020 Plan will be set forth in award agreements, which will detail the terms and conditions of the awards, including any applicable vesting and payment terms and post-termination exercise limitations. A brief description of each award type follows.

Stock options. Stock options provide for the purchase of shares of our common stock in the future at an exercise price set on the grant date. ISOs, by contrast to NSOs, may provide tax deferral beyond exercise and favorable capital gains tax treatment to their holders if certain holding period and other requirements of the
Internal Revenue Code are satisfied. The exercise price of a stock option will not be less than 100% of the fair market value of the underlying share on the date of grant (or 110% in the case of ISOs granted to certain significant stockholders), except with respect to certain substitute options granted in connection with a corporate transaction. The term of a stock option may not be longer than ten years (or five years in the case of ISOs granted to certain significant stockholders). Vesting conditions determined by the plan administrator may apply to stock options and may include continued service, performance and/or other conditions. ISOs generally may be granted only to our employees and employees of our parent or subsidiary corporations, if any.

SARs. SARs entitle their holder, upon exercise, to receive from us an amount equal to the appreciation of the shares subject to the award between the grant date and the exercise date. The exercise price of a SAR will not be less than 100% of the fair market value of the underlying share on the date of grant (except with respect to certain substitute SARs granted in connection with a corporate transaction), and the term of a SAR may not be longer than ten years. Vesting conditions determined by the plan administrator may apply to SARs and may include continued service, performance and/or other conditions.

Restricted stock and RSUs. Restricted stock is an award of nontransferable shares of our common stock that remain forfeitable unless and until specified conditions are met, and which may be subject to a purchase price. RSUs are contractual promises to deliver shares of our common stock in the future, which may also remain forfeitable unless and until specified conditions are met and may be accompanied by the right to receive the equivalent value of dividends paid on shares of our common stock prior to the delivery of the underlying shares. Delivery of the shares underlying RSUs may be deferred under the terms of the award or at the election of the participant, if the plan administrator permits such a deferral. Conditions applicable to restricted stock and RSUs may be based on continuing service, the attainment of performance goals and/or such other conditions as the plan administrator may determine.

Other stock or cash-based awards. Other stock or cash-based awards are awards of cash, fully vested shares of our common stock and other awards valued wholly or partially by referring to, or otherwise based on, shares of our common stock. Other stock or cash-based awards may be granted to participants and may also be available as a payment form in the settlement of other awards, as standalone payments and as payment in lieu of base salary, bonus, fees or other cash compensation otherwise payable to any individual who is eligible to receive awards. The plan administrator will determine the terms and conditions of other stock or cash-based awards, which may include vesting conditions based on continued service, performance and/or other conditions.

Performance Awards

Performance awards include any of the foregoing awards that are granted subject to vesting and/or payment based on the attainment of specified performance goals or other criteria the plan administrator may determine, which may or may not be objectively determinable. Performance criteria upon which performance goals are established by the plan administrator may include: net earnings or losses (either before or after one or more of interest, taxes, depreciation, amortization and non-cash equity-based compensation expense); gross or net sales or revenue or sales or revenue growth; net income (either before or after taxes) or adjusted net income; profits (including, but not limited to, gross profits, net profits, profit growth, net operation profit or economic profit), profit return ratios or operating margin; budget or operating earnings (either before or after taxes or before or after allocation of corporate overhead and bonus); cash flow (including operating cash flow and free cash flow or cash flow return on capital); return on assets; return on capital or invested capital; cost of capital; return on stockholders’ equity; total stockholder return; return on sales; costs, reductions in costs and cost control measures; expenses; working capital; earnings or loss per share; adjusted earnings or loss per share; price per share or dividends per share (or appreciation in or maintenance of such price or dividends); regulatory achievements or compliance; implementation, completion or attainment of objectives relating to research, development, regulatory, commercial or strategic milestones or developments; market share; economic value or economic value added models; division, group or corporate financial goals; customer satisfaction/growth; customer service; employee satisfaction; recruitment and maintenance of personnel; human resources
management; supervision of litigation and other legal matters; strategic partnerships and transactions; financial ratios (including those measuring liquidity, activity, profitability or leverage); debt levels or reductions; sales-related goals; financing and other capital raising transactions; cash on hand; acquisition activity; investment sourcing activity; and marketing initiatives, any of which may be measured in absolute terms or as compared to any incremental increase or decrease. Such performance goals also may be based solely by reference to our performance or the performance of a subsidiary, division, business segment or business unit, or based upon performance relative to performance of other companies or upon comparisons of any of the indicators of performance relative to performance of other companies.

Provisions of the 2020 Plan Relating to Director Compensation

The 2020 Plan provides that the plan administrator may establish compensation for non-employee directors from time to time subject to the 2020 Plan’s limitations. Prior to this offering, our stockholders will approve the initial terms of our non-employee director compensation program, which is described below under the heading “Director Compensation.” Our board of directors or its authorized committee may modify the non-employee director compensation program from time to time in the exercise of its business judgment, taking into account such factors, circumstances and considerations as it shall deem relevant from time to time, provided that the sum of any cash compensation or other compensation and the grant date fair value (as determined in accordance with ASC 718, or any successor thereto) of any equity awards granted as compensation for services as a non-employee director during any fiscal year may not exceed $\text{X}$, increased to $\text{Y}$ in the fiscal year of a non-employee director’s initial service as a non-employee director. The plan administrator may make exceptions to this limit for individual non-employee directors in extraordinary circumstances, as the plan administrator may determine in its discretion, provided that the non-employee director receiving such additional compensation may not participate in the decision to award such compensation or in other contemporaneous compensation decisions involving non-employee directors.

Certain Transactions

In connection with certain transactions and events affecting our common stock, including a change in control, or change in any applicable laws or accounting principles, the plan administrator has broad discretion to take action under the 2020 Plan to prevent the dilution or enlargement of intended benefits, facilitate such transaction or event, or give effect to such change in applicable laws or accounting principles. This includes canceling awards in exchange for either an amount in cash or other property with a value equal to the amount that would have been obtained upon exercise or settlement of the vested portion of such award or realization of the participant’s rights under the vested portion of such award, accelerating the vesting of awards, providing for the assumption or substitution of awards by a successor entity, adjusting the number and type of shares available, replacing awards with other rights or property or terminating awards under the 2020 Plan. In the event of a change in control where the acquirer does not assume awards granted under the 2020 Plan, awards issued under the 2020 Plan may be subject to accelerated vesting such that 100% of the awards will become vested and exercisable or payable, as applicable. In addition, in the event of certain non-reciprocal transactions with our stockholders (an equity restructuring) the plan administrator will make equitable adjustments to the 2020 Plan and outstanding awards as it deems appropriate to reflect the equity restructuring.

For purposes of the 2020 Plan, a “change in control” means and includes each of the following:

- a transaction or series of transactions whereby any “person” or related “group” of “persons” (as such terms are used in Sections 13(d) and 14(d)(2) of the Exchange Act) (other than our company or our subsidiaries or any employee benefit plan maintained by us or any of our subsidiaries or a “person” that, prior to such transaction, directly or indirectly controls, is controlled by, or is under common control with, us) directly or indirectly acquires beneficial ownership (within the meaning of Rule 13d-3 under the Exchange Act) of our securities possessing more than 50% of the total combined voting power of our securities outstanding immediately after such acquisition; or
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• during any period of two consecutive years, individuals who, at the beginning of such period, constitute our board of directors together with any new directors (other than a director designated by a person who shall have entered into an agreement with us to effect a change in control transaction) whose election by our board of directors or nomination for election by our stockholders was approved by a vote of at least two-thirds of the directors then still in office who either were directors at the beginning of the two-year period or whose election or nomination for election was previously so approved, cease for any reason to constitute a majority thereof; or
• the consummation by us (whether directly or indirectly) of (x) a merger, consolidation, reorganization, or business combination or (y) a sale or other disposition of all or substantially all of our assets in any single transaction or series of related transactions or (z) the acquisition of assets or stock of another entity, in each case other than a transaction:
  • which results in our voting securities outstanding immediately before the transaction continuing to represent either by remaining outstanding or by being converted into voting securities of the company or the person that, as a result of the transaction, controls, directly or indirectly, the company or owns, directly or indirectly, all or substantially all of our assets or otherwise succeeds to our business, directly or indirectly, at least a majority of the combined voting power of the successor entity’s outstanding voting securities immediately after the transaction, and
  • after which no person or group beneficially owns voting securities representing 50% or more of the combined voting power of the successor entity; provided, however, that no person or group shall be treated as beneficially owning 50% or more of the combined voting power of the successor entity solely as a result of the voting power held in our company prior to the consummation of the transaction.

Foreign Participants, Claw-back Provisions, Transferability and Participant Payments

With respect to foreign participants, the plan administrator may modify award terms, establish subplans and/or adjust other terms and conditions of awards, subject to the share limits described above. All awards will be subject to the provisions of any claw-back policy implemented by our company to the extent set forth in such claw-back policy or in the applicable award agreement. With limited exceptions for estate planning, domestic relations orders, certain beneficiary designations and the laws of descent and distribution, awards under the 2020 Plan are generally non-transferable prior to vesting and are exercisable only by the participant. With regard to tax withholding obligations arising in connection with awards under the 2020 Plan and exercise price obligations arising in connection with the exercise of stock options under the 2020 Plan, the plan administrator may, in its discretion, accept cash, wire transfer, or check, shares of our common stock that meet specified conditions (a market sell order) or such other consideration as it deems suitable or any combination of the foregoing.

Plan Amendment and Termination

Our board of directors may amend or terminate the 2020 Plan at any time; however, except in connection with certain changes in our capital structure, stockholder approval will be required for any amendment that increases the number of shares available under the 2020 Plan. The plan administrator will have the authority, without the approval of our stockholders, to amend any outstanding stock option or SAR to reduce its exercise or base price per share. No award may be granted pursuant to the 2020 Plan after the tenth anniversary of the date on which our board of directors adopts the 2020 Plan.

Securities Laws

The 2020 Plan is intended to conform to all provisions of the Securities Act, the Exchange Act and any and all regulations and rules promulgated by the SEC thereunder, including, without limitation, Exchange Act Rule 16b-3. The 2020 Plan will be administered, and awards will be granted and may be exercised, only in such a manner as to conform to such laws, rules and regulations.
Federal Income Tax Consequences

The material federal income tax consequences of the 2020 Plan under current federal income tax law are summarized in the following discussion, which deals with the general U.S. federal income tax principles applicable to the 2020 Plan. The following discussion is based upon laws, regulations, rulings and decisions now in effect, all of which are subject to change. Foreign, state and local tax laws, and employment, estate and gift tax considerations are not discussed due to the fact that they may vary depending on individual circumstances and from locality to locality.

Stock options and SARs. A 2020 Plan participant generally will not recognize taxable income and we generally will not be entitled to a tax deduction upon the grant of a stock option or SAR. The tax consequences of exercising a stock option and the subsequent disposition of the shares received upon exercise will depend upon whether the option qualifies as an ISO or an NSO. Upon exercising an NSO when the fair market value of our stock is higher than the exercise price of the option, a 2020 Plan participant generally will recognize taxable income at ordinary income tax rates equal to the excess of the fair market value of the stock on the date of exercise over the purchase price, and we (or our subsidiaries, if any) generally will be entitled to a corresponding tax deduction for compensation expense, in the amount equal to the amount by which the fair market value of the shares purchased exceeds the purchase price for the shares. Upon a subsequent sale or other disposition of the option shares, the participant will recognize a short-term or long-term capital gain or loss in the amount of the difference between the sales price of the shares and the participant’s tax basis in the shares.

Upon exercising an ISO, a 2020 Plan participant generally will not recognize taxable income, and we will not be entitled to a tax deduction for compensation expense. However, upon exercise, the amount by which the fair market value of the shares purchased exceeds the purchase price will be an item of adjustment for alternative minimum tax purposes. The participant will recognize taxable income upon a sale or other taxable disposition of the option shares. For federal income tax purposes, dispositions are divided into two categories: qualifying and disqualifying. A qualifying disposition generally occurs if the sale or disposition is made more than two years after the date the option was granted and more than one year after the date the shares are transferred upon exercise. If the sale or disposition occurs before these two periods are satisfied, then a disqualifying disposition generally will result.

Upon a qualifying disposition of ISO shares, the participant will recognize long-term capital gain in an amount equal to the excess of the amount realized upon the sale or other disposition of the shares over their purchase price. If there is a disqualifying disposition of the shares, then the excess of the fair market value of the shares on the exercise date (or, if less, the price at which the shares are sold) over their purchase price will be taxable as ordinary income to the participant. If there is a disqualifying disposition in the same year of exercise, it eliminates the item of adjustment for alternative minimum tax purposes. Any additional gain or loss recognized upon the disposition will be recognized as a capital gain or loss by the participant.

We will not be entitled to any tax deduction if the participant makes a qualifying disposition of ISO shares. If the participant makes a disqualifying disposition of the shares, we should be entitled to a tax deduction for compensation expense in the amount of the ordinary income recognized by the participant.

Upon exercising or settling a SAR, a 2020 Plan participant will recognize taxable income at ordinary income tax rates, and we should be entitled to a corresponding tax deduction for compensation expense, in the amount paid or value of the shares issued upon exercise or settlement. Payments in shares will be valued at the fair market value of the shares at the time of the payment, and upon the subsequent disposition of the shares the participant will recognize a short-term or long-term capital gain or loss in the amount of the difference between the sales price of the shares and the participant’s tax basis in the shares.

Restricted stock and RSUs. A 2020 Plan participant generally will not recognize taxable income at ordinary income tax rates and we generally will not be entitled to a tax deduction upon the grant of restricted stock or
RSUs. Upon the termination of restrictions on restricted stock or the payment of RSUs, the participant will recognize taxable income at ordinary income tax rates, and we should be entitled to a corresponding tax deduction for compensation expense, in the amount paid to the participant or the amount by which the then fair market value of the shares received by the participant exceeds the amount, if any, paid for them. Upon the subsequent disposition of any shares, the participant will recognize a short-term or long-term capital gain or loss in the amount of the difference between the sales price of the shares and the participant’s tax basis in the shares. However, a 2020 Plan participant granted restricted stock that is subject to forfeiture or repurchase through a vesting schedule such that it is subject to a risk of forfeiture (as defined in Section 83 of the Internal Revenue Code) may make an election under Section 83(b) of the Internal Revenue Code to recognize taxable income at ordinary income tax rates, at the time of the grant, in an amount equal to the fair market value of the shares of common stock on the date of grant, less the amount paid, if any, for the shares. We will be entitled to a corresponding tax deduction for compensation, in the amount recognized as taxable income by the participant. If a timely Section 83(b) election is made, the participant will not recognize any additional ordinary income on the termination of restrictions on restricted stock, and we will not be entitled to any additional tax deduction.

*Other stock or cash-based awards.* A 2020 Plan participant will not recognize taxable income and we will not be entitled to a tax deduction upon the grant of other stock or cash-based awards until cash or shares are paid or distributed to the participant. At that time, any cash payments or the fair market value of shares that the participant receives will be taxable to the participant at ordinary income tax rates and we should be entitled to a corresponding tax deduction for compensation expense. Payments in shares will be valued at the fair market value of the shares at the time of the payment. Upon the subsequent disposition of the shares, the participant will recognize a short-term or long-term capital gain or loss in the amount of the difference between the sales price of the shares and the participant’s tax basis in the shares.

**2017 Equity Incentive Plan**

Our board of directors adopted the 2017 Plan in September 2017 and our stockholders approved our 2017 Plan in September 2017. Our 2017 Plan was most recently amended by our board of directors and our stockholders in March 2020.

**Stock Awards**

Our 2017 Plan provides for the grant of ISOs (within the meaning of Section 422 of the Internal Revenue Code) to employees, including employees of any parent or subsidiary, and for the grant of NSOs, restricted stock awards, RSUs, and other stock-based awards to employees, directors and consultants.

**Authorized Shares**

Subject to certain adjustments, awards may be made under the 2017 Plan covering up to 22,500,000 shares of common stock. Shares subject to stock awards granted under our 2017 Plan that expire, lapse or are terminated, surrendered, cancelled without having been fully exercised or that are forfeited or repurchased, in any case in a manner that results in any shares of common stock covered by the award not being issued or being so reacquired, then those shares will again become available for issuance under the 2017 Plan. This includes shares used to pay the exercise price of a stock award or to satisfy the tax withholding obligations related to a stock award.

As of June 30, 2020, 15,382,110 shares of our common stock were subject to outstanding awards under the 2017 Plan and 4,960,404 shares of our common stock remained available for future issuance under the 2017 Plan. We expect that any shares remaining available for issuance under the 2017 Plan will become available for issuance under the 2020 Plan in connection with this offering.
Plan Administration

Our board of directors, or a duly authorized committee of our board of directors to which the board delegates its administrative authority, administers our 2017 Plan and is referred to as the plan administrator herein. Under our 2017 Plan, the plan administrator has the authority to, among other things, select the persons to whom awards are to be made, to determine the type or types of awards to be granted to each person, determine the number of awards to grant, determine the number of shares to be subject to awards, and the terms and conditions of awards, and make all other determinations and decisions and to take all other actions necessary or advisable for the administration of the 2017 Plan. The plan administrator is also authorized to establish, adopt, amend or revise rules relating to administration of the 2017 Plan, subject to certain restrictions.

Stock Options

ISOs and NSOs are granted under stock option agreements adopted by the plan administrator. The plan administrator determines the exercise price for stock options, within the terms and conditions of the 2017 Plan, provided that the exercise price of a stock option generally cannot be less than 100% of the fair market value of our common stock on the date of grant (or 110% of the fair market value for certain major stockholders). Options granted under the 2017 Plan vest at the rate specified in the stock option agreement, as determined by the plan administrator.

The plan administrator determines the term of stock options granted under the 2017 Plan, up to a maximum of ten years (or five years, for certain major stockholders).

Acceptable consideration for the purchase of common stock issued upon the exercise of a stock option will be determined by the plan administrator and may include (1) cash or check, (2) an irrevocable and unconditional undertaking by a broker or a copy of an irrevocable or unconditional instruction to a broker, (3) shares of our common stock owned by the optionholder, (4) shares of our common stock then issuable upon exercise of the option, (5) a promissory note, (6) property of any other kind, or (7) any combination of the above permitted forms of payment.

Unless the plan administrator provides otherwise, options generally are not transferable except by will or the laws of descent and distribution.

Tax Limitations on ISOs. The aggregate fair market value, determined at the time of grant, of our common stock with respect to ISOs that are exercisable for the first time by an optionholder during any calendar year under all of our stock plans may not exceed $100,000. Options or portions thereof that exceed such limit will generally be treated as NSOs. No ISO may be granted to any person who, at the time of the grant, owns or is deemed to own stock possessing more than 10% of our total combined voting power or that of any of our affiliates unless (1) the option exercise price is at least 110% of the fair market value of the stock subject to the option on the date of grant, and (2) the term of the ISO does not exceed five years from the date of grant.

Restricted Stock Unit Awards

RSUs are granted under RSU award agreements adopted by the plan administrator. An RSU may be settled by cash or other property as set forth in the RSU award agreement. Additionally, dividend equivalents may be paid currently or credited to an account and may be settled in cash and/or shares of common stock.

Corporate Transactions

The plan administrator has broad discretion to equitably adjust the provisions of the 2017 Plan and the terms and conditions of existing and future awards, including with respect to aggregate number and type of shares subject to the 2017 Plan and awards granted pursuant to the 2017 Plan, to prevent the dilution or enlargement of
intended benefits and/or facilitate necessary or desirable changes in the event of certain transactions and events affecting our common stock, such as stock dividends, stock splits, mergers, acquisitions, consolidations and other corporate transactions. The plan administrator may also provide for the acceleration, cash-out, termination, assumption, substitution or conversion of awards in the event of a change in control or certain other unusual or nonrecurring events or transactions. In addition, in the event of certain non-reciprocal transactions with our stockholders (an equity restructuring) the plan administrator will make equitable adjustments to the 2017 Plan and outstanding awards as it deems appropriate to reflect the equity restructuring.

Change in Control. In the event of a change in control where the acquirer does not assume awards granted under the 2017 Plan, with respect to awards issued under the 2017 Plan held by persons who have not experienced a termination of service, the plan administrator may provide for accelerated vesting such that 100% of the awards will become vested and exercisable or payable, as applicable, immediately prior to the change in control. Under the 2017 Plan, a change of control is generally defined as: (i) a merger or consolidation of our company with or into any other corporation or other entity or person; (ii) a sale, lease, exchange or other transfer in one transaction or a series of related transactions of all or substantially all of our company’s assets; or (iii) any other transaction, including the sale by us of new shares of our capital stock or a transfer of existing shares of our capital stock, the result of which is that a third party that is not an affiliate of us or our stockholders (or a group of third parties not affiliated with us or our stockholders) immediately prior to such transaction acquires or holds capital stock representing a majority of our outstanding voting power immediately following such transaction; provided that the following events shall not constitute a “change in control” under the 2017 Plan: (a) a transaction (other than a sale of all or substantially all of our assets) in which the holders of our voting securities immediately prior to the merger or consolidation hold, directly or indirectly, at least a majority of the voting securities in the successor corporation or its parent immediately after the merger or consolidation; (b) a sale, lease, exchange or other transaction in one transaction or a series of related transactions of all or substantially all of our assets to an affiliate of ours; (c) an initial public offering of any of our securities; (d) a reincorporation solely to change our jurisdiction; or (e) a transaction undertaken for the primary purpose of creating a holding company that will be owned in substantially the same proportion by the persons who held our securities immediately before such transaction.

Plan Amendment or Termination

Our board of directors has the authority to amend, suspend or terminate the 2017 Plan, provided that such action does not materially and adversely affect any award outstanding without the affected participant’s consent. Stockholder approval of any amendment to the 2017 Plan will be obtained to the extent necessary and desirable to comply with any applicable law. Unless terminated sooner, the 2017 Plan will automatically terminate in September 2027.

Securities Laws and Federal Income Tax Consequences

The 2017 Plan is designed to comply with applicable securities laws in the same manner as described above in the description of the 2020 Plan under the heading “—2020 Incentive Award Plan—Securities Laws.” The general U.S. federal income tax consequences of awards under the 2017 Plan are the same as those described above with respect to similar awards in the description of the 2020 Plan under the heading “—2020 Incentive Award Plan—Federal Income Tax Consequences.”

2020 Employee Stock Purchase Plan

In connection with this offering, we intend to adopt and ask our stockholders to approve a 2020 Employee Stock Purchase Plan, or the ESPP, which would become effective in connection with this offering. The material terms of the ESPP, as it is currently contemplated, are summarized below. Our board of directors is still in the process of developing, approving and implementing the ESPP and, accordingly, this summary is subject to change.
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Shares available; administration. A total of  Shares of our common stock are initially reserved for issuance under our ESPP. In addition, the number of shares available for issuance under the ESPP will be increased on January 1 of each calendar year beginning in 2021 and ending in 2030, by an amount equal to the lesser of: (a) 1% of the shares outstanding on the final day of the immediately preceding calendar year and (b) such smaller number of shares as is determined by our board of directors. In no event will more than  Shares of our common stock be available for issuance under the ESPP.

Our board of directors or its compensation committee will have authority to interpret the terms of the ESPP and determine eligibility of participants. We expect that the compensation committee will be the initial plan administrator of the ESPP.

Eligibility. Our employees are eligible to participate in the ESPP if they meet the eligibility requirements under the ESPP established from time to time by the plan administrator. However, an employee may not be granted rights to purchase stock under our ESPP if that employee, immediately after the grant, would own (directly or through attribution) stock possessing 5% or more of the total combined voting power or value of all classes of our common or other class of stock.

Grant of rights. The ESPP is intended to qualify under Section 423 of the Internal Revenue Code. Shares of our common stock will be offered under the ESPP during offering periods established by the plan administrator. The length of the offering periods under the ESPP will be determined by the plan administrator and may be up to 27 months long. Employee payroll deductions will be used to purchase shares on each purchase date during an offering period. The number of purchase periods within, and purchase dates during, each offering period will be established by the plan administrator prior to the commencement of each offering period. Offering periods under the ESPP will commence when determined by the plan administrator. The plan administrator may, in its discretion, modify the terms of future offering periods.

The ESPP permits participants to purchase our common stock through payroll deductions of up to  % of their eligible compensation, which includes a participant’s gross base compensation for services to us, including overtime payments, but excluding sales commissions, incentive compensation, bonuses, expense reimbursements, fringe benefits and other special payments. The plan administrator will establish a maximum number of shares that may be purchased by a participant during any offering period, which, in the absence of a contrary designation, will be  Shares. In addition, no employee will be permitted to accrue the right to purchase stock under the ESPP at a rate in excess of $25,000 worth of shares during any calendar year during which such a purchase right is outstanding (based on the fair market value per share of our common stock as of the first day of the offering period).

On the first trading day of each offering period, each participant will automatically be granted an option to purchase shares of our common stock. The option will be exercised on the applicable purchase date(s) during the offering period, to the extent of the payroll deductions accumulated during the applicable purchase period. The purchase price of the shares, in the absence of a contrary determination by the plan administrator, will be 85% of the lower of the fair market value of our common stock on (a) the first trading day of the offering period or (b) the applicable purchase date, which will be the final trading day of the applicable purchase period. Participants may voluntarily end their participation in the ESPP at any time at least one week prior to the end of the applicable offering period (or such shorter or longer period specified by the plan administrator), and will be paid their accrued payroll deductions that have not yet been used to purchase shares of common stock. Participation ends automatically upon a participant’s termination of employment.

A participant may not transfer rights granted under the ESPP other than by will, the laws of descent and distribution or as otherwise provided under the ESPP.

Certain Transactions. In the event of certain transactions or events affecting our common stock, such as any stock dividend or other distribution, change in control, reorganization, merger, consolidation or other corporate
transaction, the plan administrator will make equitable adjustments to the ESPP and outstanding rights thereunder. In addition, in the event of the
foregoing transactions or events or certain significant transactions, including a change in control, the plan administrator may provide for (1) either the
replacement of outstanding rights with other rights or property or termination of outstanding rights in exchange for cash, (2) the assumption or
substitution of outstanding rights by the successor or survivor corporation or parent or subsidiary thereof, if any, (3) the adjustment in the number and
type of shares of stock subject to outstanding rights, (4) the use of participants’ accumulated payroll deductions to purchase stock on a new purchase
date prior to the next scheduled purchase date and termination of any rights under ongoing offering periods or (5) the termination of all outstanding
rights. Under the ESPP, a change in control has the same definition as given to such term in the 2020 Plan.

Plan amendment; Termination. The plan administrator may amend, suspend or terminate the ESPP at any time. However, stockholder approval of
any amendment to the ESPP must be obtained for any amendment which increases the aggregate number or changes the type of shares that may be sold
pursuant to rights under the ESPP, changes the corporations or classes of corporations whose employees are eligible to participate in the ESPP or
changes the ESPP in any manner that would cause the ESPP to no longer be an employee stock purchase plan within the meaning of Section 423(b)
of the Internal Revenue Code. The ESPP will terminate on the tenth anniversary of the date it is initially approved by our board of directors.

Securities Laws. The ESPP has been designed to comply with various securities laws in the same manner as described above in the description of
the 2020 Plan.

Federal Income Taxes. The material federal income tax consequences of the ESPP under current federal income tax law are summarized in the
following discussion, which deals with the general U.S. federal income tax principles applicable to the ESPP. The following discussion is based upon
laws, regulations, rulings and decisions now in effect, all of which are subject to change. Foreign, state and local tax laws, and employment, estate and
gift tax considerations are not discussed due to the fact that they may vary depending on individual circumstances and from locality to locality.

The ESPP, and the right of participants to make purchases thereunder, is intended to qualify under the provisions of Section 423 of the Internal
Revenue Code. Under the applicable Internal Revenue Code provisions, no income will be taxable to a participant until the sale or other disposition of
the shares purchased under the ESPP. This means that an eligible employee will not recognize taxable income on the date the employee is granted an
option under the ESPP (i.e., the first day of the offering period). In addition, the employee will not recognize taxable income upon the purchase of
shares. Upon such sale or disposition, the participant will generally be subject to tax in an amount that depends upon the length of time such shares are
held by the participant prior to disposing of them. If the shares are sold or disposed of more than two years from the first day of the offering period
during which the shares were purchased and more than one year from the date of purchase, or if the participant dies while holding the shares, the
participant (or his or her estate) will recognize ordinary income measured as the lesser of: (1) the excess of the fair market value of the shares at the time
of such sale or disposition over the purchase price; or (2) an amount equal to 15% of the fair market value of the shares as of the first day of the offering
period. Any additional gain will be treated as long-term capital gain. If the shares are held for the holding periods described above but are sold for a
price that is less than the purchase price, there is no ordinary income and the participating employee has a long-term capital loss for the difference
between the sale price and the purchase price.

If the shares are sold or otherwise disposed of before the expiration of the holding periods described above, the participant will recognize ordinary
income generally measured as the excess of the fair market value of the shares on the date the shares are purchased over the purchase price and we will
be entitled to a tax deduction for compensation expense in the amount of ordinary income recognized by the employee. Any additional gain or loss on
such sale or disposition will be long-term or short-term capital gain or loss, depending on how long the shares were held following the date they were
purchased by the participant prior to disposing of them. If the shares are
sold or otherwise disposed of before the expiration of the holding periods described above but are sold for a price that is less than the purchase price, the participant will recognize ordinary income equal to the excess of the fair market value of the shares on the date of purchase over the purchase price (and we will be entitled to a corresponding deduction), but the participant generally will be able to report a capital loss equal to the difference between the sales price of the shares and the fair market value of the shares on the date of purchase.

**Director Compensation**

From time to time, we have granted stock-based compensation to the non-employee members of our board of directors for their services as directors.

To date, we have not paid any cash compensation to the non-employee members of our board of directors for their service as directors, with the exception of Dr. Yamada and Dr. Sandborn. Dr. Yamada receives an annual cash fee of $100,000, paid monthly, for his service as Chairman of our board of directors. Dr. Sandborn was provided a $25,000 cash payment for his services during 2019.

We have provided stock-based compensation to certain of our non-employee directors. Dr. Sandborn is the only non-employee director who received an equity award during 2019. Effective November 7, 2019, we granted Dr. Sandborn options to purchase 100,000 shares of our common stock under our 2017 Plan as consideration for his service on our board of directors. Twenty-five percent of the options vest on the first anniversary of the date of grant and 1/48th of the options vest monthly thereafter, subject to Dr. Sandborn’s continuous service through each vesting date. The stock options have a ten-year term and an exercise price of $0.29 per share, which our board of directors determined was equal to the fair market value per share of our common stock on the date of grant.

In addition, we have reimbursed, and will continue to reimburse, our non-employee directors for their actual out-of-pocket costs and expenses incurred in connection with attending board meetings. Mark C. McKenna, our President and Chief Executive Officer, is also a member of our board of directors, but does not receive any additional compensation for his service as a director.

The following table summarizes compensation received by our non-employee directors during the year ended December 31, 2019. Messrs. McKenna and Glenn are excluded from the following table because they served as executive officers during 2019. Their compensation is included in the Summary Compensation Table above.

<table>
<thead>
<tr>
<th>Name</th>
<th>Fees Earned or Paid in Cash ($)</th>
<th>Option Awards ($)</th>
<th>Total ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grégory Behar</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Rolf J. Benirschke(2)</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Shlomo Melmed, M.B., Ch.B.</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Gerald T. Proehl(3)</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>William Sandborn, M.D.(4)</td>
<td>25,000</td>
<td>17,000</td>
<td>42,000</td>
</tr>
<tr>
<td>Mark Stenhouse</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Douglas Wall</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Shierley Widjaja</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Tadataka (Tachi) Yamada, M.D.</td>
<td>100,000</td>
<td>—</td>
<td>100,000</td>
</tr>
</tbody>
</table>

(1) Represents the grant date fair value of stock options to purchase shares of common stock of Prometheus Biosciences, Inc. computed in accordance with FASB ASC 718. See Note 8 to the consolidated financial statements for the fiscal year ended December 31, 2019 included with this prospectus for a description of the assumptions used in valuing our stock options.

(2) Mr. Benirschke resigned from our board of directors effective June 30, 2019, but continues to serve as an advisor to the company.
Mr. Proehl resigned from our board of directors effective March 27, 2020.

Dr. Sandborn is married to Allison Luo, our Chief Medical Officer. Dr. Luo’s compensation is described above under “Executive Compensation.”

The aggregate number of shares subject to stock options outstanding at December 31, 2019 for the individuals who served as non-employee directors during 2019 was as follows:

<table>
<thead>
<tr>
<th>Name</th>
<th>Number of Securities Underlying Options Outstanding at December 31, 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grégory Behar</td>
<td>—</td>
</tr>
<tr>
<td>Rolf J. Benirschke</td>
<td>150,000</td>
</tr>
<tr>
<td>Shlomo Melmed, M.B., Ch.B.</td>
<td>—</td>
</tr>
<tr>
<td>Gerald T. Proehl</td>
<td>400,000</td>
</tr>
<tr>
<td>William Sandborn, M.D.</td>
<td>100,000</td>
</tr>
<tr>
<td>Mark Stenhouse</td>
<td>400,000</td>
</tr>
<tr>
<td>Douglas Wall</td>
<td>150,000</td>
</tr>
<tr>
<td>Shierley Widjaja</td>
<td>—</td>
</tr>
<tr>
<td>Tadataka (Tachi) Yamada, M.D.</td>
<td>1,400,000</td>
</tr>
</tbody>
</table>

Dr. Sandborn also held 650,000 shares of common stock as of December 31, 2019, which shares were issued to him upon the early exercise of stock options granted to him prior to 2019, 290,625 of which remained restricted as of December 31, 2019.

In connection with this offering, we intend to adopt and ask our stockholders to approve the initial terms of our non-employee director compensation program. The material terms of the non-employee director compensation program, as it is currently contemplated, are summarized below. Our board of directors is still in the process of developing, approving and implementing the non-employee director compensation program and, accordingly, this summary is subject to change.

The non-employee director compensation policy will provide for annual retainers fees and/or equity awards for our non-employee directors. We expect each non-employee director will receive an annual retainer of $ . A non-employee director serving as the chair of the audit, compensation and nominating and corporate governance committees will receive additional annual retainers of $ , $ and $ , respectively. A non-employee director serving as a member of the audit, compensation and nominating and corporate governance committees will receive additional annual retainers of $ , $ and $ , respectively. The non-employee directors will also receive initial grants of options to purchase shares of our common stock, vesting over three years, upon election to the board of directors, and thereafter annual grants of options to purchase shares of our common stock, vesting on the first to occur of (1) the first anniversary of the grant date or (2) the next occurring annual meeting of our stockholders, in each case subject to the non-employee director’s continued service through the applicable vesting date. In addition, equity awards granted to our non-employee directors will vest upon a change in control of our company.

Compensation under our non-employee director compensation policy will be subject to the annual limits on non-employee director compensation set forth in the 2020 Plan, as described above. Our board of directors or its authorized committee may modify the non-employee director compensation program from time to time in the exercise of its business judgment, taking into account such factors, circumstances and considerations as it shall deem relevant from time to time, subject to the annual limit on non-employee director compensation set forth in the 2020 Plan. As provided in the 2020 Plan, our board of directors or its authorized committee may make exceptions to this limit for individual non-employee directors in extraordinary circumstances, as the board of directors or its authorized committee may determine in its discretion, provided that the non-employee director receiving such additional compensation may not participate in the decision to award such compensation or in other compensation decisions involving non-employee directors.
Limitations of Liability and Indemnification Matters

Our amended and restated certificate of incorporation and our amended and restated bylaws provide that we will indemnify our directors and officers to the fullest extent permitted by the Delaware General Corporation Law, which prohibits our amended and restated certificate of incorporation from limiting the liability of our directors for the following:

- any breach of the director’s duty of loyalty to us or our stockholders;
- acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- unlawful payment of dividends or unlawful stock repurchases or redemptions; or
- any transaction from which the director derived an improper personal benefit.

Our amended and restated certificate of incorporation and our amended and restated bylaws also provide that if Delaware law is amended to authorize corporate action further eliminating or limiting the personal liability of a director, then the liability of our directors will be eliminated or limited to the fullest extent permitted by Delaware law, as so amended. This limitation of liability does not apply to liabilities arising under the federal securities laws and does not affect the availability of equitable remedies such as injunctive relief or rescission.

Our amended and restated certificate of incorporation and our amended and restated bylaws also provide that we shall have the power to indemnify our employees and agents to the fullest extent permitted by law. Our amended and restated bylaws also permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in this capacity, regardless of whether our amended and restated bylaws would permit indemnification. We have obtained directors’ and officers’ liability insurance.

We have entered into separate indemnification agreements with our directors and executive officers, in addition to indemnification provided for in our amended and restated certificate of incorporation and amended and restated bylaws. These agreements, among other things, provide for indemnification of our directors and executive officers for expenses, judgments, fines and settlement amounts incurred by this person in any action or proceeding arising out of this person’s services as a director or executive officer or at our request. We believe that these provisions in our amended and restated certificate of incorporation and amended and restated bylaws and indemnification agreements are necessary to attract and retain qualified persons as directors and executive officers.

The above description of the indemnification provisions of our amended and restated certificate of incorporation, our amended and restated bylaws and our indemnification agreements is not complete and is qualified in its entirety by reference to these documents, each of which is filed as an exhibit to the registration statement of which this prospectus is a part.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might benefit us and our stockholders. A stockholder’s investment may be harmed to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions. Insofar as indemnification for liabilities under the Securities Act may be permitted to directors, officers or persons controlling us pursuant to the foregoing provisions, we have been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable. There is no pending litigation or proceeding naming any of our directors or officers as to which indemnification is being sought, nor are we aware of any pending or threatened litigation that may result in claims for indemnification by any director or officer.
CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS

The following includes a summary of transactions since January 1, 2017 to which we have been a party in which the amount involved exceeded or will exceed the lesser of $120,000 and one percent of the average of our total assets at year-end for the last two completed fiscal years, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described under “Executive and Director Compensation.” We also describe below certain other transactions with our directors, executive officers and stockholders.

Preferred Stock Financings

**Series B Convertible Preferred Stock Financings.** In November 2018, we entered into a Series B preferred stock purchase agreement, pursuant to which we sold to investors in an initial closing and subsequent closing in November 2018 and May 2019, respectively, in private placements, an aggregate of 26,666,667 shares of Series B convertible preferred stock. The per share purchase price was $0.75, and we received gross proceeds of approximately $20 million.

**Series C Convertible Preferred Stock Financings.** In June 2019, we entered into a Series C preferred stock purchase agreement, as amended in March 2020, pursuant to which we sold to investors in an initial closing and subsequent closing in June 2019 and March 2020, respectively, in a private placement, an aggregate of 53,063,500 shares of Series C convertible preferred stock, including shares issued to Nestlé Health Science US Holdings Inc. (NHS) and Société des Produits Nestlé S.A. (SPN) as part of our acquisition of PLI described below. The per share purchase price was $1.00, and we received gross proceeds of approximately $28.1 million from the sale of stock to investors, excluding NHS and SPN.

The following table sets forth the aggregate number of these securities acquired by the listed directors, executive officers or holders of more than 5% of our capital stock, or their affiliates. Each outstanding share of preferred stock, will convert into shares of common stock at a ratio of one-for-one immediately prior to the closing of this offering.

<table>
<thead>
<tr>
<th>Participants</th>
<th>Series B Preferred Shares</th>
<th>Series C Preferred Shares</th>
</tr>
</thead>
<tbody>
<tr>
<td>5% or Greater Stockholders(1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cedars-Sinai Medical Center</td>
<td>12,000,000</td>
<td>25,000,000</td>
</tr>
<tr>
<td>Société des Produits Nestlé S.A.(2)</td>
<td>—</td>
<td>16,450,000</td>
</tr>
<tr>
<td>Ascend Global Investment Fund SPC—Strategic Segregated Portfolio</td>
<td>10,084,791</td>
<td>—</td>
</tr>
<tr>
<td>Nestlé Health Science US Holdings Inc.(3)</td>
<td>—</td>
<td>8,550,000</td>
</tr>
<tr>
<td>Entities affiliated with Life Ventures(4)</td>
<td>2,666,667</td>
<td>2,000,000</td>
</tr>
<tr>
<td><strong>Officers and Directors</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tadataka Yamada, M.D.</td>
<td>133,334</td>
<td></td>
</tr>
</tbody>
</table>

(1) Additional details regarding these stockholders and their equity holdings are provided in the section titled “Principal Stockholders.”
(2) Represents securities acquired by SPN in connection with our acquisition of PLI.
(3) Represents 3,550,000 shares acquired by NHS in June 2019 and 5,000,000 shares acquired by NHS in June 2020 upon conversion of deferred purchase price from cash to stock, in connection with our acquisition of PLI.
(4) Represents securities acquired by Life Ventures I LP and Life Ventures II LP (collectively, Life Ventures). Douglas F. Wall, a member of our board of directors, is the Managing Member and Managing Director of Life Ventures.
Agreements with Cedars-Sinai

In September 2017 and March 2019, we and Cedars-Sinai, one of our 5% stockholders, entered into exclusive license agreements. Such agreements are described in “Business—Collaboration and License Agreement Overview—Our Collaboration with Cedars-Sinai Medical Center.” In May 2018, Prometheus Laboratories, Inc. and Cedars-Sinai entered into a reference laboratory services agreement, which agreement was amended in June 2019 and October 2019, under which we provide certain laboratory services to Cedars-Sinai on an ongoing basis. As more fully described below, we acquired Prometheus Laboratories in June 2019. During the year ended, December 31, 2019, Cedars-Sinai has paid us approximately $0.2 million for such services.

Shlomo Melmed, M.D., a member of our board of directors, is the Executive Vice President of Academic Affairs, Dean of the Medical Faculty and Professor of Medicine at Cedars-Sinai. James Laur, also a member of our board of directors, is the Vice President, Intellectual Property for Cedars-Sinai.

Acquisition of Prometheus Laboratories, Inc.

In June 2019, we, NHS and SPN entered into a stock purchase agreement whereby we acquired 100% of the issued and outstanding equity of PLI from NHS, as well as certain intellectual property rights from SPN. In consideration for the acquisition, we issued to NHS and SPN an aggregate of 25,000,000 shares of Series C convertible preferred stock in connection with our Series C convertible preferred stock financing described above (or approximately $25 million of stock based upon a fair market value of $1.00 per share). Under the terms of the agreement, we are also required to pay NHS $10 million on December 31, 2021. Grégory Behar, a member of our board of directors, is the Chief Executive Officer of NHS.

Registration Rights Agreement

We entered into an amended and restated investors’ rights agreement in November 2018, as amended and restated in June 2019, with the holders of our convertible preferred stock, including entities with which certain of our directors are affiliated. The registration rights agreement provides for certain rights relating to the registration of their shares of common stock issuable upon conversion of their convertible preferred stock and certain additional covenants made by us. Except for the registration rights (including the related provisions pursuant to which we have agreed to indemnify the parties to the investors’ rights agreement), all rights under this agreement will terminate upon closing of this offering. The registration rights will continue following this offering and will terminate seven years after the closing of this offering. See the section titled “Description of Capital Stock—Registration Rights” for more information regarding these registration rights.

Voting Agreement

We entered into an amended and restated voting agreement in November 2018, as amended and restated in March 2020, as further amended in August 2020, with the holders of our convertible preferred stock, including entities with which certain of our directors are affiliated, pursuant to which the following directors were each elected to serve as members on our board of directors and, as of the date of this prospectus, continue to so serve: Grégory Behar, Scott L. Glenn, James Laur, Mark C. McKenna, Shlomo Melmed, M.D., Joseph C. Papa, William Sandborn, M.D., Mark Stenhouse, Tadataka Yamada, M.D., Douglas F. Wall and Shierley Widjaja. Pursuant to the voting agreement, Mr. McKenna, as our Chief Executive Officer, serves on our board of directors as the CEO director. Mr. Behar, Mr. Laur and Dr. Melmed, Mr. Wall and Ms. Widjaja were initially selected to serve on our board of directors as representatives of the holders of our convertible preferred stock, as designated by NHS, Cedars-Sinai, Life Ventures and Ascend Global Investment Fund SPC—Strategic Segregated Portfolio, respectively. Mr. Glenn, Mr. Papa, Dr. Sandborn, Mr. Stenhouse and Dr. Yamada were initially selected to serve on our board of directors as representatives of the holders of our common stock and convertible preferred stock, as designated by a majority of our common and preferred stockholders, voting together as a single class.
The voting agreement will terminate upon the closing of this offering, and members previously elected to our board of directors pursuant to this agreement will continue to serve as directors until they resign, are removed or their successors are duly elected by holders of our common stock. The composition of our board of directors after this offering is described in more detail under “Management—Board Composition and Election of Directors.”

Equity Grants to Executive Officers and Directors

We have granted restricted stock and stock options to certain of our executive officers and non-employee directors, as more fully described in “Executive and Director Compensation” with respect to our NEOs and non-employee directors.

Employment Arrangements

We have entered into employment letter agreements with our executive officers. For more information regarding these letter agreements, see the section titled “Executive and Director Compensation—Employment Letter Agreements with our NEOs.”

Director and Officer Indemnification

We have entered into indemnification agreements with each of our directors and executive officers. These agreements, among other things, require us or will require us to indemnify each director (and in certain cases their related venture capital funds) and executive officer to the fullest extent permitted by Delaware law, including indemnification of expenses such as attorneys’ fees, judgments, fines and settlement amounts incurred by the director or executive officer in any action or proceeding, including any action or proceeding by or in right of us, arising out of the person’s services as a director or executive officer.

Our amended and restated certificate of incorporation and our amended and restated bylaws provide that we will indemnify each of our directors and officers to the fullest extent permitted by the Delaware General Corporation Law. Further, we have purchased a policy of directors’ and officers’ liability insurance that insures our directors and officers against the cost of defense, settlement or payment of a judgment under certain circumstances. For further information, see the section titled “Executive and Director Compensation—Limitations of Liability and Indemnification Matters.”

Other Arrangements

Connor Glenn, who is the child of Scott Glenn, who is currently a member of our board of directors and formerly our CEO, was a full-time employee of Prometheus from May 2018 to June 2020. In 2019 and 2020, Mr. Glenn received total cash compensation of $132,495 and $89,646. As of June 30, 2020 we are obligated to provide future severance payments of $121,800 in the aggregate. In connection with his separation, we entered into an agreement with Mr. Glenn, pursuant to which we agreed to provide accelerated vesting of his outstanding stock options.

Policies and Procedures for Related Person Transactions

Our board of directors will adopt a written related person transaction policy, to be effective upon the closing of this offering, setting forth the policies and procedures for the review and approval or ratification of related-person transactions. This policy will cover, with certain exceptions set forth in Item 404 of Regulation S-K under the Securities Act, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships in which we were or are to be a participant, where the amount involved exceeds the lesser of $120,000 or one percent of the average of our total assets at year-end for the last two completed fiscal years, and a related person had or will have a direct or indirect material interest, including, without limitation, purchases of goods or services by or from the related person or entities in which the related person has a material
interest, indebtedness, guarantees of indebtedness and employment by us of a related person. In reviewing and approving any such transactions, our audit committee is tasked to consider all relevant facts and circumstances, including, but not limited to, whether the transaction is on terms comparable to those that could be obtained in an arm’s length transaction and the extent of the related person’s interest in the transaction. All of the transactions described in this section occurred prior to the adoption of this policy.
The following table sets forth information with respect to the beneficial ownership of our common stock as of June 30, 2020, and as adjusted to reflect the sale of shares of common stock in this offering, by:

- our named executive officers;
- each of our directors;
- all of our executive officers and directors as a group; and
- each person or group of affiliated persons known by us to beneficially own more than 5% of our common stock.

The number of shares beneficially owned by each stockholder is determined under rules issued by the SEC. Under these rules, beneficial ownership includes any shares as to which a person has sole or shared voting power or investment power. Applicable percentage ownership is based on 111,239,386 shares of common stock outstanding on June 30, 2020, which gives effect to the automatic conversion of all outstanding shares of our convertible preferred stock into 94,709,367 shares of our common stock immediately prior to the closing of this offering and includes 1,764,870 shares subject to forfeiture or a right of repurchase. In computing the number of shares beneficially owned by a person and the percentage ownership of that person, shares of common stock subject to warrants, options or other rights held by such person that are currently exercisable or will become exercisable within 60 days of June 30, 2020 are considered outstanding, although these shares are not considered outstanding for purposes of computing the percentage ownership of any other person.

Unless otherwise indicated, the address of each beneficial owner listed below is c/o Prometheus Biosciences, Inc., 9410 Carroll Park Dr., San Diego, California 92121. We believe, based on information provided to us, that each of the stockholders listed below has sole voting and investment power with respect to the shares beneficially owned by the stockholder unless noted otherwise, subject to community property laws where applicable.

<table>
<thead>
<tr>
<th>Name of Beneficial Owner</th>
<th>Number of Shares Beneficially Owned</th>
<th>Percentage of Shares Beneficially Owned</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>5% or Greater Stockholders</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cedars-Sinai Medical Center(1)</td>
<td>43,925,000</td>
<td>39.5%</td>
</tr>
<tr>
<td>Entities affiliated with Nestlé S.A.(2)</td>
<td>25,000,000</td>
<td>22.5%</td>
</tr>
<tr>
<td>Ascend Global Investment Fund SPC—Strategic Segregated Portfolio(3)</td>
<td>16,084,791</td>
<td>14.5%</td>
</tr>
<tr>
<td>Entities affiliated with Life Ventures Management(4)</td>
<td>10,266,667</td>
<td>9.2%</td>
</tr>
<tr>
<td><strong>Executive Officers and Directors</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mark C. McKenna</td>
<td>—</td>
<td>*</td>
</tr>
<tr>
<td>Allison Luo, M.D.(5)</td>
<td>967,708</td>
<td>*</td>
</tr>
<tr>
<td>Lauren G. Otsuki(6)</td>
<td>1,500,000</td>
<td>1.3%</td>
</tr>
<tr>
<td>Tadataka Yamada, M.D.(7)</td>
<td>981,250</td>
<td>*</td>
</tr>
<tr>
<td>Grégory Behar</td>
<td>—</td>
<td>*</td>
</tr>
<tr>
<td>Scott L. Glenn(8)</td>
<td>5,007,285</td>
<td>4.5%</td>
</tr>
<tr>
<td>James Laur</td>
<td>—</td>
<td>*</td>
</tr>
<tr>
<td>Shlomo Melmed, M.D.</td>
<td>—</td>
<td>*</td>
</tr>
<tr>
<td>Joseph C. Papa(9)</td>
<td>4,166</td>
<td>*</td>
</tr>
<tr>
<td>William Sandborn, M.D.(10)</td>
<td>967,708</td>
<td>*</td>
</tr>
<tr>
<td>Mark Stenhouse(11)</td>
<td>225,000</td>
<td>*</td>
</tr>
<tr>
<td>Douglas F. Wall(4)(12)</td>
<td>10,369,792</td>
<td>9.3%</td>
</tr>
<tr>
<td>Shierley Widjaja(3)</td>
<td>16,084,791</td>
<td>14.5%</td>
</tr>
<tr>
<td>All executive officers and directors as a group (15 persons)(13)</td>
<td>36,368,116</td>
<td>32.1%</td>
</tr>
</tbody>
</table>

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* Less than 1%.

(1) Includes 43,925,000 shares held by Cedars-Sinai Medical Center. Thomas M. Priselac, the President and Chief Executive Officer of Cedars-Sinai Medical Center, and Edward M. Prunchunas, the Senior Vice President and Chief Financial Officer of Cedars-Sinai Medical Center, are deemed to share voting and dispositive power with respect to the shares held by Cedars-Sinai Medical Center.

(2) Includes (i) 8,550,000 shares of common stock held by NHS and (ii) 16,450,000 shares of common stock held by SPN. Each of (a) SPN, an indirect parent of NHS, (b) NIMCO US, Inc., or NIMCO, the direct parent of NHS, (c) Nestlé US Holdco, Inc., or Nestlé US Holdco, an indirect parent of NHS, and (d) Nestlé S.A. a publicly traded company and the ultimate parent of each of NHS, NIMCO, Nestlé US Holdco and SPN, has shared voting power and shared dispositive power with respect to the 8,550,000 shares held by NHS. Each of (x) SPN and (y) Nestlé S.A. has shared voting power and shared dispositive power with respect to the 16,450,000 shares held by SPN. The principal executive office of NHS, NIMCO and Nestlé US Holdco is 1812 North Moore Street, Arlington, VA 22209 and the principal executive office of SPN and Nestlé S.A. is Avenue Nestlé 55, CH-1800, Vevey Switzerland.

(3) Consists of 16,084,791 shares of common stock held by Ascend Global Investment Fund SPC – Strategic Segregated Portfolio, or Ascend Global. Ascend Global is managed by Ascend Capital Advisors (S) Pte. Ltd, or Ascend Capital. SJE Investments is an adviser of Ascend Capital. Ms. Widjaja is an Executive Director and Chief Investment Officer of SJE Investments and as such may be deemed to beneficially own such shares. Ms. Widjaja disclaims beneficial ownership of such shares except to the extent of any pecuniary interest therein.

(4) Includes (i) 7,133,333 shares of common stock held by Life Ventures I LP and (ii) 3,133,334 shares of common stock held by Life Ventures II LP (collectively with Life Ventures I LP, the Life Ventures Funds). Mr. Wall is the Managing Member and Managing Director of Life Ventures Management, LLC, the general partner of the Life Ventures Funds, and as such has voting and investment power over the shares held by the Life Ventures Funds. Mr. Wall disclaims beneficial ownership of such shares except to the extent of any pecuniary interest therein.

(5) Consists of (i) 250,000 shares of common stock held by Dr. Luo, (ii) 67,708 shares of common stock underlying options held by Dr. Luo that are exercisable as of June 30, 2020 or that will become exercisable within 60 days after such date, and (iii) 650,000 shares of common stock held by Dr. Sandborn, Dr. Luo’s spouse.

(6) Consists of 1,500,000 shares of common stock held by a family trust. Ms. Otsuki and her spouse, Christopher W. Blake are co-trustees of the family trust and in such capacity have joint power to vote and dispose of such shares.

(7) Consists of (i) 133,334 shares of common stock held by Dr. Yamada and (ii) 847,917 shares of common stock underlying options held by Dr. Yamada that are exercisable as of June 30, 2020 or that will become exercisable within 60 days after such date.

(8) Consists of (i) 500,000 shares of common stock held by Mr. Glenn’s spouse, Susan Nancarrow, (ii) 3,600,000 shares of common stock held by a family trust, (iii) 193,000 shares of common stock held by Glenn Holdings, L.P., and (iv) 714,285 shares of common stock underlying options held by Mr. Glenn that are exercisable as of June 30, 2020 or that will become exercisable within 60 days after such date. Mr. Glenn and Ms. Nancarrow are co-trustees of both the family trusts and in such capacity have joint power to vote and dispose of such shares. Mr. Glenn is the general partner of Glenn Holdings, L.P. and as such may be deemed to beneficially own such shares. Mr. Glenn disclaims beneficial ownership of such shares except to the extent of any pecuniary interest therein.

(9) Consists of 4,166 shares of common stock underlying options held by Mr. Papa that are exercisable as of June 30, 2020 or that will become exercisable within 60 days after such date.

(10) Consists of (i) 650,000 shares of common stock held by Dr. Sandborn, (ii) 250,000 shares of common stock held by Dr. Luo, Dr. Sandborn’s spouse, and (ii) 67,708 shares of common stock underlying options held by Dr. Luo that are exercisable as of June 30, 2020 or that will become exercisable within 60 days after such date.
(11) Consists of 225,000 shares of common stock underlying options held by Mr. Stenhouse that are exercisable as of June 30, 2020 or that will become exercisable within 60 days after such date.

(12) Includes 103,125 shares of common stock underlying options held by Mr. Wall that are exercisable as of June 30, 2020 or that will become exercisable within 60 days after such date.

(13) Consists of (i) the shares described in footnotes 3 through 12 above and (ii) 260,416 shares of common stock underlying options held by Laurens Kruidenier, our Chief Scientific Officer, that are exercisable as of June 30, 2020 or that will become exercisable within 60 days after such date.
DESCRIPTION OF CAPITAL STOCK

General

The following description summarizes some of the terms of our amended and restated certificate of incorporation and amended and restated bylaws, the investors’ rights agreement and of the Delaware General Corporation Law. Because it is only a summary, it does not contain all the information that may be important to you. For a complete description you should refer to our amended and restated certificate of incorporation, amended and restated bylaws and registration rights agreement, copies of which have been filed as exhibits to the registration statement of which this prospectus is a part.

Following the closing of this offering, our authorized capital stock will consist of shares of common stock, $0.0001 par value per share, and shares of preferred stock, $0.0001 par value per share.

Common Stock

As of June 30, 2020, there were 111,239,386 shares of our common stock outstanding and held of record by 31 stockholders, including 1,764,870 shares of restricted common stock which are subject to forfeiture or our right of repurchase, after giving effect to the automatic conversion of all outstanding shares of our convertible preferred stock into 94,709,367 shares of common stock, which will automatically occur immediately prior to the closing of this offering. Based on the number of shares of common stock outstanding as of June 30, 2020, and further assuming the issuance by us of shares of common stock in this offering, there will be shares of common stock outstanding upon the closing of this offering.

Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders, including the election of directors, and do not have cumulative voting rights. Accordingly, the holders of a majority of the outstanding shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they so choose, other than any directors that holders of any preferred stock we may issue may be entitled to elect. Subject to the supermajority votes for some matters, other matters shall be decided by the affirmative vote of our stockholders having a majority in voting power of the votes cast by the stockholders present or represented and voting on such matter. Our amended and restated certificate of incorporation and amended and restated bylaws also provide that our directors may be removed only for cause and only by the affirmative vote of the holders of at least two-thirds in voting power of the outstanding shares of capital stock entitled to vote thereon. In addition, the affirmative vote of the holders of at least two-thirds in voting power of the outstanding shares of capital stock entitled to vote thereon is required to amend or repeal, or to adopt any provision inconsistent with, several of the provisions of our amended and restated certificate of incorporation. See below under the heading “—Anti-Takeover Effects of Delaware Law and Our Certificate of Incorporation and Bylaws—Amendment of Charter Provisions.”

Subject to preferences that may be applicable to any then outstanding preferred stock, holders of common stock are entitled to receive ratably those dividends, if any, as may be declared by the board of directors out of legally available funds. In the event of our liquidation, dissolution or winding up, the holders of common stock will be entitled to share ratably in the assets legally available for distribution to stockholders after the payment of or provision for all of our debts and other liabilities, subject to the prior rights of any preferred stock then outstanding. Holders of common stock have no preemptive or conversion rights or other subscription rights and there are no redemption or sinking funds provisions applicable to the common stock. All outstanding shares of common stock are, and the common stock to be outstanding upon the closing of this offering will be, duly authorized, validly issued, fully paid and nonassessable. The rights, preferences and privileges of holders of common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

Preferred Stock

Upon the closing of this offering, all of our previously outstanding shares of convertible preferred stock will have been converted into common stock, there will be no authorized shares of our previously outstanding
We will not have any shares of preferred stock outstanding. Under the terms of our amended and restated certificate of incorporation, our board of directors has the authority, without further action by our stockholders, to issue up to shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the dividend, voting and other rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon, and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding.

Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of the common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deterring or preventing a change in our control and may adversely affect the market price of the common stock and the voting and other rights of the holders of common stock. We have no current plans to issue any shares of preferred stock.

**Warrants**

On January 24, 2020, in connection with our Loan Agreement with Oxford, we issued Oxford a warrant to purchase 112,500 Series C convertible preferred stock at an exercise price of $1.00 per share. In connection with this offering, the warrant will convert into a warrant to purchase 112,500 shares of common stock. The warrant contains a cashless exercise provision under which Oxford may, in lieu of payment of the exercise price in cash, surrender the warrant and receive a net amount of shares of our common stock based on the fair market value of our common stock at the time of the net exercise of the warrant after deduction of the aggregate exercise price. The warrant expires ten years from its date of issuance.

**Options**

As of June 30, 2020, options to purchase 15,382,110 shares of our common stock were outstanding, of which 2,544,271 were vested and exercisable as of that date. For additional information regarding the terms of our 2017 Plan, see the section titled “Executive and Director Compensation—Other Elements of Compensation—2017 Equity Incentive Plan.”

**Registration Rights**

As of June 30, 2020, upon the closing of this offering holders of shares of our common stock, which includes all of the shares of common stock issuable upon the automatic conversion convertible preferred stock immediately prior to the closing of this offering, will be entitled to the following rights with respect to the registration of such shares for public resale under the Securities Act, pursuant to investors’ rights agreement by and among us and certain investors. The registration of shares of common stock as a result of the following rights being exercised would enable holders to trade these shares without restriction under the Securities Act when the applicable registration statement is declared effective.

**Demand Registration Rights**

Form S-1. If at any time beginning six months following the effective date of the registration statement of which this prospectus forms a part, the holders of at least a majority of the registrable securities request in writing that we effect a registration with respect to all or a part of the registrable securities then outstanding where the aggregate price to the public of the offering is $10.0 million or more, we may be required to provide notice to all holders of registrable securities and to use commercially reasonable efforts to effect such registration; provided, however, that we will not be required to effect such a registration if, among other things, within the preceding 12 months, we have already effected two registrations for the holders of registrable securities in response to these demand registration rights.
Form S-3. If at any time we become entitled under the Securities Act to register our shares on Form S-3, the holders of the registrable securities request in writing that we effect a registration with respect to all or a part of the registrable securities then outstanding where the price to the public of the offering is $5.0 million or more, we may be required to provide notice to all holders of registrable securities and to use commercially reasonable efforts to effect such registration; provided, however, that we will not be required to effect such a registration if, among other things, within the preceding 12 months, we have already effected two registrations on Form S-3 for the holders of registrable securities.

If the holders requesting registration intend to distribute their shares by means of an underwriting, the underwriter of such offering will have the right to limit the numbers of shares to be underwritten for reasons related to the marketing of the shares.

Piggyback Registration Rights

If at any time following the closing of this offering we propose to register any shares of our common stock under the Securities Act, subject to certain exceptions, the holders of registrable securities will be entitled to notice of the registration and to include their shares of registrable securities in the registration. If our proposed registration involves an underwriting, the managing underwriter of such offering will have the right to limit the number of shares to be underwritten for reasons related to the marketing of the shares.

Indemnification

Our registration rights agreement contains customary cross indemnification provisions, under which we are obligated to indemnify holders of registrable securities in the event of material misstatements or omissions in a registration statement attributable to us, and they are obligated to indemnify us for material misstatements or omissions attributable to them.

Expenses

Ordinarily, other than underwriting discounts and commissions, we will be required to pay all expenses incurred by us related to any registration effected pursuant to the exercise of these registration rights. These expenses may include all registration and filing fees, printing expenses, fees and disbursements of our counsel, reasonable fees and disbursements of a counsel for the selling securityholders, blue sky fees and expenses and the expenses of any special audits incident to the registration.

Termination of Registration Rights

The registration rights terminate three years after the closing of this offering.

Anti-Takeover Effects of Delaware Law and Our Certificate of Incorporation and Bylaws

Some provisions of Delaware law, our amended and restated certificate of incorporation and our amended and restated bylaws contain provisions that could make the following transactions more difficult: an acquisition of us by means of a tender offer; an acquisition of us by means of a proxy contest or otherwise; or the removal of our incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interest or in our best interests, including transactions which provide for payment of a premium over the market price for our shares.

These provisions, summarized below, are intended to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of the increased protection of our potential
ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

Undesignated Preferred Stock

The ability of our board of directors, without action by the stockholders, to issue up to shares of undesignated preferred stock with voting or other rights or preferences as designated by our board of directors could impede the success of any attempt to change control of us. These and other provisions may have the effect of deflecting hostile takeovers or delaying changes in control or management of our company.

Stockholder Meetings

Our amended and restated bylaws provide that a special meeting of stockholders may be called only by our chairman of the board of directors, chief executive officer or president, or by a resolution adopted by a majority of our board of directors.

Requirements for Advance Notification of Stockholder Nominations and Proposals

Our amended and restated bylaws establish advance notice procedures with respect to stockholder proposals to be brought before a stockholder meeting and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of directors.

Elimination of Stockholder Action by Written Consent

Our amended and restated certificate of incorporation and amended and restated bylaws eliminate the right of stockholders to act by written consent without a meeting.

Staggered Board of Directors

Our amended and restated bylaws provides that our board of directors will be divided into three classes. The directors in each class will serve for a three-year term, with one class being elected each year by our stockholders. For more information on the classified board of directors, see “Management —Board Composition and Election of Directors.” This system of electing directors may tend to discourage a third party from attempting to obtain control of us, because it generally makes it more difficult for stockholders to replace a majority of the directors.

Removal of Directors

Our amended and restated certificate of incorporation provides that no member of our board of directors may be removed from office except for cause and, in addition to any other vote required by law, upon the approval of not less than two thirds of the total voting power of all of our outstanding voting stock then entitled to vote in the election of directors.

Stockholders Not Entitled to Cumulative Voting

Our amended and restated certificate of incorporation does not permit stockholders to cumulate their votes in the election of directors. Accordingly, the holders of a majority of the outstanding shares of our common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they choose, other than any directors that holders of our preferred stock may be entitled to elect.
Delaware Anti-Takeover Statute

We are subject to Section 203 of the Delaware General Corporation Law, which prohibits persons deemed to be “interested stockholders” from engaging in a “business combination” with a publicly held Delaware corporation for three years following the date these persons become interested stockholders unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. Generally, an “interested stockholder” is a person who, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation’s voting stock. Generally, a “business combination” includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. The existence of this provision may have an anti-takeover effect with respect to transactions not approved in advance by the board of directors.

Choice of Forum

Our amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative form, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of breach of a fiduciary duty or other wrongdoing by any of our directors, officers, employees or agents to us or our stockholders, creditors or other constituents; (iii) any action asserting a claim against us arising pursuant to any provision of the General Corporation Law of the State of Delaware or our amended and restated certificate of incorporation or amended and restated bylaws; (iv) any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or bylaws; or (v) any action asserting a claim governed by the internal affairs doctrine. The provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, our amended and restated certificate of incorporation will also provide that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint arising under the Securities Act. In any case, stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder. The enforceability of similar choice of forum provisions in other companies’ certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. Our amended and restated certificate of incorporation also provides that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock will be deemed to have notice of and to have consented to this choice of forum provision.

Amendment of Charter Provisions

The amendment of any of the above provisions, except for the provision making it possible for our board of directors to issue preferred stock, would require approval by holders of at least two thirds of the total voting power of all of our outstanding voting stock.

The provisions of Delaware law, our amended and restated certificate of incorporation and our amended and restated bylaws could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in the composition of our board of directors and management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock will be . The transfer agent and registrar’s address is .

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Nasdaq Listing

We intend to apply to have our common stock listed on Nasdaq under the symbol “RXDX.”

Limitations of Liability and Indemnification Matters

For a discussion of liability and indemnification, see the section titled “Executive and Director Compensation—Limitations of Liability and Indemnification Matters.”
SHARES ELIGIBLE FOR FUTURE SALE

Immediately prior to this offering, there was no public market for our common stock. Future sales of substantial amounts of common stock in the public market, or the perception that such sales may occur, could adversely affect the market price of our common stock. Although we intend to apply to have our common stock listed on Nasdaq, we cannot assure you that there will be an active public market for our common stock.

Based on the number of shares of our common stock outstanding as of June 30, 2020, and assuming (i) the issuance of shares in this offering, (ii) the automatic conversion of all of our outstanding shares of convertible preferred stock into 94,709,367 shares of common stock and the related reclassification of the carrying value of the convertible preferred stock to permanent equity upon the closing of this offering, (iii) no exercise of the underwriters’ option to purchase additional shares of common stock and (iv) no exercise or vesting of outstanding options, warrants or other rights, we will have outstanding an aggregate of shares of common stock.

Of these shares, all shares sold in this offering will be freely tradable without restriction or further registration under the Securities Act, except for any shares purchased by our “affiliates,” as that term is defined in Rule 144 under the Securities Act. Shares purchased by our affiliates would be subject to the Rule 144 resale restrictions described below, other than the holding period requirement.

The remaining shares of common stock will be “restricted securities,” as that term is defined in Rule 144 under the Securities Act. These restricted securities are eligible for public sale only if they are registered under the Securities Act or if they qualify for an exemption from registration under Rule 144 or 701 under the Securities Act, each of which is summarized below. We expect that substantially all of these shares will be subject to the 180-day lock-up period under the lock-up agreements described below.

Lock-Up Agreements

We, our officers, directors and holders of substantially all of our securities have agreed with the underwriters that for a period of 180 days, after the date of this prospectus, subject to specified exceptions, we or they will not offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to sell, or otherwise dispose of or transfer any shares of common stock or any securities convertible into or exercisable or exchangeable for shares of common stock, request or demand that we file a registration statement related to our common stock or enter into any swap or other agreement that transfers to another, in whole or in part, directly or indirectly, the economic consequence of ownership of the common stock. Upon expiration of the lock-up period, certain of our stockholders will have the right to require us to register their shares under the Securities Act. See the section titled “—Registration Rights” below and “Description of Capital Stock—Registration Rights.”

SVB Leerink LLC and Credit Suisse Securities (USA) LLC may, in their sole discretion and at any time or from time to time before the termination of the lock-up period, in certain cases without public notice, release all or any portion of the securities subject to lock-up agreements. There are no existing agreements between the underwriters and any of our stockholders who will execute a lock-up agreement providing consent to the sale of shares prior to the expiration of the lock-up period.

Upon the expiration of the lock-up period, substantially all of the shares subject to such lock-up restrictions will become eligible for sale, subject to the limitations discussed above.

Rule 10b5-1 Trading Plans

Following the closing of this offering, certain of our officers, directors and significant stockholders may adopt written plans, known as Rule 10b5-1 trading plans, in which they will contract with a broker to buy or sell
shares of our common stock on a periodic basis to diversify their assets and investments. Under these 10b5-1 trading plans, a broker may execute trades pursuant to parameters established by the officer, director or stockholder when entering into the plan, without further direction from such officer, director or stockholder. Such sales would not commence until the expiration of the applicable lock-up agreements entered into by such officer, director or stockholder in connection with this offering.

Rule 144

Affiliate Resales of Restricted Securities

In general, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is an affiliate of ours, or who was an affiliate at any time during the 90 days before a sale, who has beneficially owned shares of our common stock for at least six months would be entitled to sell in “broker’s transactions” or certain “riskless principal transactions” or to market makers, a number of shares within any three-month period that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately shares immediately after this offering; or
- the average weekly trading volume in our common stock on Nasdaq during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Affiliate resales under Rule 144 are also subject to the availability of current public information about us. In addition, if the number of shares being sold under Rule 144 by an affiliate during any three-month period exceeds 5,000 shares or has an aggregate sale price in excess of $50,000, the seller must file a notice on Form 144 with the SEC and Nasdaq concurrently with either the placing of a sale order with the broker or the execution of a sale directly with a market maker.

Non-Affiliate Resales of Restricted Securities

In general, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is not an affiliate of ours at the time of sale, and has not been an affiliate at any time during the three months preceding a sale, and who has beneficially owned shares of our common stock for at least six months but less than a year, is entitled to sell such shares subject only to the availability of current public information about us. If such person has held our shares for at least one year, such person can resell under Rule 144(b)(1) without regard to any Rule 144 restrictions, including the 90-day public company requirement and the current public information requirement.

Non-affiliate resales are not subject to the manner of sale, volume limitation or notice filing provisions of Rule 144.

Rule 701

In general, under Rule 701, any of an issuer’s employees, directors, officers, consultants or advisors who purchases shares from the issuer in connection with a compensatory stock or option plan or other written agreement before the effective date of a registration statement under the Securities Act is entitled to sell such shares 90 days after such effective date in reliance on Rule 144. An affiliate of the issuer can resell shares in reliance on Rule 144 without having to comply with the holding period requirement, and non-affiliates of the issuer can resell shares in reliance on Rule 144 without having to comply with the current public information and holding period requirements.

Equity Plans

We intend to file one or more registration statements on Form S-8 under the Securities Act to register all shares of common stock subject to outstanding stock options and common stock issued or issuable under our
equity incentive plans and employee stock purchase plan. We expect to file the registration statement covering shares offered pursuant to these stock plans shortly after the date of this prospectus, permitting the resale of such shares by non-affiliates in the public market without restriction under the Securities Act and the sale by affiliates in the public market subject to compliance with the resale provisions of Rule 144.

Registration Rights

As of June 30, 2020, upon the closing of this offering holders of shares of our common stock, which includes all of the shares of common stock issuable upon the automatic conversion of our convertible preferred stock into 94,709,367 shares of our common stock immediately prior to the closing of this offering, will be entitled to various rights with respect to the registration of these shares under the Securities Act upon the closing of this offering. Registration of these shares under the Securities Act would result in these shares becoming fully tradable without restriction under the Securities Act immediately upon the effectiveness of the registration, except for shares purchase by our affiliates. See the section titled “Description of Capital Stock—Registration Rights” for additional information. Shares covered by a registration statement will be eligible for sale in the public market upon the expiration or release from the terms of the lock-up agreement.
MATERIAL UNITED STATES FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS

The following discussion is a summary of the material U.S. federal income tax consequences to Non-U.S. Holders (as defined below) of the purchase, ownership and disposition of our common stock issued pursuant to this offering, but does not purport to be a complete analysis of all potential tax effects. The effects of other U.S. federal tax laws, such as estate and gift tax laws, and any applicable state, local or non-U.S. tax laws are not discussed. This discussion is based on the U.S. Internal Revenue Code of 1986, as amended (the Code), Treasury Regulations promulgated thereunder, judicial decisions, and published rulings and administrative pronouncements of the U.S. Internal Revenue Service (IRS), in each case in effect as of the date hereof. These authorities may change or be subject to differing interpretations. Any such change or differing interpretation may be applied retroactively in a manner that could adversely affect a Non-U.S. Holder of our common stock. We have not sought and will not seek any rulings from the IRS regarding the matters discussed below. There can be no assurance the IRS or a court will not take a contrary position to that discussed below regarding the tax consequences of the purchase, ownership and disposition of our common stock.

This discussion is limited to Non-U.S. Holders that hold our common stock as a “capital asset” within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all U.S. federal income tax consequences relevant to a Non-U.S. Holder’s particular circumstances, including the impact of the Medicare contribution tax on net investment income or the alternative minimum tax. In addition, it does not address consequences relevant to Non-U.S. Holders subject to special rules, including, without limitation:

- U.S. expatriates and former citizens or long-term residents of the United States;
- persons holding our common stock as part of a hedge, straddle or other risk reduction strategy or as part of a conversion transaction or other integrated investment;
- banks, insurance companies, and other financial institutions;
- brokers, dealers or traders in securities;
- “controlled foreign corporations,” “passive foreign investment companies,” and corporations that accumulate earnings to avoid U.S. federal income tax;
- partnerships or other entities or arrangements treated as partnerships for U.S. federal income tax purposes (and investors therein);
- tax-exempt organizations or governmental organizations;
- persons deemed to sell our common stock under the constructive sale provisions of the Code;
- persons who hold or receive our common stock pursuant to the exercise of any employee stock option or otherwise as compensation;
- persons subject to special tax accounting rules as a result of any item of gross income with respect to our common stock being taken into account in an “applicable financial statement” (as defined in the Code);
- tax-qualified retirement plans; and
- “qualified foreign pension funds” as defined in Section 897(l)(2) of the Code and entities all of the interests of which are held by qualified foreign pension funds.

If an entity treated as a partnership for U.S. federal income tax purposes holds our common stock, the tax treatment of a partner in the partnership will depend on the status of the partner, the activities of the partnership and certain determinations made at the partner level. Accordingly, partnerships holding our common stock and the partners in such partnerships should consult their tax advisors regarding the U.S. federal income tax consequences to them.
Definition of a Non-U.S. Holder

For purposes of this discussion, a “Non-U.S. Holder” is any beneficial owner of our common stock that is neither a “U.S. person” nor an entity treated as a partnership for U.S. federal income tax purposes. A U.S. person is any person that, for U.S. federal income tax purposes, is or is treated as any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation created or organized under the laws of the United States, any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust that (i) is subject to the primary supervision of a U.S. court and the control of one or more “United States persons” (within the meaning of Section 7701(a)(30) of the Code), or (ii) has a valid election in effect to be treated as a United States person for U.S. federal income tax purposes.

Distributions

As described in the section entitled “Dividend Policy,” we do not anticipate declaring or paying cash dividends to holders of our common stock in the foreseeable future. However, if we do make distributions of cash or property on our common stock, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and first be applied against and reduce a Non-U.S. Holder’s adjusted tax basis in its common stock, but not below zero. Any excess will be treated as capital gain and will be treated as described below under “—Sale or Other Taxable Disposition.”

Subject to the discussion below on effectively connected income, dividends paid to a Non-U.S. Holder of our common stock will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends (or such lower rate specified by an applicable income tax treaty, provided the Non-U.S. Holder furnishes a valid IRS Form W-8BEN or W-8BEN-E (or other applicable documentation) certifying qualification for the lower treaty rate). If a Non-U.S. Holder holds the stock through a financial institution or other intermediary, the Non-U.S. Holder will be required to provide appropriate documentation to the intermediary, which then will be required to provide certification to the applicable withholding agent, either directly or through other intermediaries. A Non-U.S. Holder that does not timely furnish the required documentation, but that qualifies for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. Non-U.S. Holders should consult their tax advisors regarding their entitlement to benefits under any applicable income tax treaty.

If dividends paid to a Non-U.S. Holder are effectively connected with the Non-U.S. Holder’s conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such dividends are attributable), the Non-U.S. Holder will be exempt from the U.S. federal withholding tax described above. To claim the exemption, the Non-U.S. Holder must furnish to the applicable withholding agent a valid IRS Form W-8ECI, certifying that the dividends are effectively connected with the Non-U.S. Holder’s conduct of a trade or business within the United States.
Any such effectively connected dividends will be subject to U.S. federal income tax on a net income basis at the regular rates. A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected dividends, as adjusted for certain items. Non-U.S. Holders should consult their tax advisors regarding any applicable tax treaties that may provide for different rules.

**Sale or Other Taxable Disposition**

A Non-U.S. Holder will not be subject to U.S. federal income tax on any gain realized upon the sale or other taxable disposition of our common stock unless:

- the gain is effectively connected with the Non-U.S. Holder’s conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such gain is attributable);
- the Non-U.S. Holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition and certain other requirements are met; or
- our common stock constitutes a U.S. real property interest, or USRPI, by reason of our status as a U.S. real property holding corporation, or USRPHC, for U.S. federal income tax purposes.

Gain described in the first bullet point above generally will be subject to U.S. federal income tax on a net income basis at the regular rates. A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected gain, as adjusted for certain items.

Gain described in the second bullet point above will be subject to U.S. federal income tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty), which may be offset by U.S. source capital losses of the Non-U.S. Holder (even though the Non-U.S. Holder is not considered a resident of the United States), provided the Non-U.S. Holder has timely filed U.S. federal income tax returns with respect to such losses.

With respect to the third bullet point above, we believe we currently are not, and do not anticipate becoming, a USRPHC. Because the determination of whether we are a USRPHC depends, however, on the fair market value of our USRPIs relative to the fair market value of our non-U.S. real property interests and our other business assets, there can be no assurance we currently are not a USRPHC or will not become one in the future. Even if we are or were to become a USRPHC, gain arising from the sale or other taxable disposition by a Non-U.S. Holder of our common stock will not be subject to U.S. federal income tax if our common stock is “regularly traded,” as defined by applicable Treasury Regulations, on an established securities market, and such Non-U.S. Holder owned, actually and constructively, 5% or less of our common stock throughout the shorter of the five-year period ending on the date of the sale or other taxable disposition or the Non-U.S. Holder’s holding period.

Non-U.S. Holders should consult their tax advisors regarding potentially applicable income tax treaties that may provide for different rules.

**Information Reporting and Backup Withholding**

Payments of dividends on our common stock will not be subject to backup withholding, provided the applicable withholding agent does not have actual knowledge or reason to know the holder is a United States person and the holder either certifies its non-U.S. status, such as by furnishing a valid IRS Form W-8BEN, W-8BEN-E or W-8ECI, or otherwise establishes an exemption. However, information returns are required to be filed with the IRS in connection with any distributions on our common stock paid to the Non-U.S. Holder,
regardless of whether such distributions constitute dividends or whether any tax was actually withheld. In addition, proceeds of the sale or other taxable
disposition of our common stock within the United States or conducted through certain U.S.-related brokers generally will not be subject to backup
withholding or information reporting, if the applicable withholding agent receives the certification described above and does not have actual knowledge
or reason to know that such holder is a United States person, or the holder otherwise establishes an exemption. Proceeds of a disposition of our common
stock conducted through a non-U.S. office of a non-U.S.-related broker generally will not be subject to backup withholding or information reporting.

Copies of information returns that are filed with the IRS may also be made available under the provisions of an applicable treaty or agreement to
the tax authorities of the country in which the Non-U.S. Holder resides or is established.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit
against a Non-U.S. Holder’s U.S. federal income tax liability, provided the required information is timely furnished to the IRS.

Additional Withholding Tax on Payments Made to Foreign Accounts

Withholding taxes may be imposed under Sections 1471 to 1474 of the Code (such Sections are commonly referred to as the Foreign Account Tax
Compliance Act, or FATCA) on certain types of payments made to non-U.S. financial institutions and certain other non-U.S. entities. Specifically, a
30% withholding tax may be imposed on dividends on, or subject to the proposed Treasury Regulations discussed below, gross proceeds from the sale or
other disposition of, our common stock paid to a “foreign financial institution” or a “non-financial foreign entity” (each as defined in the Code), unless
(i) the foreign financial institution undertakes certain diligence and reporting obligations, (ii) the non-financial foreign entity either certifies it does not
have any “substantial United States owners” (as defined in the Code) or furnishes identifying information regarding each substantial United States
owner, or (iii) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. If the payee is a
foreign financial institution and is subject to the diligence and reporting requirements in clause (i) above, it must enter into an agreement with the U.S.
Department of the Treasury requiring, among other things, that it undertake to identify accounts held by certain “specified United States persons” or
“United States owned foreign entities” (each as defined in the Code), annually report certain information about such accounts, and withhold 30% on
certain payments to non-compliant foreign financial institutions and certain other account holders. Foreign financial institutions located in jurisdictions
that have an intergovernmental agreement with the United States governing FATCA may be subject to different rules.

Under the applicable Treasury Regulations and administrative guidance, withholding under FATCA generally applies to payments of dividends on
our common stock. While withholding under FATCA would also have applied to payments of gross proceeds from the sale or other disposition of stock
on or after January 1, 2019, proposed Treasury Regulations eliminate FATCA withholding on payments of gross proceeds entirely. Taxpayers generally
may rely on these proposed Treasury Regulations until final Treasury Regulations are issued.

Prospective investors should consult their tax advisors regarding the potential application of withholding under FATCA to their investment in our
common stock.
SVB Leerink LLC and Credit Suisse Securities (USA) LLC are acting as representatives of each of the underwriters named below and as joint bookrunning managers for this offering. Subject to the terms and conditions set forth in the underwriting agreement among us and the underwriters, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the number of shares of common stock set forth opposite its name below.

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<tr>
<th>Underwriter</th>
<th>Number of Shares</th>
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<tr>
<td>SVB Leerink LLC</td>
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<tr>
<td>Credit Suisse Securities (USA) LLC</td>
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<tr>
<td>BMO Capital Markets Corp.</td>
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<tr>
<td>Guggenheim Securities, LLC</td>
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<td><strong>Total</strong></td>
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Subject to the terms and conditions set forth in the underwriting agreement, the underwriters have agreed, severally and not jointly, to purchase all of the shares sold under the underwriting agreement if any of the shares are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the non-defaulting underwriters may be increased or the underwriting agreement may be terminated.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, or to contribute to payments the underwriters may be required to make in respect of those liabilities.

The underwriters are offering the shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel, including the validity of the shares, and subject to other conditions contained in the underwriting agreement, such as the receipt by the underwriters of officers’ certificates and legal opinions. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

**Discounts and Commissions**

The representatives have advised us that the underwriters propose initially to offer the shares to the public at the initial public offering price set forth on the cover page of this prospectus and to dealers at that price less a concession not in excess of $ per share. After the initial offering of the shares, the public offering price, concession or any other term of this offering may be changed by the representatives.

The following table shows the initial public offering price, underwriting discounts and commissions and proceeds, before expenses, to us. The information assumes either no exercise or full exercise by the underwriters of their over-allotment option.

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<th>Per Share</th>
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<tr>
<td>Initial public offering price</td>
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<tr>
<td>Underwriting discounts and commissions</td>
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</tr>
<tr>
<td>Proceeds, before expenses, to us</td>
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</tr>
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</table>

We estimate expenses payable by us in connection with this offering, other than the underwriting discounts and commissions referred to above, will be approximately $. We also have agreed to reimburse the underwriters for up to $ for their FINRA counsel fee. In accordance with FINRA Rule 5110, this reimbursed fee is deemed underwriting compensation for this offering.
Over-Allotment Option

We have granted an option to the underwriters, exercisable for 30 days after the date of this prospectus, to purchase up to additional shares at the initial public offering price, less underwriting discounts and commissions. If the underwriters exercise this option, each underwriter will be obligated, subject to the conditions contained in the underwriting agreement, to purchase a number of additional shares proportionate to that underwriter’s initial amount reflected in the above table. The underwriters may exercise this option solely for the purpose of covering over-allotments, if any, made in connection with the offering of the shares of common stock offered by this prospectus.

No Sales of Similar Securities

We, our executive officers and directors and all of our other existing security holders have agreed not to sell or transfer any common stock or securities convertible into or exchangeable or exercisable for common stock, for 180 days after the date of this prospectus without first obtaining the written consent of SVB Leerink LLC and Credit Suisse Securities (USA) LLC on behalf of the underwriters. Specifically, we and these other persons have agreed, with certain limited exceptions, not to directly or indirectly:

• offer, pledge, sell or contract to sell any common stock;
• sell any option or contract to purchase any common stock;
• purchase any option or contract to sell any common stock;
• grant any option, right or warrant for the sale of any common stock;
• otherwise dispose of or transfer any common stock;
• request or demand that we file a registration statement related to the common stock; or
• enter into any swap or other agreement or any transaction that transfers, in whole or in part, the economic consequence of ownership of any common stock, whether any such swap, agreement or transaction is to be settled by delivery of shares or other securities, in cash or otherwise.

The restrictions described in the paragraph above relating to the officers, directors, and our shareholders do not apply, subject in certain cases to various conditions (including no filing requirements and the transfer of the lock-up restrictions), to transfers:

• as a bona fide gift or gifts;
• to any trust for the direct or indirect benefit of the lock-up party or the immediate family of the lock-up party (for purposes of the lock-up agreement, “immediate family” shall mean any relationship by blood, marriage or adoption, not more remote than first cousin);
• as a distribution or other transfer by a partnership to its partners or former partners or by a limited liability company to its members or retired members or by a corporation to its stockholders or former stockholders or to any wholly-owned subsidiary of such corporation;
• if the lock-up party is a corporation, partnership, limited liability company or other business entity, in connection with the sale or other bona fide transfer in a single transaction of all or substantially all of the lock-up party’s capital stock, partnership interests, membership interests or other similar equity interests, as the case may be, or all or substantially all of the lock-up party’s assets, in any such case not undertaken for the purpose of avoiding the restrictions imposed by this agreement;
• to the lock-up party’s affiliates or to any investment fund or other entity controlled or managed by the lock-up party;
• pursuant to a court or regulatory agency order, a qualified domestic relations order or in connection with a divorce settlement;
by will or intestate succession upon the death of the lock-up party;

• if the lock-up party is a trust, to a trustor, trustee (or co-trustee) or beneficiary of the trust or to the estate of the beneficiary of such trustor; or

• to us in satisfaction of any tax withholding obligation.

The lock-up provisions apply to common stock and to securities convertible into or exchangeable or exercisable for common stock. They also apply to common stock owned now or acquired later by the person executing the lock-up agreement or for which the person executing the lock-up agreement later acquires the power of disposition.

Nasdaq Global Market Listing

We have applied to list our common stock on the Nasdaq Global Market, subject to notice of issuance, under the symbol “RXDX.”

Determination of Offering Price

Prior to this offering, there has been no public market for our common stock. The initial public offering price for our common stock will be determined through negotiations between us and the representatives. In addition to prevailing market conditions, the factors to be considered in determining the initial public offering price are:

• the valuation multiples of publicly traded companies that the representatives believe to be comparable to us;
• our financial information;
• the history of, and the prospects for, our company and the industry in which we compete;
• an assessment of our management, its past and present operations, and the prospects for, and timing of, our future revenues;
• the present state of our development; and
• the above factors in relation to market values and various valuation measures of other companies engaged in activities similar to ours.

An active trading market for the shares may not develop. It is also possible that after this offering, our common stock will not trade in the public market at or above the initial public offering price.

The underwriters do not expect to sell more than 5% of the shares in the aggregate to accounts over which they exercise discretionary authority.

Price Stabilization, Short Positions and Penalty Bids

Until the distribution of the shares is completed, SEC rules may limit underwriters and selling group members from bidding for and purchasing our common stock. However, the representatives may engage in transactions that stabilize the price of the common stock, such as bids or purchases to peg, fix or maintain that price.

In connection with this offering, the underwriters may purchase and sell our common stock in the open market. These transactions may include short sales, purchases on the open market to cover positions created by short sales and stabilizing transactions. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in this offering. “Covered” short sales are sales made in an amount not
greater than the underwriters' over-allotment option described above. The underwriters may close out any covered short position by either exercising their over-allotment option or purchasing shares in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the over-allotment option granted to them under the underwriting agreement described above. “Naked” short sales are sales in excess of such over-allotment option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of our common stock in the open market after pricing that could adversely affect investors who purchase in this offering. Stabilizing transactions consist of various bids for or purchases of shares of common stock made by the underwriters in the open market prior to the closing of this offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Similar to other purchase transactions, the underwriters’ purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. The underwriters may conduct these transactions on the Nasdaq Global Market, in the over-the-counter market or otherwise.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. In addition, neither we nor any of the underwriters make any representation that the representatives will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice.

Electronic Distribution

In connection with this offering, certain of the underwriters or securities dealers may distribute prospectuses by electronic means, such as e-mail.

Other Relationships

The underwriters and certain of their affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. Some of the underwriters and certain of their affiliates may in the future engage in investment banking and other commercial dealings in the ordinary course of business with us and our affiliates, for which they may in the future receive customary fees, commissions and expenses.

In addition, in the ordinary course of their business activities, the underwriters and their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers. Such investments and securities activities may involve securities and/or instruments of ours or our affiliates. The underwriters and their affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or financial instruments and may hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Selling Restrictions

**European Economic Area and the United Kingdom**

In relation to each Member State of the European Economic Area and the United Kingdom (each, a “Relevant State”), no shares have been offered or will be offered pursuant to the offering to the public in that
Relevant State prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Relevant State or, where appropriate, approved in another Relevant State and notified to the competent authority in that Relevant State, all in accordance with the Prospectus Regulation, except that offers of shares may be made to the public in that Relevant State at any time under the following exemptions under the Prospectus Regulation:

A. to any legal entity which is a qualified investor as defined under the Prospectus Regulation;
B. to fewer than 150 natural or legal persons (other than qualified investors as defined under the Prospectus Regulation), subject to obtaining the prior consent of the underwriters for any such offer; or
C. in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of shares shall require us or any of the underwriters to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

For the purposes of this provision, the expression an “offer to the public” in relation to any shares in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares, and the expression “Prospectus Regulation” means Regulation (EU) 2017/1129, as amended.

Notice to Prospective Investors in the United Kingdom

In addition, in the United Kingdom, this document is being distributed only to, and is directed only at, and any offer subsequently made may only be directed at persons who are “qualified investors” (as defined in the Prospectus Regulation) (i) who have professional experience in matters relating to investments falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the “Order”) and/or (ii) who are high net worth companies (or persons to whom it may otherwise be lawfully communicated) falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as “relevant persons”) or otherwise in circumstances which have not resulted and will not result in an offer to the public of the shares in the United Kingdom within the meaning of the Financial Services and Markets Act 2000, as amended.

Any person in the United Kingdom that is not a relevant person should not act or rely on the information included in this document or use it as basis for taking any action. In the United Kingdom, any investment or investment activity that this document relates to may be made or taken exclusively by relevant persons.

Notice to Prospective Investors in Canada

The shares may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the shares must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser’s province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser’s province or territory for particulars of these rights or consult with a legal advisor.
Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts ("NI 33-105"), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

**Notice to Prospective Investors in Switzerland**

This document is not intended to constitute an offer or solicitation to purchase or invest in the shares. The shares may not be publicly offered, directly or indirectly, in Switzerland within the meaning of the Swiss Financial Services Act ("FinSA") and no application has or will be made to admit the shares to trading on any trading venue (exchange or multilateral trading facility) in Switzerland. Neither this prospectus nor any other offering or marketing material relating to the shares constitutes a prospectus pursuant to the FinSA, and neither this document nor any other offering or marketing material relating to the shares may be publicly distributed or otherwise made publicly available in Switzerland.

**Notice to Prospective Investors in Australia**

This prospectus is not a disclosure document for the purposes of Australia’s Corporations Act 2001 (Cth) of Australia, or Corporations Act, has not been lodged with the Australian Securities & Investments Commission and is only directed to the categories of exempt persons set out below. Accordingly, if you receive this prospectus in Australia:

You confirm and warrant that you are either:

• a “sophisticated investor” under section 708(8)(a) or (b) of the Corporations Act;
• a “sophisticated investor” under section 708(8)(c) or (d) of the Corporations Act and that you have provided an accountant’s certificate to the Company which complies with the requirements of section 708(8)(c)(i) or (ii) of the Corporations Act and related regulations before the offer has been made; or
• a “professional investor” within the meaning of section 708(11)(a) or (b) of the Corporations Act.

To the extent that you are unable to confirm or warrant that you are an exempt sophisticated investor or professional investor under the Corporations Act any offer made to you under this prospectus is void and incapable of acceptance.

You warrant and agree that you will not offer any of the shares issued to you pursuant to this prospectus for resale in Australia within 12 months of those securities being issued unless any such resale offer is exempt from the requirement to issue a disclosure document under section 708 of the Corporations Act.

**Notice to Prospective Investors in the People’s Republic of China (the “PRC”)**

This prospectus has not been and will not be circulated or distributed in the PRC, and no securities may be offered or sold, or will be offered or sold, to any person for re-offering or resale, directly or indirectly, to any resident of the PRC except pursuant to applicable laws and regulations of the PRC.

**Notice to Prospective Investors in Hong Kong**

No securities have been offered or sold, and no securities may be offered or sold, in Hong Kong, by means of any document, other than to persons whose ordinary business is to buy or sell shares or debentures, whether as principal or agent; or to “professional investors” as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong (the “SFO”) and any rules made under that Ordinance; or in other circumstances which do not result in the document being a “prospectus” as defined in the Companies Ordinance (Cap. 32) of Hong Kong (the “CO”), or which do not constitute an offer to the public for the purpose of the CO or the SFO. No document,
invitation or advertisement relating to the securities has been issued or may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted under the securities laws of Hong Kong) other than with respect to securities which are or are intended to be disposed of only to persons outside Hong Kong or only to “professional investors” as defined in the SFO and any rules made under that Ordinance.

This prospectus has not been registered with the Registrar of Companies in Hong Kong. Accordingly, this prospectus may not be issued, circulated or distributed in Hong Kong, and the securities may not be offered for subscription to members of the public in Hong Kong. Each person acquiring the securities will be required, and is deemed by the acquisition of the securities, to confirm that he is aware of the restriction on offers of the securities described in this prospectus and the relevant offering documents and that he is not acquiring, and has not been offered any securities in circumstances that contravene any such restrictions.

Notice to Prospective Investors in Israel

This document does not constitute a prospectus under the Israeli Securities Law, 5728-1968 (the “Securities Law”), and has not been filed with or approved by the Israel Securities Authority. In the State of Israel, this document is being distributed only to, and is directed only at, any offer of the shares is directed only at, (i) a limited number of persons in accordance with section 15A of the Securities Law and (ii) investors listed in the first addendum (the “Addendum”), to the Israeli Securities Law, consisting primarily of joint investment in trust funds, provident funds, insurance companies, banks, portfolio managers, investment advisors, members of the Tel Aviv Stock Exchange, underwriters, venture capital funds, entities with equity in excess of NIS 50 million and “qualified individuals,” each as defined in the Addendum (as it may be amended from time to time), collectively referred to as qualified investors (in each case purchasing for their own account or, where permitted under the Addendum, for the accounts of their clients who are investors listed in the Addendum). Qualified investors will be required to submit written confirmation that they fall within the scope of the Addendum, are aware of the meaning of same and agree to it.

Notice to Prospective Investors in Japan

The offering has not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948 of Japan, as amended) (the “FIEL”) and the underwriters will not offer or sell any securities, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means, unless otherwise provided herein, any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the FIEL and any other applicable laws, regulations and ministerial guidelines of Japan.

Notice to Prospective Investors in Singapore

This prospectus has not been and will not be lodged or registered with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or the invitation for subscription or purchase of the securities may not be issued, circulated or distributed, nor may the securities be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to the public or any member of the public in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore (the SFA) (ii) to a relevant person as defined under Section 275(2), or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions, specified in Section 275 of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of any other applicable provision of the SFA.
Where the securities are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- a corporation (which is not an accredited investor as defined under Section 4A of the SFA) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
- a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary is an accredited investor,

securities (as defined in Section 239(1) of the SFA) of that corporation or the beneficiaries’ rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares of common stock pursuant to an offer made under Section 275 of the SFA except:

- to an institutional investor or to a relevant person defined in Section 275(2) of the SFA, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(B) of the SFA;
- where no consideration is or will be given for the transfer;
- where the transfer is by operation of law;
- as specified in Section 276(7) of the SFA; or
- as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore.
LEGAL MATTERS

The validity of the shares of common stock offered hereby will be passed upon for us by Latham & Watkins LLP, San Diego, California. The underwriters are being represented by Davis Polk & Wardwell LLP, New York, New York.

EXPERTS

The consolidated financial statements as of December 31, 2018 and 2019 and for the years then ended included in this prospectus and in the registration statement of which this prospectus forms a part have been so included in reliance on the report of BDO USA, LLP, an independent registered public accounting firm (the report on the consolidated financial statements contains an explanatory paragraph regarding the Company’s ability to continue as a going concern) appearing elsewhere herein and in the registration statement, given on the authority of said firm as experts in auditing and accounting.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of our common stock offered hereby. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits and schedules filed therewith. For further information about us and our common stock offered hereby, we refer you to the registration statement and the exhibits and schedules filed thereto. Statements contained in this prospectus regarding the contents of any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and each such statement is qualified in all respects by reference to the full text of such contract or other document filed as an exhibit to the registration statement. Upon the closing of this offering, we will be required to file periodic reports, proxy statements and other information with the SEC pursuant to the Exchange Act. The SEC maintains an Internet website that contains reports, proxy statements and other information about registrants, like us, that file electronically with the SEC. The address of that site is www.sec.gov.

Upon the closing of this offering, we will become subject to the information and periodic reporting requirements of the Exchange Act and, in accordance therewith, will file periodic reports, proxy statements and other information with the SEC. Such periodic reports, proxy statements and other information will be available at the website of the SEC referred to above. We maintain a website at www.prometheusbiosciences.com. Upon the closing of this offering, you may access our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act with the SEC free of charge at our website as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. The reference to our website address does not constitute incorporation by reference of the information contained on our website, and you should not consider the contents of our website in making an investment decision with respect to our common stock.
# PROMETHEUS BIOSCIENCES, INC.

## Index to Consolidated Financial Statements

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<th>Page</th>
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</thead>
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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors
Prometheus Biosciences, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Prometheus Biosciences, Inc. (the Company) as of December 31, 2018 and 2019, the related consolidated statements of operations, convertible preferred stock and stockholders’ deficit, and cash flows for the years then ended, and the related notes (collectively referred to as the financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2019, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Uncertainty

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As described in Note 1 to the consolidated financial statements, the Company has suffered recurring losses and negative cash flows from operations that raise substantial doubt about its ability to continue as a going concern. Management’s plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB and in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ BDO USA, LLP

We have served as the Company’s auditor since 2018.
San Diego, California
August 28, 2020
### Prometheus Biosciences, Inc.
#### Consolidated Balance Sheets
(in thousands, except share data and par value)

<table>
<thead>
<tr>
<th></th>
<th>December 31, 2018</th>
<th>Pro Forma December 31, 2019 (unaudited)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Assets</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Current assets</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cash and cash equivalents</td>
<td>$10,880</td>
<td>$8,371</td>
</tr>
<tr>
<td>Accounts receivable, net</td>
<td>—</td>
<td>11,947</td>
</tr>
<tr>
<td>Amounts due from Nestlé—related party</td>
<td>—</td>
<td>11,292</td>
</tr>
<tr>
<td>Prepaid expenses and other current assets</td>
<td>150</td>
<td>3,699</td>
</tr>
<tr>
<td>Other current assets</td>
<td>—</td>
<td>2,225</td>
</tr>
<tr>
<td>Total current assets</td>
<td>$11,030</td>
<td>37,534</td>
</tr>
<tr>
<td>Property and equipment, net</td>
<td>77</td>
<td>6,813</td>
</tr>
<tr>
<td>Intangible assets, net</td>
<td>—</td>
<td>5,412</td>
</tr>
<tr>
<td>Goodwill</td>
<td>—</td>
<td>724</td>
</tr>
<tr>
<td><strong>Total assets</strong></td>
<td>$11,107</td>
<td>$50,483</td>
</tr>
</tbody>
</table>

| **Liabilities, Convertible Preferred Stock and Stockholders’ Equity (Deficit)** |                  |                                        |
| **Current liabilities** |                  |                                        |
| Accounts payable | $837 | $4,408 |
| Accrued compensation | 202 | 4,535 |
| Accrued expenses and other current liabilities | 206 | 3,331 |
| Accrued rebates and sales returns | — | 12,618 |
| Amounts due to Nestlé, current—related party | — | 4,992 |
| Deferred revenue | — | 1,992 |
| Total current liabilities | $1,245 | 21,876 |

| **Commitments and contingencies (Note 9)** |                  |                                        |
| Convertible preferred stock—$0.0001 par value; 41,645,867 shares and 91,645,867 shares authorized at December 31, 2018 and 2019, respectively; 28,561,076 shares and 61,645,867 shares issued at December 31, 2018 and 2019, respectively; 28,561,076 shares and 58,145,867 shares outstanding at December 31, 2018 and 2019, respectively; liquidation preferences of $17,676 and $43,990 at December 31, 2018 and 2019, respectively; no shares issued and outstanding pro forma (unaudited) | 17,500 | 43,740 |
| Common stock—$0.0001 par value; 66,000,000 shares and 125,000,000 shares authorized as of December 31, 2018 and 2019, respectively; 14,170,000 shares and 15,820,658 shares issued at December 31, 2018 and 2019, respectively; 9,585,105 shares and 13,513,836 shares outstanding at December 31, 2018 and 2019, respectively; shares issued and outstanding at December 31, 2019, pro forma (unaudited) | 1 | 1 |
| Additional-paid in capital | 89 | 482 |
| Accumulated deficit | $(7,728) | $(37,451) |
| **Total stockholders’ equity (deficit)** | $(7,638) | $(36,968) |
| **Total liabilities, convertible preferred stock and stockholders’ equity (deficit)** | $11,107 | $50,483 |

See accompanying notes to the consolidated financial statements.

F-3
# Prometheus Biosciences, Inc.
## Consolidated Statements of Operations

(in thousands, except share and per share data)

<table>
<thead>
<tr>
<th>Years Ended December 31</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2018</td>
<td>2019</td>
</tr>
</tbody>
</table>

## Revenue:

- **Diagnostic services revenue**: $— $22,674
- **Collaboration revenue**: $— $1,118

## Operating expenses:

- **Cost of diagnostic services revenue**: $— $8,864
- **Research and development**: $4,386 $14,436
- **Sales and marketing**: $— $10,036
- **General and administrative**: $2,413 $13,976
- **Amortization of intangibles**: $— $488
- **Restructuring**: $— $5,484

## Total operating expense

<table>
<thead>
<tr>
<th></th>
<th>2018</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>6,799</td>
<td>53,284</td>
</tr>
</tbody>
</table>

## Loss from operations

<table>
<thead>
<tr>
<th></th>
<th>2018</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(6,799)</td>
<td>(29,492)</td>
</tr>
</tbody>
</table>

## Other income (expense), net:

- **Interest income**: 5 38
- **Interest expense**: $— $(770)

## Total other income (expense), net

<table>
<thead>
<tr>
<th></th>
<th>2018</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>5</td>
<td>(732)</td>
</tr>
</tbody>
</table>

## Loss before income taxes

<table>
<thead>
<tr>
<th></th>
<th>2018</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(6,794)</td>
<td>(30,224)</td>
</tr>
</tbody>
</table>

## Income tax expense (benefit)

<table>
<thead>
<tr>
<th></th>
<th>2018</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td>(501)</td>
</tr>
</tbody>
</table>

## Net loss

<table>
<thead>
<tr>
<th></th>
<th>2018</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$(6,795)</td>
<td>$(29,723)</td>
</tr>
</tbody>
</table>

## Net loss per share, basic and diluted

<table>
<thead>
<tr>
<th></th>
<th>2018</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$(0.91)</td>
<td>$(2.65)</td>
</tr>
</tbody>
</table>

## Weighted average shares outstanding, basic and diluted

<table>
<thead>
<tr>
<th></th>
<th>2018</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>7,471,474</td>
<td>11,227,009</td>
</tr>
</tbody>
</table>

## Pro forma net loss per share, basic and diluted (unaudited) (Note 2)

<table>
<thead>
<tr>
<th></th>
<th>2018</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$</td>
<td></td>
</tr>
</tbody>
</table>

## Pro forma weighted average shares outstanding, basic and diluted (unaudited) (Note 2)

<table>
<thead>
<tr>
<th></th>
<th>2018</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$</td>
<td></td>
</tr>
</tbody>
</table>

See accompanying notes to the consolidated financial statements.

F-4
### Prometheus Biosciences, Inc.

**Consolidated Statements of Convertible Preferred Stock and Stockholders’ Deficit**

*(in thousands, except share data)*

<table>
<thead>
<tr>
<th>Shares</th>
<th>Amount</th>
<th>Shares</th>
<th>Amount</th>
<th>Additional Paid-in Capital</th>
<th>Accumulated Deficit</th>
<th>Total Stockholders’ Deficit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Balance at December 31, 2017</td>
<td>14,979,200</td>
<td>$7,391</td>
<td>5,996,875</td>
<td>$1</td>
<td>$15</td>
<td>$ (933)</td>
</tr>
<tr>
<td>Issue of Series B convertible preferred stock for cash, net of issuance costs of $76</td>
<td>13,581,876</td>
<td>10,109</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Vesting of common shares issued for licensing rights</td>
<td>—</td>
<td>—</td>
<td>1,116,667</td>
<td>—</td>
<td>1</td>
<td>—</td>
</tr>
<tr>
<td>Vesting of common shares issued to founders</td>
<td>—</td>
<td>—</td>
<td>1,856,250</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Issue of common stock in exchange for services</td>
<td>—</td>
<td>—</td>
<td>520,000</td>
<td>—</td>
<td>27</td>
<td>—</td>
</tr>
<tr>
<td>Issue of common stock upon exercise of stock options</td>
<td>—</td>
<td>—</td>
<td>37,500</td>
<td>—</td>
<td>2</td>
<td>—</td>
</tr>
<tr>
<td>Vesting of early exercised stock options</td>
<td>—</td>
<td>—</td>
<td>57,813</td>
<td>—</td>
<td>2</td>
<td>—</td>
</tr>
<tr>
<td>Stock-based compensation</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>42</td>
<td>—</td>
</tr>
<tr>
<td>Net loss</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>(6,795)</td>
</tr>
<tr>
<td>Balance at December 31, 2018</td>
<td>28,561,076</td>
<td>17,500</td>
<td>9,585,105</td>
<td>1</td>
<td>89</td>
<td>(7,728)</td>
</tr>
<tr>
<td>Issue of Series B convertible preferred stock for cash, net of issuance costs of $22</td>
<td>13,084,791</td>
<td>9,792</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Issue of Series C convertible preferred stock in acquisition, net of issuance costs of $52</td>
<td>16,500,000</td>
<td>16,448</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Issue of common stock in exchange for services</td>
<td>—</td>
<td>—</td>
<td>502,533</td>
<td>—</td>
<td>146</td>
<td>—</td>
</tr>
<tr>
<td>Vesting of common shares issued to founders</td>
<td>—</td>
<td>—</td>
<td>1,668,750</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Vesting of common shares issued for licensing rights</td>
<td>—</td>
<td>—</td>
<td>1,116,667</td>
<td>—</td>
<td>1</td>
<td>—</td>
</tr>
<tr>
<td>Issue of common stock upon exercise of stock options</td>
<td>—</td>
<td>—</td>
<td>396,875</td>
<td>—</td>
<td>8</td>
<td>—</td>
</tr>
<tr>
<td>Vesting of early exercised stock options</td>
<td>—</td>
<td>—</td>
<td>243,906</td>
<td>—</td>
<td>11</td>
<td>—</td>
</tr>
<tr>
<td>Stock-based compensation</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>227</td>
<td>—</td>
</tr>
<tr>
<td>Net loss</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>(29,723)</td>
</tr>
<tr>
<td>Balance at December 31, 2019</td>
<td>58,145,867</td>
<td>$43,740</td>
<td>13,513,836</td>
<td>$1</td>
<td>$482</td>
<td>(37,451)</td>
</tr>
</tbody>
</table>

See accompanying notes to the consolidated financial statements.

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<table>
<thead>
<tr>
<th>Table of Contents</th>
<th>Prometheus Biosciences, Inc.</th>
<th>Consolidated Statements of Cash Flows</th>
<th>(in thousands)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Years Ended December 31,</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Cash flows from operating activities</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Net loss</td>
<td>$(6,795)</td>
<td>$(29,723)</td>
<td></td>
</tr>
<tr>
<td>Adjustments to reconcile net loss to net cash used in operating activities:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depreciation and amortization</td>
<td>5</td>
<td>1,696</td>
<td></td>
</tr>
<tr>
<td>Stock-based compensation expenses</td>
<td>42</td>
<td>227</td>
<td></td>
</tr>
<tr>
<td>Common stock issued in exchange for services</td>
<td>27</td>
<td>146</td>
<td></td>
</tr>
<tr>
<td>Noncash interest expense</td>
<td>—</td>
<td>770</td>
<td></td>
</tr>
<tr>
<td>Deferred income taxes</td>
<td>—</td>
<td>(506)</td>
<td></td>
</tr>
<tr>
<td>Changes in operating assets and liabilities, net of acquisitions:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Accounts receivable</td>
<td>—</td>
<td>43</td>
<td></td>
</tr>
<tr>
<td>Amounts due from Nestlé – related party</td>
<td>—</td>
<td>576</td>
<td></td>
</tr>
<tr>
<td>Prepaid expenses and other current assets</td>
<td>(150)</td>
<td>1,196</td>
<td></td>
</tr>
<tr>
<td>Other current assets</td>
<td>—</td>
<td>16,825</td>
<td></td>
</tr>
<tr>
<td>Accounts payable</td>
<td>399</td>
<td>(14,060)</td>
<td></td>
</tr>
<tr>
<td>Accrued compensation</td>
<td>202</td>
<td>(4,148)</td>
<td></td>
</tr>
<tr>
<td>Accrued expenses and other current liabilities</td>
<td>171</td>
<td>2,786</td>
<td></td>
</tr>
<tr>
<td>Accrued rebates and sales returns</td>
<td>—</td>
<td>2,420</td>
<td></td>
</tr>
<tr>
<td>Amounts due to Nestlé – related party</td>
<td>—</td>
<td>(372)</td>
<td></td>
</tr>
<tr>
<td>Deferred revenue</td>
<td>—</td>
<td>1,927</td>
<td></td>
</tr>
<tr>
<td>Net cash used in operating activities</td>
<td>(6,099)</td>
<td>(20,197)</td>
<td></td>
</tr>
<tr>
<td><strong>Cash flows from investing activities</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Purchase of property and equipment</td>
<td>(82)</td>
<td>(984)</td>
<td></td>
</tr>
<tr>
<td>Cash acquired in PLI acquisition</td>
<td>—</td>
<td>8,917</td>
<td></td>
</tr>
<tr>
<td>Net cash (used in) provided by investing activities</td>
<td>(82)</td>
<td>7,933</td>
<td></td>
</tr>
<tr>
<td><strong>Cash flows from financing activities</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proceeds from issuance of convertible preferred stock, net of issuance costs</td>
<td>10,131</td>
<td>9,792</td>
<td></td>
</tr>
<tr>
<td>Payments of stock issuance costs</td>
<td>—</td>
<td>(75)</td>
<td></td>
</tr>
<tr>
<td>Proceeds from issuance of common stock upon stock option exercises</td>
<td>10</td>
<td>38</td>
<td></td>
</tr>
<tr>
<td>Net cash provided by financing activities</td>
<td>10,141</td>
<td>9,755</td>
<td></td>
</tr>
<tr>
<td>Net increase (decrease) in cash and cash equivalents</td>
<td>3,960</td>
<td>(2,509)</td>
<td></td>
</tr>
<tr>
<td>Cash and cash equivalents at beginning of year</td>
<td>6,920</td>
<td>10,880</td>
<td></td>
</tr>
<tr>
<td>Cash and cash equivalents cash at end of year</td>
<td>$10,880</td>
<td>$8,371</td>
<td></td>
</tr>
<tr>
<td><strong>Supplemental disclosures</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cash paid for income taxes</td>
<td>$1</td>
<td>$5</td>
<td></td>
</tr>
<tr>
<td><strong>Supplemental schedule of non-cash investing and financing activities</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Convertible preferred stock issuance costs included in accounts payable</td>
<td>$23</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>Convertible preferred stock issued in acquisition of PLI</td>
<td>—</td>
<td>$16,500</td>
<td></td>
</tr>
<tr>
<td>Acquisition-related consideration held in escrow</td>
<td>—</td>
<td>$3,500</td>
<td></td>
</tr>
<tr>
<td>Deferred purchase price payments related to PLI acquisition</td>
<td>—</td>
<td>$12,269</td>
<td></td>
</tr>
<tr>
<td>Net assets acquired in acquisition of PLI</td>
<td>—</td>
<td>$31,662</td>
<td></td>
</tr>
<tr>
<td>Vesting of unvested issued common stock</td>
<td>$5</td>
<td>$13</td>
<td></td>
</tr>
<tr>
<td>Costs incurred, but not paid, in connection with capital expenditures included in accounts payable</td>
<td>—</td>
<td>$49</td>
<td></td>
</tr>
</tbody>
</table>

See accompanying notes to the consolidated financial statements.

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PROMETHEUS BIOSCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization

Prometheus Biosciences, Inc. (the Company) was incorporated in the state of Delaware on October 26, 2016 under the name Precision IBD, Inc. and is headquartered in San Diego, California. The Company changed its name to Prometheus Biosciences, Inc. on October 1, 2019. The Company's business is focused on the discovery, development and commercialization of therapeutic and companion diagnostic products for the treatment of inflammatory bowel disease (IBD).

In June 2019, the Company acquired Prometheus Laboratories, Inc. (PLI) and the related intangible assets used by PLI. PLI was wholly owned by Nestlé Health Science US Holdings, Inc. and the related intangible assets were owned by Société Des Produits Nestlé S.A (together, Nestlé) (see Note 7). PLI markets and conducts several laboratory developed tests useful to gastroenterologists in monitoring their IBD patients’ disease state and informing their therapeutic decisions.

Liquidity and Going Concern

The Company has incurred net losses since inception, experienced negative cash flows from operations, and as of December 31, 2019, has an accumulated deficit of $37.5 million. The Company has historically financed its operations primarily through private placements of convertible preferred stock. The Company expects operating losses and negative cash flows from operations to continue for the foreseeable future. The Company believes its current capital resources will not be sufficient for the Company to continue as a going concern for at least one year from the issuance date of these consolidated financial statements. The Company’s history of recurring losses and its anticipated expenditures raise substantial doubt about the Company’s ability to continue as a going concern.

As a result, the Company will be required to raise additional capital, however, there can be no assurance as to whether additional financing will be available on terms acceptable to the Company, if at all. If sufficient funds on acceptable terms are not available when needed, it would have a negative impact on the Company’s financial condition and could force the Company to delay, limit, reduce, or terminate product development or future commercialization efforts or grant rights to develop and market product candidates or testing products that the Company would otherwise plan to develop.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The accompanying consolidated financial statements do not reflect any adjustments relating to the recoverability and reclassifications of assets and liabilities that might be necessary if the Company is unable to continue as a going concern.

2. Summary of Significant Accounting Policies

Basis of Presentation and Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States (GAAP) requires management to make estimates and assumptions that impact the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities in the Company’s consolidated financial statements and accompanying notes. Although these estimates are based on the Company’s knowledge of current events and actions it may undertake in the future, actual results may materially differ from these estimates and assumptions.

On an ongoing basis, management evaluates its estimates, primarily related to revenue recognition, stock-based compensation, fair value of common stock, fair value of the convertible preferred stock, acquired...
intangible assets and accrued research and development costs. These estimates are based on historical data and experience, as well as various other factors that management believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Estimates relating to the valuation of stock require the selection of appropriate valuation methodologies and models, and significant judgment in evaluating ranges of assumptions and financial inputs.

**Principles of Consolidation**

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, Prometheus Laboratories, Inc. and have been prepared in conformity with GAAP. All intercompany accounts and transactions have been eliminated in consolidation.

**Unaudited Pro Forma Financial Information**

The unaudited pro forma balance sheet information as of December 31, 2019 reflects (i) the receipt of net proceeds of $28.0 million from the sale of 28,063,500 shares of Series C preferred stock in March 2020 (See Note 14), (ii) the issuance of 8,500,000 shares of Series C preferred stock in June 2020 related to the release of 3,500,000 shares from escrow and the conversion of a $5.0 million of deferred purchase price payment in connection with the PLI acquisition to 5,000,000 shares of Series C preferred stock, (iii) the conversion of all outstanding shares of the Company’s convertible preferred stock into shares of the Company’s common stock, and (iv) the related reclassification of the carrying value of the preferred stock to permanent equity, all of which will occur immediately prior to the completion of the Company’s planned initial public offering (IPO). The unaudited pro forma balance sheet assumes that the completion of the IPO had occurred as of December 31, 2019 and excludes shares of common stock issued in the IPO and any related net proceeds.

Unaudited pro forma net loss per common share is computed using the weighted-average number of common shares outstanding after giving effect to the conversion of all the outstanding convertible preferred stock into shares of common stock as if such conversion had occurred at the beginning of the period presented, or the date of original issuance, if later.

**Segment Reporting**

The Company’s Chief Executive Officer, who is considered to be the chief operating decision maker (CODM), reviews financial information presented on a consolidated basis, accompanied by information about operating segments for purposes of making operating decisions and assessing financial performance. Operating segments are defined as components of an enterprise about which separate financial information is available that is evaluated regularly by the CODM in deciding how to allocate resources and in assessing performance.

The Company determined its operating segments to be the therapeutics and diagnostic services businesses. The therapeutics business derives substantially all of its revenue from collaboration agreements and devotes all of its efforts to development of product candidates and companion diagnostics in the IBD space. The diagnostic services business derives its revenue from diagnostic services in the IBD space generated from the conduct of laboratory developed tests.

**Cash and Cash Equivalents**

The Company considers all highly liquid investments with an original maturity of three months or less when purchased to be cash equivalents. The cash and cash equivalents balance at December 31, 2018 and 2019 represents cash in readily available checking and money market accounts.

**Concentration of Credit Risk**

Financial instruments, which potentially subject the Company to concentration of credit risk, consist primarily of cash, cash equivalents, and accounts receivable. The Company maintains deposits in federally
insured financial institutions in excess of federally insured limits. Management believes that the Company is not exposed to significant credit risk due to
the financial position of the depository institutions in which those deposits are held.

Significant payors are those which represent more than 10% of the Company’s total revenue or accounts receivable balance at each respective
balance sheet date. For each significant payor, diagnostic services revenue as a percentage of total diagnostic services revenue and accounts receivable
as a percentage of total accounts receivable are as follows:

<table>
<thead>
<tr>
<th>Payors</th>
<th>Diagnostics Services Revenue Year Ended December 31, 2019</th>
<th>Accounts Receivable As of December 31, 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Client Payors</td>
<td>64%</td>
<td>49%</td>
</tr>
<tr>
<td>Healthcare Insurers</td>
<td>29%</td>
<td>47%</td>
</tr>
<tr>
<td>Government Payors</td>
<td>7%</td>
<td>4%</td>
</tr>
</tbody>
</table>

For the year ended December 31, 2019, approximately 38% of the Company’s revenue was related to the Anser® test, its lead diagnostic test.

The Company is dependent on key suppliers for certain laboratory materials. An interruption in the supply of these materials would temporarily
impact the Company’s ability to perform testing services.

Disaggregation of Revenue

The following table includes the Company’s diagnostic services revenue as disaggregated by payor and customer category for the year ended
December 31, 2019 (in thousands):

<table>
<thead>
<tr>
<th>Payors</th>
<th>Revenue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Client Payors</td>
<td>$ 14,594</td>
</tr>
<tr>
<td>Healthcare Insurers</td>
<td>6,528</td>
</tr>
<tr>
<td>Government Payors</td>
<td>1,552</td>
</tr>
<tr>
<td>Total diagnostic services revenue</td>
<td>$ 22,674</td>
</tr>
</tbody>
</table>

Property and Equipment, Net

Property and equipment, including leasehold improvements, are stated at cost less accumulated depreciation and amortization. Depreciation and
amortization are recorded using the straight-line method over the estimated useful lives of the related assets, which ranges from three to seven years.
Leasehold improvements are amortized on a straight-line basis over the shorter of the estimated useful lives of the assets or the remaining lease term.
Repairs and maintenance charges that do not increase the useful life of the assets are charged to operating expenses as incurred.

Long-Lived Assets and Goodwill

The Company’s long-lived assets are comprised principally of its property and equipment, finite lived intangible assets, and goodwill.

Goodwill represents the excess of the purchase price over the net amount of identifiable assets acquired and liabilities assumed in the acquisition
of PLI measured at fair value. Goodwill is reviewed for impairment annually (during the fourth quarter) or more frequently if indicators of impairment
exist. We performed a qualitative impairment test during the fourth quarter of 2019 and concluded that there was no indication of impairment of
goodwill.
Intangible assets acquired in a business combination are recognized separately from goodwill and are initially recognized at their fair value at the acquisition date (which is regarded as their cost). Intangible assets are amortized over the estimated useful life of the asset on a basis that approximates the pattern of economic benefit. Intangible assets are reviewed for impairment at least annually or if indicators of potential impairment exist. There was no indication of impairment of intangible assets for any of the periods presented.

If the Company identifies a change in the circumstances related to its long-lived assets, such as property and equipment and intangible assets (other than goodwill), that indicates the carrying value of any such asset may not be recoverable, the Company will perform an impairment analysis. A long-lived asset (other than goodwill) is not recoverable when the undiscounted cash flows expected to be generated by the asset (or asset group) are less than the asset’s carrying amount. Any required impairment loss would be measured as the amount by which the asset’s carrying value exceeds its fair value, and would be recorded as a reduction in the carrying value of the related asset and a charge to operating expense.

Deferred Rent

Rent expense is recorded on a straight-line basis over the term of the Company’s facility lease. The difference between rent expense and amounts paid under the lease are recorded as deferred rent in the accompanying consolidated balance sheets.

Revenue Recognition

The Company recognizes revenue in accordance with Accounting Standards Update (ASU) No. 2014-09, Revenue from Contracts with Customers (ASC 606). In accordance with ASC 606, the Company performs the following steps in determining the appropriate amount of revenue to be recognized as it fulfills its obligations under each of these agreements: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when, or as, the Company satisfies each performance obligation. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Diagnostic Services Revenue

Substantially all of the Company’s revenue has been derived from sales in the Company’s diagnostic services business and are primarily comprised of a high volume of relatively low-dollar transactions. The diagnostic services business, which provides clinical testing services to gastroenterologists, satisfies its performance obligation and recognizes revenue upon completion of the testing process, when results are reported. The Company’s service is a single performance obligation. The healthcare professionals who order the Company’s testing products and to whom test results are reported are generally not responsible for payment for these products. The parties that pay for these services consist of client payors (i.e., hospitals, other laboratories, etc.), healthcare insurers, government payors (primarily Medicare and Medicaid), and patient self-pay. The Company estimates the amount of consideration it expects to be entitled to receive from customer groups, using the portfolio approach, in exchange for providing services. These estimates include the impact of contractual allowances, including payor denials, and price concessions, as discussed below. The portfolios determined using the portfolio approach consist of the following groups of customers: client payors, healthcare insurers, and government payors. Contracts with customers in the diagnostic services business do not contain significant financing components based on the typical period of time between performance of services and collection of consideration.
The process for estimating revenue and the ultimate collection of accounts receivable involves significant judgment and estimation. The Company follows a standard process, which considers historical denial and collection experience and other factors (including the period the receivables have been outstanding), to estimate contractual allowances and implicit price concessions, recording adjustments in the current period as changes in estimates. Further adjustments to the allowances, based on actual receipts, may be recorded upon settlement.

The following are descriptions of the diagnostic services business’ portfolios:

**Client Payors**

Client payors include hospitals and commercial laboratories and are billed based on negotiated fee schedules. Credit risk and ability to pay are more of a consideration for these payors than healthcare insurers and government payors. Collection of consideration the Company expects to receive generally occurs within 60 to 90 days of billing. In addition to the Company’s standard approach to establishing allowances for doubtful accounts (which considers a number of factors including the period the receivables have been outstanding), the Company’s approach to client payor receivables also focuses on specific account reviews, historical collection experience and other factors.

**Healthcare Insurers and Government Payors**

Healthcare insurers and government payors are billed at the Company’s list price. Net revenue recognized consist of amounts billed net of allowances for differences between amounts billed and the estimated consideration the Company expects to receive from such payors. The process for estimating revenue and the ultimate collection of accounts receivable involves significant judgment and estimation. The Company follows a standard process, which considers historical denial and collection experience, insurance reimbursement policies and other factors, to estimate allowances and implicit price concessions, recording adjustments in the current period as changes in estimates. Further adjustments to the allowances, based on actual receipts, is recorded upon settlement. The transaction price is estimated using an expected value method on a portfolio basis. The Company’s portfolios are grouped per payor (i.e. each individual third-party insurance, Medicare, patient self-pay, etc.) and per test basis. Collection of the Company’s net revenue from healthcare insurers and government payors is normally a function of providing complete and correct billing information to the healthcare insurers and government payors and generally occurs within 30 to 150 days of billing.

As of December 31, 2019, unbilled receivables totaled $0.8 million. The unbilled receivables are amounts that will become due for which an unconditional right to consideration exists.

**Therapeutics Collaboration Revenue**

To date, all of the Company’s collaboration revenue has been derived from its development agreement with Millennium Pharmaceuticals, Inc., a subsidiary of Takeda Pharmaceutical Company Limited (collectively, Takeda) as described in Note 6. The terms of this arrangement include the following types of payments to the Company: non-refundable, up-front license fees; development, regulatory and commercial milestone payments; payments for research and development services provided by the Company; and royalties on net sales of licensed products. At the initiation of an agreement, the Company analyzes whether each unit of account results in a contract with a customer under ASC 606 or in an arrangement with a collaborator subject to guidance under ASC 808, Collaborative Arrangements (ASC 808).

The Company considers a variety of factors in determining the appropriate estimates and assumptions under these arrangements, such as whether the elements are distinct performance obligations, whether there are observable stand-alone prices, and whether any licenses are functional or symbolic. The Company evaluates each performance obligation to determine if it can be satisfied and recognized as revenue at a point in time or over time. Typically, license fees, non-refundable upfront fees, and funding of research activities are considered fixed,
while milestone payments are identified as variable consideration which must be evaluated to determine if it is constrained and, therefore, excluded from the transaction price. The Company estimates the amount of variable consideration using the most likely amount, as milestone payments typically only have two possible outcomes. The Company recognizes revenue for sales-based royalty promised in exchange for the license of intellectual property only when the subsequent sale occurs.

The Company may allocate transaction price using a number of methods including estimating standalone selling price of performance obligations and using the residual approach when the standalone selling price of the license is highly variable or uncertain, and observable standalone selling prices exist for the other goods or services promised in the contract.

The Company receives payments from its collaborators based on terms established in each contract. Upfront payments and other payments may require deferral of revenue recognition to a future period until the Company performs its obligation under its collaboration arrangements. Amounts are recorded as accounts receivable when the Company’s right to consideration is unconditional. The Company does not assess whether a contract has a significant financing component if the expectation at contract inception is such that the payment by the customer is akin to a deposit for research and development services.

Cost of Revenue

Cost of diagnostic services revenue generally consists of the cost of materials and consumables, personnel-related expenses (comprised of salaries, benefits, bonuses, and stock-based compensation), shipping and handling, royalties, professional services, equipment and allocated overhead costs associated with delivery of diagnostic services. Allocated overhead costs include allocated occupancy costs.

Research and Development and Clinical Trial Accruals

Research and development costs are charged to expense as incurred. Research and development expenses include certain payroll and personnel expenses, laboratory supplies, consulting costs, external contract research and development expenses, and allocated overhead, including rent, equipment depreciation and utilities. Advance payments for goods or services for future research and development activities are deferred and expensed as the goods are delivered or the related services are performed.

The Company estimates preclinical studies and clinical trial expenses based on the services performed pursuant to contracts with research institutions and clinical research organizations that conduct and manage preclinical studies and trials on the Company’s behalf. In addition, clinical study and trial materials are manufactured by contract manufacturing organizations. In accruing for these services, the Company estimates the time period over which services will be performed and the level of effort to be expended in each period. These estimates are based on communications with the third-party service providers and the Company’s estimates of accrued expenses and on information available at each balance sheet date. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company will adjust the accrual accordingly.

Advertising and Marketing Costs

Costs associated with advertising and marketing activities are expensed as incurred. Total advertising and marketing costs were $0 and $1.0 million for the years ended December 31, 2018 and 2019, respectively.

Shipping and Handling Costs

Costs incurred for shipping and handling are included in costs of diagnostic services revenue in the accompanying consolidated statements of operations and were $0 and $1.2 million for the years ended December 31, 2018 and 2019, respectively.

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Patent Costs

Costs related to filing and pursuing patent applications are recorded as general and administrative expense in the accompanying consolidated statements of operations and are expensed as incurred since recoverability of such expenditures is uncertain.

Restructuring Costs

A liability for costs associated with an exit or disposal activity under a restructuring project is recognized when the plan has been finalized. Employee termination benefits considered as post-employment benefits are accrued when the obligation is probable and estimable, such as benefits stipulated by human resource policies and practices or statutory requirements. One-time termination benefits are recognized at the date the employee is notified. If the employee must provide future service greater than 60 days, such benefits are recognized ratably over the future service period.

Fair Value Measurements

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. The carrying amounts of the Company’s financial instruments, including cash equivalents, accounts receivable, prepaid expenses and other current assets, accounts payable, accrued expenses and other current liabilities approximate fair value due to their short-term nature.

Stock-Based Compensation

The Company expenses stock-based compensation to employees and non-employees over the requisite service period (usually the vesting period) on a straight-line basis, net of actual forfeitures during the period, based on the estimated grant-date fair value of the awards. The Company estimates the fair value of stock option grants using the Black-Scholes option pricing model, and the assumptions used in calculating the fair value of stock-based awards represent management’s best estimates and involve inherent uncertainties and the application of management’s judgment.

For restricted stock awards, the fair value of the award is the estimated fair value of the Company’s common stock on the grant date, as determined by the Company’s board of directors.

Valuation of Common Stock

Given the absence of a public trading market for the Company’s common stock, its board of directors exercised their judgment and considered a number of objective and subjective factors to determine the best estimate of the fair value of the Company’s common stock, such as: contemporaneous valuations performed by independent third-party specialists, its stage of development, including the status of its research and development efforts of its therapeutic product candidates, the financial results of the Diagnostic services business and the material risks related to its businesses and industry, its results of operations and financial position, including its levels of capital resources, the prices at which its sold shares of its convertible preferred stock, the rights, preferences and privileges of its convertible preferred stock relative to those of its common stock, the conditions in the biotechnology industry and the economy in general, the stock price performance and volatility of comparable life sciences public companies, as well as recently completed mergers and acquisitions of peer companies, the likelihood of achieving a liquidity event for the holders of its common stock or convertible preferred stock, such as an IPO or a sale of the Company given prevailing market conditions, trends and developments in its industry, external market conditions affecting the life sciences and biotechnology sectors, and the lack of liquidity of its common stock, among other factors.
After the completion of the IPO, the Company’s board of directors will determine the fair value of each share of underlying common stock based on the closing price of the Company’s common stock as reported by the then applicable trading market on the date of the grant. The Company’s board of directors intended all options granted to be exercisable at a price per share not less than the per share fair value of its common stock underlying those options on the grant date.

**Income Taxes**

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities are determined on the basis of the differences between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

The Company recognizes net deferred tax assets to the extent that the Company believes these assets are more likely than not to be realized. In making such a determination, management considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. If management determines that the Company would be able to realize its deferred tax assets in the future in excess of their net recorded amount, management would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

The Company records uncertain tax positions on the basis of a two-step process whereby (1) management determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (2) for those tax positions that meet the more-likely-than-not recognition threshold, management recognizes the largest amount of tax benefit that is more than 50 percent likely to be realized upon ultimate settlement with the related tax authority. The Company recognizes interest and penalties related to unrecognized tax benefits within income tax expense. Any accrued interest and penalties are included within the related tax liability.

**Net Loss Per Share**

Basic net loss per share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the period. Diluted net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common stock equivalents outstanding for the period determined using the treasury-stock method. The Company has excluded 6,209,923 and 3,585,808 weighted-average shares subject to repurchase or forfeiture from the weighted-average number of common shares outstanding for the years ended December 31, 2018 and 2019, respectively. Dilutive common stock equivalents are comprised of convertible preferred stock and options outstanding under the Company’s stock option plan.

Basic and diluted net loss per share attributable to common holders per share is presented in conformity with the two-class method required for participating securities as the convertible preferred stock are considered participating securities. The Company’s participating securities do not have a contractual obligation to share in the Company’s losses. As such, the net loss was attributed entirely to common stockholders. Accordingly, for the years ended December 31, 2018 and 2019, there is no difference in the number of shares used to calculate basic and diluted shares outstanding.
Potentially dilutive securities not included in the calculation of diluted net loss per share because to do so would be anti-dilutive are as follows (in common stock equivalent shares):

<table>
<thead>
<tr>
<th></th>
<th>December 31, 2018</th>
<th>December 31, 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Convertible preferred stock outstanding</td>
<td>28,561,076</td>
<td>58,145,867</td>
</tr>
<tr>
<td>Common stock options issued and outstanding</td>
<td>5,460,000</td>
<td>13,843,336</td>
</tr>
<tr>
<td>Total</td>
<td>34,021,076</td>
<td>71,989,203</td>
</tr>
</tbody>
</table>

**Unaudited Pro Forma Net Loss Per Share**

Unaudited basic and diluted pro forma net loss per share were computed to give effect to the conversion of the Company’s convertible Preferred stock using the as-if converted method into common shares as though the conversion had occurred as of the beginning of the period presented, or the date of issuance, if later. The following table summarizes the Company’s unaudited pro forma net loss per share for the year ended December 31, 2019 (in thousands, except share and per share data):

<table>
<thead>
<tr>
<th>Numerator</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Net loss attributable to common stockholders</td>
<td>$(2,065,037)</td>
<td>$(2,065,037)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Denominator</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Weighted-average common shares outstanding, basic and diluted</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pro forma adjustments to reflect assumed conversion of convertible preferred stock</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Weighted-average shares used to compute pro forma net loss per share, basic and diluted</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pro forma net loss per share attributable to common stockholders, basic and diluted</td>
<td>$(0.16)</td>
<td>$(0.16)</td>
</tr>
</tbody>
</table>

**Comprehensive Loss**

Net loss and comprehensive loss were the same for the periods presented; therefore, a separate statement of comprehensive loss is not included in the accompanying consolidated financial statements.

**Recent Accounting Standards**

From time to time, new accounting standards are issued by the Financial Accounting Standards Board (FASB) or other standard setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the impact of recently issued standards that are not yet effective will not have a material impact on the Company’s financial position or results of operations upon adoption.

**New Accounting Pronouncements Not Yet Adopted**

In April 2012, the Jump-Start Our Business Startups Act (the JOBS Act) was signed into law. The JOBS Act contains provisions that, among other things, reduce certain reporting requirements for an emerging growth company. As an emerging growth company, the Company may elect to adopt new or revised accounting standards when they become effective for non-public companies, which typically is later than when public companies must adopt the standards. The Company has elected to take advantage of the extended transition period afforded by the JOBS Act and, as a result, will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for emerging growth companies, which are the dates included below.

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842), which supersedes FASB ASC Topic 840, Leases (Topic 840), and provides principles for the recognition, measurement, presentation and disclosure of
leases for both lessees and lessors. The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method for finance leases or on a straight-line basis over the term of the lease for operating leases. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of classification. Leases with a term of 12 months or less will be accounted for similar to existing guidance for operating leases. The Company anticipates implementing the accounting guidance for leases beginning with the annual reporting period ending December 31, 2022 and interim reporting periods in 2023. The Company is still assessing the impact that the new leasing standard will have on operations and financial position.

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments—Credit Losses: Measurement of credit Losses on Financial Instruments (ASU 2016-13), which amends the impairment model by requiring entities to use a forward looking approach based on expected losses to estimate credit losses on certain types of financial instruments, including trade receivables and available-for sale debt securities. The standard is effective for the company beginning in the first quarter of 2023, with early adoption permitted. The Company is currently evaluating the expected impact of ASU 2016-13 on its consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-13, Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement. The primary focus of the standard is to improve the effectiveness of the disclosure requirements for fair value measurements. The standard is effective for fiscal years and interim periods beginning after December 15, 2019. The Company is currently evaluating the impact of adopting this standard.

3. Fair Value Measurements and Fair Value of Financial Instruments

The accounting guidance defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the accounting guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

**Level 1** — Quoted prices in active markets for identical assets or liabilities.

**Level 2** — Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

**Level 3** — Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company’s assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability.

The Company’s financial instruments consist of Level 3 liabilities. There were no transfers within the hierarchy during the years ended December 31, 2018 and 2019. Level 3 liabilities that are measured at fair value on a recurring basis consists of the acquisition-related consideration held in escrow issued in connection with the acquisition of PLI.
Acquisition-related Consideration Held in Escrow

The fair value of the Acquisition-related consideration held in escrow represents contingent consideration recorded in connection with the acquisition of PLI and consisted of 3,500,000 shares of the Company’s Series C preferred stock and was included in the purchase price consideration. The fair value of the Series C preferred shares was determined based on recent financing transactions involving the same securities. There were no changes to the fair value during the period the obligation remained outstanding (see Note 14).

The following table summarizes the activity of the financial instruments valued using Level 3 inputs for the year ended December 31, 2019 (in thousands):

<table>
<thead>
<tr>
<th>Description</th>
<th>December 31, 2018</th>
<th>Fair value of acquisition-related consideration recorded in connection with acquisition of PLI</th>
<th>December 31, 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Balance at December 31, 2018</td>
<td>$ —</td>
<td>$3,500</td>
<td>$3,500</td>
</tr>
</tbody>
</table>

4. Balance Sheet Details

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following (in thousands):

<table>
<thead>
<tr>
<th>Description</th>
<th>December 31, 2018</th>
<th>December 31, 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnostic testing supplies</td>
<td>$—</td>
<td>$1,934</td>
</tr>
<tr>
<td>Deposits</td>
<td>63</td>
<td>400</td>
</tr>
<tr>
<td>Other prepaid expenses</td>
<td>87</td>
<td>1,365</td>
</tr>
<tr>
<td>Total</td>
<td>$150</td>
<td>$3,699</td>
</tr>
</tbody>
</table>

Property and Equipment, Net

Property and equipment, net, consist of the following (in thousands):

<table>
<thead>
<tr>
<th>Description</th>
<th>December 31, 2018</th>
<th>December 31, 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laboratory equipment</td>
<td>$58</td>
<td>$3,153</td>
</tr>
<tr>
<td>Office equipment and furniture</td>
<td>24</td>
<td>288</td>
</tr>
<tr>
<td>Leasehold improvements</td>
<td>—</td>
<td>1,195</td>
</tr>
<tr>
<td>Construction in process</td>
<td>—</td>
<td>3,390</td>
</tr>
<tr>
<td>Less accumulated depreciation and amortization</td>
<td>(5)</td>
<td>(1,213)</td>
</tr>
<tr>
<td>Total</td>
<td>$77</td>
<td>$6,813</td>
</tr>
</tbody>
</table>

Depreciation and amortization expense related to property and equipment was $5,000 and $1.2 million for the years ended December 31, 2018 and 2019, respectively.

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Intangible Assets

Intangible assets, net, all of which were recorded in connection with the acquisition of PLI in 2019, consist of the following at December 31, 2019 (in thousands, except years):

<table>
<thead>
<tr>
<th>Intangible assets subject to amortization:</th>
<th>Weighted Average Amortization Period (in years)</th>
<th>Gross Amount</th>
<th>Accumulated Amortization</th>
<th>Intangible assets, net</th>
</tr>
</thead>
<tbody>
<tr>
<td>Developed technology</td>
<td>10.0</td>
<td>$2,600</td>
<td>$130</td>
<td>$2,470</td>
</tr>
<tr>
<td>Trademarks and tradenames</td>
<td>6.0</td>
<td>800</td>
<td>108</td>
<td>692</td>
</tr>
<tr>
<td>Customer relationships</td>
<td>7.0</td>
<td>2,500</td>
<td>250</td>
<td>2,250</td>
</tr>
<tr>
<td><strong>Total intangibles subject to amortization</strong></td>
<td><strong>8.2</strong></td>
<td><strong>$5,900</strong></td>
<td><strong>488</strong></td>
<td><strong>$5,412</strong></td>
</tr>
</tbody>
</table>

Amortization expense related to intangible assets was $0 and $0.5 million for the years ended December 31, 2018 and 2019, respectively.

As of December 31, 2019, total future amortization expense related to assets subject to amortization is as follows (in thousands):

<table>
<thead>
<tr>
<th>Years ended December 31,</th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>2020</td>
<td>$1,200</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2021</td>
<td>854</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2022</td>
<td>727</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2023</td>
<td>639</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2024</td>
<td>568</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thereafter through 2029</td>
<td>1,424</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total future amortization expense</strong></td>
<td><strong>$5,412</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>December 31,</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2018</td>
</tr>
<tr>
<td>Accrued research and development</td>
<td>$—</td>
</tr>
<tr>
<td>Accrued legal and consulting</td>
<td>119</td>
</tr>
<tr>
<td>Accrued clinical study expenses</td>
<td>—</td>
</tr>
<tr>
<td>Accrued royalties</td>
<td>—</td>
</tr>
<tr>
<td>Unvested early exercise liability</td>
<td>10</td>
</tr>
<tr>
<td>Accrued other</td>
<td>77</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>$206</strong></td>
</tr>
</tbody>
</table>

Accrued Rebates and Sales Returns

At December 31, 2019, accrued rebates and sales returns consist of the following (in thousands):

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Accrued rebates</td>
<td>$10,381</td>
<td></td>
</tr>
<tr>
<td>Accrued sales returns</td>
<td>2,237</td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>$12,618</strong></td>
<td></td>
</tr>
</tbody>
</table>
As further discussed in Note 7, the Company has recorded liabilities for rebates and sales returns associated with PLI which existed as of the purchase date for pharmaceutical products divested by PLI prior to the acquisition by the Company. As a result of the PLI acquisition, the Company assumed a liability of approximately $9.0 million related to state government rebates for pharmaceutical products previously divested by PLI and recorded a corresponding indemnification asset of approximately $7.0 million for the expected reimbursement to be received from Nestlé as rebates are settled by the Company. No payments were made or reimbursements received during the year ended December 31, 2019 related to this liability and asset. The Company plans to dispute a portion of this liability with state governments; however, it is uncertain that the Company will be successful. If the Company is successful, this could have a material impact on the consolidated statements of operations in the future. Also included in the December 31, 2019 balance is approximately $1.4 million related to accrued rebate amounts that the Company expects to receive full reimbursement for from the entity that acquired the pharmaceutical products divested by PLI. A corresponding receivable is included in other current assets in the consolidated balance sheet as of December 31, 2019.

The Company also assumed liabilities related to returns of previously divested pharmaceutical products. The return window for the product returns ends on October 31, 2020. The Company estimated the expected returns using historical sales and returns information. Actual returns may materially differ from these estimates and the change in estimate may have a material impact on the consolidated statements of operations in the future.

5. Restructuring

During the year ended December 31, 2019, the Company recorded restructuring charges of $5.5 million within the diagnostic services reportable segment. The charges were primarily for severance and other personnel costs resulting from workforce reduction initiatives associated with the Company’s integration and restructuring activities of PLI after the acquisition. At December 31, 2019, the Company had paid the entire $5.5 million of the accrued severance and personnel costs and the restructuring was completed by December 31, 2019.

The following table summarizes the restructuring liability activity for the year ended December 31, 2019 (in thousands):

<table>
<thead>
<tr>
<th>Description</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Balance at December 31, 2018</td>
<td>$ —</td>
</tr>
<tr>
<td>Restructuring liability incurred</td>
<td>5,484</td>
</tr>
<tr>
<td>Restructuring liability paid</td>
<td>(5,484)</td>
</tr>
<tr>
<td>Balance at December 31, 2019</td>
<td>$ —</td>
</tr>
</tbody>
</table>

6. Collaboration and License Agreements

Cedars-Sinai Medical Center

In September 2017, the Company entered into an Exclusive License Agreement (License Agreement) with Cedars-Sinai Medical Center (Cedars-Sinai), a related party. Under the terms of the License Agreement, Cedars-Sinai granted the Company an exclusive, worldwide, royalty bearing license with respect to certain patent rights, information and materials related to therapeutic targets and companion diagnostic products, in each case to conduct research, develop, and commercialize therapeutic and diagnostic products for the diagnosis and treatment of IBD. The licensed technology includes information and materials arising out of Cedars-Sinai’s database and biobank, as well as exclusive access to this database and biobank to develop diagnostic and therapeutic products for human use, which biobank is an integral part of the Company’s Prometheus 360 platform.

As consideration for the license rights, in September 2017 the Company issued (i) 2,575,000 shares of fully vested common stock, and (ii) 3,350,000 shares of unvested restricted common stock. The fair value of all of the shares were measured at the date of issuance. The shares of unvested restricted common stock have vesting
conditions that are tied to continuing services required of certain Cedars-Sinai employees pursuant to consulting agreements with the Company. One third of the restricted shares are released from restriction annually on the anniversary of the Agreement over a three-year period. Additionally, the Company is obligated to pay Cedars-Sinai low- to mid-single digit percentage royalties on net sales of products covered under the License Agreement. The term of, and the Company’s royalty obligations under, the License Agreement expires on a licensed product-by-product and country-by-country basis on the later of ten years from the date of first commercial sale or when there is no longer a valid patent claim covering such licensed product in such country.

In 2017, the Company and Cedars-Sinai also entered into Research agreements, under which the parties can provide research services to each other at pricing specified in individual statements of work. During the years ended December 31, 2018 and 2019, no services were provided under the agreements.

Collaboration Agreement with Millennium Pharmaceuticals, Inc., a subsidiary of Takeda Pharmaceutical Company Limited

In March 2019, the Company entered into a Companion Diagnostics Development and Collaboration Agreement (the Takeda Collaboration Agreement) with Millennium Pharmaceuticals, Inc., a wholly-owned subsidiary of Takeda. Pursuant to this agreement, the Company established a strategic collaboration under which it will develop a companion diagnostic product (Diagnostic Product) for one selected drug target, with the option for Takeda to select an additional drug target (each, a Collaboration Target), in support of development and potential commercialization by Takeda of any therapeutic clinical candidates that it develops in connection with the agreement directed against a Collaboration Target for the treatment of IBD (Takeda Drugs). The Company will be responsible for development and commercialization of the Diagnostic Product(s) pursuant to the terms and conditions of the agreement, while Takeda will be responsible for all future clinical development and commercialization of the Takeda Drug(s).

In consideration of the rights granted to Takeda under the agreement, the Company received a one-time upfront payment of $1.5 million and is eligible to receive future development and regulatory milestone payments of up to $47.9 million for each Collaboration Target, commercial milestone payments of up to $25.0 million in connection with each Collaboration Target for successful commercialization of the applicable Takeda Drug and the associated Diagnostic Product, and sales milestone payments of up to $75.0 million in connection with each Collaboration Target, provided that regulatory approval for the applicable Takeda Drug includes use of the associated Diagnostic Product. In addition, the Company is eligible to receive low-single digit percentage royalties on net sales of all Takeda Drugs. In addition, Takeda is obligated to pay the Company for certain research expenses incurred under the agreement up to $1.8 million. The term of, and the royalty obligations under, the Takeda Agreement expires on a Takeda Drug-by-Takeda Drug and country-by-country basis on the later of (i) ten years from the date of first commercial sale, (ii) when there is no longer a valid patent claim covering a Takeda Drug in such country, and (iii) expiration of any applicable regulatory exclusivity for such Takeda Drug.

At inception and through December 31, 2019, the Company has identified one performance obligation per each target for all the deliverables under the agreement since the delivered elements are not distinct within the context of the contract. Accordingly, the Company will recognize revenue for the transaction price in an amount proportional to the collaboration expenses incurred and the total estimated collaboration expenses over the three-year period over which it expects to satisfy its performance obligations. The Company included one milestone in the transaction price as it was deemed not probable of significant reversal at the inception of the agreement. Due to the uncertainty in the achievement of the developmental and commercial milestones, the variable consideration associated with these future milestone payments has been fully constrained (excluded) from the transaction price until such time that the Company concludes that it is probable that a significant reversal of previously recognized revenue will not occur. These estimates will be re-assessed at each reporting period. In connection with the Takeda Collaboration Agreement, the Company recognized revenue of $1.1 million for the year ended December 31, 2019 and had deferred revenue of $1.5 million as of December 31, 2019. This deferred revenue balance is expected to be recognized in 2020.

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A reconciliation of deferred revenue related to the Takeda Collaboration Agreement for the year ended December 31, 2019 is as follows (in thousands):

<table>
<thead>
<tr>
<th>Description</th>
<th>Amount (in thousands)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Balance at December 31, 2018</td>
<td>$ —</td>
</tr>
<tr>
<td>Amounts received in 2019</td>
<td>2,660</td>
</tr>
<tr>
<td>Revenue recognized in 2019</td>
<td>(1,118)</td>
</tr>
<tr>
<td>Balance at December 31, 2019</td>
<td>$ 1,542</td>
</tr>
</tbody>
</table>

**Master Services Agreement with Takeda Pharmaceutical Company Limited**

During December 2019, the Company entered into a Master Service Agreement with Takeda that provides Takeda a license to commercialize one of the Company’s diagnostic products, as well as an obligation by the Company to administer the diagnostic tests and report the results of tests performed, including customer service support, logistics and quality assurance activities.

Pursuant to the terms of the agreement, the Company will receive payments based on the number of tests performed and reimbursement for defined expenses. Additionally, the Company will receive two milestone payments, each for $0.5 million, upon the achievement of defined results in 2020. As of December 31, 2019, activities under the agreement had not commenced, no consideration had been received, and no revenue has been recognized during the year ended December 31, 2019.

7. **BUSINESS COMBINATION**

On June 30, 2019 (the Closing Date), the Company acquired 100% of the common stock of PLI and the related intangible assets used by PLI for total consideration of approximately $31.7 million, consisting of the issuance of 16.5 million shares of the Company’s Series C convertible preferred stock with a fair value of $16.5 million, the present value of $15.0 million in deferred cash payments due as follows: $5.0 million due on June 30, 2020 and $10.0 million due on June 30, 2021, and acquisition-related contingent consideration consisting of 3.5 million shares of the of the Company’s Series C convertible preferred stock with a fair value of $3.5 million. The deferred cash payments totaling $15.0 million are not contingent upon any event and to reflect the interest component were discounted at 12%. On June 30, 2020, $5.0 million of deferred cash payments were converted to 5,000,000 Series C preferred stock (see Note 14). The acquisition-related contingent consideration stipulated certain revenue thresholds for the Anser® test during the first calendar year following the acquisition. The shares were released from escrow on June 30, 2020 (see Note 14). As part of the acquisition, the Company acquired PLI’s Clinical Laboratory Improvement Amendments (CLIA) laboratory.

Total transaction costs incurred in connection with this acquisition totaled $0.5 million in the year ended December 31, 2019 and are included in general and administrative expenses in the accompanying consolidated statements of operations.

Consideration transferred was allocated to the tangible and intangible assets acquired and liabilities assumed based on their fair values as of the acquisition date. Management estimated the fair value of tangible and intangible assets and liabilities in accordance with the applicable accounting guidance for business combinations and utilized the assistance of third-party valuation specialists. The significant assumptions used to estimate the fair value of the acquired intangible assets included projected cash flows, discount rates, net working capital and long-term growth rate. The initial allocation of the consideration transferred is based on a preliminary valuation and is subject to adjustments. Balances subject to adjustment primarily include the valuations of acquired assets (tangible and intangible), liabilities assumed, as well as tax-related matters. During the measurement period, the Company may record adjustments to the provisional amounts recognized. The initial allocation of the consideration transferred will be finalized within the measurement period (up to one year from the acquisition date).
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The initial allocation of the purchase price is as follows (in thousands):

<table>
<thead>
<tr>
<th>Fair Value</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>$8,917</td>
<td>Cash</td>
</tr>
<tr>
<td>11,989</td>
<td>Accounts receivable</td>
</tr>
<tr>
<td>6,975</td>
<td>Indemnification receivable from Nestlé—related party</td>
</tr>
<tr>
<td>4,318</td>
<td>Receivables from Nestlé—related party</td>
</tr>
<tr>
<td>22,473</td>
<td>Assets related to divested therapeutic product</td>
</tr>
<tr>
<td>2,852</td>
<td>Diagnostic testing supplies</td>
</tr>
<tr>
<td>1,666</td>
<td>Other current assets</td>
</tr>
<tr>
<td>6,910</td>
<td>Property and equipment</td>
</tr>
<tr>
<td>5,900</td>
<td>Intangible assets</td>
</tr>
<tr>
<td>724</td>
<td>Goodwill</td>
</tr>
<tr>
<td>(10,891)</td>
<td>Current liabilities</td>
</tr>
<tr>
<td>(400)</td>
<td>Payable to Nestlé—related party</td>
</tr>
<tr>
<td>(2,040)</td>
<td>Liabilities associated with terminated compensation plans</td>
</tr>
<tr>
<td>(27,225)</td>
<td>Liabilities associated with divested therapeutic product</td>
</tr>
<tr>
<td>(506)</td>
<td>Deferred income tax liabilities</td>
</tr>
<tr>
<td>$31,662</td>
<td>Total estimated purchase price allocation</td>
</tr>
</tbody>
</table>

The sales and purchase agreement, as amended, contains an indemnification clause in which Nestlé agreed to reimburse the Company certain amounts for certain claims that existed at the Closing Date. Included in the initial allocation of the purchase price is a liability of approximately $9.0 million related to state government rebates for pharmaceutical products previously divested by PLI. In addition, the initial allocation of the purchase price includes an indemnification asset of approximately $7.0 million for the expected reimbursement the Company expects to receive from Nestlé as these rebates are settled by the Company, in accordance with the purchase agreements, as amended.

In addition, the Company recorded a receivable from Nestlé totaling approximately $4.3 million related to liabilities resulting from the termination of certain Nestlé compensation plans at the time of the acquisition. Pursuant to the terms of the acquisition, Nestlé was obligated to reimburse the Company for these costs. During the year ended December 31, 2019, the Company received and settled $3.3 million related to this arrangement (see Note 11).

Additionally, the Company recorded acquired assets and liabilities related to pharmaceutical products divested by PLI prior to the acquisition by the Company. All these assets and liabilities were settled prior to December 31, 2019, other than the liabilities related to accrued rebates and sales returns (see Note 4).

The Company acquired intangible assets that consisted of developed technology, trademarks and tradenames and customer relationships, which had an estimated fair value in total of $5.9 million. The fair values of these assets were determined using a multi-period income approach, which was based on the present value of projected cash flows. The intangible asset recorded for developed technology will be amortized on a straight-line basis over its estimated useful lives. The intangible assets recorded for customer relationships and trademarks and tradenames will be amortized using an accelerated method of amortization representing the expected pattern of economic benefit.

The excess of the fair value of the total purchase price consideration over the fair value of the net assets acquired was recorded as goodwill. The goodwill reflects the Company’s expectations to leverage the acquired intellectual property and related know-how to help the Company develop companion diagnostics for multiple therapeutic product candidates for the treatment of IBD. The goodwill associated with the acquisition of PLI is not deductible for tax purposes.

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8. Stockholders’ Equity (Deficit)

Convertible Preferred Stock

During 2018, the Company issued 13,581,876 shares of Series B convertible preferred stock at a purchase price of $0.75 per share, raising net cash proceeds of $10.1 million.

During 2019, the Company issued an additional 13,084,791 shares of Series B convertible preferred stock at a purchase price of $0.75 per share, raising net cash proceeds of $9.8 million.

Also during 2019, the Company issued 16,500,000 shares of Series C convertible preferred stock at a price of $1.00 per share in connection with the acquisition of PLI.

The authorized, issued and outstanding shares of convertible preferred stock as of December 31, 2018 consist of the following (in thousands, except share and per share amounts):

<table>
<thead>
<tr>
<th>Series</th>
<th>Shares Authorized</th>
<th>Shares Issued and Outstanding</th>
<th>Per Share Original Issue Price</th>
<th>Liquidation Preference</th>
<th>Carrying Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>14,979,200</td>
<td>14,979,200</td>
<td>$0.50</td>
<td>$7,490</td>
<td>$7,391</td>
</tr>
<tr>
<td>B</td>
<td>26,666,667</td>
<td>13,581,876</td>
<td>$0.75</td>
<td>10,186</td>
<td>10,109</td>
</tr>
<tr>
<td>Total</td>
<td>41,645,867</td>
<td>28,561,076</td>
<td>$17,676</td>
<td>$17,500</td>
<td></td>
</tr>
</tbody>
</table>

The authorized, issued and outstanding shares of convertible preferred stock as of December 31, 2019 consist of the following (in thousands, except share and per share amounts):

<table>
<thead>
<tr>
<th>Series</th>
<th>Shares Authorized</th>
<th>Shares Issued and Outstanding</th>
<th>Per Share Original Issue Price</th>
<th>Liquidation Preference</th>
<th>Carrying Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>14,979,200</td>
<td>14,979,200</td>
<td>$0.50</td>
<td>$7,490</td>
<td>$7,391</td>
</tr>
<tr>
<td>B</td>
<td>26,666,667</td>
<td>26,666,667</td>
<td>$0.75</td>
<td>20,000</td>
<td>19,901</td>
</tr>
<tr>
<td>C</td>
<td>50,000,000</td>
<td>16,500,000</td>
<td>$1.00</td>
<td>16,500</td>
<td>16,448</td>
</tr>
<tr>
<td>Total</td>
<td>91,645,867</td>
<td>58,145,867</td>
<td>$43,990</td>
<td>$43,740</td>
<td></td>
</tr>
</tbody>
</table>

The rights, preferences and privileges of the convertible preferred stock as of December 31, 2019 were as follows:

Dividends

The Corporation shall not declare, pay or set aside any dividends on shares of any other class or series of capital stock unless the holders of Series A, B and C convertible preferred stock (collectively referred to as Preferred Stock) shall first receive, or simultaneously receive, a dividend on each outstanding share of Preferred Stock in an amount equal to (on an as-if-converted to Common Stock basis) the amount paid or set aside for each share of Common Stock. There have been no dividends declared by the board as of December 31, 2019.

Liquidation

In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company or Deemed Liquidation Event, as defined, each holder of Series C Preferred Stock is entitled to receive, prior and in preference to any distributions to the holders of Series A preferred stock, Series B preferred stock and common stock, an amount equal to the greater of (i) the Original Issue Price per share, plus any declared but unpaid dividends thereon or (ii) the amount such holder would have received if such holder had converted its shares into common stock immediately prior to such liquidation event. Subject to the prior payment of all amounts due to...
holders of Series C preferred stock, each holder of Series A and Series B preferred stock is entitled to receive, prior and in preference to any
distributions to the common stockholders, an amount equal to the greater of (i) the Original Issue Price per share, plus any declared but unpaid dividends
thereon or (ii) the amount such holder would have received if such holder had converted its shares into common stock immediately prior to such
liquidation event. In the event that the assets available for distribution to the holders of preferred stock are insufficient to pay such holders the full
amounts to which they are entitled, the assets available for distribution will be distributed on a pro rata basis among the holders of the preferred stock in
proportion to the respective amounts that would otherwise be payable in respect of such stock. After all preferential payments have been made to the
holders of preferred stock, the remaining amounts would be distributed among the holders of the Preferred Stock and common stock, pro rata based on
the number of shares held by each holder. The maximum aggregate amount the holders of Series A, B and C preferred stock are entitled to receive is
$1.50, $2.25 and $3.00 per share, respectively.

Conversion

The shares of Preferred Stock are convertible into an equal number of shares of common stock, at the option of the holder, subject to certain anti-
dilution adjustments. Each share of preferred stock is automatically converted into common stock, (A) at any time upon the affirmative election of the
holders of at least a majority of the outstanding shares of the Preferred Stock, or (B) immediately upon the closing of a firmly underwritten public
offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, covering the offer and sale of common stock for
the account of the Company in which the per share price is at least $3.00 and the aggregate gross proceeds, net of underwriting discount and
commissions, to the Company is at least $30.0 million.

Voting

The holders of Preferred stock are entitled to one vote for each share of common stock into which it would convert and to vote as one class with
the common stockholders on all matters. Also, the preferred stockholders have been granted certain rights with regard to the election of members of the
Company’s Board of Directors.

Presentation of Convertible Preferred Stock

The Company’s Preferred Stock have been classified as temporary equity in the accompanying balance sheets in accordance with authoritative
guidance for the classification and measurement of potentially redeemable securities whose redemption is based upon certain change in control events
outside of the Company’s control, including liquidation, sale or transfer of control of the Company. The Company has determined not to adjust the
carrying values of the convertible preferred stock to the liquidation preferences of such shares because the occurrence of any such change of control
event is not probable.

Common Stock

Founder Stock

During 2016 and 2017, in connection with the founding of the Company, shares of common stock were sold to certain founders (the Founder
Stock) at a price of $0.001 per share, of which 7,425,000 shares remain outstanding at December 31, 2018 and 2019, and which are subject to vesting,
genernally over a period of four years. The repurchase liability for the Founder Stock was nominal for all periods presented. For accounting purposes, the
unvested shares are not considered to be outstanding.
The following table summarizes the activity of the unvested founder stock for the years ended December 31, 2018 and 2019:

<table>
<thead>
<tr>
<th></th>
<th>December 31,</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2018</td>
<td>2019</td>
<td></td>
</tr>
<tr>
<td>Unvested at beginning</td>
<td>4,012,500</td>
<td>2,156,250</td>
<td></td>
</tr>
<tr>
<td>Vested</td>
<td>(1,856,250)</td>
<td>(1,668,750)</td>
<td></td>
</tr>
<tr>
<td>Unvested at end of</td>
<td>2,156,250</td>
<td>487,500</td>
<td></td>
</tr>
<tr>
<td>year</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Restricted Shares Issued to Cedars-Sinai**

As previously described in Note 6, in 2017, as consideration for a license agreement, the Company granted 3,350,000 shares of restricted common stock to Cedars-Sinai that vest on the anniversary date of the grant date over a three-year period.

The following table summarizes the activity of the unvested stock issued to Cedars-Sinai for the years ended December 31, 2018 and 2019:

<table>
<thead>
<tr>
<th></th>
<th>December 31,</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2018</td>
<td>2019</td>
<td></td>
</tr>
<tr>
<td>Unvested at beginning</td>
<td>3,350,000</td>
<td>2,233,333</td>
<td></td>
</tr>
<tr>
<td>Vested</td>
<td>(1,116,667)</td>
<td>(1,116,667)</td>
<td></td>
</tr>
<tr>
<td>Unvested at end of</td>
<td>2,233,333</td>
<td>1,116,666</td>
<td></td>
</tr>
<tr>
<td>year</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Chief Executive Officer Stock Option Award**

In connection with the employment of the Company’s Chief Executive Officer and President, the Company committed to grant options to purchase additional shares of the Company’s common stock under the 2017 Equity Incentive Plan upon the achievement of specified performance conditions involving the consummation of additional equity financings. As of December 31, 2019, the performance conditions were not achieved and no expense was recorded in connection with this commitment, as the achievement of the performance conditions was not considered probable.

**2017 Equity Incentive Plan**

In 2017, the Company adopted the 2017 Equity Incentive Plan (the Plan), which as amended, has 17,500,000 shares of common stock reserved for issuance. Under the Plan, the Company may grant stock options, stock appreciation rights, restricted stock, restricted stock units and other awards to individuals who are employees, non-employee directors or consultants of the Company or its subsidiaries. The maximum term of the options granted under the Plan is no more than ten years. Grants generally vest at 25% one year from the vesting commencement date and ratably each month thereafter for a period of 36 months, subject to continuous service. The Plan allows for the early exercise of all stock options granted if authorized by the board of directors at the time of grant. At December 31, 2018 and 2019, 4,240,000 shares and 2,208,539 shares, respectively, remain available for future grant under the Plan.
The Company’s stock option activity for the year ended December 31, 2019 is summarized in the following table:

<table>
<thead>
<tr>
<th></th>
<th>Number</th>
<th>Weighted-Average Exercise Price</th>
<th>Weighted-Average Remaining Contractual Term</th>
<th>Weighted-Average Grant Date (Fair Value)</th>
<th>Aggregate Intrinsic Value (in thousands)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outstanding at December 31, 2018</td>
<td>5,460,000</td>
<td>$0.05</td>
<td>9.9</td>
<td>$0.16</td>
<td>$600</td>
</tr>
<tr>
<td>Granted</td>
<td>9,721,461</td>
<td>$0.28</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exercised</td>
<td>(1,148,125)</td>
<td>$0.05</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cancelled/forfeited</td>
<td>(190,000)</td>
<td>$0.10</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Outstanding at December 31, 2019</td>
<td>13,843,336</td>
<td>$0.21</td>
<td>9.4</td>
<td>$1,104</td>
<td></td>
</tr>
<tr>
<td>Vested or expected to vest at December 31, 2019</td>
<td>13,843,336</td>
<td>$0.21</td>
<td>9.4</td>
<td>$1,104</td>
<td></td>
</tr>
<tr>
<td>Exercisable at December 31, 2019</td>
<td>5,492,857</td>
<td>$0.09</td>
<td>8.6</td>
<td>$1,104</td>
<td></td>
</tr>
</tbody>
</table>

The total intrinsic value of options exercised during the years ended December 31, 2018 and 2019 was $0 and $0.2 million, respectively. The total intrinsic value of options vested during the years ended December 31, 2018 and 2019 was $0.1 million and $0.5 million, respectively.

The grant date fair value of stock options was determined using the Black-Scholes option pricing model with the following assumptions for the years ended:

<table>
<thead>
<tr>
<th></th>
<th>2018</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk-free interest rate</td>
<td>2.3–3.0%</td>
<td>1.6–2.6%</td>
</tr>
<tr>
<td>Expected volatility</td>
<td>78–79%</td>
<td>62–70%</td>
</tr>
<tr>
<td>Expected term (in years)</td>
<td>7</td>
<td>5.0–6.1</td>
</tr>
</tbody>
</table>

**Expected Term**—The expected term of options granted represents the period of time that the options are expected to be outstanding. Due to the lack of historical exercise history, the expected term of the Company’s employee stock options has been determined utilizing the simplified method for awards that qualify as plain-vanilla options.

**Expected Volatility**—The estimated volatility was based on the historical volatility of the common stock of a group of publicly traded companies deemed comparable to the Company.

**Risk-Free Interest Rate**—The risk-free interest rate is the implied yield in effect at the time of the option grant based on U.S. Treasury securities with contract maturities similar to the expected term of the Company’s stock options.

**Dividend Rate**—The Company has not paid any cash dividends on common stock since inception and does not anticipate paying any dividends in the foreseeable future. Consequently, an expected dividend yield of zero was used.

**Early Exercise Liability**

The unvested shares of the early-exercised options are held in escrow until the stock option becomes fully vested or until the employee’s termination, whichever occurs first. The right to repurchase these shares lapses over the four-year vesting period. As of December 31, 2018 and 2019, the early exercise liability was approximately $10,000 and $29,000, respectively. For accounting purposes, the early exercise of options is not considered to be a substantive exercise until the underlying awards vest.
The following table summarizes the activity of the unvested common stock issued pursuant to an early exercise of stock option awards the years ended December 31, 2018 and 2019:

<table>
<thead>
<tr>
<th></th>
<th>Years Ended December 31,</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2018</td>
</tr>
<tr>
<td>Unvested at beginning of year</td>
<td>103,125</td>
</tr>
<tr>
<td>Early exercised stock options during the period</td>
<td>150,000</td>
</tr>
<tr>
<td>Vested</td>
<td>(57,813)</td>
</tr>
<tr>
<td>Unvested at end of year</td>
<td>195,312</td>
</tr>
</tbody>
</table>

**Stock-Based Compensation Expense**

The following table summarizes the components of stock-based compensation expense recognized in the accompanying statements of operations (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>Years Ended December 31,</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2018</td>
</tr>
<tr>
<td>Cost of revenues</td>
<td>—</td>
</tr>
<tr>
<td>Research and development</td>
<td>14</td>
</tr>
<tr>
<td>Sales and marketing</td>
<td>—</td>
</tr>
<tr>
<td>General and administrative</td>
<td>28</td>
</tr>
<tr>
<td>Total stock-based compensation</td>
<td>$ 42</td>
</tr>
</tbody>
</table>

The total unrecognized compensation cost related to unvested stock-based awards as of December 31, 2019 was $1.6 million and is expected to be recognized over a weighted average period of 3.4 years.

**Common Stock Reserved for Future Issuance**

Common stock reserved for future issuance consists of the following as of December 31, 2018 and 2019:

<table>
<thead>
<tr>
<th></th>
<th>December 31,</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2018</td>
</tr>
<tr>
<td>Conversion of convertible preferred stock</td>
<td>28,561,076</td>
</tr>
<tr>
<td>Common stock options issued and outstanding</td>
<td>5,460,000</td>
</tr>
<tr>
<td>Equity awards available for future issuance</td>
<td>4,240,000</td>
</tr>
<tr>
<td>Total</td>
<td>38,261,076</td>
</tr>
</tbody>
</table>

**9. Commitments and Contingencies**

**Leases**

Through August 2019, the Company rented office and lab space under a monthly operating rental agreement. As a result of the acquisition of PLI, the Company leases office and laboratory space under a non-cancellable operating lease agreement, as amended (PLI Lease), that expires in December 2022. Rent expense under these operating lease agreements totaled $0.2 million and $1.7 million for the years ended December 31, 2018 and 2019, respectively.

Starting July 2019, the Company agreed to sublet certain office and laboratory space under the PLI Lease through May 31, 2020. Sublease rental income recorded in the year ended December 31, 2019 totaled
$0.3 million. Future minimum sublease rental payments to be received pursuant to the lease agreement total $0.3 million.

As of December 31, 2019, the Company’s net minimum payments under the non-cancellable operating lease is as follows (in thousands):

<table>
<thead>
<tr>
<th>Year ended December 31</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$2,020</td>
</tr>
<tr>
<td>2020</td>
<td></td>
</tr>
<tr>
<td>2021</td>
<td>2,113</td>
</tr>
<tr>
<td>2022</td>
<td>2,205</td>
</tr>
<tr>
<td>Total</td>
<td>$6,338</td>
</tr>
</tbody>
</table>

**Litigation**

From time to time, the Company may become involved in legal proceedings or be subject to claims arising in the ordinary course of its business. Regardless of outcome, legal proceedings or claims can have an adverse impact on the company because of defense and settlement costs, diversion of resources and other factors, and there can be no assurances that favorable outcomes will be obtained.

The regulations governing government reimbursement programs (e.g., Medicaid, Tricare, and Medicare) and commercial payor reimbursement programs are complex and subject to interpretation. As a provider of services to patients covered under government and commercial payor programs, post payment review audits, and other forms of reviews and investigations are routine. The Company believes it complies in all material respects with the statutes, regulations, and other requirements applicable to its laboratory operations.

The Company is currently a party to the following legal proceedings, all related to alleged conduct occurring prior to the acquisition of PLI on June 30, 2019.

Between July 2019 and August 2019, PLI was served with six lawsuits alleging injuries suffered by plaintiffs were due to the ingestion of a generic allopurinol and making claims against PLI under a theory of innovator liability seeking monetary relief; the alleged ingestion of allopurinol by the plaintiffs occurred during the period from March 2016 to March 2017. PLI has since tendered to Sebela Pharmaceuticals Inc. (Sebela) for defense and indemnification of all such legal claims related to the personal injury matters and putative class action arising from these suits; PLI had previously sold the NDA relating to the innovator product (Zyloprim) to Sebela in December, 2015. As of July 2019, Sebela had assumed the defense of the cases.

In March 2018, PLI received a demand letter from James Pepio, a former employee who had been terminated as part of a reduction in force. The demand letter sought to resolve potential claims relating to alleged off-label promotion of PROLEUKIN and wrongful termination, and was rejected by PLI. In August 2019, the Company received a copy of an amended complaint in a qui tam action that had been filed under seal by Mr. Pepio in U.S. District Court for the Middle District of Florida, styled United States ex rel. James Pepio v. Prometheus Laboratories, Inc. The amended complaint brought claims on behalf of the United States and the state of Florida and alleged that the PLI violated the Federal and Florida False Claims Acts and related laws through the promotion and marketing of PROLEUKIN. The amended complaint seeks, among other things, treble damages, civil penalties for each alleged false claim, and attorneys’ fees and costs. In March 2020, the United States and the State of Florida declined to intervene in the Action and the amended complaint was subsequently unsealed. The decision not to intervene does not prevent Mr. Pepio from litigating the Action, and the United States and Florida may later seek to intervene in it. The Company accepted service of the amended complaint and intends to defend the Action vigorously. The Company’s defense of this matter is subject to its indemnification agreement with Nestlé.

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The Company records accruals for loss contingencies associated with legal matters when it is probable that a liability will be incurred and the amount of the loss can be reasonably estimated. As of December 31, 2019, the Company has determined that the liabilities associated with these certain litigation matters are not probable and cannot be reasonably estimated. Therefore, the Company has not recorded an accrual for these matters; however, the Company will continue to monitor each related legal issue and evaluate the need to adjust the related accruals based on new information and further developments. Amounts accrued for legal contingencies often result from a complex series of judgments about future events and uncertainties that rely heavily on estimates and assumptions including timing of related payments. The ability to make such estimates and judgments can be affected by various factors including, among other things, whether damages sought in the proceedings are unsubstantiated or indeterminate; scientific and legal discovery has not commenced or is not complete; proceedings are in early stages; matters present legal uncertainties; there are significant facts in dispute; procedural or jurisdictional issues; the uncertainty and unpredictability of the number of potential claims; or there are numerous parties involved. To the extent adverse verdicts are rendered against the Company, the Company does not record an accrual until a loss is determined to be probable and can be reasonably estimated.

**Indemnification Agreements**

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with officers and members of its board of directors that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. At December 31, 2018 and 2019, no claims exist under indemnification arrangements and accordingly, no amounts have been accrued in its consolidated financial statements as of December 31, 2018 and 2019.

**10. Income Taxes**

The provision for income taxes for the years ended December 31, 2018 and 2019 consists of the following (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>Years Ended December 31,</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2018</td>
<td>2019</td>
<td></td>
</tr>
<tr>
<td><strong>Current income taxes</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Federal</td>
<td>$—</td>
<td>$—</td>
<td></td>
</tr>
<tr>
<td>State</td>
<td>1</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td><strong>Total current</strong></td>
<td>1</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td><strong>Deferred income taxes</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Federal</td>
<td>—</td>
<td>(281)</td>
<td></td>
</tr>
<tr>
<td>State</td>
<td>—</td>
<td>(225)</td>
<td></td>
</tr>
<tr>
<td><strong>Total deferred</strong></td>
<td>—</td>
<td>(506)</td>
<td></td>
</tr>
<tr>
<td><strong>Provision for income taxes</strong></td>
<td>$1</td>
<td>$(501)</td>
<td></td>
</tr>
</tbody>
</table>

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A reconciliation of the Company’s effective tax rate and federal statutory tax rate is summarized as follows (in thousands):

<table>
<thead>
<tr>
<th>Years Ended December 31</th>
<th>2018</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Income tax expense (benefit) at statutory rates</td>
<td>$(1,427)</td>
<td>$(6,348)</td>
</tr>
<tr>
<td>State income tax, net of federal benefit</td>
<td>(473)</td>
<td>(1,137)</td>
</tr>
<tr>
<td>Permanent items</td>
<td>4</td>
<td>286</td>
</tr>
<tr>
<td>Change in valuation allowance</td>
<td>2,176</td>
<td>7,864</td>
</tr>
<tr>
<td>Return to provision adjustment</td>
<td>—</td>
<td>(51)</td>
</tr>
<tr>
<td>Research and development tax credits</td>
<td>(279)</td>
<td>(1,115)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>$1</td>
<td>$(501)</td>
</tr>
</tbody>
</table>

Deferred income taxes reflect the net tax effects of loss and credit carryforwards and temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company’s deferred tax assets and liabilities for federal and state income taxes are follows (in thousands):

<table>
<thead>
<tr>
<th>December 31</th>
<th>2018</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deferred tax assets:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Net operating loss carryforward</td>
<td>$2,143</td>
<td>$8,065</td>
</tr>
<tr>
<td>Research tax credits</td>
<td>298</td>
<td>1,317</td>
</tr>
<tr>
<td>Intangible assets</td>
<td>—</td>
<td>2,663</td>
</tr>
<tr>
<td>Reserves</td>
<td>—</td>
<td>519</td>
</tr>
<tr>
<td>Accrued and other</td>
<td>8</td>
<td>853</td>
</tr>
<tr>
<td>Stock-based compensation</td>
<td>10</td>
<td>29</td>
</tr>
<tr>
<td><strong>Total deferred tax assets</strong></td>
<td>2,455</td>
<td>13,446</td>
</tr>
<tr>
<td>Less valuation allowance</td>
<td>(2,455)</td>
<td>(11,714)</td>
</tr>
<tr>
<td><strong>Net deferred tax assets</strong></td>
<td>$4</td>
<td>1,732</td>
</tr>
</tbody>
</table>

Deferred tax liabilities:

<table>
<thead>
<tr>
<th>December 31</th>
<th>2018</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Property and equipment</td>
<td>(4)</td>
<td>(1,478)</td>
</tr>
<tr>
<td>Prepaid expenses and other current assets</td>
<td>—</td>
<td>(254)</td>
</tr>
<tr>
<td><strong>Total deferred tax liabilities</strong></td>
<td>(4)</td>
<td>(1,732)</td>
</tr>
<tr>
<td><strong>Net deferred tax assets</strong></td>
<td>$—</td>
<td>$—</td>
</tr>
</tbody>
</table>

A valuation allowance is required to be established when it is more likely than not that all or a portion of a deferred tax asset will not be realized. Realization of deferred tax assets is dependent upon future earnings, the timing and amount of which are uncertain. A full review of all positive and negative evidence needs to be considered. The Company has established a full valuation allowance against the net deferred tax assets as of December 31, 2018 and 2019. The valuation allowance increased by $9.3 million between December 31, 2018 and December 31, 2019 due primarily to the generation of current year operating losses.

As of December 31, 2019, the Company has net operating loss carryforwards for federal and state income tax purposes of $27.7 million and $36.1 million, respectively. The federal net operating loss carryforwards generated prior to 2018 and state net operating loss carryforwards, if not utilized, will expire beginning in 2036. Federal net operating losses generated in 2018 and after carryover indefinitely and may generally be used to fully offset future taxable income through December 31, 2020 and 80% of future taxable income thereafter.

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The Company has research credit carryforwards for federal and state income tax purposes of approximately $0.9 million each as of December 31, 2019. The federal credits begin to expire in 2027 and the state credits can be carried forward indefinitely.

Utilization of some of the federal and state net operating loss and credit carryforwards may be subject to annual limitations due to the change in ownership provisions of the Internal Revenue Code of 1986 (Internal Revenue Code) and similar state provisions. The annual limitation may result in the expiration of net operating losses and credits before utilization. The Company has not performed a study under Section 382 of the Internal Revenue Code to determine if a change in control did occur and, as such, is not able to determine the impact on the net operating loss carryforwards, if any, as of the date of the financial statements.

The Company recognizes a tax benefit from uncertain tax positions when it is more likely than not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, based on the technical merits. Due to the existence of the full valuation allowance, future changes in unrecognized tax benefits will not impact the Company’s effective tax rate. The Company does not foresee material changes to its liability for uncertain tax benefits within the next 12 months.

The following table summarizes the activity in the Company’s gross unrecognized tax benefits (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>December 31,</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2018</td>
</tr>
<tr>
<td>Balance at beginning of period</td>
<td>$ —</td>
</tr>
<tr>
<td>Increase related to prior year positions</td>
<td>—</td>
</tr>
<tr>
<td>Increase related to current year positions</td>
<td>—</td>
</tr>
<tr>
<td>Balance at the end of the year</td>
<td>$ —</td>
</tr>
</tbody>
</table>

During the years ended December 31, 2018 and 2019, no interest or penalties were required to be recognized relating for unrecognized tax benefits.

The Company files tax returns in the United States and California. The Company is not currently under examination in any of these jurisdictions and all of the Company’s tax years remain effectively open to examination due to net operating loss carryforwards.

On March 27, 2020, the United States enacted the Coronavirus Aid, Relief and Economic Security Act (CARES Act). The CARES Act is an emergency economic stimulus package that includes spending and tax breaks to strengthen the United States economy and fund a nationwide effort to curtail the effect of COVID-19. While the CARES Act provides sweeping tax changes in response to the COVID-19 pandemic, some of the more significant provisions which are expected to impact the Company’s financial statements include removal of certain limitations on utilization of net operating losses, increasing the loss carryback period for certain losses to five years, and increasing the ability to deduct interest expense, as well as amending certain provisions of the previously enacted Tax Cuts and Jobs Act. Due to the loss position of the U.S. entities, many provisions of the CARES Act do not impact the Company and the CARES Act did not have an impact on the Company’s income tax provision for the year ended December 31, 2019.

11. Related Party Transactions

During the year ended December 31, 2018, the Company incurred $0.1 million for consulting services to a member of its board of directors who was also a vendor.

As discussed in Note 6, in September 2017, the Company entered into the Agreement with Cedars-Sinai. As consideration for the license rights, the Company issued (i) 2,575,000 common stock shares at par value of $0.0001 per share, and (ii) 3,350,000 unvested restricted common stock shares at par value of $0.0001 per share.
The parties also entered into additional license agreements as well as research agreements, under which the parties can provide research services to each other at pricing specified in the individual statements of work. During the years ended December 31, 2018 and 2019, no services were provided under the research agreements. During the year ended December 31, 2019, the Company purchased data from Cedars-Sinai for $0.3 million and this is recorded in research and development expenses in the accompanying consolidated statements of operations.

Additionally, PLI has provided laboratory services to Cedars-Sinai since May 2018. During the year ended December 31, 2019, Cedars-Sinai paid approximately $0.2 million for such services. At December 31, 2019, the Company had a receivable of $0.1 million from Cedars-Sinai included in accounts receivable, net in the accompanying consolidated balance sheets. Two members of the Company’s board of directors are employees of Cedars-Sinai.

During the years ended December 31, 2018 and 2019, the Company incurred compensation related expenses for two employees, each of whom is an immediate family member of a different member of the Company’s board of directors. These expenses totaled $0.1 million and $0.4 million for the years ended December 31, 2018 and 2019, respectively, of which $0.1 million is included in general and administrative expenses in the accompanying consolidated statement of operations for each of the years ended December 31, 2018 and 2019, and $0 and $0.4 million are included in research and development expenses for the years ended December 31, 2018 and 2019, respectively.

During the year ended December 31, 2019, the Company exchanged various payments with Nestlé pursuant to the terms of the PLI acquisition agreement. At the time of the acquisition, the Company assumed liabilities in the amount of $4.3 million related to Nestlé compensation plans terminated at the time of the acquisition. Pursuant to the purchase agreement, Nestlé was contractually obligated to settle these liabilities and the Company recorded a corresponding receivable for the same amount in the initial purchase price allocation. During the year ended December 31, 2019, the Company received and settled $3.3 million related to this arrangement. At December 31, 2019, $0.7 million remained as an accrual and a receivable due from Nestlé related to this item in the accompanying consolidated balance sheets. Additionally, at December 31, 2019, the Company recorded an accrued of $0.3 related to payments due to Nestlé for cash not distributed to the former PLI employees in accordance with the purchase agreement. All liabilities and receivables recorded at December 31, 2019 for amounts between Nestlé and the Company were settled in 2020.

During the year ended December 31, 2019, the Company paid Nestlé $0.4 million related to a deposit made by Nestlé on behalf of the Company at the time of the PLI acquisition.

As a result of the PLI acquisition, the Company entered into a transition services arrangement with ProciseDx, a wholly owned subsidiary of Nestlé. During the year ended December 31, 2019, both companies provided administrative and research related services to one another. As a result of this arrangement, during the year ended December 31, 2019, the Company received payments of $1.8 million from ProciseDx and paid $23,000 to ProciseDx. At December 31, 2019, the Company had a receivable for $1.3 million from ProciseDx included in the amount reported as due from Nestlé and a payable of $27,000 included in the amount due to Nestlé in the accompanying consolidated balance sheets.

The Company has an ongoing collaboration with Regents of the University of California, where a member of its Board of Directors is employed. During the year ended December 31, 2019, the Company incurred $0.2 million in expense related to this collaboration that was recorded in research and development expenses in the accompanying consolidated statements of operations.

12. Business Segment and Product Information

Through June 30, 2019, the Company operated in one segment. Upon the acquisition of PLI in June 2019, the Company determined it had two operating segments, the therapeutics and diagnostic services businesses. The
therapeutics business derives substantially all of its revenue from collaboration agreements and devotes all of its efforts to development of product candidates and companion diagnostics in the IBD space. The diagnostic services business derives all of its revenue from the conduct of laboratory developed tests in the IBD space.

Segment asset information is not presented because it is not used by the CODM at the segment level. Operating loss of each segment represents revenues less directly identifiable expenses to arrive at operating loss for the segment. Unallocated general and administrative corporate expenses are included in Corporate below.

Summarized financial information by segment for the year ended December 31, 2019 is as follows (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>Diagnostic Services</th>
<th>Therapeutics</th>
<th>Corporate</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revenues</td>
<td>$22,674</td>
<td>$1,118</td>
<td>$—</td>
<td>$23,792</td>
</tr>
<tr>
<td>Loss from operations</td>
<td>$(7,523)</td>
<td>$(11,092)</td>
<td>$(10,877)</td>
<td>$(29,492)</td>
</tr>
<tr>
<td>Depreciation and amortization</td>
<td>$995</td>
<td>$35</td>
<td>$178</td>
<td>$1,208</td>
</tr>
</tbody>
</table>

The Company operates solely in the United States.

13. **401(k) Plan**

Effective January 1, 2018, the Company maintains a defined contribution 401(k) plan available to eligible employees. Employee contributions are voluntary and are determined on an individual basis, limited to the maximum amount allowable under federal tax regulations. The Company, at its discretion, may make certain contributions to the 401(k) plan. Company contributions made during the years ended December 31, 2018 and 2019 were $0 and $0.4 million, respectively.

14. **Subsequent Events**

The Company has evaluated subsequent events for financial statement purposes occurring through August 28, 2020, the date when these financial statements are available to be issued.

**COVID-19 Outbreak**

The current COVID-19 worldwide pandemic has presented substantial public health challenges and is affecting the Company’s employees, patients, physicians and other healthcare providers, communities and business operations, as well as the U.S. and global economies and financial markets. International and U.S. governmental authorities in impacted regions are taking actions in an effort to slow the spread of COVID-19, including issuing varying forms of “stay-at-home” orders, and restricting business functions outside of one’s home. As a result of these measures and the reordering of priorities across the U.S. healthcare system, our test volumes experienced a temporary substantial reduction in April, but have since substantially recovered on a month-to-month basis. In March 2020, as a result of the impacts of the COVID-19 pandemic, the Company implemented a reduction in workforce which resulted in the recognition of a restructuring charge for termination benefits of $2.5 million, of which $2.3 million was paid as of June 30, 2020.

With respect to our diagnostic services business, as a result of government measures and the reordering of priorities across the U.S. healthcare system, our test volumes experienced a temporary substantial reduction in April, but have since substantially recovered on a month-to-month basis. Although the cumulative impact of these disruptions has had a significant impact on the Company’s diagnostic service business, as of the date of this filing, the Company cannot predict the specific extent, duration, or scope of the impact that the COVID-19 pandemic will have on its financial results.

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) was enacted in response to the COVID-19 pandemic. The CARES Act, among other things, permits NOL carryovers and
carrybacks to offset 100% of taxable income for taxable years beginning before 2021. Under the Tax Cuts and Jobs Act (TCJA), NOLs generated post TCJA were allowed to be carried forward indefinitely but were only allowed to offset 80% of taxable income.

**Amended Articles of Incorporation**

In March 2020, the Company amended its Certificate of Incorporation to authorize 138,630,900 shares of common stock and 101,645,867 shares of convertible preferred stock, designated as 14,979,200 shares of Series A, 26,666,667 shares of Series B and 60,000,000 shares of Series C.

**Sale of Series C Preferred Stock**

In March 2020, the Company sold 28,063,500 shares of Series C convertible preferred stock and received gross proceeds totaling $28.1 million.

**2020 Stock Option Grants**

In March 2020, the common stock reserved for issuance increased by 5,000,000 shares to 22,500,000 shares. Through August 2020, the Company granted options to purchase 4,429,400 shares of common stock to employees and consultants at exercise prices ranging from $0.17 to $0.31 per share.

**Debt Agreement**

On January 20, 2020, the Company entered into a Loan and Security Agreement with Oxford Finance LLC and its affiliates (Oxford) (the Oxford Loan) which provides for total borrowings of up to $25.0 million, of which $7.5 million was drawn upon execution of the agreement. The Oxford Loan provides for an additional minimum of $5.0 million and up to $17.5 million to be drawn down at the option of the Company beginning upon the receipt of a Series C convertible preferred stock financing of at least $30.0 million (Equity Event) and ending on the earliest of (i) 90 days after the occurrence of the Equity Event; (ii) September 30, 2020; or (iii) upon an event of default. Interest accrues at an annual rate at the greater of (a) the 30-day U.S. LIBOR rate reported the last business day of the month that immediately precedes the month in which the interest will accrue, or 2.01%, plus (b) 5.98%. Notwithstanding the foregoing, the rate from the period of the effective date through and including January 31, 2020, is 7.99%; and (y) the annual rate shall at no time be less than 7.99%. From March 1, 2020, through February 28, 2022, the Company is required to makes interest only payments. Beginning March 1, 2023, in addition to interest payments, the monthly payments will include an amount equal to the outstanding principal divided by 24 months. At maturity (or earlier prepayment), the Company is required to make a final payment equal to 4.0% of the original principal amount borrowed and 3% of the future amount to be funded. The Oxford Loan is collateralized by a first priority security interest in substantially all of the Company’s current and future assets, other than its intellectual property.

In addition, warrants to purchase 112,500 shares of Series C convertible preferred stock were issued to Oxford in conjunction with the execution of the agreement at an exercise price of $1.00 per share. The warrants have a ten-year life and are exercisable immediately. The warrants contain antidilution protection in the event an issuance of common stock is lower than the if converted Series C convertible preferred stock, subject to customary exceptions as set forth in the Company’s Certificate of Incorporation.

**Amendment to the PLI Acquisition Agreement**

On June 30, 2020, the Company amended its stock purchase agreement with Nestlé as follows: (i) the $5,000,000 deferred cash payment due on June 30, 2020 was settled with the issuance of 5,000,000 shares of Series C convertible preferred stock; (ii) the due date of the $10,000,000 deferred cash payment was extended from June 30, 2021 to December 31, 2021; (iii) the acquisition-related contingent consideration of 3,500,000
shares of Series C convertible preferred stock was released from escrow; and (iv) Nestlé agreed to reimburse the Company for 77.5% of a pre-acquisition rebate liability of $9.0 million and 50% of any amounts settled by the Company that are above $9.0 million.

**Dr. Falk Pharma GmbH Collaboration Agreement**

In July 2020, the Company entered into a Co-Development and Manufacturing Agreement (the Co-Development Agreement) with Dr. Falk Pharma GMBH (Falk), pursuant to which the parties will co-develop and commercialize, exclusively in their respective territories, therapeutic product candidates targeting members of the TNF super family for the treatment of UC and CD under the Company’s PR600 program. The Company will be responsible for regulatory approvals and commercialization of any products in the United States and the rest of the world, other than the Falk territory. Falk is responsible for regulatory approvals and commercialization of any products in in the European Union, United Kingdom, Switzerland, the countries of the European Economic Area (excluding Malta and the Republic of Cyprus), Australia and New Zealand (Falk territory). Under the Co-Development Agreement, Falk agreed to fund 25% of the Company’s third party development costs set forth in a mutually agreed upon development plan. In addition, Falk is obligated to make future development milestone payments, and a mid-single digit to low-double digit royalty on net sales of all products incorporating antibodies covered by the agreement in the Falk territory. The Company agreed to pay Falk a low-single digit royalty on net sales for such products in the Company’s territory.

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Shares

Prometheus Biosciences

Common Stock

SVB Leerink
Credit Suisse
BMO Capital Markets
Guggenheim Securities

Through and including , 2020 (the 25th day after the date of this prospectus) all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers’ obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.
Part II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

The following table indicates the expenses to be incurred in connection with the offering described in this registration statement, other than underwriting discounts and commissions, all of which will be paid by us. All amounts are estimated except the SEC registration fee, the Financial Industry Regulatory Authority, Inc., or FINRA, filing fee and the Nasdaq Global Market listing fee.

<table>
<thead>
<tr>
<th>Amount paid or to be paid</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>SEC registration fee</td>
<td>$*</td>
</tr>
<tr>
<td>FINRA filing fee</td>
<td></td>
</tr>
<tr>
<td>Nasdaq Global Market listing fee</td>
<td></td>
</tr>
<tr>
<td>Accountants’ fees and expenses</td>
<td></td>
</tr>
<tr>
<td>Legal fees and expenses</td>
<td></td>
</tr>
<tr>
<td>Transfer Agent’s fees and expenses</td>
<td></td>
</tr>
<tr>
<td>Printing and engraving expenses</td>
<td></td>
</tr>
<tr>
<td>Miscellaneous</td>
<td></td>
</tr>
<tr>
<td><strong>Total expenses</strong></td>
<td>$*</td>
</tr>
</tbody>
</table>

* To be provided by amendment.


Section 102 of the General Corporation Law of the State of Delaware permits a corporation to eliminate the personal liability of directors of a corporation to the corporation or its stockholders for monetary damages for a breach of fiduciary duty as a director, except where the director breached his duty of loyalty, failed to act in good faith, engaged in intentional misconduct or knowingly violated a law, authorized the payment of a dividend or approved a stock repurchase in violation of Delaware corporate law or obtained an improper personal benefit. Our certificate of incorporation provides that no director of the Registrant shall be personally liable to it or its stockholders for monetary damages for any breach of fiduciary duty, except to the extent that the General Corporation Law of the State of Delaware prohibits the elimination or limitation of liability of directors for breaches of fiduciary duty.

Section 145 of the General Corporation Law of the State of Delaware provides that a corporation has the power to indemnify a director, officer, employee or agent of the corporation, or a person serving at the request of the corporation for another corporation, partnership, joint venture, trust or other enterprise in related capacities against expenses (including attorneys’ fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with an action, suit or proceeding to which he was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding by reason of such position, if such person acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation, and, in any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful, except that, in the case of actions brought by or in the right of the corporation, no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or other adjudicating court determines that, despite the adjudication of liability but in view of all of the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.

Our amended and restated certificate of incorporation, which will become effective immediately prior to the closing of this offering, provides that we will indemnify each person who was or is a party or threatened to be
made a party to any threatened, pending or completed action, suit or proceeding (other than an action by or in the right of us) by reason of the fact that he or she is or was, or has agreed to become, a director or officer, or is or was serving, or has agreed to serve, at our request as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise (all such persons being referred to as an “Indemnitee”), or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys’ fees), judgments, fines and amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding and any appeal therefrom, if such Indemnitee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, our best interests, and, with respect to any criminal action or proceeding, he or she had no reasonable cause to believe his or her conduct was unlawful. Our amended and restated certificate of incorporation provides that we will indemnify any Indemnitee who was or is a party to an action or suit by or in the right of us to procure a judgment in our favor by reason of the fact that the Indemnitee is or was, or has agreed to become, a director or officer, or is or was serving, or has agreed to serve, at our request as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise, or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys’ fees) and, to the extent permitted by law, amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding, and any appeal therefrom, if the Indemnitee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, our best interests, except that no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to us, unless a court determines that, despite such adjudication but in view of all of the circumstances, he or she is entitled to indemnification of such expenses. Notwithstanding the foregoing, to the extent that any Indemnitee has been successful, on the merits or otherwise, he or she will be indemnified by us against all expenses (including attorneys’ fees) actually and reasonably incurred in connection therewith. Expenses must be advanced to an Indemnitee under certain circumstances.

We have entered into indemnification agreements with each of our directors and officers. These indemnification agreements may require us, among other things, to indemnify our directors and officers for some expenses, including attorneys’ fees, judgments, fines and settlement amounts incurred by a director or officer in any action or proceeding arising out of his or her service as one of our directors or officers, or any of our subsidiaries or any other company or enterprise to which the person provides services at our request.

We maintain a general liability insurance policy that covers certain liabilities of directors and officers of our corporation arising out of claims based on acts or omissions in their capacities as directors or officers.

In any underwriting agreement we enter into in connection with the sale of common stock being registered hereby, the underwriters will agree to indemnify, under certain conditions, us, our directors, our officers and persons who control us within the meaning of the Securities Act, against certain liabilities.

**Item 15. Recent Sales of Unregistered Securities.**

Set forth below is information regarding unregistered securities issued by us since January 1, 2017. Also included is the consideration received by us for such securities and information relating to the section of the Securities Act, or rule of the SEC, under which exemption from registration was claimed.

(a) Issuances of Securities

1. From September to October 2017 we issued an aggregate of 14,979,200 shares of Series A convertible preferred stock to investors at a purchase price of $0.50 per share, for aggregate consideration of approximately $7.5 million.

2. From November 2018 to May 2019 we issued an aggregate of 26,666,667 shares of Series B convertible preferred stock to investors at a purchase price of $0.75 per share, for aggregate consideration of approximately $20 million.

3. In June 2019 and June 2020, as partial consideration for our acquisition of Prometheus Laboratories, Inc., we issued an aggregate of 25,000,000 shares of Series C convertible preferred stock.
In March 2020 we issued an aggregate of 28,063,500 shares of Series C convertible preferred stock to investors at a purchase price of $1.00 per share, for aggregate consideration of approximately $28.1 million.

In January 2020, we issued to a lender a warrant to purchase 112,500 shares of Series C convertible preferred stock at an exercise price of $1.00 per share in connection with our entry into a loan and security agreement.

No underwriters were involved in the foregoing issuances of securities. The securities described in this section (a) of Item 15 were issued to investors in reliance upon the exemption from the registration requirements of the Securities Act, as set forth in Section 4(a)(2) under the Securities Act and Regulation D promulgated thereunder relative to transactions by an issuer not involving any public offering, to the extent an exemption from such registration was required. All holders of securities described above represented to us in connection with their purchase or issuance that they were accredited investors and were acquiring the securities for their own account for investment purposes only and not with a view to, or for sale in connection with, any distribution thereof and that they could bear the risks of the investment and could hold the securities for an indefinite period of time. The holders received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration statement or an available exemption from such registration.

(b) Grants of Stock Options

1. From January 2017 through July 31, 2020, we granted stock options to purchase an aggregate of 18,744,901 shares of our common stock at a weighted-average exercise price of $0.20 per share, to certain of our employees, consultants and directors in connection with services provided to us by such persons. 2,157,486 of these options have been exercised and 1,234,305 have been cancelled through July 31, 2020.

The stock options and common stock issuable upon exercise of such options as described in this section (b) of Item 15 were issued pursuant to written compensatory plans or arrangements with our employees and directors, in reliance on the exemption from the registration requirements of the Securities Act provided by Rule 701 promulgated under the Securities Act or the exemption set forth in Section 4(a)(2) under the Securities Act and Regulation D promulgated thereunder relative to transactions by an issuer not involving any public offering. All recipients either received adequate information about us or had access, through employment or other relationships, to such information.

All of the foregoing securities are deemed restricted securities for purposes of the Securities Act. All certificates representing the issued shares of capital stock described in this Item 15 included appropriate legends setting forth that the securities had not been registered and the applicable restrictions on transfer.


(c) Exhibits. See Exhibit Index attached to this registration statement, which is incorporated by reference herein.

(d) Financial Statement Schedules. Schedules not listed above have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

Item 17. Undertakings.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or
controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
<table>
<thead>
<tr>
<th>Exhibit Number</th>
<th>Description of Exhibit</th>
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<tbody>
<tr>
<td>1.1*</td>
<td>Form of Underwriting Agreement</td>
</tr>
<tr>
<td>3.1</td>
<td>Amended and Restated Certificate of Incorporation (currently in effect)</td>
</tr>
<tr>
<td>3.2</td>
<td>Bylaws (currently in effect)</td>
</tr>
<tr>
<td>3.3*</td>
<td>Form of Amended and Restated Certificate of Incorporation (to be effective immediately prior to the closing of this offering)</td>
</tr>
<tr>
<td>3.4*</td>
<td>Form of Amended and Restated Bylaws (to be effective immediately prior to the closing of this offering)</td>
</tr>
<tr>
<td>4.1*</td>
<td>Specimen stock certificate evidencing the shares of common stock</td>
</tr>
<tr>
<td>4.2</td>
<td>Amended and Restated Investors’ Rights Agreement, dated March 27, 2020, by and among the Registrant and certain of its stockholders.</td>
</tr>
<tr>
<td>4.3</td>
<td>Warrant issued to Oxford Finance LLC, dated January 24, 2020</td>
</tr>
<tr>
<td>5.1*</td>
<td>Opinion of Latham &amp; Watkins LLP</td>
</tr>
<tr>
<td>10.1#</td>
<td>Prometheus Biosciences, Inc. 2017 Equity Incentive Plan, as amended, including form of stock option agreement thereunder</td>
</tr>
<tr>
<td>10.2#*</td>
<td>Prometheus Biosciences, Inc. 2020 Incentive Award Plan and form of stock option grant notice and stock option agreement thereunder</td>
</tr>
<tr>
<td>10.3#*</td>
<td>Prometheus Biosciences, Inc. 2020 Employee Stock Purchase Plan</td>
</tr>
<tr>
<td>10.4#*</td>
<td>Non-Employee Director Compensation Program</td>
</tr>
<tr>
<td>10.5#*</td>
<td>Amended and Restated Employment Letter Agreement, dated , by and between Mark C. McKenna and the Registrant</td>
</tr>
<tr>
<td>10.6#*</td>
<td>Employment Letter Agreement, dated , by and between Keith W. Marshall, Ph.D. and the Registrant</td>
</tr>
<tr>
<td>10.7#*</td>
<td>Amended and Restated Employment Letter Agreement, dated , by and between Laurens Kruidenier, Ph.D. and the Registrant</td>
</tr>
<tr>
<td>10.8#*</td>
<td>Amended and Restated Employment Letter Agreement, dated , by and between Allison Luo, M.D. and the Registrant</td>
</tr>
<tr>
<td>10.9#*</td>
<td>Amended and Restated Employment Letter Agreement, dated , by and between Lauren G. Otsuki and the Registrant</td>
</tr>
<tr>
<td>10.10#*</td>
<td>Form of Indemnification Agreement for Directors and Officers</td>
</tr>
<tr>
<td>10.11</td>
<td>Loan and Security Agreement, dated January 24, 2020, by and among Oxford Finance LLC, Prometheus Laboratories, Inc. and the Registrant</td>
</tr>
<tr>
<td>10.12</td>
<td>Lease Agreement, dated June 22, 2005, by and between The Irvine Company LLC and Prometheus Laboratories, Inc., as amended</td>
</tr>
<tr>
<td>10.13†*</td>
<td>Exclusive License Agreement, dated September 1, 2017, by and between Cedars-Sinai Medical Center and the Registrant, as amended</td>
</tr>
<tr>
<td>10.14†*</td>
<td>Exclusive License Agreement, dated March 22, 2019, by and between Cedars-Sinai Medical Center and the Registrant</td>
</tr>
<tr>
<td>10.15†*</td>
<td>Exclusive License Agreement, dated March 22, 2019, by and between Cedars-Sinai Medical Center and the Registrant</td>
</tr>
<tr>
<td>Exhibit Number</td>
<td>Description of Exhibit</td>
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</tr>
<tr>
<td>10.16†*</td>
<td>Companion Diagnostics Development and Collaboration Agreement, dated as of March 25, 2019, by and between Millennium Pharmaceuticals, Inc. and the Registrant</td>
</tr>
<tr>
<td>10.17*</td>
<td>License Agreement, dated March 18, 2020, by and between Alloy Therapeutics, LLC and the Registrant</td>
</tr>
<tr>
<td>10.18†*</td>
<td>Co-development and Manufacturing Agreement, dated as of July 30, 2020, by and between Dr. Falk Pharma GmbH and the Registrant</td>
</tr>
<tr>
<td>23.1*</td>
<td>Consent of BDO USA, LLP, independent registered public accounting firm</td>
</tr>
<tr>
<td>23.2*</td>
<td>Consent of Latham &amp; Watkins LLP (included in Exhibit 5.1)</td>
</tr>
<tr>
<td>24.1*</td>
<td>Power of Attorney (included on signature page)</td>
</tr>
</tbody>
</table>

* To be filed by amendment.
# Indicates management contract or compensatory plan.
† Portions of this exhibit have been omitted for confidentiality purposes.
SIGNATURES

Pursuant to the requirements of the Securities Act, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of San Diego, State of California, on this day of , 2020.

PROMETHEUS BIOSCIENCES, INC.

By: ______________________________________
Mark C. McKenna
President, Chief Executive Officer and Director

SIGNATURES AND POWER OF ATTORNEY

We, the undersigned officers and directors of Prometheus Biosciences, Inc., hereby severally constitute and appoint Mark C. McKenna and Keith W. Marshall, Ph.D., and each of them singly (with full power to each of them to act alone), our true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution in each of them for him or her and in his or her name, place and stead, and in any and all capacities, to sign any and all amendments (including post-effective amendments) to this registration statement (or any other registration statement for the same offering that is to be effective upon filing pursuant to Rule 462(b) under the Securities Act of 1933), and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises, as full to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or any of them, or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities held on the dates indicated.

<table>
<thead>
<tr>
<th>Signature</th>
<th>Title</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mark C. McKenna</td>
<td>President, Chief Executive Officer and Director (principal executive officer)</td>
<td>2020</td>
</tr>
<tr>
<td>Keith W. Marshall, Ph.D.</td>
<td>Chief Financial Officer (principal financial and accounting officer)</td>
<td>2020</td>
</tr>
<tr>
<td>Tadataka Yamada, M.D.</td>
<td>Chairman of the Board</td>
<td>2020</td>
</tr>
<tr>
<td>Grégory Behar</td>
<td>Director</td>
<td>2020</td>
</tr>
<tr>
<td>Scott L. Glenn</td>
<td>Director</td>
<td>2020</td>
</tr>
<tr>
<td>James Laur</td>
<td>Director</td>
<td>2020</td>
</tr>
<tr>
<td>Shlomo Melmed, M.D.</td>
<td></td>
<td>2020</td>
</tr>
<tr>
<td>Signature</td>
<td>Title</td>
<td>Date</td>
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<tr>
<td>Jospeh C. Papa</td>
<td>Director</td>
<td></td>
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<tr>
<td>William Sandborn, M.D.</td>
<td>Director</td>
<td></td>
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<tr>
<td>Mark Stenhouse</td>
<td>Director</td>
<td></td>
</tr>
<tr>
<td>Douglas F. Wall</td>
<td>Director</td>
<td></td>
</tr>
<tr>
<td>Shierley Widjaja</td>
<td>Director</td>
<td></td>
</tr>
</tbody>
</table>
AMENDED AND RESTATED
CERTIFICATE OF INCORPORATION
OF
PROMETHEUS BIOSCIENCES, INC.
(Pursuant to Sections 242 and 245 of the
General Corporation Law of the State of Delaware)

Prometheus Biosciences, Inc., a corporation organized and existing under and by virtue of the provisions of the General Corporation Law of the State of Delaware (the “General Corporation Law”),

DOES HEREBY CERTIFY:

1. That the name of this corporation is Prometheus Biosciences, Inc., and that this corporation was originally incorporated pursuant to the General Corporation Law on October 26, 2016 under the name Precision IBD, Inc.

2. That the Board of Directors duly adopted resolutions proposing to amend and restate the Certificate of Incorporation of this corporation, declaring said amendment and restatement to be advisable and in the best interests of this corporation and its stockholders, and authorizing the appropriate officers of this corporation to solicit the consent of the stockholders therefor, which resolution setting forth the proposed amendment and restatement is as follows:

RESOLVED, that the Certificate of Incorporation of this corporation be amended and restated in its entirety to read as follows:

FIRST: The name of this corporation is Prometheus Biosciences, Inc. (the “Corporation”).

SECOND: The address of the registered office of the Corporation in the State of Delaware is Corporation Trust Center, 1209 Orange Street, Wilmington, New Castle County, Delaware 19801. The name of its registered agent at such address is The Corporation Trust Company.

THIRD: The nature of the business or purposes to be conducted or promoted is to engage in any lawful act or activity for which corporations may be organized under the General Corporation Law.

FOURTH: The total number of shares of all classes of stock which the Corporation shall have authority to issue is (i) 138,630,900 shares of Common Stock, par value $0.0001 per share (“Common Stock”) and (ii) 101,645,867 shares of Preferred Stock, par value $0.0001 per share (“Preferred Stock”).

The following is a statement of the designations and the powers, privileges and rights, and the qualifications, limitations or restrictions thereof in respect of each class of capital stock of the Corporation.
A. COMMON STOCK

1. **General.** The voting, dividend and liquidation rights of the holders of the Common Stock are subject to and qualified by the rights, powers and preferences of the holders of the Preferred Stock set forth herein.

2. **Voting.** The holders of the Common Stock are entitled to one (1) vote for each share of Common Stock held at all meetings of stockholders (and written actions in lieu of meetings); provided, however, that, except as otherwise required by law, holders of Common Stock, as such, shall not be entitled to vote on any amendment to this Amended and Restated Certificate of Incorporation (the “Restated Certificate”) that relates solely to the terms of one or more outstanding series of Preferred Stock if the holders of such affected series are entitled, either separately or together with the holders of one or more other such series, to vote thereon pursuant to the Restated Certificate or pursuant to the General Corporation Law. There shall be no cumulative voting. The number of authorized shares of Common Stock may be increased or decreased (but not below the number of shares thereof then outstanding) by (in addition to any vote of the holders of one or more series of Preferred Stock that may be required by the terms of the Restated Certificate) the affirmative vote of the holders of shares of capital stock of the Corporation representing a majority of the votes represented by all outstanding shares of capital stock of the Corporation entitled to vote, irrespective of the provisions of Section 242(b)(2) of the General Corporation Law.

B. PREFERRED STOCK

14,979,200 shares of the authorized and unissued Preferred Stock of the Corporation are hereby designated as a series known as Series A Preferred Stock, par value $0.0001 per share (the “Series A Preferred Stock”), 26,666,667 shares of the authorized and unissued Preferred Stock of the Corporation are hereby designated as a series known as Series B Preferred Stock, par value $0.0001 per share (the “Series B Preferred Stock”) and 60,000,000 shares of the authorized and unissued Preferred Stock of the Corporation are hereby designated as a series known as Series C Preferred Stock, par value $0.0001 per share (the “Series C Preferred Stock”), with the following rights, preferences, powers, privileges and restrictions, qualifications and limitations. Unless otherwise indicated, references to “sections” or “subsections” in this Part B of this Article Fourth refer to sections and subsections of Part B of this Article Fourth.

1. **Dividends.**

The Corporation shall not declare, pay or set aside any dividends on shares of any other class or series of capital stock of the Corporation (other than dividends on shares of Common Stock payable in shares of Common Stock) unless (in addition to the obtaining of any consents required elsewhere in this Restated Certificate) the holders of the Preferred Stock then outstanding shall first receive, or simultaneously receive, a dividend on each outstanding share of Preferred Stock in an amount at least equal to (i) in the case of a dividend on Common Stock or any class or series that is convertible into Common Stock, that dividend per share of Preferred Stock as would equal the product of (A) the dividend payable on each share of such class or series determined, if applicable, as if all shares of such class or series had been converted into Common Stock and (B)
the number of shares of Common Stock issuable upon conversion of a share of Preferred Stock, in each case calculated on the record date for
determination of holders entitled to receive such dividend or (ii) in the case of a dividend on any class or series that is not convertible into Common
Stock, at a rate per share of Preferred Stock determined by (A) dividing the amount of the dividend payable on each share of such class or series of
capital stock by the original issuance price of such class or series of capital stock (subject to appropriate adjustment in the event of any stock dividend,
stock split, combination or other similar recapitalization with respect to such class or series) and (B) multiplying such fraction by an amount equal to the
applicable Original Issue Price (as defined below); provided that, if the Corporation declares, pays or sets aside, on the same date, a dividend on shares
of more than one class or series of capital stock of the Corporation, the dividend payable to the holders of Preferred Stock pursuant to this Section 1
shall be calculated based upon the dividend on the class or series of capital stock that would result in the highest Preferred Stock dividend. The “Series
A Original Issue Price” shall mean $0.50 per share, subject to appropriate adjustment in the event of any stock dividend, stock split, combination or
other similar recapitalization with respect to the Series A Preferred Stock. The “Series B Original Issue Price” shall mean $0.75 per share, subject to
appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series B Preferred
Stock. The “Series C Original Issue Price” shall mean $1.00 per share, subject to appropriate adjustment in the event of any stock dividend, stock split,
combination or other similar recapitalization with respect to the Series C Preferred Stock. Each of the Series A Original Issue Price, Series B Original
Issue Price and Series C Original Issue Price are sometimes referred to herein as the “Original Issue Price.”

2. Liquidation, Dissolution or Winding Up; Certain Mergers, Consolidations and Asset Sales.

2.1 Preferential Payments to Holders of Series C Preferred Stock. In the event of any voluntary or involuntary liquidation,
dissolution or winding up of the Corporation or Deemed Liquidation Event, the holders of shares of Series C Preferred Stock then outstanding shall be
entitled to be paid out of the assets of the Corporation available for distribution to its stockholders before any payment shall be made to the holders of
Series A Preferred Stock, Series B Preferred Stock or Common Stock by reason of their ownership thereof, an amount per share equal to the Series C
Original Issue Price, plus any dividends declared but unpaid thereon. If upon any such liquidation, dissolution or winding up of the Corporation or
Deemed Liquidation Event, the assets of the Corporation available for distribution to its stockholders shall be insufficient to pay the holders of shares of
Series C Preferred Stock the full amount to which they shall be entitled under this Section 2.1, the holders of shares of Series C Preferred Stock shall
share ratably in any distribution of the assets available for distribution in proportion to the respective amounts which would otherwise be payable in
respect of the shares held by them upon such distribution if all amounts payable on or with respect to such shares were paid in full.

2.2 Preferential Payments to Holders of Series A and Series B Preferred Stock. In the event of any voluntary or involuntary
liquidation, dissolution or winding up of the Corporation or Deemed Liquidation Event, after the payment of all preferential amounts required to be paid
to the holders of shares of Series C Preferred Stock, the holders of shares of Series A Preferred Stock and Series B Preferred Stock then outstanding
shall be entitled to be paid out of the assets of the Corporation available for distribution to its stockholders before any payment shall
be made to the holders of Common Stock by reason of their ownership thereof, an amount per share equal to the applicable Original Issue Price, plus any dividends declared but unpaid thereon. If upon any such liquidation, dissolution or winding up of the Corporation or Deemed Liquidation Event, the assets of the Corporation available for distribution to its stockholders shall be insufficient to pay the holders of shares of Series A Preferred Stock and Series B Preferred Stock the full amount to which they shall be entitled under this Section 2.2, the holders of shares of Series A Preferred Stock and Series B Preferred Stock shall share ratably in any distribution of the assets available for distribution in proportion to the respective amounts which would otherwise be payable in respect of the shares held by them upon such distribution if all amounts payable on or with respect to such shares were paid in full.

2.3 Distribution of Remaining Assets. In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Corporation or Deemed Liquidation Event, after the payment of all preferential amounts required to be paid to the holders of shares of Preferred Stock, the remaining assets of the Corporation available for distribution to its stockholders shall be distributed among the holders of shares of Preferred Stock and Common Stock, pro rata based on the number of shares held by each such holder, treating for this purpose all such securities as if they had been converted to Common Stock pursuant to the terms of the Restated Certificate immediately prior to such liquidation, dissolution or winding up of the Corporation or Deemed Liquidation Event; provided, however, that if the aggregate amount which the holders of Series A Preferred Stock are entitled to receive under Sections 2.2 and 2.3 shall exceed $1.50 per share (subject to appropriate adjustment in the event of a stock split, stock dividend, combination, reclassification, or similar event affecting the Series A Preferred Stock) (the “Series A Maximum Participation Amount”), each holder of Series A Preferred Stock shall be entitled to receive only up to the Series A Maximum Participation Amount pursuant to Sections 2.2 and 2.3. The aggregate amount which a holder of a share of Series A Preferred Stock is entitled to receive under Sections 2.2 and 2.3 is hereinafter referred to as the “Series A Liquidation Amount.” Provided further, that if the aggregate amount which the holders of Series B Preferred Stock are entitled to receive under Sections 2.2 and 2.3 shall exceed $2.25 per share (subject to appropriate adjustment in the event of a stock split, stock dividend, combination, reclassification, or similar event affecting the Series B Preferred Stock) (the “Series B Maximum Participation Amount”), each holder of Series B Preferred Stock shall be entitled to receive only up to the Series B Maximum Participation Amount pursuant to Sections 2.2 and 2.3. The aggregate amount which a holder of a share of Series B Preferred Stock is entitled to receive under Sections 2.2 and 2.3 is hereinafter referred to as the “Series B Liquidation Amount.” Provided further, that if the aggregate amount which the holders of Series C Preferred Stock are entitled to receive under Sections 2.1 and 2.3 shall exceed $3.00 per share (subject to appropriate adjustment in the event of a stock split, stock dividend, combination, reclassification, or similar event affecting the Series C Preferred Stock) (the “Series C Maximum Participation Amount”), each holder of Series C Preferred Stock shall be entitled to receive only up to the Series C Maximum Participation Amount pursuant to Sections 2.1 and 2.3. The aggregate amount which a holder of a share of Series C Preferred Stock is entitled to receive under Sections 2.1 and 2.3 is hereinafter referred to as the “Series C Liquidation Amount.”

2.4 Deemed Conversion. Notwithstanding Sections 2.1, 2.2 and 2.3 above, for purposes of determining the amount each holder of shares of Preferred Stock is entitled to receive in the event of any voluntary or involuntary liquidation, dissolution or winding up of
the Corporation or Deemed Liquidation Event, each holder of shares of Preferred Stock shall be deemed to have converted (regardless of whether such
holder actually converted) such holder’s shares of Preferred Stock into shares of Common Stock immediately prior to the Liquidation Event if, as a
result of an actual conversion, such holder would receive, in the aggregate, an amount greater than the amount that would be distributed to such holder if
such holder did not convert such Preferred Stock into shares of Common Stock. If any such holder shall be deemed to have converted shares of
Preferred Stock into Common Stock pursuant to this Section 2.4, then such holder shall not be entitled to receive any distribution that would otherwise be
made to holders of Preferred Stock pursuant to Sections 2.1, 2.2 and 2.3 above.

2.5  Deemed Liquidation Events.

2.5.1  Definition. Each of the following events shall be considered a “Deemed Liquidation Event” unless the holders of at
least sixty percent (60%) of the outstanding shares of Preferred Stock (voting together as a single class, on an as-converted to Common Stock basis, the
“Requisite Holders”) elect otherwise:

(a)  a merger or consolidation in which:
    (i)  the Corporation is a constituent party, or
    (ii)  a subsidiary of the Corporation is a constituent party and the Corporation issues shares of its capital
stock pursuant to such merger or consolidation,
except any such merger or consolidation involving the Corporation or a subsidiary in which the shares of capital stock of the Corporation outstanding
immediately prior to such merger or consolidation continue to represent, or are converted into or exchanged for shares of capital stock that represent,
immediately following such merger or consolidation, a majority, by voting power, of the capital stock of (1) the surviving or resulting corporation; or
(2) if the surviving or resulting corporation is a wholly owned subsidiary of another corporation immediately following such merger or consolidation,
the parent corporation of such surviving or resulting corporation; or

(b)  the sale, lease, transfer, exclusive license or other disposition, in a single transaction or series of related
transactions, by the Corporation or any subsidiary of the Corporation of all or substantially all the assets of the Corporation and its subsidiaries taken as
a whole, or the sale or disposition (whether by merger, consolidation or otherwise) of one or more subsidiaries of the Corporation if substantially all of
the assets of the Corporation and its subsidiaries taken as a whole are held by such subsidiary or subsidiaries, except where such sale, lease, transfer,
exclusive license or other disposition is to a wholly owned subsidiary of the Corporation.

2.5.2  Effecting a Deemed Liquidation Event.

(a)  The Corporation shall not have the power to effect a Deemed Liquidation Event referred to in Section 2.5.1(a)(i)
unless the agreement or plan of merger or consolidation for such transaction (the “Merger Agreement”) provides that the consideration payable to the
stockholders of the Corporation shall be allocated among the holders of capital stock of the Corporation in accordance with Sections 2.1, 2.2, 2.3 and 2.4
hereof.
In the event of a Deemed Liquidation Event referred to in Section 2.5.1(a)(ii) or 2.5.1(b), if the Corporation does not effect a dissolution of the Corporation under the General Corporation Law within ninety (90) days after such Deemed Liquidation Event, then (i) the Corporation shall send a written notice to each holder of Preferred Stock no later than the ninetieth (90th) day after the Deemed Liquidation Event advising such holders of their right (and the requirements to be met to secure such right) pursuant to the terms of the following clause (ii) to require the redemption of such shares of Preferred Stock, and (ii) if the Requisite Holders so request in a written instrument delivered to the Corporation not later than one hundred twenty (120) days after such Deemed Liquidation Event, the Corporation shall use the consideration received by the Corporation for such Deemed Liquidation Event (net of any retained liabilities associated with the assets sold or licensed, as determined in good faith by the Board of Directors), together with any other assets of the Corporation available for distribution to its stockholders, all to the extent permitted by Delaware law governing distributions to stockholders (the “Available Proceeds”), on the one hundred fiftieth (150th) day after such Deemed Liquidation Event (the “Redemption Date”), to redeem all outstanding shares of Preferred Stock at a price per share equal to the Series A Liquidation Amount, Series B Liquidation Amount or Series C Liquidation Amount, as applicable (the “Redemption Price”). Notwithstanding the foregoing, in the event of a redemption pursuant to the preceding sentence, if the Available Proceeds are not sufficient to redeem all outstanding shares of Preferred Stock, the Corporation shall ratably redeem each holder’s shares of Preferred Stock to the fullest extent of such Available Proceeds, and shall redeem the remaining shares as soon as it may lawfully do so under Delaware law governing distributions to stockholders. Prior to the distribution or redemption provided for in this Section 2.5.2(b), the Corporation shall not expend or dissipate the consideration received for such Deemed Liquidation Event, except to discharge expenses incurred in connection with such Deemed Liquidation Event or in the ordinary course of business.

(c) Redemption Notice. In connection with the redemption of Preferred Stock as set forth in this Section 2.5.2, the Corporation shall send written notice of such redemption (the “Redemption Notice”) to each holder of record of Preferred Stock not less than forty (40) days prior to the Redemption Date. Each Redemption Notice shall state: (i) the number of shares of Preferred Stock held by the holder that the Corporation shall redeem on the Redemption Date; (ii) the Redemption Date and the Redemption Price; (iii) the date upon which the holder’s right to convert such shares terminates (as determined in accordance with Section 4.1); and (iv) for holders of shares in certificated form, that the holder is to surrender to the Corporation, in the manner and at the place designated, his, her or its certificate or certificates representing the shares of Preferred Stock to be redeemed.

(d) Surrender of Certificates; Payment. On or before the Redemption Date, each holder of shares of Preferred Stock to be redeemed, unless such holder has exercised his, her or its right to convert such shares as provided in Section 4, shall, if a holder of shares in certificated form, surrender the certificate or certificates representing such shares (or, if such registered holder alleges that such certificate has been lost, stolen or destroyed, a lost certificate affidavit and agreement reasonably acceptable to the Corporation to indemnify the Corporation against any claim that may be made against the Corporation on account of the alleged
loss, theft or destruction of such certificate) to the Corporation, in the manner and at the place designated in the Redemption Notice, and thereupon the Redemption Price for such shares shall be payable to the order of the person whose name appears on such certificate or certificates as the owner thereof. In the event less than all of the shares of Preferred Stock represented by a certificate are redeemed, a new certificate, instrument, or book entry representing the unredeemed shares of Preferred Stock shall promptly be issued to such holder.

(e) Rights Subsequent to Redemption. If the Redemption Notice shall have been duly given, and if on the Redemption Date the Redemption Price payable upon redemption of the shares of Preferred Stock to be redeemed on the Redemption Date is paid or tendered for payment or deposited with an independent payment agent so as to be available therefor in a timely manner, then notwithstanding that any certificates evidencing any of the shares of Preferred Stock so called for redemption shall not have been surrendered, dividends with respect to such shares of Preferred Stock shall cease to be owed by the Corporation after such Redemption Date and all rights with respect to such shares shall forthwith after the Redemption Date terminate, except only the right of the holders to receive the Redemption Price without interest upon surrender of any such certificate or certificates therefor.

2.5.3 Amount Deemed Paid or Distributed. The amount deemed paid or distributed to the holders of capital stock of the Corporation upon any such merger, consolidation, sale, transfer, exclusive license, other disposition or redemption shall be the cash or the value of the property, rights or securities paid or distributed to such holders by the Corporation or the acquiring person, firm or other entity. The value of such property, rights or securities shall be determined in good faith by the Board of Directors.

2.5.4 Allocation of Escrow and Contingent Consideration. In the event of a Deemed Liquidation Event pursuant to Section 2.5.1(a)(i), if any portion of the consideration payable to the stockholders of the Corporation is payable only upon satisfaction of contingencies (the “Additional Consideration”), the Merger Agreement shall provide that (a) the portion of such consideration that is not Additional Consideration (such portion, the “Initial Consideration”) shall be allocated among the holders of capital stock of the Corporation in accordance with Sections 2.1, 2.2, 2.3 and 2.4 as if the Initial Consideration were the only consideration payable in connection with such Deemed Liquidation Event; and (b) any Additional Consideration which becomes payable to the stockholders of the Corporation upon satisfaction of such contingencies shall be allocated among the holders of capital stock of the Corporation in accordance with Sections 2.1, 2.2, 2.3 and 2.4 after taking into account the previous payment of the Initial Consideration as part of the same transaction. For the purposes of this Section 2.5.4, consideration placed into escrow or retained as holdback to be available for satisfaction of indemnification or similar obligations in connection with such Deemed Liquidation Event shall be deemed to be Additional Consideration.


3.1 General. On any matter presented to the stockholders of the Corporation for their action or consideration at any meeting of stockholders of the Corporation (or by written consent of stockholders in lieu of meeting), each holder of outstanding shares of Preferred Stock shall be entitled to cast the number of votes equal to the number of whole shares
of Common Stock into which the shares of Preferred Stock held by such holder are convertible as of the record date for determining stockholders entitled to vote on such matter. Except as provided by law or by the other provisions of the Restated Certificate, holders of Preferred Stock shall vote together with the holders of Common Stock as a single class.

3.2 **Election of Directors.** The holders of record of the shares of Series C Preferred Stock, exclusively and as a separate class, shall be entitled to elect three (3) directors of the Corporation, the holders of record of the shares of Series B Preferred Stock, exclusively and as a separate class, shall be entitled to elect one (1) director of the Corporation, the holders of record of the shares of Series A Preferred Stock, exclusively and as a separate class, shall be entitled to elect one (1) director of the Corporation, and the holders of record of the shares of Common Stock, exclusively and as a separate class, shall be entitled to elect one (1) director of the Corporation. Any director elected as provided in the preceding sentence may be removed without cause by, and only by, the affirmative vote of the holders of the shares of the class or series of capital stock entitled to elect such director or directors, given either at a special meeting of such stockholders duly called for that purpose or pursuant to a written consent of stockholders. If the holders of shares of Series C Preferred Stock, Series B Preferred Stock, Series A Preferred Stock or Common Stock, as the case may be, fail to elect a sufficient number of directors to fill all directorships for which they are entitled to elect directors, voting exclusively and as a separate class, pursuant to the first sentence of this Section 3.2, then any directorship not so filled shall remain vacant until such time as the holders of the Series C Preferred Stock, Series B Preferred Stock, Series A Preferred Stock or Common Stock, as the case may be, elect a person to fill such directorship by vote or written consent in lieu of a meeting; and no such directorship may be filled by stockholders of the Corporation other than by the stockholders of the Corporation that are entitled to elect a person to fill such directorship, voting exclusively and as a separate class. The holders of record of the shares of Common Stock and of any other class or series of voting stock (including the Preferred Stock voting on an as-converted to Common Stock basis), exclusively and voting together as a single class, shall be entitled to elect the balance of the total number of directors of the Corporation. At any meeting held for the purpose of electing a director, the presence in person or by proxy of the holders of a majority of the outstanding shares of the class or series entitled to elect such director shall constitute a quorum for the purpose of electing such director. Except as otherwise provided in this Section 3.2, a vacancy in any directorship filled by the holders of any class or series shall be filled only by vote or written consent in lieu of a meeting of the holders of such class or series or by any remaining director or directors elected by the holders of such class or series pursuant to this Section 3.2.

3.3 **Preferred Stock Protective Provisions.** At any time when shares of Preferred Stock are outstanding, the Corporation shall not, either directly or indirectly by amendment, merger, consolidation or otherwise, do any of the following without (in addition to any other vote required by law or the Restated Certificate) the written consent or affirmative vote of the Requisite Holders, given in writing or by vote at a meeting, consenting or voting (as the case may be) separately as a class, and any such act or transaction entered into without such consent or vote shall be null and void ab initio, and of no force or effect:

3.3.1 declare or pay any dividends or make any distributions on any capital stock of the Corporation;
3.3.2 redeem or repurchase capital stock of the Corporation except in connection with the repurchase of shares of Common Stock issued to or held by employees, consultants, officers and directors upon termination of their employment or services pursuant to agreements providing for the right of said repurchase, which agreements were authorized by the Board of Directors;

3.3.3 take any action which would result in a Liquidation Event or a Deemed Liquidation Event;

3.3.4 increase or decrease the total number of authorized members of the Board of Directors;

3.3.5 authorize, create or issue (whether by merger, consolidation, reclassification, amendment of this Restated Certificate, sale or otherwise) shares of any class or series of stock not authorized herein having rights, preferences or privileges superior to or on parity with the Preferred Stock;

3.3.6 take any action (whether by merger, consolidation, reclassification, amendment or waiver of this Restated Certificate, sale or otherwise) which would change the rights, preferences or privileges expressly afforded the Preferred Stock;

3.3.7 increase or decrease the total number of authorized shares of the Corporation’s Common Stock or Preferred Stock;

3.3.8 take any action which would result in the incurrence of indebtedness for borrowed money in excess of $1,000,000, either individually or cumulatively for all such indebtedness, unless such action is approved by the Board of Directors; or

3.3.9 enter into any agreement to do any of the foregoing.

4. Optional Conversion.

The holders of the Preferred Stock shall have conversion rights as follows (the “Conversion Rights”):

4.1 Right to Convert.

4.1.1 Conversion Ratio. Each share of Preferred Stock shall be convertible, at the option of the holder thereof, at any time and from time to time, and without the payment of additional consideration by the holder thereof, into such number of fully paid and non-assessable shares of Common Stock as is determined by dividing the applicable Original Issue Price by the applicable Conversion Price (as defined below) in effect at the time of conversion. The Conversion Price per share for the Series A Preferred Stock shall initially be equal to $0.50, the Conversion Price per share for the Series B Preferred Stock shall initially be equal to $0.75 and the Conversion Price per share for the Series C Preferred Stock shall initially be equal to $1.00 (as applicable, the “Conversion Price”). Such initial Conversion Prices, and the rate at which shares of Preferred Stock may be converted into shares of Common Stock, shall be subject to adjustment as provided below.
4.1.2  **Termination of Conversion Rights.** In the event of a liquidation, dissolution or winding up of the Corporation or a Deemed Liquidation Event, the Conversion Rights shall terminate at the close of business on the last full day preceding the date fixed for the payment of any such amounts distributable on such event to the holders of Preferred Stock.

4.2  **Fractional Shares.** No fractional shares of Common Stock shall be issued upon conversion of the Preferred Stock. In lieu of any fractional shares to which the holder would otherwise be entitled, the Corporation shall pay cash equal to such fraction multiplied by the fair market value of a share of Common Stock as determined in good faith by the Board of Directors. Whether or not fractional shares would be issuable upon such conversion shall be determined on the basis of the total number of shares of Preferred Stock the holder is at the time converting into Common Stock and the aggregate number of shares of Common Stock issuable upon such conversion.

4.3  **Mechanics of Conversion.**

4.3.1  **Notice of Conversion.** In order for a holder of Preferred Stock to voluntarily convert shares of Preferred Stock into shares of Common Stock, such holder shall (a) provide written notice to the Corporation’s transfer agent at the office of the transfer agent for the Preferred Stock (or at the principal office of the Corporation if the Corporation serves as its own transfer agent) that such holder elects to convert all or any number of such holder’s shares of Preferred Stock and, if applicable, any event on which such conversion is contingent and (b), if such holder’s shares are certificated, surrender the certificate or certificates for such shares of Preferred Stock (or, if such registered holder alleges that such certificate has been lost, stolen or destroyed, a lost certificate affidavit and agreement reasonably acceptable to the Corporation to indemnify the Corporation against any claim that may be made against the Corporation on account of the alleged loss, theft or destruction of such certificate), at the office of the transfer agent for the Preferred Stock (or at the principal office of the Corporation if the Corporation serves as its own transfer agent). Such notice shall state such holder’s name or the names of the nominees in which such holder wishes the shares of Common Stock to be issued. If required by the Corporation, any certificates surrendered for conversion shall be endorsed or accompanied by a written instrument or instruments of transfer, in form satisfactory to the Corporation, duly executed by the registered holder or his, her or its attorney duly authorized in writing. The close of business on the date of receipt by the transfer agent (or by the Corporation if the Corporation serves as its own transfer agent) of such notice and, if applicable, certificates (or lost certificate affidavit and agreement) shall be the time of conversion (the “Conversion Time”), and the shares of Common Stock issuable upon conversion of the specified shares shall be deemed to be outstanding of record as of such date. The Corporation shall, as soon as practicable after the Conversion Time (i) issue and deliver to such holder of Preferred Stock, or to his, her or its nominees, a certificate or certificates for the number of full shares of Common Stock issuable upon such conversion in accordance with the provisions hereof and a certificate for the number (if any) of the shares of Preferred Stock represented by the surrendered certificate that were not converted into Common Stock, (ii) pay in cash such amount as provided in Section 4.2 in lieu of any fraction of a share of Common Stock otherwise issuable upon such conversion and (iii) pay all declared but unpaid dividends on the shares of Preferred Stock converted.
4.3.2 Reservation of Shares. The Corporation shall at all times when the Preferred Stock shall be outstanding, reserve and keep available out of its authorized but unissued capital stock, for the purpose of effecting the conversion of the Preferred Stock, such number of its duly authorized shares of Common Stock as shall from time to time be sufficient to effect the conversion of all outstanding Preferred Stock; and if at any time the number of authorized but unissued shares of Common Stock shall not be sufficient to effect the conversion of all then outstanding shares of the Preferred Stock, the Corporation shall take such corporate action as may be necessary to increase its authorized but unissued shares of Common Stock to such number of shares as shall be sufficient for such purposes, including, without limitation, engaging in best efforts to obtain the requisite stockholder approval of any necessary amendment to the Restated Certificate. Before taking any action which would cause an adjustment reducing the applicable Conversion Price below the then par value of the shares of Common Stock issuable upon conversion of the Preferred Stock, the Corporation will take any corporate action which may, in the opinion of its counsel, be necessary in order that the Corporation may validly and legally issue fully paid and non-assessable shares of Common Stock at such adjusted applicable Conversion Price.

4.3.3 Effect of Conversion. All shares of Preferred Stock which shall have been surrendered for conversion as herein provided shall no longer be deemed to be outstanding and all rights with respect to such shares shall immediately cease and terminate at the Conversion Time, except only the right of the holders thereof to receive shares of Common Stock in exchange therefor, to receive payment in lieu of any fraction of a share otherwise issuable upon such conversion as provided in Section 4.2, and to receive payment of any dividends declared but unpaid thereon. Any shares of Preferred Stock so converted shall be retired and cancelled and may not be reissued as shares of such series, and the Corporation may thereafter take such appropriate action (without the need for stockholder action) as may be necessary to reduce the authorized number of shares of Preferred Stock accordingly.

4.3.4 No Further Adjustment. Upon any such conversion, no adjustment to the Conversion Price shall be made for any declared but unpaid dividends on the Preferred Stock surrendered for conversion or on the Common Stock delivered upon conversion.

4.3.5 Taxes. The Corporation shall pay any and all issue and other similar taxes that may be payable in respect of any issuance or delivery of shares of Common Stock upon conversion of shares of Preferred Stock pursuant to this Section 4. The Corporation shall not, however, be required to pay any tax which may be payable in respect of any transfer involved in the issuance and delivery of shares of Common Stock in a name other than that in which the shares of Preferred Stock so converted were registered, and no such issuance or delivery shall be made unless and until the person or entity requesting such issuance has paid to the Corporation the amount of any such tax or has established, to the satisfaction of the Corporation, that such tax has been paid.

4.4 Adjustments to Conversion Price for Diluting Issues.

4.4.1 Special Definitions. For purposes of this Article Fourth, the following definitions shall apply:

(a) “Option” shall mean rights, options or warrants to subscribe for, purchase or otherwise acquire Common Stock or Convertible Securities.
(b) “Series C Original Issue Date” shall mean the date on which the first share of Series C Preferred Stock was issued.

(c) “Convertible Securities” shall mean any evidences of indebtedness, shares or other securities directly or indirectly convertible into or exchangeable for Common Stock, but excluding Options.

(d) “Additional Shares of Common Stock” shall mean all shares of Common Stock issued (or, pursuant to Section 4.4.3 below, deemed to be issued) by the Corporation after the Series C Original Issue Date, other than (1) the following shares of Common Stock and (2) shares of Common Stock deemed issued pursuant to the following Options and Convertible Securities (clauses (1) and (2), collectively, “Exempted Securities”):

(i) shares of Common Stock, Options or Convertible Securities issued as a dividend or distribution on Preferred Stock;

(ii) shares of Common Stock, Options or Convertible Securities issued by reason of a dividend, stock split, split-up or other distribution on shares of Common Stock that is covered by Section 4.5, 4.6, 4.7 or 4.8;

(iii) shares of Common Stock, Options or Convertible Securities issued to employees, officers, directors, outside consultants or contractors of the Corporation or any of its subsidiaries pursuant to a plan, agreement or arrangement approved by the Board of Directors;

(iv) shares of Common Stock or Convertible Securities actually issued upon the exercise of Options outstanding as of the date hereof or shares of Common Stock actually issued upon the conversion or exchange of Convertible Securities outstanding as of the date hereof;

(v) shares of Common Stock, Options or Convertible Securities issued in connection with the Corporation obtaining lease financing, whether issued to a lessor, guarantor or other person, provided that such issuance is pursuant to an agreement or arrangement duly approved by the Board of Directors;

(vi) shares of Common Stock, Options or Convertible Securities issued in connection with any borrowings, direct or indirect, from a bank or other financial institution by the Corporation, provided that such issuance is pursuant to an agreement or arrangement duly approved by the Board of Directors;

(vii) shares of Common Stock, Options or Convertible Securities issued in connection with the acquisition of all or a substantial portion of the assets or the business of another entity by the Corporation, provided that such issuance is pursuant to an agreement or arrangement duly approved by the Board of Directors;
(viii) shares of Common Stock, Options or Convertible Securities issued in connection with any corporate partnering transaction or collaboration, strategic alliance, license, technology transfer or similar transaction between the Corporation and any other person, provided that such issuance is pursuant to an agreement or arrangement duly approved by the Board of Directors; or

(ix) shares of Series C Preferred Stock issued pursuant to that certain Series C Preferred Stock Purchase Agreement, dated on or after the filing date of this Restated Certificate, among the Corporation and the Investors named therein, or shares of Common Stock issued on conversion thereof.

4.4.2 No Adjustment of Conversion Price. No adjustment in the applicable Conversion Price shall be made as the result of the issuance or deemed issuance of Additional Shares of Common Stock if the Corporation receives written notice from the Requisite Holders agreeing that no such adjustment shall be made as the result of the issuance or deemed issuance of such Additional Shares of Common Stock.

4.4.3 Deemed Issue of Additional Shares of Common Stock.

(a) If the Corporation at any time or from time to time after the Series C Original Issue Date shall issue any Options or Convertible Securities (excluding Options or Convertible Securities which are themselves Exempted Securities) or shall fix a record date for the determination of holders of any class of securities entitled to receive any such Options or Convertible Securities, then the maximum number of shares of Common Stock (as set forth in the instrument relating thereto, assuming the satisfaction of any conditions to exercisability, convertibility or exchangeability but without regard to any provision contained therein for a subsequent adjustment of such number) issuable upon the exercise of such Options or, in the case of Convertible Securities and Options therefor, the conversion or exchange of such Convertible Securities, shall be deemed to be Additional Shares of Common Stock issued as of the time of such issue or, in case such a record date shall have been fixed, as of the close of business on such record date.

(b) If the terms of any Option or Convertible Security, the issuance of which resulted in an adjustment to the applicable Conversion Price pursuant to the terms of Section 4.4.4, are revised as a result of an amendment to such terms or any other adjustment pursuant to the provisions of such Option or Convertible Security (but excluding automatic adjustments to such terms pursuant to anti-dilution or similar provisions of such Option or Convertible Security) to provide for either (1) any increase or decrease in the number of shares of Common Stock issuable upon the exercise, conversion and/or exchange of any such Option or Convertible Security or (2) any increase or decrease in the consideration payable to the Corporation upon such exercise, conversion and/or exchange, then, effective upon such increase or decrease becoming effective, the applicable Conversion Price computed upon the original issue of such Option or Convertible Security (or upon the occurrence of a record date with respect thereto) shall be readjusted to such applicable Conversion Price as would have obtained had such revised terms been in effect upon the original date of issuance of such Option or Convertible Security. Notwithstanding the foregoing, no readjustment pursuant to this clause (b) shall have the effect of increasing the applicable Conversion Price to an amount which exceeds the lower of (i) the
applicable Conversion Price in effect immediately prior to the original adjustment made as a result of the issuance of such Option or Convertible Security, (or ii) the applicable Conversion Price that would have resulted from any issuances of Additional Shares of Common Stock (other than deemed issuances of Additional Shares of Common Stock as a result of the issuance of such Option or Convertible Security) between the original adjustment date and such readjustment date.

(c) If the terms of any Option or Convertible Security (excluding Options or Convertible Securities which are themselves Exempted Securities), the issuance of which did not result in an adjustment to the applicable Conversion Price pursuant to the terms of Section 4.4.4 (either because the consideration per share (determined pursuant to Section 4.4.5) of the Additional Shares of Common Stock subject thereto was equal to or greater than the applicable Conversion Price then in effect, or because such Option or Convertible Security was issued before the Series C Original Issue Date), are revised after the Series C Original Issue Date as a result of an amendment to such terms or any other adjustment pursuant to the provisions of such Option or Convertible Security (but excluding automatic adjustments to such terms pursuant to anti-dilution or similar provisions of such Option or Convertible Security) to provide for either (1) any increase in the number of shares of Common Stock issuable upon the exercise, conversion or exchange of any such Option or Convertible Security or (2) any decrease in the consideration payable to the Corporation upon such exercise, conversion or exchange, then such Option or Convertible Security, as so amended or adjusted, and the Additional Shares of Common Stock subject thereto (determined in the manner provided in Section 4.4.3(g) shall be deemed to have been issued effective upon such increase or decrease becoming effective.

(d) Upon the expiration or termination of any unexercised Option or unconverted or unexchanged Convertible Security (or portion thereof) which resulted (either upon its original issuance or upon a revision of its terms) in an adjustment to the applicable Conversion Price pursuant to the terms of Section 4.4.4, the applicable Conversion Price shall be readjusted to such applicable Conversion Price as would have obtained had such Option or Convertible Security (or portion thereof) never been issued.

(e) If the number of shares of Common Stock issuable upon the exercise, conversion and/or exchange of any Option or Convertible Security, or the consideration payable to the Corporation upon such exercise, conversion and/or exchange, is calculable at the time such Option or Convertible Security is issued or amended but is subject to adjustment based upon subsequent events, any adjustment to the applicable Conversion Price provided for in this Section 4.4.3 shall be effected at the time of such issuance or amendment based on such number of shares or amount of consideration without regard to any provisions for subsequent adjustments (and any subsequent adjustments shall be treated as provided in clauses (b) and (c) of this Section 4.4.3). If the number of shares of Common Stock issuable upon the exercise, conversion and/or exchange of any Option or Convertible Security, or the consideration payable to the Corporation upon such exercise, conversion and/or exchange, cannot be calculated at all at the time such Option or Convertible Security is issued or amended, any adjustment to the applicable Conversion Price that would result under the terms of this Section 4.4.3 at the time of such issuance or amendment shall instead be effected at the time such number of shares and/or amount of consideration is first calculable (even if subject to subsequent adjustments), assuming for purposes of calculating such adjustment to the applicable Conversion Price that such issuance or amendment took place at the time such calculation can first be made.
4.4.4 Adjustment of Conversion Price Upon Issuance of Additional Shares of Common Stock. In the event the Corporation shall at any time after the Series C Original Issue Date issue Additional Shares of Common Stock (including Additional Shares of Common Stock deemed to be issued pursuant to Section 4.4.3), without consideration or for a consideration per share less than the applicable Conversion Price in effect immediately prior to such issue, then the applicable Conversion Price shall be reduced, concurrently with such issue, to a price (calculated to the nearest one-hundredth of a cent) determined in accordance with the following formula:

\[ CP_2 = CP_1 \times \frac{A + B}{A + C} \]

For purposes of the foregoing formula, the following definitions shall apply:

(a) “\( CP_2 \)” shall mean the applicable Conversion Price in effect immediately after such issue of Additional Shares of Common Stock;

(b) “\( CP_1 \)” shall mean the applicable Conversion Price in effect immediately prior to such issue of Additional Shares of Common Stock;

(c) “\( A \)” shall mean the number of shares of Common Stock outstanding immediately prior to such issue of Additional Shares of Common Stock (treating for this purpose as outstanding all shares of Common Stock issuable upon exercise of Options outstanding immediately prior to such issue or upon conversion or exchange of Convertible Securities (including the Preferred Stock) outstanding (assuming exercise of any outstanding Options therefor) immediately prior to such issue);

(d) “\( B \)” shall mean the number of shares of Common Stock that would have been issued if such Additional Shares of Common Stock had been issued at a price per share equal to \( CP_1 \) (determined by dividing the aggregate consideration received by the Corporation in respect of such issue by \( CP_1 \)); and

(e) “\( C \)” shall mean the number of such Additional Shares of Common Stock issued in such transaction.

4.4.5 Determination of Consideration. For purposes of this Section 4.4, the consideration received by the Corporation for the issue of any Additional Shares of Common Stock shall be computed as follows:

(a) **Cash and Property:** Such consideration shall:

   (i) insofar as it consists of cash, be computed at the aggregate amount of cash received by the Corporation, excluding amounts paid or payable for accrued interest;

   (ii) insofar as it consists of property other than cash, be computed at the fair market value thereof at the time of such issue, as determined in good faith by the Board of Directors; and
in the event Additional Shares of Common Stock are issued together with other shares or securities or other assets of the Corporation for consideration which covers both, be the proportion of such consideration so received, computed as provided in clauses (i) and (ii) above, as determined in good faith by the Board of Directors.

(b) Options and Convertible Securities. The consideration per share received by the Corporation for Additional Shares of Common Stock deemed to have been issued pursuant to Section 4.4.3, relating to Options and Convertible Securities, shall be determined by dividing:

(i) The total amount, if any, received or receivable by the Corporation as consideration for the issue of such Options or Convertible Securities, plus the minimum aggregate amount of additional consideration (as set forth in the instruments relating thereto, without regard to any provision contained therein for a subsequent adjustment of such consideration) payable to the Corporation upon the exercise of such Options or the conversion or exchange of such Convertible Securities, or in the case of Options for Convertible Securities, the exercise of such Options for Convertible Securities and the conversion or exchange of such Convertible Securities, by

(ii) the maximum number of shares of Common Stock (as set forth in the instruments relating thereto, without regard to any provision contained therein for a subsequent adjustment of such number) issuable upon the exercise of such Options or the conversion or exchange of such Convertible Securities, or in the case of Options for Convertible Securities, the exercise of such Options for Convertible Securities and the conversion or exchange of such Convertible Securities.

4.4.6 Multiple Closing Dates. In the event the Corporation shall issue on more than one date Additional Shares of Common Stock that are a part of one transaction or a series of related transactions and that would result in an adjustment to the applicable Conversion Price pursuant to the terms of Section 4.4.4, and such issuance dates occur within a period of no more than ninety (90) days from the first such issuance to the final such issuance, then, upon the final such issuance, the applicable Conversion Price shall be readjusted to give effect to all such issuances as if they occurred on the date of the first such issuance (and without giving effect to any additional adjustments as a result of any such subsequent issuances within such period).

4.5 Adjustment for Stock Splits and Combinations. If the Corporation shall at any time or from time to time after the Series C Original Issue Date effect a subdivision of the outstanding Common Stock, the applicable Conversion Price in effect immediately before that subdivision shall be proportionately decreased so that the number of shares of Common Stock issuable on conversion of each share of such series shall be increased in proportion to such increase in the aggregate number of shares of Common Stock outstanding. If the Corporation shall at any time or from time to time after the Series C Original Issue Date combine the outstanding shares of Common Stock, the applicable Conversion Price in effect immediately before the combination shall be proportionately increased so that the number of shares of Common Stock issuable on conversion of each share of such series shall be decreased in proportion to such decrease in the aggregate number of shares of Common Stock outstanding. Any adjustment under this Section 4.5 shall become effective at the close of business on the date the subdivision or combination becomes effective.
4.6 Adjustment for Certain Dividends and Distributions. In the event the Corporation at any time or from time to time after the Series C Original Issue Date shall make or issue, or fix a record date for the determination of holders of Common Stock entitled to receive, a dividend or other distribution payable on the Common Stock in additional shares of Common Stock, then and in each such event the applicable Conversion Price in effect immediately before such event shall be decreased as of the time of such issuance or, in the event such a record date shall have been fixed, as of the close of business on such record date, by multiplying the applicable Conversion Price then in effect by a fraction:

(1) the numerator of which shall be the total number of shares of Common Stock issued and outstanding immediately prior to the time of such issuance or the close of business on such record date, and

(2) the denominator of which shall be the total number of shares of Common Stock issued and outstanding immediately prior to the time of such issuance or the close of business on such record date plus the number of shares of Common Stock issuable in payment of such dividend or distribution.

Notwithstanding the foregoing (a) if such record date shall have been fixed and such dividend is not fully paid or if such distribution is not fully made on the date fixed therefor, the applicable Conversion Price shall be recomputed accordingly as of the close of business on such record date and thereafter the applicable Conversion Price shall be adjusted pursuant to this Section 4.6 as of the time of actual payment of such dividends or distributions; and (b) that no such adjustment shall be made if the holders of Preferred Stock simultaneously receive a dividend or other distribution of shares of Common Stock in a number equal to the number of shares of Common Stock as they would have received if all outstanding shares of Preferred Stock had been converted into Common Stock on the date of such event.

4.7 Adjustments for Other Dividends and Distributions. In the event the Corporation at any time or from time to time after the Series C Original Issue Date shall make or issue, or fix a record date for the determination of holders of Common Stock entitled to receive, a dividend or other distribution payable in securities of the Corporation (other than a distribution of shares of Common Stock in respect of outstanding shares of Common Stock) or in other property and the provisions of Section 1 do not apply to such dividend or distribution, then and in each such event the holders of Preferred Stock shall receive, simultaneously with the distribution to the holders of Common Stock, a dividend or other distribution of such securities or other property in an amount equal to the amount of such securities or other property as they would have received if all outstanding shares of Preferred Stock had been converted into Common Stock on the date of such event.

4.8 Adjustment for Merger or Reorganization, etc. Subject to the provisions of Section 2.5, if there shall occur any reorganization, recapitalization, reclassification, consolidation or merger involving the Corporation in which the Common Stock (but not the
Preferred Stock) is converted into or exchanged for securities, cash or other property (other than a transaction covered by Sections 4.4, 4.6 or 4.7), then, following any such reorganization, recapitalization, reclassification, consolidation or merger, each share of Preferred Stock shall thereafter be convertible in lieu of the Common Stock into which it was convertible prior to such event into the kind and amount of securities, cash or other property which a holder of the number of shares of Common Stock of the Corporation issuable upon conversion of one share of Preferred Stock immediately prior to such reorganization, recapitalization, reclassification, consolidation or merger would have been entitled to receive pursuant to such transaction; and, in such case, appropriate adjustment (as determined in good faith by the Board of Directors) shall be made in the application of the provisions in this Section 4 with respect to the rights and interests thereafter of the holders of the Preferred Stock, to the end that the provisions set forth in this Section 4 (including provisions with respect to changes in and other adjustments of the applicable Conversion Price) shall thereafter be applicable, as nearly as reasonably may be, in relation to any securities or other property thereafter deliverable upon the conversion of the Preferred Stock. For the avoidance of doubt, nothing in this Subsection 4.8 shall be construed as preventing the holders of Preferred Stock from seeking any appraisal rights to which they are otherwise entitled under the General Corporation Law in connection with a merger triggering an adjustment hereunder, nor shall this Subsection 4.8 be deemed conclusive evidence of the fair value of the shares of Preferred Stock in any such appraisal proceeding.

4.9 Certificate as to Adjustments. Upon the occurrence of each adjustment or readjustment of the applicable Conversion Price pursuant to this Section 4, the Corporation at its expense shall, as promptly as reasonably practicable (but in any event not later than ten (10) days thereafter), compute such adjustment or readjustment in accordance with the terms hereof and furnish to each holder of Preferred Stock a certificate setting forth such adjustment or readjustment (including the kind and amount of securities, cash or other property into which the Preferred Stock is convertible) and showing in detail the facts upon which such adjustment or readjustment is based. The Corporation shall, as promptly as reasonably practicable after the written request at any time of any holder of Preferred Stock (but in any event not later than ten (10) days thereafter), furnish or cause to be furnished to such holder a certificate setting forth (i) the applicable Conversion Price then in effect, and (ii) the number of shares of Common Stock and the amount, if any, of other securities, cash or property which then would be received upon the conversion of Preferred Stock.

4.10 Notice of Record Date. In the event:

(a) the Corporation shall take a record of the holders of its Common Stock (or other capital stock or securities at the time issuable upon conversion of the Preferred Stock) for the purpose of entitling or enabling them to receive any dividend or other distribution, or to receive any right to subscribe for or purchase any shares of capital stock of any class or any other securities, or to receive any other security; or

(b) of any capital reorganization of the Corporation, any reclassification of the Common Stock of the Corporation, or any Deemed Liquidation Event; or

(c) of the voluntary or involuntary dissolution, liquidation or winding up of the Corporation,
5. **Mandatory Conversion.**

5.1 **Trigger Events.** Upon either (a) the closing of the sale of shares of Common Stock to the public at a price of at least $3.00 per share (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Common Stock) in a firm-commitment underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, resulting in at least $30,000,000 of gross proceeds to the Corporation (a “Qualified IPO”) or (b) the date and time, or the occurrence of an event, specified by vote or written consent of the Requisite Holders (the time of such closing or the date and time specified or the time of the event specified in such vote or written consent is referred to herein as the “Mandatory Conversion Time”), then (i) all outstanding shares of Preferred Stock shall automatically be converted into shares of Common Stock, at the then effective conversion rate as calculated pursuant to Section 4.1.1 and (ii) such shares may not be reissued by the Corporation.

5.2 **Procedural Requirements.** All holders of record of shares of Preferred Stock shall be sent written notice of the Mandatory Conversion Time and the place designated for mandatory conversion of all such shares of Preferred Stock pursuant to this Section 5. Such notice need not be sent in advance of the occurrence of the Mandatory Conversion Time. Upon receipt of such notice, each holder of shares of Preferred Stock in certificated form shall surrender his, her or its certificate or certificates for all such shares (or, if such holder alleges that such certificate has been lost, stolen or destroyed, a lost certificate affidavit and agreement reasonably acceptable to the Corporation to indemnify the Corporation against any claim that may be made against the Corporation on account of the alleged loss, theft or destruction of such certificate) to the Corporation at the place designated in such notice. If so required by the Corporation, any certificates surrendered for conversion shall be endorsed or accompanied by written instrument or instruments of transfer, in form satisfactory to the Corporation, duly executed by the registered holder or by his, her or its attorney duly authorized in writing. All rights with respect to the Preferred Stock converted pursuant to Section 5.1, including the rights, if any, to receive notices and vote (other than as a holder of Common Stock), will terminate at the Mandatory Conversion Time (notwithstanding the failure of the holder or holders thereof to surrender any certificates at or prior to such time), except only the rights of the holders thereof, upon surrender
of any certificate or certificates of such holders (or lost certificate affidavit and agreement) therefor, to receive the items provided for in the next sentence of this Section 5.2. As soon as practicable after the Mandatory Conversion Time and, if applicable, the surrender of any certificate or certificates (or lost certificate affidavit and agreement) for Preferred Stock, the Corporation shall (a) issue and deliver to such holder, or to his, her or its nominees, a certificate or certificates for the number of full shares of Common Stock issuable on such conversion in accordance with the provisions hereof and (b) pay cash as provided in Section 4.2 in lieu of any fraction of a share of Common Stock otherwise issuable upon such conversion and the payment of any declared but unpaid dividends on the shares of Preferred Stock converted. Such converted Preferred Stock shall be retired and cancelled and may not be reissued as shares of such series, and the Corporation may thereafter take such appropriate action (without the need for stockholder action) as may be necessary to reduce the authorized number of shares of Preferred Stock accordingly.

6. **Redemption.** The shares of Preferred Stock are not redeemable except in accordance with Section 2.5.2.

7. **Redeemed or Otherwise Acquired Shares.** Any shares of Preferred Stock that are redeemed or otherwise acquired by the Corporation or any of its subsidiaries shall be automatically and immediately cancelled and retired and shall not be reissued, sold or transferred. Neither the Corporation nor any of its subsidiaries may exercise any voting or other rights granted to the holders of Preferred Stock following redemption.

8. **Waiver.** Any of the rights, powers, preferences and other terms of the Preferred Stock set forth herein may be waived on behalf of all holders of Preferred Stock by the affirmative written consent or vote of the Requisite Holders.

9. **Notices.** Any notice required or permitted by the provisions of this Article Fourth to be given to a holder of shares of Preferred Stock shall be mailed, postage prepaid, to the post office address last shown on the records of the Corporation, or given by electronic communication in compliance with the provisions of the General Corporation Law, and shall be deemed sent upon such mailing or electronic transmission.

**FIFTH:** Subject to any additional vote required by the Restated Certificate or Bylaws, in furtherance and not in limitation of the powers conferred by statute, the Board of Directors is expressly authorized to make, repeal, alter and rescind any or all of the Bylaws of the Corporation.

**SIXTH:** Subject to any additional vote required by the Restated Certificate, the number of directors of the Corporation shall be determined in the manner set forth in the Bylaws of the Corporation.

**SEVENTH:** Elections of directors need not be by written ballot unless the Bylaws of the Corporation shall so provide.

**EIGHTH:** Meetings of stockholders may be held within or without the State of Delaware, as the Bylaws of the Corporation may provide. The books of the Corporation may be kept outside the State of Delaware at such place or places as may be designated from time to time by the Board of Directors or in the Bylaws of the Corporation.
NINTH: To the fullest extent permitted by law, a director of the Corporation shall not be personally liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a director. If the General Corporation Law or any other law of the State of Delaware is amended after approval by the stockholders of this Article Ninth to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director of the Corporation shall be eliminated or limited to the fullest extent permitted by the General Corporation Law as so amended.

Any repeal or modification of the foregoing provisions of this Article Ninth by the stockholders of the Corporation shall not adversely affect any right or protection of a director of the Corporation existing at the time of, or increase the liability of any director of the Corporation with respect to any acts or omissions of such director occurring prior to, such repeal or modification.

TENTH: To the fullest extent permitted by applicable law, the Corporation is authorized to provide indemnification of (and advancement of expenses to) directors, officers and agents of the Corporation (and any other persons to which the General Corporation Law permits the Corporation to provide indemnification) through Bylaw provisions, agreements with such agents or other persons, vote of stockholders or disinterested directors or otherwise, in excess of the indemnification and advancement otherwise permitted by Section 145 of the General Corporation Law.

Any amendment, repeal or modification of the foregoing provisions of this Article Tenth shall not adversely affect any right or protection of any director, officer or other agent of the Corporation existing at the time of such amendment, repeal or modification.

ELEVENTH: The Corporation renounces, to the fullest extent permitted by law, any interest or expectancy of the Corporation in, or in being offered an opportunity to participate in, any Excluded Opportunity. An “Excluded Opportunity” is any matter, transaction or interest that is presented to, or acquired, created or developed by, or which otherwise comes into the possession of, (i) any director of the Corporation who is not an employee of the Corporation or any of its subsidiaries, or (ii) any holder of Preferred Stock or any partner, member, director, stockholder, employee or agent of any such holder, other than someone who is an employee of the Corporation or any of its subsidiaries (collectively, “Covered Persons”), unless such matter, transaction or interest is presented to, or acquired, created or developed by, or otherwise comes into the possession of, a Covered Person expressly and solely in such Covered Person’s capacity as a director of the Corporation.

TWELFTH: Unless the Corporation consents in writing to the selection of an alternative forum, the Court of Chancery in the State of Delaware shall be the sole and exclusive forum for any stockholder (including a beneficial owner) to bring (i) any derivative action or proceeding brought on behalf of the Corporation, (ii) any action asserting a claim of breach of fiduciary duty owed by any director, officer or other employee of the Corporation to the Corporation or the Corporation’s stockholders, (iii) any action asserting a claim against the
Corporation, its directors, officers or employees arising pursuant to any provision of the Delaware General Corporation Law or the Corporation’s Restated Certificate or Bylaws or (iv) any action asserting a claim against the Corporation, its directors, officers or employees governed by the internal affairs doctrine, except for, as to each of (i) through (iv) above, any claim as to which the Court of Chancery determines that there is an indispensable party not subject to the jurisdiction of the Court of Chancery (and the indispensable party does not consent to the personal jurisdiction of the Court of Chancery within ten (10) days following such determination), which is vested in the exclusive jurisdiction of a court or forum other than the Court of Chancery, or for which the Court of Chancery does not have subject matter jurisdiction. If any provision or provisions of this Article Twelfth shall be held to be invalid, illegal or unenforceable as applied to any person or entity or circumstance for any reason whatsoever, then, to the fullest extent permitted by law, the validity, legality and enforceability of such provisions in any other circumstance and of the remaining provisions of this Article Twelfth (including, without limitation, each portion of any sentence of this Article Twelfth containing any such provision held to be invalid, illegal or unenforceable that is not itself held to be invalid, illegal or unenforceable) and the application of such provision to other persons or entities and circumstances shall not in any way be affected or impaired thereby.

THIRTEENTH: For purposes of Section 500 of the California Corporations Code (to the extent applicable), in connection with any repurchase of shares of Common Stock permitted under this Restated Certificate from employees, officers, directors, advisors, consultants or other persons performing services for the Corporation in connection with a termination of employment or services pursuant to agreements or arrangements approved by the Board of Directors (in addition to any other consent required under this Restated Certificate), such repurchase may be made without regard to any “preferential dividends arrears amount” or “preferential rights amount” (as those terms are defined in Section 500 of the California Corporations Code). Accordingly, for purposes of making any calculation under California Corporations Code Section 500 in connection with such repurchase, the amount of any “preferential dividends arrears amount” or “preferential rights amount” (as those terms are defined therein) shall be deemed to be zero (0).

*    *    *

3. That the foregoing amendment and restatement was approved by the holders of the requisite number of shares of this corporation in accordance with Section 228 of the General Corporation Law.

4. That this Restated Certificate, which restates and integrates and further amends the provisions of this Corporation’s Amended and Restated Certificate of Incorporation, has been duly adopted in accordance with Sections 242 and 245 of the General Corporation Law.

[Remainder of Page Intentionally Left Blank]
IN WITNESS WHEREOF, this Amended and Restated Certificate of Incorporation has been executed by a duly authorized officer of this corporation on this 27th day of March, 2020.

By:  /s/ Mark McKenna
Name: Mark McKenna
Title: President and Chief Executive Officer
BYLAWS

OF

PROMETHEUS BIOSCIENCES, INC.
# BYLAWS

## OF

## PROMETHEUS BIOSCIENCES, INC.

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BYLAWS

OF

PROMETHEUS BIOSCIENCES, INC.

ARTICLE I

OFFICES

Section 1. REGISTERED OFFICE. The registered office shall be in the City of Wilmington, County of New Castle, State of Delaware.

Section 2. OTHER OFFICES. The corporation may also have offices at such other places both within and without the State of Delaware as the Board of Directors may from time to time determine or the business of the corporation may require.

ARTICLE II

MEETINGS OF STOCKHOLDERS

Section 1. PLACE OF MEETINGS. Meetings of stockholders shall be held at any place within or outside the State of Delaware designated by the Board of Directors. In the absence of any such designation, stockholders’ meetings shall be held at the principal executive office of the corporation.

Section 2. ANNUAL MEETING OF STOCKHOLDERS. The annual meeting of stockholders shall be held each year on a date and a time designated by the Board of Directors. At each annual meeting directors shall be elected in the manner provided in the certificate of incorporation of the corporation (the “Certificate of Incorporation”) and in the Bylaws, and any other proper business may be transacted.

Section 3. QUORUM; ADJOURNED MEETINGS AND NOTICE THEREOF. A majority of the stock issued and outstanding and entitled to vote at any meeting of stockholders, the holders of which are present in person or represented by proxy, shall constitute a quorum for the transaction of business except as otherwise provided by law, by the Certificate of Incorporation, or by these Bylaws. A quorum, once established, shall not be broken by the withdrawal of enough votes to leave less than a quorum and the votes present may continue to transact business until adjournment. If, however, such quorum shall not be present or represented at any meeting of the stockholders, a majority of the voting stock represented in person or by proxy may adjourn the meeting from time to time, without notice other than announcement at the meeting, until a quorum shall be present or represented. At such adjourned meeting at which a quorum shall be present or represented, any business may be transacted which might have been transacted at the meeting as originally notified. If the adjournment is for more than thirty (30) days, or if after the adjournment a new record date is fixed for the adjourned meeting, a notice of the adjourned meeting shall be given to each stockholder of record entitled to vote thereat.
Section 4. VOTING. When a quorum is present at any meeting, in all matters other than the election of directors, the vote of the holders of a majority of the stock having voting power present in person or represented by proxy shall decide any question brought before such meeting, unless the question is one upon which by express provision of the statutes, or the Certificate of Incorporation, or these Bylaws, a different vote is required in which case such express provision shall govern and control the decision of such question. Directors shall be elected by a plurality of the votes of the shares present in person or represented by proxy at the meeting and entitled to vote on the election of directors.

Section 5. PROXIES. At each meeting of the stockholders, each stockholder having the right to vote may vote in person or may authorize another person or persons to act for him or her by proxy appointed by an instrument in writing subscribed by such stockholder and bearing a date not more than three (3) years prior to said meeting, unless said instrument provides for a longer period. All proxies must be filed with the Secretary of the corporation at the beginning of each meeting in order to be counted in any vote at the meeting. Except as may be otherwise provided in the Certificate of Incorporation, each stockholder shall have one vote for each share of stock having voting power, registered in his or her name on the books of the corporation on the record date set by the Board of Directors as provided in Article VII, Section 6 hereof.

Section 6. SPECIAL MEETINGS. Special meetings of the stockholders, for any purpose, or purposes, unless otherwise prescribed by statute or by the Certificate of Incorporation, may be called by the Chairman of the Board or the President and shall be called by the Chairman of the Board, President or the Secretary at the request in writing of a majority of the Board of Directors, or at the request in writing of stockholders owning a majority in amount of the entire capital stock of the corporation issued and outstanding, and entitled to vote. Such request shall state the purpose or purposes of the proposed meeting. Business transacted at any special meeting of stockholders shall be limited to the purposes stated in the notice.

Section 7. NOTICE OF STOCKHOLDERS’ MEETINGS. Whenever stockholders are required or permitted to take any action at a meeting, a written notice of the meeting shall be given which notice shall state the place, date and hour of the meeting, and, in the case of a special meeting, the purpose or purposes for which the meeting is called. The written notice of any meeting shall be given to each stockholder entitled to vote at such meeting not less than ten (10) nor more than sixty (60) days before the date of the meeting. If mailed, notice is given when deposited in the United States mail, postage prepaid, directed to the stockholder at his or her address as it appears on the records of the corporation. If electronically transmitted, then notice is deemed given when transmitted and directed to a facsimile number or electronic mail address at which the stockholder has consented to receive notice. An affidavit of the secretary or an assistant secretary or of the transfer agent or other agent of the corporation that the notice has been given shall, in the absence of fraud, be prima facie evidence of the facts stated therein.

Section 8. MAINTENANCE AND INSPECTION OF STOCKHOLDER LIST. The officer who has charge of the stock ledger of the corporation shall prepare and make, at least ten (10) days before every meeting of stockholders, a complete list of the stockholders entitled to vote at the meeting, arranged in alphabetical order, and showing the address of each stockholder and the number of shares registered in the name of each stockholder. Such list shall be open to the examination of any stockholder, for any purpose germane to the meeting, during ordinary business hours, for a period of at least ten (10) days prior to the meeting, either at a place within the city where the meeting is to be held, which place shall be specified in the notice of the meeting, or, if not so specified, at the place where the meeting is to be held. The list shall also be produced and kept at the time and place of the meeting during the whole time thereof, and may be inspected by any stockholder who is present.
Section 9. STOCKHOLDER ACTION BY WRITTEN CONSENT WITHOUT A MEETING. Unless otherwise provided in the Certificate of Incorporation, any action required to be taken at any annual or special meeting of stockholders of the corporation, or any action which may be taken at any annual or special meeting of such stockholders, may be taken without a meeting, without prior notice and without a vote, if a consent in writing, setting forth the action so taken, shall be signed by the holders of outstanding stock having not less than the minimum number of votes that would be necessary to authorize or take such action at a meeting at which all shares entitled to vote thereon were present and voted and shall be delivered to the corporation by delivery to its registered office in Delaware, its principal place of business, or to an officer or agent of the corporation having custody of the book in which proceedings of meetings of stockholders are recorded. Except with respect to any telegram, cablegram or other electronic transmission, delivery made to a corporation’s registered office shall be by hand or by certified or registered mail, return receipt requested. Every written consent shall bear the date of signature of each stockholder who signs the consent and no written consent shall be effective to take the corporate action referred to therein unless, within sixty (60) days of the earliest dated consent delivered in the manner required by this Section 9 to the corporation, written consents signed by a sufficient number of holders to take action are delivered to the corporation by delivery to its registered office in Delaware, its principal place of business or to an officer or agent of the corporation having custody of the book in which proceedings of meetings of stockholders are recorded.

A telegram, cablegram or other electronic transmission consenting to an action to be taken and transmitted by a stockholder or proxyholder, or by a person or persons authorized to act for a stockholder or proxyholder, shall be deemed to be written, signed and dated for the purposes of this Section 9, provided that any such telegram, cablegram or other electronic transmission sets forth or is delivered with information from which the corporation can determine (i) that the telegram, cablegram or other electronic transmission was transmitted by the stockholder or proxyholder or by a person or persons authorized to act for the stockholder or proxyholder and (ii) the date on which such stockholder or proxyholder or authorized person or persons transmitted such telegram, cablegram or electronic transmission. The date on which such telegram, cablegram or electronic transmission is transmitted shall be deemed to be the date on which such consent was signed. Consents given by telegram, cablegram or other electronic transmission shall be deemed delivered if transmitted to the principal place of business of the corporation or to an officer or agent of the corporation having custody of the book in which proceedings of meetings of stockholders are recorded, and the telegram, cablegram or other electronic transmission is reproduced in paper form and filed with the book in which proceedings of meetings of stockholders are recorded.

Any copy, facsimile or other reliable reproduction of a consent in writing may be substituted or used in lieu of the original writing for any and all purposes for which the original writing could be used, provided that such copy, facsimile or other reproduction shall be a complete reproduction of the entire original writing. Prompt notice of the taking of the corporate action without a meeting by less than unanimous written consent shall be given to those stockholders who have not consented in writing.

ARTICLE III

DIRECTORS

Section 1. THE NUMBER OF DIRECTORS. Unless otherwise provided by law, the number of directors which shall constitute the whole Board of Directors shall be determined from time to time solely by resolution adopted by the affirmative vote of a majority of the directors. The directors need not be stockholders. The directors shall be elected at the annual meeting of the stockholders, except
as provided in Section 2 of this Article, and each director elected shall hold office until his or her successor is elected and qualified; provided, however, that unless otherwise restricted by the Certificate of Incorporation or by law, any director or the entire Board of Directors may be removed, either with or without cause, from the Board of Directors at any meeting of stockholders by a majority of the stock represented and entitled to vote thereat.

Section 2. VACANCIES. Vacancies on the Board of Directors by reason of death, resignation, retirement, disqualification, removal from office, or otherwise, and newly created directorships resulting from any increase in the authorized number of directors may be filled by a majority of the directors then in office, although less than a quorum, or by a sole remaining director. The directors so chosen shall hold office until the next annual election of directors and until their successors are duly elected and shall qualify, unless sooner displaced. If there are no directors in office, then an election of directors may be held in the manner provided by statute. If, at the time of filling any vacancy or any newly created directorship, the directors then in office shall constitute less than a majority of the whole Board of Directors (as constituted immediately prior to any such increase), the Court of Chancery may, upon application of any stockholder or stockholders holding at least ten percent of the total number of the shares at the time outstanding having the right to vote for such directors, summarily order an election to be held to fill any such vacancies or newly created directorships, or to replace the directors chosen by the directors then in office.

Section 3. POWERS. The property and business of the corporation shall be managed by or under the direction of its Board of Directors. In addition to the powers and authorities by these Bylaws expressly conferred upon them, the Board of Directors may exercise all such powers of the corporation and do all such lawful acts and things as are not by statute or by the Certificate of Incorporation or by these Bylaws directed or required to be exercised or done by the stockholders.

Section 4. PLACE OF DIRECTORS’ MEETINGS. The directors may hold their meetings and have one or more offices, and keep the books of the corporation outside of the State of Delaware.

Section 5. REGULAR MEETINGS. Regular meetings of the Board of Directors may be held without notice at such time and place as shall from time to time be determined by the Board of Directors.

Section 6. SPECIAL MEETINGS. Special meetings of the Board of Directors may be called by the President on forty-eight (48) hours notice to each director, either personally or by mail, e-mail or by telegram; special meetings shall be called by the Chairman of the Board, President or the Secretary in like manner and on like notice on the written request of two directors unless the Board of Directors consists of only one director; in which case special meetings shall be called by the Chairman of the Board, President or Secretary in like manner or on like notice on the written request of the sole director.

Section 7. QUORUM. At all meetings of the Board of Directors a majority of the authorized number of directors shall be necessary and sufficient to constitute a quorum for the transaction of business, and the vote of a majority of the directors present at any meeting at which there is a quorum, shall be the act of the Board of Directors, except as may be otherwise specifically provided by statute, by the Certificate of Incorporation or by these Bylaws. If a quorum shall not be present at any meeting of the Board of Directors, the directors present at such meeting may adjourn the meeting from time to time, without notice other than announcement at the meeting, until a quorum shall be present. If only one director is authorized, such sole director shall constitute a quorum.
Section 8. ACTION WITHOUT MEETING. Unless otherwise restricted by the Certificate of Incorporation or these Bylaws, any action required or permitted to be taken at any meeting of the Board of Directors or of any committee thereof may be taken without a meeting, if all members of the Board of Directors or committee, as the case may be, consent thereto in writing or by electronic transmission and the writing or writings or electronic transmission or transmissions are filed with the minutes of proceedings of the Board of Directors or committee.

Section 9. TELEPHONIC MEETINGS. Unless otherwise restricted by the Certificate of Incorporation or these Bylaws, members of the Board of Directors, or any committee designated by the Board of Directors, may participate in a meeting of the Board of Directors, or any committee, by means of conference telephone or similar communications equipment by means of which all persons participating in the meeting can hear each other, and such participation in a meeting shall constitute presence in person at such meeting.

Section 10. COMMITTEES OF DIRECTORS. The Board of Directors may, by resolution passed by a majority of the whole Board of Directors, designate one or more committees, each such committee to consist of one or more of the directors of the corporation. The Board of Directors may designate one or more directors as alternate members of any committee, who may replace any absent or disqualified member at any meeting of the committee. In the absence or disqualification of a member of a committee, the member or members thereof present at any meeting and not disqualified from voting, whether or not he or she or they constitute a quorum, may unanimously appoint another member of the Board of Directors to act at the meeting in the place of any such absent or disqualified member. Any such committee, to the extent provided in the resolution of the Board of Directors, shall have and may exercise all the powers and authority of the Board of Directors in the management of the business and affairs of the corporation; but no such committee shall have the power or authority in reference to amending the Certificate of Incorporation, adopting an agreement of merger or consolidation, recommending to the stockholders the sale, lease or exchange of all or substantially all of the corporation’s property and assets, recommending to the stockholders a dissolution of the corporation or a revocation of a dissolution, or amending the Bylaws of the corporation; and, unless the resolution or the Certificate of Incorporation expressly so provide, no such committee shall have the power or authority to declare a dividend or to authorize the issuance of stock.

Section 11. MINUTES OF COMMITTEE MEETINGS. Each committee shall keep regular minutes of its meetings and report the same to the Board of Directors when required.

Section 12. CHAIRMAN OF THE BOARD. The Board of Directors may designate one of its members to serve as Chairman of the Board, and if so, the Chairman of the Board shall, if present, preside at all meetings of the Board of Directors and stockholders, and exercise and perform such other powers and duties as may be from time to time assigned to him or her by the Board of Directors or prescribed by these Bylaws.

Section 13. COMPENSATION OF DIRECTORS. Unless otherwise restricted by the Certificate of Incorporation or these Bylaws, the Board of Directors shall have the authority to fix the compensation of directors. The directors may be paid their expenses, if any, of attendance at each meeting of the Board of Directors and may be paid a fixed sum for attendance at each meeting of the Board of Directors or a stated salary as director. No such payment shall preclude any director from serving the corporation in any other capacity and receiving compensation therefor. Members of special or standing committees may be allowed like compensation for attending committee meetings.
ARTICLE IV

OFFICERS

Section 1. OFFICERS. The officers of this corporation shall be chosen by the Board of Directors and shall include a President and a Secretary. The corporation may also have at the discretion of the Board of Directors such other officers as are desired, including a Vice-Chairman of the Board of Directors, a Chief Executive Officer, a Chief Financial Officer or Treasurer, one or more Vice Presidents, one or more Assistant Secretaries and Assistant Treasurers, and such other officers as may be appointed in accordance with the provisions of Section 3 hereof. In the event there are two or more Vice Presidents, then one or more may be designated as Executive Vice President, Senior Vice President, or other similar or dissimilar title. At the time of the election of officers, the directors may by resolution determine the order of their rank. Any number of offices may be held by the same person, unless the Certificate of Incorporation or these Bylaws otherwise provide.

Section 2. ELECTION OF OFFICERS. The Board of Directors, at its first meeting after each annual meeting of stockholders, shall choose the officers of the corporation.

Section 3. SUBORDINATE OFFICERS. The Board of Directors may appoint such other officers and agents as it shall deem necessary who shall hold their offices for such terms and shall exercise such powers and perform such duties as shall be determined from time to time by the Board of Directors.

Section 4. COMPENSATION OF OFFICERS. The salaries of all officers and agents of the corporation shall be fixed by the Board of Directors.

Section 5. TERM OF OFFICE; REMOVAL AND VACANCIES. The officers of the corporation shall hold office until their successors are chosen and qualified in their stead. Any officer elected or appointed by the Board of Directors may be removed at any time by the affirmative vote of a majority of the Board of Directors. If the office of any officer or officers becomes vacant for any reason, the vacancy shall be filled by the Board of Directors.

Section 6. PRESIDENT. Subject to such supervisory powers, if any, as may be given by the Board of Directors to the Chairman of the Board, the President shall be the Chief Executive Officer of the corporation and shall, subject to the control of the Board of Directors, have general supervision, direction and control of the business and officers of the corporation. In the absence of the Chairman of the Board, the President shall preside at all meetings of the stockholders and at all meetings of the Board of Directors. He or she shall be an ex-officio member of all committees and shall have the general powers and duties of management usually vested in the office of President and Chief Executive Officer of corporations, and shall have such other powers and duties as may be prescribed by the Board of Directors or these Bylaws.

Section 7. VICE PRESIDENTS. In the absence or disability of the President, the Vice Presidents in order of their rank as fixed by the Board of Directors, or if not ranked, the Vice President designated by the Board of Directors, shall perform all the duties of the President, and when so acting shall have all the powers of and be subject to all the restrictions upon the President. The Vice Presidents shall have such other duties as from time to time may be prescribed for them, respectively, by the Board of Directors.
Section 8. SECRETARY. The Secretary shall attend all sessions of the Board of Directors and all meetings of the stockholders and record all votes and the minutes of all proceedings in a book to be kept for that purpose; and shall perform like duties for the standing committees when required by the Board of Directors. He or she shall give, or cause to be given, notice of all meetings of the stockholders and of the Board of Directors, and shall perform such other duties as may be prescribed by the Board of Directors or these Bylaws.

Section 9. ASSISTANT SECRETARY. The Assistant Secretary, or if there be more than one, the Assistant Secretaries in the order determined by the Board of Directors, or if there be no such determination, the Assistant Secretary designated by the Board of Directors, shall, in the absence or disability of the Secretary, perform the duties and exercise the powers of the Secretary and shall perform such other duties and have such other powers as the Board of Directors may from time to time prescribe.

Section 10. CHIEF FINANCIAL OFFICER OR TREASURER. The Chief Financial Officer or Treasurer shall have the custody of the corporate funds and securities and shall keep full and accurate accounts of receipts and disbursements in books belonging to the corporation and shall deposit all moneys, and other valuable effects in the name and to the credit of the corporation, in such depositories as may be designated by the Board of Directors. He or she shall disburse the funds of the corporation as may be ordered by the Board of Directors, taking proper vouchers for such disbursements, and shall render to the Board of Directors, at its regular meetings, or when the Board of Directors so requires, an account of all his or her transactions as Chief Financial Officer or Treasurer and of the financial condition of the corporation. If required by the Board of Directors, he or she shall give the corporation a bond, in such sum and with such surety or sureties as shall be satisfactory to the Board of Directors, for the faithful performance of the duties of his or her office and for the restoration to the corporation, in case of his or her death, resignation, retirement or removal from office, of all books, papers, vouchers, money and other property of whatever kind in his or her possession or under his or her control belonging to the corporation.

Section 11. ASSISTANT TREASURER. The Assistant Treasurer, or if there shall be more than one, the Assistant Treasurers in the order determined by the Board of Directors, or if there be no such determination, the Assistant Treasurer designated by the Board of Directors, shall, in the absence or disability of the Chief Financial Officer or Treasurer, perform the duties and exercise the powers of the Chief Financial Officer or Treasurer and shall perform such other duties and have such other powers as the Board of Directors may from time to time prescribe.

ARTICLE V

INDEMNIFICATION OF DIRECTORS AND OFFICERS

(a) The corporation shall indemnify to the maximum extent permitted by law any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the corporation) by reason of the fact that he or she is or was a director or officer of the corporation, or is or was serving at the request of the corporation as a director or officer of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys’ fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by him or her in connection with such action, suit or proceeding if he or she acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful. The termination of any action, suit or proceeding by judgment, order, settlement, conviction, or upon a
plea of nolo contendere or its equivalent, shall not, of itself, create a presumption that the person did not act in good faith and in a manner which he or she reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had reasonable cause to believe that his or her conduct was unlawful.

(b) The corporation shall indemnify to the maximum extent permitted by law any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the corporation to procure a judgment in its favor by reason of the fact that he or she is or was a director or officer of the corporation, or is or was serving at the request of the corporation as a director or officer of another corporation, partnership, joint venture, trust or other enterprise against expenses (including attorneys’ fees) actually and reasonably incurred by him or her in connection with the defense or settlement of such action or suit if he or she acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of the corporation and except that no such indemnification shall be made in respect of any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery of Delaware or the court in which such action or suit was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which such Court of Chancery or such other court shall deem proper.

(c) To the extent that a director or officer of the corporation shall be successful on the merits or otherwise in defense of any action, suit or proceeding referred to in paragraphs (a) and (b), or in defense of any claim, issue or matter therein, he or she shall be indemnified against expenses (including attorneys’ fees) actually and reasonably incurred by him or her in connection therewith.

(d) Any indemnification under paragraphs (a) and (b) (unless ordered by a court) shall be made by the corporation only as authorized in the specific case upon a determination that indemnification of the director or officer is proper in the circumstances because he or she has met the applicable standard of conduct set forth in paragraphs (a) and (b). Such determination shall be made (1) by a majority vote of the directors who are not parties to such action, suit or proceeding, even though less than a quorum, or (2) if there are no such directors, or if such directors so direct, by independent legal counsel in a written opinion, or (3) by the stockholders. The corporation, acting through its Board of Directors or otherwise, shall cause such determination to be made if so requested by any person who is indemnifiable under this Article V.

(e) Expenses (including attorneys’ fees) incurred by an officer or director in defending any civil, criminal, administrative or investigative action, suit or proceeding shall be paid by the corporation in advance of the final disposition of such action, suit or proceeding upon receipt of an undertaking by or on behalf of such director or officer to repay such amount if it shall ultimately be determined that he or she is not entitled to be indemnified by the corporation as authorized in this Article V.

(f) The indemnification and advancement of expenses provided by, or granted pursuant to, the other paragraphs of this Article V shall not be deemed exclusive of any other rights to which those seeking indemnification or advancement of expenses may be entitled under any bylaw, agreement, vote of stockholders or disinterested directors or otherwise, both as to action in his or her official capacity and as to action in another capacity while holding such office.

(g) The Board of Directors may authorize, by a vote of a majority of a quorum of the Board of Directors, the corporation to purchase and maintain insurance on behalf of any person who is or
was a director or officer of the corporation, or is or was serving at the request of the corporation as a director or officer of another corporation, partnership, joint venture, trust or other enterprise against any liability asserted against him or her and incurred by him or her in any such capacity, or arising out of his or her status as such, whether or not the corporation would have the power to indemnify him or her against such liability under the provisions of this Article V.

(h) For the purposes of this Article V, references to “the corporation” shall include, in addition to the resulting corporation, any constituent corporation (including any constituent of a constituent) absorbed in a consolidation or merger which, if its separate existence had continued, would have had power and authority to indemnify its directors or officers so that any person who is or was a director or officer of such constituent corporation, or is or was serving at the request of such constituent corporation as a director or officer of another corporation, partnership, joint venture, trust or other enterprise, shall stand in the same position under the provisions of this Article V with respect to the resulting or surviving corporation as he or she would have with respect to such constituent corporation if its separate existence had continued.

(i) For purposes of this section, references to “other enterprises” shall include employee benefit plans; references to “fines” shall include any excise taxes assessed on a person with respect to an employee benefit plan; and references to “serving at the request of the corporation” shall include service as a director or officer of the corporation which imposes duties on, or involves services by, such director or officer with respect to an employee benefit plan, its participants or beneficiaries; and a person who acted in good faith and in a manner he or she reasonably believed to be in the interest of the participants and beneficiaries of an employee benefit plan shall be deemed to have acted in a manner “not opposed to the best interests of the corporation” as referred to in this section.

(j) The indemnification and advancement of expenses provided by, or granted pursuant to, this Article V shall, unless otherwise provided when authorized or ratified, continue as to a person who has ceased to be a director or officer and shall inure to the benefit of the heirs, executors and administrators of such a person.

(k) The corporation shall be required to indemnify a person in connection with an action, suit or proceeding (or part thereof) initiated by such person only if the action, suit or proceeding (or part thereof) was authorized by the Board of Directors of the corporation.

ARTICLE VI

INDEMNIFICATION OF EMPLOYEES AND AGENTS

The corporation may indemnify every person who was or is a party or is or was threatened to be made a party to any action, suit, or proceeding, whether civil, criminal, administrative or investigative, by reason of the fact that he or she is or was an employee or agent of the corporation or, while an employee or agent of the corporation, is or was serving at the request of the corporation as an employee or agent or trustee of another corporation, partnership, joint venture, trust, employee benefit plan or other enterprise, against expenses (including attorneys’ fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by him or her in connection with such action, suit or proceeding, to the extent permitted by applicable law.
ARTICLE VII

CERTIFICATES OF STOCK

Section 1. CERTIFICATES. The shares of the Corporation shall be represented by certificates, provided that the Board of Directors of the Corporation may provide by resolution or resolutions that some or all of any or all classes or series of its stock shall be uncertificated shares. Any such resolution shall not apply to shares represented by a certificate until such certificate is surrendered to the Corporation. Every holder of stock represented by certificates shall be entitled to have a certificate, in such form as may be prescribed by law and by the Board of Directors, signed in a manner that complies with Section 158 of the Delaware General Corporation Law, representing the number of shares held by such holder registered in certificate form. Any or all the signatures on the certificate may be a facsimile or pdf.

Section 2. SIGNATURES ON CERTIFICATES. Any or all of the signatures on the certificate may be a facsimile. In case any officer, transfer agent, or registrar who has signed or whose facsimile signature has been placed upon a certificate shall have ceased to be such officer, transfer agent, or registrar before such certificate is issued, it may be issued by the corporation with the same effect as if he or she were such officer, transfer agent, or registrar at the date of issue.

Section 3. STATEMENT OF STOCK RIGHTS, PREFERENCES, PRIVILEGES. If the corporation shall be authorized to issue more than one class of stock or more than one series of any class, the powers, designations, preferences and relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights shall be set forth in full or summarized on the face or back of the certificate which the corporation shall issue to represent such class or series of stock, provided that, except as otherwise provided in Section 202 of the General Corporation Law of Delaware, in lieu of the foregoing requirements, there may be set forth on the face or back of the certificate which the corporation shall issue to represent such class or series of stock, a statement that the corporation will furnish without charge to each stockholder who so requests the powers, designations, preferences and relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights.

Section 4. LOST CERTIFICATES. The Board of Directors may direct a new certificate or certificates to be issued in place of any certificate or certificates theretofore issued by the corporation alleged to have been lost, stolen or destroyed, upon the making of an affidavit of that fact by the person claiming the certificate of stock to be lost, stolen or destroyed. When authorizing such issue of a new certificate or certificates, the Board of Directors may, in its discretion and as a condition precedent to the issuance thereof, require the owner of such lost, stolen or destroyed certificate or certificates, or his or her legal representative, to advertise the same in such manner as it shall require and/or to give the corporation a bond in such sum as it may direct as indemnity against any claim that may be made against the corporation with respect to the certificate alleged to have been lost, stolen or destroyed.

Section 5. TRANSFERS OF STOCK. Upon surrender to the corporation, or the transfer agent of the corporation, of a certificate for shares duly endorsed or accompanied by proper evidence of succession, assignment or authority to transfer, it shall be the duty of the corporation to issue a new certificate to the person entitled thereto, cancel the old certificate and record the transaction upon its books.

Section 6. FIXED RECORD DATE. In order that the corporation may determine the stockholders entitled to notice of or to vote at any meeting of the stockholders, or any adjournment thereof, or entitled to receive payment of any dividend or other distribution or allotment of any rights, or entitled to exercise any rights in respect of any change, conversion or exchange of stock or for the
purpose of any other lawful action, the Board of Directors may fix a record date which shall not precede the date upon which the resolution fixing the
record date is adopted by the Board of Directors, and which record date shall not be more than sixty nor less than ten (10) days before the date of such
meeting. A determination of stockholders of record entitled to notice of or to vote at a meeting of stockholders shall apply to any adjournment of the
meeting; provided, however, that the Board of Directors may fix a new record date for the adjourned meeting. In order that the corporation may
determine the stockholders entitled to consent to corporate action in writing without a meeting, the Board of Directors may fix a record date which shall
not be more than ten (10) days after the date upon which the resolution fixing the record date is adopted by the Board of Directors.

Section 7. REGISTERED STOCKHOLDERS. The corporation shall be entitled to treat the holder of record of any share or shares of stock as the
holder in fact thereof and accordingly shall not be bound to recognize any equitable or other claim or interest in such share on the part of any other
person, whether or not it shall have express or other notice thereof, save as expressly provided by the laws of the State of Delaware.

ARTICLE VIII

GENERAL PROVISIONS

Section 1. DIVIDENDS. Dividends upon the capital stock of the corporation, subject to the provisions of the Certificate of Incorporation, if any,
may be declared by the Board of Directors at any regular or special meeting, pursuant to and subject to law. Dividends may be paid in cash, in property,
or in shares of the capital stock, subject to the provisions of the Certificate of Incorporation.

Section 2. PAYMENT OF DIVIDENDS; DIRECTORS’ DUTIES. Before payment of any dividend there may be set aside out of any funds of the
corporation available for dividends such sum or sums as the directors from time to time, in their absolute discretion, think proper as a reserve fund to
meet contingencies, or for equalizing dividends, or for repairing or maintaining any property of the corporation, or for such other purpose as the
directors shall think conducive to the interests of the corporation, and the directors may abolish any such reserve.

Section 3. CHECKS. All checks or demands for money and notes of the corporation shall be signed by such officer or officers as the Board of
Directors may from time to time designate.

Section 4. FISCAL YEAR. The fiscal year of the corporation shall be fixed by resolution of the Board of Directors.

Section 5. MANNER OF GIVING NOTICE. Whenever, under the provisions of the statutes or of the Certificate of Incorporation or of these
Bylaws, notice is required to be given to any director or stockholder, it shall not be construed to mean personal notice, but such notice may be given in
writing, by mail, addressed to such director or stockholder, at his or her address as it appears on the records of the corporation, with postage thereon
prepaid, and such notice shall be deemed to be given at the time when the same shall be deposited in the United States mail. Notice to directors may also
be given by telegram.

Section 6. WAIVER OF NOTICE. Whenever any notice is required to be given under the provisions of the statutes or of the Certificate of
Incorporation or of these Bylaws, a waiver thereof in writing or by electronic transmission to the extent permitted by the General Corporation Law of
the State of Delaware, signed by the person or persons entitled to said notice, whether before or after the time stated therein, shall be deemed equivalent thereto.
Section 7. ANNUAL STATEMENT. The Board of Directors shall present at each annual meeting, and at any special meeting of the stockholders when called for by vote of the stockholders, a full and clear statement of the business and condition of the corporation.

Section 8. FORUM. Unless the corporation consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for (i) any derivative action or proceeding brought on behalf of the corporation, (ii) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of the corporation to the corporation or the corporation’s stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, or (iv) any action asserting a claim governed by the internal affairs doctrine. Any person or entity purchasing or otherwise acquiring any interest in shares of capital stock of the corporation shall be deemed to have notice of and consented to the provisions of this Section 8.

ARTICLE IX

AMENDMENTS

Section 1. AMENDMENT BY DIRECTORS OR STOCKHOLDERS. These Bylaws may be altered, amended or repealed or new Bylaws may be adopted by the stockholders or by the Board of Directors, when such power is conferred upon the Board of Directors by the Certificate of Incorporation, at any regular meeting of the stockholders or of the Board of Directors or at any special meeting of the stockholders or of the Board of Directors if notice of such alteration, amendment, repeal or adoption of new Bylaws be contained in the notice of such special meeting. If the power to adopt, amend or repeal Bylaws is conferred upon the Board of Directors by the Certificate of Incorporation it shall not divest or limit the power of the stockholders to adopt, amend or repeal Bylaws.

ARTICLE X

RIGHT OF FIRST REFUSAL

Section 1. RESTRICTION ON TRANSFER. No stockholder of the corporation shall transfer, assign, hypothecate, encumber, pledge or otherwise alienate (hereinafter “Transfer”) any shares of Common Stock of the corporation (the “Common Stock”) owned by such stockholder unless such stockholder previously complied with all provisions of this Article X. Any Transfer not made in accordance with this Article X shall be void, and the corporation shall not treat the transferee in such transaction as a stockholder for any purpose.

Section 2. NOTICE REQUIREMENT. If a stockholder seeks to Transfer any Common Stock, whether voluntarily or involuntarily, such stockholder (the “Offering Stockholder”) shall first give simultaneous written notice of such intention (“Notice of Transfer”) to the Secretary of the corporation. The Notice of Transfer shall specify the number of shares of Common Stock to be transferred (the “Offered Shares”), and state the price and all other terms of the proposed transaction. The Notice of Transfer shall constitute an irrevocable offer to sell the Offered Shares during the periods described below.
Section 3. OPTION OF THE CORPORATION. For twenty-five (25) days following the delivery of a Notice of Transfer (the “Option Period”), the corporation shall have an irrevocable right to purchase all or a portion of the Offered Shares in accordance with the terms stated in the Notice of Transfer. The right may be exercised by a written notice, signed by the President of the corporation (the “Corporation Notice”), stating that the corporation desires to purchase the Offered Shares and tendering the purchase price therefor. Such notice and the purchase price for the Offered Shares shall be delivered to the Offering Stockholder before expiration of the Option Period. Failure to so respond within the Option Period to the Notice of Transfer shall be deemed an irrevocable waiver by the corporation of its right to acquire the Offered Shares. The corporation shall effect the purchase of the Offered Shares, including payment of the purchase price, not more than five (5) business days after delivery of the Corporation Notice, and at such time the Offering Stockholder shall deliver to the corporation the certificate(s) representing the Offered Shares to be purchased by the corporation, each certificate to be properly endorsed for transfer. Any Common Stock so purchased by the corporation shall thereupon be cancelled and cease to be issued and outstanding shares of the corporation’s Common Stock.

Section 4. SPECIAL PROVISIONS REGARDING EXCHANGES. If the Notice of Transfer specifies consideration other than cash, then the Offered Shares may be purchased in cash for the fair market value of such property, as determined in good faith by the Board of Directors. In the event that the Board of Directors decides to hire an independent appraiser in connection with such determination, all expenses for such independent appraiser shall be borne by the Offering Stockholder.

Section 5. EFFECT OF PURCHASE. For purposes of Section 3 of this Article X, the purchase price for Offered Shares shall be deemed tendered, and said Offered Shares shall be deemed purchased, at such time as the Offering Stockholder receives written notice enclosing a cashier’s check for the purchase price or stating that the purchase price has been delivered to a third party (such as counsel to the corporation) with instructions to deliver such amount to the Offering Stockholder upon surrender of certificates representing the Offered Shares, duly endorsed with signatures guaranteed. All rights accorded the Offering Stockholder with respect to the Offered Shares, other than the right to payment therefor, shall cease at that time. If payment is tendered directly to the Offering Stockholder, the Offering Stockholder shall promptly, but in no event later than five (5) business days, cause to be delivered certificate(s) representing the Offered Shares, duly endorsed with signatures guaranteed, to the corporation’s transfer agent for cancellation or transfer.

Section 6. CERTAIN TRANSFERS EXEMPT. Notwithstanding anything else contained in this Article X to the contrary, an Offering Stockholder shall be permitted to make Transfers of certain shares of Common Stock held by such Offering Stockholder without complying with the provisions of Sections 1 through 5 of this Article X above if such Transfer is:

(a) to the Offering Stockholder’s spouse, parents, children, or siblings or other members of the Offering Stockholder’s family (including relatives by marriage), or to a trust for the benefit of the Offering Stockholder or any of the foregoing members of his or her family, or to a custodian, trustee or other fiduciary for the account of the Offering Stockholder or any of the foregoing members of his or her family in connection with a bona fide estate planning transaction; provided, however, that this Section shall not permit any Transfer to be made by the Offering Stockholder in connection with the dissolution of the Offering Stockholder’s marriage or the legal separation of the Offering Stockholder and Offering Stockholder’s spouse to such spouse on the account of any settlement of any community property or other marital property rights such spouse may have in such shares;

(b) by way of bequest or inheritance upon death;
(c) to any person, association or entity that, directly or indirectly, through one or more intermediaries, has voting control or has its voting controlled by, or is under common voting control with, such Offering Stockholder;

(d) by way of a bona fide gift;

(e) in connection with a Change of Control (as defined in Section 7 of this Article X below); or

(f) subject to an alternative right of first refusal or similar right granted by the Offering Stockholder to the corporation, including in certain circumstances, but not limited to, restricted stock purchase agreements, co-sale agreements and equity incentive award plans.

Any Transfer set forth in clauses (a) through (f) of this Section 6 may be referred to herein as a “Permitted Transfer.”

Section 7. LIMITATIONS ON RIGHT OF FIRST REFUSAL. The restrictions imposed by this Article X shall not apply to and shall terminate upon (i) the closing of a firmly underwritten public offering of Common Stock or (ii) the closing of any transaction or series of related transactions constituting (a) a reorganization, merger, consolidation or sale of all or substantially all of the corporation’s stock, as a result of which transaction or series of related transactions the corporation’s stockholders of record as constituted immediately prior to such transaction or series of related transactions hold less than a majority of the outstanding voting power of the surviving or acquiring entity after the consummation of such transaction or series of related transactions; or (b) a sale of all or substantially all of the assets of the corporation (each of clauses (a) and (b) a “Change of Control”).

Section 8. WAIVER. The provisions of this Article X may be waived with respect to any Transfer only in writing signed by the corporation.

Section 9. ASSIGNMENT; ALTERNATIVE RIGHTS. The corporation may assign its rights under this Article X or grant alternative rights of first refusal or similar rights to a third party or parties.

Section 10. LEGEND. Any and all certificates representing any shares of Common Stock shall bear a legend referring to the restrictions imposed by this Article X in substantially the form below:

“THE SHARES REPRESENTED BY THIS CERTIFICATE ARE SUBJECT TO A RIGHT OF FIRST REFUSAL OPTION IN FAVOR OF THE CORPORATION AND/OR ITS ASSIGNEE(S), AS PROVIDED IN THE BYLAWS OF THE CORPORATION, A COPY OF WHICH ARE ON FILE WITH THE SECRETARY OF THE CORPORATION.”
AMENDED AND RESTATED INVESTORS’ RIGHTS AGREEMENT

THIS AMENDED AND RESTATED INVESTORS’ RIGHTS AGREEMENT is made as of March 27, 2020 by and among Prometheus Biosciences, Inc., a Delaware corporation formerly known as Precision IBD, Inc. (the “Company”), and each of the investors listed on SCHEDULE A hereto, each of which is referred to in this Agreement as an “Investor.”

RECITALS

A. Certain of the Investors (the “Existing Investors”) hold shares of the Company’s Series A Preferred Stock, par value $0.0001 per share (the “Series A Preferred Stock”), Series B Preferred Stock, par value $0.0001 per share (the “Series B Preferred Stock”) and/or Series C Preferred Stock, par value $0.0001 per share (the “Series C Preferred Stock”) and possess registration rights, information rights, rights of first offer, and other rights pursuant to that certain Amended and Restated Investors’ Rights Agreement dated as of June 30, 2019, by and among the Company and such Existing Investors (the “Prior Agreement”).

B. The Existing Investors are holders of a majority of the Registrable Securities of the Company (as defined in the Prior Agreement), and desire to amend and restate the Prior Agreement in its entirety and to accept the rights created pursuant to this Agreement in lieu of the rights granted to them under the Prior Agreement.

C. Certain of the Investors are parties to that certain Series C Preferred Stock Purchase Agreement dated as of June 30, 2019, by and among the Company and such Investors, as amended by Amendment No. 1 thereto dated as of even date herewith (as the same may be further amended from time to time, the “Purchase Agreement”).

NOW, THEREFORE, the parties, intending to be legally bound, hereby agree as follows:

1. Definitions. For purposes of this Agreement:

1.1 “Affiliate” means, with respect to any specified Person, any other Person who, directly or indirectly, controls, is controlled by, or is under common control with such Person, including, without limitation, any general partner, managing member, director, officer or trustee of such Person, or any venture capital fund, private investment fund or registered investment company now or hereafter existing that is controlled by one or more general partners, managing members, investment advisers or investment advisers directly or indirectly owned or controlled by such Person, or shares the same management company or investment adviser with such Person.

1.2 “Common Stock” means shares of the Company’s common stock, par value $0.0001 per share.

1.3 “Competitor” means a Person engaged, directly or indirectly (including through any partnership, limited liability company, corporation, joint venture or similar arrangement (whether now existing or formed hereafter)), in pharmaceutical research, development or commercialization, but shall not include (i) Cedars-Sinai Medical Center, (ii) Nestlé Health Science US Holdings, Inc., Société des Produits Nestlé S.A. or their respective Affiliates or (iii) any financial investment firm or collective investment vehicle that, together with its Affiliates, holds less than thirty percent (30%) of the outstanding equity of any Competitor and does not, nor do any of its Affiliates, have a right to designate any members of the board of directors of any Competitor.
1.4 “Damages” means any loss, damage, claim or liability (joint or several) to which a party hereto may become subject under the Securities Act, the Exchange Act, or other federal or state law, insofar as such loss, damage, claim or liability (or any action in respect thereof) arises out of or is based upon (a) any untrue statement or alleged untrue statement of a material fact contained in any registration statement of the Company, including any preliminary prospectus or final prospectus contained therein or any amendments or supplements thereto; (b) an omission or alleged omission to state therein a material fact required to be stated therein, or necessary to make the statements therein not misleading; or (c) any violation or alleged violation by the indemnifying party (or any of its agents or Affiliates) of the Securities Act, the Exchange Act, any state securities law, or any rule or regulation promulgated under the Securities Act, the Exchange Act, or any state securities law.

1.5 “Derivative Securities” means any securities or rights convertible into, or exercisable or exchangeable for (in each case, directly or indirectly), Common Stock, including options and warrants.


1.7 “Excluded Registration” means (a) a registration relating to the sale of securities to employees of the Company or a subsidiary pursuant to a stock option, stock purchase, or similar plan; (b) a registration relating to an SEC Rule 145 transaction; (c) a registration on any form that does not include substantially the same information as would be required to be included in a registration statement covering the sale of the Registrable Securities; or (d) a registration in which the only Common Stock being registered is Common Stock issuable upon conversion of debt securities that are also being registered.

1.8 “Form S-1” means such form under the Securities Act as in effect on the date hereof or any successor registration form under the Securities Act subsequently adopted by the SEC.

1.9 “Form S-3” means such form under the Securities Act as in effect on the date hereof or any registration form under the Securities Act subsequently adopted by the SEC that permits incorporation of substantial information by reference to other documents filed by the Company with the SEC.

1.10 “GAAP” means generally accepted accounting principles in the United States.

1.11 “Holder” means any Investor owning Registrable Securities.

1.12 “Immediate Family Member” means a child, stepchild, grandchild, parent, stepparent, grandparent, spouse, sibling, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law, including adoptive relationships, of a natural person referred to herein.

1.13 “Initiating Holders” means, collectively, Holders who properly initiate a registration request under this Agreement.

1.14 “IPO” means the Company’s first underwritten public offering of its Common Stock under the Securities Act.
1.15 "Major Investor" means any Investor that, individually or together with such Investor’s Affiliates, holds at least 1,000,000 shares of Common Stock issuable or issued upon conversion of the Preferred Stock (as adjusted for any stock split, stock dividend, combination or other recapitalization or reclassification effected after the date hereof).

1.16 "New Securities" means, collectively, equity securities of the Company or its subsidiaries, whether or not currently authorized, as well as rights, options, or warrants to purchase such equity securities, or securities of any type whatsoever that are, or may become, convertible or exchangeable into or exercisable for such equity securities.

1.17 "Person" means any individual, corporation, partnership, trust, limited liability company, association or other entity.

1.18 "Preferred Stock" means collectively, Series A Preferred Stock, Series B Preferred Stock and Series C Preferred Stock.

1.19 "Registrable Securities" means (a) the Common Stock issuable or issued upon conversion of the Preferred Stock; (b) any Common Stock, or any Common Stock issued or issuable (directly or indirectly) upon conversion and/or exercise of any other securities of the Company, held by the Investors; (c) any Common Stock issued as (or issuable upon the conversion or exercise of any warrant, right, or other security that is issued as) a dividend or other distribution with respect to, or in exchange for or in replacement of, the shares referenced in clauses (a) and (b) above; excluding in all cases, however, any Registrable Securities sold by a Person in a transaction in which the applicable rights under this Agreement are not assigned pursuant to Section 6.1, and excluding for purposes of Section 2 any shares for which registration rights have terminated pursuant to Section 2.13 of this Agreement.

1.20 "Registrable Securities then outstanding" means the number of shares determined by adding the number of shares of outstanding Common Stock that are Registrable Securities and the number of shares of Common Stock issuable (directly or indirectly) pursuant to then exercisable and/or convertible securities that are Registrable Securities.

1.21 "Restricted Securities" means the securities of the Company required to bear the legend set forth in Section 2.12 hereof.

1.22 "SEC" means the Securities and Exchange Commission.

1.23 "SEC Rule 144" means Rule 144 promulgated by the SEC under the Securities Act.

1.24 "SEC Rule 145" means Rule 145 promulgated by the SEC under the Securities Act.

1.25 "Securities Act" means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

1.26 "Selling Expenses" means all underwriting discounts, selling commissions, and stock transfer taxes applicable to the sale of Registrable Securities, and fees and disbursements of counsel for any Holder, except for the fees and disbursements of the Selling Holder Counsel borne and paid by the Company as provided in Section 2.6.
1.27 “Series A Preferred Stock” means shares of the Company’s Series A Preferred Stock, par value $0.0001 per share.

1.28 “Series B Preferred Stock” means shares of the Company’s Series B Preferred Stock, par value $0.0001 per share.

1.29 “Series C Preferred Stock” means shares of the Company’s Series C Preferred Stock, par value $0.0001 per share.

2. Registration Rights. The Company covenants and agrees as follows:

2.1 Demand Registration.

(a) Form S-1 Demand. If at any time after the date that is five (5) years after the date of this Agreement, the Company receives a request from Holders of at least a majority of the Registrable Securities then outstanding that the Company file a Form S-1 registration statement with respect to outstanding Registrable Securities of such Holders having an anticipated aggregate offering price, net of Selling Expenses, of at least $10,000,000, then the Company shall (i) within ten (10) days after the date such request is given, give notice thereof (the “Demand Notice”) to all Holders other than the Initiating Holders; and (ii) as soon as practicable, and in any event within sixty (60) days after the date such request is given by the Initiating Holders, file a Form S-1 registration statement under the Securities Act covering all Registrable Securities that the Initiating Holders requested to be registered and any additional Registrable Securities requested to be included in such registration by any other Holders, as specified by notice given by each such Holder to the Company within twenty (20) days of the date the Demand Notice is given, and in each case, subject to the limitations of Section 2.1(c) and Section 2.3.

(b) Form S-3 Demand. If at any time when it is eligible to use a Form S-3 registration statement, the Company receives from any Holder or Holders a request that the Company file a Form S-3 registration statement with respect to outstanding Registrable Securities of such Holder or Holders having an anticipated aggregate offering price, net of Selling Expenses, of at least $5,000,000, then the Company shall (i) within ten (10) days after the date such request is given, give a Demand Notice to all Holders other than the Initiating Holders; and (ii) as soon as practicable, and in any event within forty-five (45) days after the date such request is given by the Initiating Holders, file a Form S-3 registration statement under the Securities Act covering all Registrable Securities requested to be included in such registration by any other Holders, as specified by notice given by each such Holder to the Company within twenty (20) days of the date the Demand Notice is given, and in each case, subject to the limitations of Section 2.1(c) and Section 2.3.

(c) Notwithstanding the foregoing obligations, if the Company furnishes to Holders requesting a registration pursuant to this Section 2.1 a certificate signed by the Company’s chief executive officer stating that in the good faith judgment of the Company’s Board of Directors (the “Board”) it would be materially detrimental to the Company and its stockholders for such registration statement to either become effective or remain effective for as long as such registration statement otherwise would be required to remain effective, because such action would (i) materially interfere with a significant acquisition, corporate reorganization, or other similar transaction involving the Company; (ii) require premature disclosure of material information that the Company has a bona fide business purpose for preserving as confidential; or (iii) render the Company unable to comply with requirements under the Securities Act or Exchange Act, then the Company shall have the right to defer taking action with respect to such filing, and any time periods with respect to filing or effectiveness thereof shall be tolled correspondingly, for a period of not more than ninety (90) days after the request of the Initiating Holders is given for any registration pursuant to Section 2.1(g) or 2.1(b); provided, however, that
the Company may not invoke this right more than once in any twelve (12) month period; and provided further that the Company shall not register any securities for its own account or that of any other stockholder during such ninety-day period, other than an Excluded Registration.

(d) The Company shall not be obligated to effect, or to take any action to effect, any registration pursuant to Section 2.1(a): (i) during the period starting with the date of filing of, and ending on a date that is one hundred eighty (180) days after the effective date of, a Company-initiated registration, provided, that the Company is actively employing in good faith commercially reasonable efforts to cause such registration statement to become effective; (ii) after the Company has effected two (2) registrations pursuant to Section 2.1(a); or (iii) if within thirty (30) days of receipt of a request from any Holder or Holders pursuant to Section 2.1(a), the Company gives notice to such Holder or Holders of the Company’s intention to make a public offering within one hundred twenty (120) days. The Company shall not be obligated to effect, or to take any action to effect, any registration pursuant to Section 2.1(b): (i) if within thirty (30) days of receipt of a request from any Holder or Holders pursuant to Section 2.1(b), the Company gives notice to such Holder or Holders of the Company’s intention to make a public offering within ninety (90) days; or (ii) if the Company has effected two (2) registrations pursuant to Section 2.1(b) within the twelve (12) month period immediately preceding the date of such request. A registration shall not be counted as “effected” for purposes of this Section 2.1(d) until such time as the applicable registration statement has been declared effective by the SEC, unless the Initiating Holders withdraw their request for such registration, elect not to pay the registration expenses therefor, and forfeit their right to one demand registration statement pursuant to Section 2.6, in which case such withdrawn registration statement shall be counted as “effected” for purposes of this Section 2.1(d).

2.2 Company Registration. If the Company proposes to register (including, for this purpose, a registration effected by the Company for stockholders other than the Holders) any of its securities under the Securities Act in connection with the public offering of such securities solely for cash (other than in an Excluded Registration), the Company shall, at such time, promptly give each Holder notice of such registration. Upon the request of each Holder given within twenty (20) days after such notice is given by the Company, the Company shall, subject to the provisions of Section 2.3, cause to be registered all of the Registrable Securities that each such Holder has requested to be included in such registration. The Company shall have the right to terminate or withdraw any registration initiated by it under this Section 2.2 before the effective date of such registration, whether or not any Holder has elected to include Registrable Securities in such registration. The expenses (other than Selling Expenses) of such withdrawn registration shall be borne by the Company in accordance with Section 2.6.

2.3 Underwriting Requirements. (a) If, pursuant to Section 2.1, the Initiating Holders intend to distribute the Registrable Securities covered by their request by means of an underwriting, they shall so advise the Company as a part of their request made pursuant to Section 2.1, and the Company shall include such information in the Demand Notice. The underwriter(s) will be selected by the Company and shall be reasonably acceptable to a majority in interest of the Initiating Holders. In such event, the right of any Holder to include such Holder’s Registrable Securities in such registration shall be conditioned upon such Holder’s participation in such underwriting and the inclusion of such Holder’s Registrable Securities in the underwriting to the extent provided herein. All Holders proposing to distribute their securities through such underwriting shall (together with the Company as provided in Section 2.4(e) enter into an underwriting agreement in customary form with the underwriter(s) selected for such underwriting. Notwithstanding any other provision of this Section 2.3, if the underwriter(s) advise(s) the Initiating Holders in writing that marketing factors require a limitation on the number of shares to be underwritten, then the Initiating Holders shall so advise all Holders of Registrable Securities that otherwise would be underwritten pursuant hereto,
and the number of Registrable Securities that may be included in the underwriting shall be allocated among such Holders of Registrable Securities, including the Initiating Holders, in proportion (as nearly as practicable) to the number of Registrable Securities owned by each Holder or in such other proportion as shall mutually be agreed to by all such selling Holders; provided, however, that the number of Registrable Securities held by the Holders to be included in such underwriting shall not be reduced unless all other securities are first entirely excluded from the underwriting. To facilitate the allocation of shares in accordance with the above provisions, the Company or the underwriters may round the number of shares allocated to any Holder to the nearest one hundred (100) shares.

(b) In connection with any offering involving an underwriting of shares of the Company’s capital stock pursuant to Section 2.2, the Company shall not be required to include any of the Holders’ Registrable Securities in such underwriting unless the Holders accept the terms of the underwriting as agreed upon between the Company and its underwriters, and then only in such quantity as the underwriters in their sole discretion determine will not jeopardize the success of the offering by the Company. If the total number of securities, including Registrable Securities, requested by stockholders to be included in such offering exceeds the number of securities to be sold (other than by the Company) that the underwriters in their reasonable discretion determine is compatible with the success of the offering, then the Company shall be required to include in the offering only that number of such securities, including Registrable Securities, which the underwriters and the Company in their sole discretion determine will not jeopardize the success of the offering. If the underwriters determine that less than all of the Registrable Securities requested to be registered can be included in such offering, then the Registrable Securities that are included in such offering shall be allocated among the selling Holders in proportion (as nearly as practicable to) the number of Registrable Securities owned by each selling Holder or in such other proportions as shall mutually be agreed to by all such selling Holders. To facilitate the allocation of shares in accordance with the above provisions, the Company or the underwriters may round the number of shares allocated to any Holder to the nearest one hundred (100) shares. Notwithstanding the foregoing, in no event shall (i) the number of Registrable Securities included in the offering be reduced unless all other securities (other than securities to be sold by the Company) are first entirely excluded from the offering, or (ii) the number of Registrable Securities included in the offering be reduced below twenty percent (20%) of the total number of securities included in such offering, unless such offering is the IPO, in which case the selling Holders may be excluded further if the underwriters make the determination described above and no other stockholder’s securities are included in such offering. For purposes of the provision in this Section 2.3(b) concerning apportionment, for any selling Holder that is a partnership, limited liability company, or corporation, the partners, members, retired partners, retired members, stockholders, and Affiliates of such Holder, or the estates and Immediate Family Members of any such partners, retired partners, members, and retired members and any trusts for the benefit of any of the foregoing Persons, shall be deemed to be a single “selling Holder,” and any pro rata reduction with respect to such “selling Holder” shall be based upon the aggregate number of Registrable Securities owned by all Persons included in such “selling Holder,” as defined in this sentence.

(c) For purposes of Section 2.1, a registration shall not be counted as “effected” if, as a result of an exercise of the underwriter’s cutback provisions in Section 2.3(a), fewer than fifty percent (50%) of the total number of Registrable Securities that Holders have requested to be included in such registration statement are actually included.

2.4 Obligations of the Company. Whenever required under this Section 2 to effect the registration of any Registrable Securities, the Company shall, as expeditiously as reasonably possible:

(a) prepare and file with the SEC a registration statement with respect to such Registrable Securities and use its commercially reasonable efforts to cause such registration statement to
become effective and, upon the request of the Holders of a majority of the Registrable Securities registered thereunder, keep such registration statement effective for a period of up to one hundred twenty (120) days or, if earlier, until the distribution contemplated in the registration statement has been completed; provided, however, that (i) such one hundred twenty (120) day period shall be extended for a period of time equal to the period the Holder refrains, at the request of an underwriter of Common Stock (or other securities) of the Company, from selling any securities included in such registration, and (ii) in the case of any registration of Registrable Securities on Form S-3 that are intended to be offered on a continuous or delayed basis, subject to compliance with applicable SEC rules, such one hundred twenty (120) day period shall be extended for up to one hundred eighty (180) days, if necessary, to keep the registration statement effective until all such Registrable Securities are sold;

(b) prepare and file with the SEC such amendments and supplements to such registration statement, and the prospectus used in connection with such registration statement, as may be necessary to comply with the Securities Act in order to enable the disposition of all securities covered by such registration statement;

(c) furnish to the selling Holders such numbers of copies of a prospectus, including a preliminary prospectus, as required by the Securities Act, and such other documents as the Holders may reasonably request in order to facilitate their disposition of their Registrable Securities;

(d) use its commercially reasonable efforts to register and qualify the securities covered by such registration statement under such other securities or blue-sky laws of such jurisdictions as shall be reasonably requested by the selling Holders; provided that the Company shall not be required to qualify to do business or to file a general consent to service of process in any such states or jurisdictions, unless the Company is already subject to service in such jurisdiction and except as may be required by the Securities Act;

(e) in the event of any underwritten public offering, enter into and perform its obligations under an underwriting agreement, in usual and customary form, with the underwriter(s) of such offering;

(f) use its commercially reasonable efforts to cause all such Registrable Securities covered by such registration statement to be listed on a national securities exchange or trading system and each securities exchange and trading system (if any) on which similar securities issued by the Company are then listed;

(g) provide a transfer agent and registrar for all Registrable Securities registered pursuant to this Agreement and provide a CUSIP number for all such Registrable Securities, in each case not later than the effective date of such registration;

(h) promptly make available for inspection by the selling Holders, any underwriter(s) participating in any disposition pursuant to such registration statement, and any attorney or accountant or other agent retained by any such underwriter or selected by the selling Holders, all financial and other records, pertinent corporate documents, and properties of the Company, and cause the Company’s officers, directors, employees, and independent accountants to supply all information reasonably requested by any such seller, underwriter, attorney, accountant, or agent, in each case, as necessary or advisable to verify the accuracy of the information in such registration statement and to conduct appropriate due diligence in connection therewith;
(i) notify each selling Holder, promptly after the Company receives notice thereof, of the time when such registration statement has been declared effective or a supplement to any prospectus forming a part of such registration statement has been filed; and

(j) after such registration statement becomes effective, notify each selling Holder of any request by the SEC that the Company amend or supplement such registration statement or prospectus.

In addition, the Company shall ensure that, at all times after any registration statement covering a public offering of securities of the Company under the Securities Act shall have become effective, its insider trading policy shall provide that the Company’s directors may implement a trading program under Rule 10b5-1 of the Exchange Act.

2.5 Furnish Information. It shall be a condition precedent to the obligations of the Company to take any action pursuant to this Section 2 with respect to the Registrable Securities of any selling Holder that such Holder shall furnish to the Company such information regarding itself, the Registrable Securities held by it, and the intended method of disposition of such securities as is reasonably required to effect the registration of such Holder’s Registrable Securities.

2.6 Expenses of Registration. All expenses (other than Selling Expenses) incurred in connection with registrations, filings, or qualifications pursuant to Section 2, including all registration, filing, and qualification fees; printers’ and accounting fees; fees and disbursements of counsel for the Company; and the reasonable fees and disbursements, not to exceed $50,000 per registration, of one counsel for the selling Holders (“Selling Holder Counsel”), shall be borne and paid by the Company; provided, however, that the Company shall not be required to pay for any expenses of any registration proceeding begun pursuant to Section 2.1 if the registration request is subsequently withdrawn at the request of the Holders of a majority of the Registrable Securities to be registered (in which case all selling Holders shall bear such expenses pro rata based upon the number of Registrable Securities that were to be included in the withdrawn registration), unless the Holders of a majority of the Registrable Securities agree to forfeit their right to one registration pursuant to Section 2.1(a) or Section 2.1(b), as the case may be; provided further that if, at the time of such withdrawal, the Holders shall have learned of a material adverse change in the financial condition, business, or prospects of the Company from that known to the Holders at the time of their request and have withdrawn the request with reasonable promptness after learning of such information, then the Holders shall not be required to pay any of such expenses and shall not forfeit their right to one registration pursuant to Section 2.1(a) or Section 2.1(b). All Selling Expenses relating to Registrable Securities registered pursuant to this Section 2 shall be borne and paid by the Holders pro rata on the basis of the number of Registrable Securities registered on their behalf.

2.7 Delay of Registration. No Holder shall have any right to obtain or seek an injunction restraining or otherwise delaying any registration pursuant to this Agreement as the result of any controversy that might arise with respect to the interpretation or implementation of this Section 2.

2.8 Indemnification. If any Registrable Securities are included in a registration statement under this Section 2:

(a) To the extent permitted by law, the Company will indemnify and hold harmless each selling Holder, and the partners, members, officers, directors, and stockholders of each such Holder; legal counsel and accountants for each such Holder; any underwriter (as defined in the Securities Act) for each such Holder; and each Person, if any, who controls such Holder or underwriter within the meaning of the Securities Act or the Exchange Act, against any Damages, and the Company will pay to each such Holder, underwriter, controlling Person, or other aforementioned Person any legal or other
expenses reasonably incurred thereby in connection with investigating or defending any claim or proceeding from which Damages may result, as such expenses are incurred; provided, however, that the indemnity agreement contained in this Section 2.8(a) shall not apply to amounts paid in settlement of any such claim or proceeding if such settlement is effected without the consent of the Company, which consent shall not be unreasonably withheld, nor shall the Company be liable for any Damages to the extent that they arise out of or are based upon actions or omissions made in reliance upon and in conformity with written information furnished by or on behalf of any such Holder, underwriter, controlling Person, or other aforementioned Person expressly for use in connection with such registration.

(b) To the extent permitted by law, each selling Holder, severally and not jointly, will indemnify and hold harmless the Company, and each of its directors, each of its officers who has signed the registration statement, each Person (if any), who controls the Company within the meaning of the Securities Act, legal counsel and accountants for the Company, any underwriter (as defined in the Securities Act), any other Holder selling securities in such registration statement, and any controlling Person of any such underwriter or other Holder, against any Damages, in each case only to the extent that such Damages arise out of or are based upon actions or omissions made in reliance upon and in conformity with written information furnished by or on behalf of such selling Holder expressly for use in connection with such registration; and each such selling Holder will pay to the Company and each other aforementioned Person any legal or other expenses reasonably incurred thereby in connection with investigating or defending any claim or proceeding from which Damages may result, as such expenses are incurred; provided, however, that the indemnity agreement contained in this Section 2.8(b) shall not apply to amounts paid in settlement of any such claim or proceeding if such settlement is effected without the consent of the Company, which consent shall not be unreasonably withheld; and provided further that in no event shall the aggregate amounts payable by any Holder by way of indemnity or contribution under Sections 2.8(b) and 2.8(d) exceed the proceeds from the offering received by such Holder (net of any Selling Expenses paid by such Holder), except in the case of fraud or willful misconduct by such Holder.

(c) Promptly after receipt by an indemnified party under this Section 2.8 of notice of the commencement of any action (including any governmental action) for which a party may be entitled to indemnification hereunder, such indemnified party will, if a claim in respect thereof is to be made against any indemnifying party under this Section 2.8, give the indemnifying party notice of the commencement thereof. The indemnifying party shall have the right to participate in such action and, to the extent the indemnifying party so desires, participate jointly with any other indemnifying party to which notice has been given, and to assume the defense thereof with counsel mutually satisfactory to the parties; provided, however, that an indemnified party (together with all other indemnified parties that may be represented without conflict by one counsel) shall have the right to retain one separate counsel, with the fees and expenses to be paid by the indemnifying party, if representation of such indemnified party by the counsel retained by the indemnifying party would be inappropriate due to actual or potential differing interests between such indemnified party and any other party represented by such counsel in such action. The failure to give notice to the indemnifying party within a reasonable time of the commencement of any such action shall relieve such indemnifying party of any liability to the indemnified party under this Section 2.8, to the extent that such failure materially prejudices the indemnifying party’s ability to defend such action. The failure to give notice to the indemnifying party will not relieve it of any liability that it may have to any indemnified party otherwise than under this Section 2.8.

(d) Notwithstanding anything else herein to the contrary, the foregoing indemnity agreements of the Company and the selling Holders are subject to the condition that, insofar as they relate to any Damages arising from any untrue statement or alleged untrue statement of a material fact contained in, or omission or alleged omission of a material fact from, a preliminary prospectus (or necessary to make the statements therein not misleading) that has been corrected in the form of prospectus included
in the registration statement at the time it becomes effective, or any amendment or supplement thereto filed with the SEC pursuant to Rule 424(b) under the Securities Act (the “Final Prospectus”), such indemnity agreement shall not inure to the benefit of any Person if a copy of the Final Prospectus was furnished to the indemnified party and such indemnified party failed to deliver, at or before the confirmation of the sale of the shares registered in such offering, a copy of the Final Prospectus to the Person asserting the loss, liability, claim, or damage in any case in which such delivery was required by the Securities Act.

(e) To provide for just and equitable contribution to joint liability under the Securities Act in any case in which either (i) any party otherwise entitled to indemnification hereunder makes a claim for indemnification pursuant to this Section 2.8 but it is judicially determined (by the entry of a final judgment or decree by a court of competent jurisdiction and the expiration of time to appeal or the denial of the last right of appeal) that such indemnification may not be enforced in such case, notwithstanding the fact that this Section 2.8 provides for indemnification in such case, or (ii) contribution under the Securities Act may be required on the part of any party hereto for which indemnification is provided under this Section 2.8, then, and in each such case, such parties will contribute to the aggregate losses, claims, damages, liabilities, or expenses to which they may be subject (after contribution from others) in such proportion as is appropriate to reflect the relative fault of each of the indemnifying party and the indemnified party in connection with the statements, omissions, or other actions that resulted in such loss, claim, damage, liability, or expense, as well as to reflect any other relevant equitable considerations. The relative fault of the indemnifying party and of the indemnified party shall be determined by reference to, among other things, whether the untrue or allegedly untrue statement of a material fact, or the omission or alleged omission of a material fact, relates to information supplied by the indemnifying party or by the indemnified party and the parties’ relative intent, knowledge, access to information, and opportunity to correct or prevent such statement or omission; provided, however, that, in any such case, (1) no Holder will be required to contribute any amount in excess of the public offering price of all such Registrable Securities offered and sold by such Holder pursuant to such registration statement, and (2) no Person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) will be entitled to contribution from any Person who was not guilty of such fraudulent misrepresentation; and provided further that in no event shall a Holder’s liability pursuant to this Section 2.8(d), when combined with the amounts paid or payable by such Holder pursuant to Section 2.8(b), exceed the proceeds from the offering received by such Holder (net of any Selling Expenses paid by such Holder), except in the case of willful misconduct or fraud by such Holder.

(f) Notwithstanding the foregoing, to the extent that the provisions on indemnification and contribution contained in the underwriting agreement entered into in connection with the underwritten public offering are in conflict with the foregoing provisions, the provisions in the underwriting agreement shall control.

(g) Unless otherwise superseded by an underwriting agreement entered into in connection with the underwritten public offering, the obligations of the Company and Holders under this Section 2.8 shall survive the completion of any offering of Registrable Securities in a registration under this Section 2, and otherwise shall survive the termination of this Agreement.

2.9 Reports Under Exchange Act. With a view to making available to the Holders the benefits of SEC Rule 144 and any other rule or regulation of the SEC that may at any time permit a Holder to sell securities of the Company to the public without registration or pursuant to a registration on Form S-3, the Company shall:

(a) make and keep available adequate current public information, as those terms are understood and defined in SEC Rule 144, at all times after the effective date of the registration statement filed by the Company for the IPO;
(b) use commercially reasonable efforts to file with the SEC in a timely manner all reports and other documents required of the Company under the Securities Act and the Exchange Act (at any time after the Company has become subject to such reporting requirements); and

(c) furnish to any Holder, so long as the Holder owns any Registrable Securities, forthwith upon request (i) to the extent accurate, a written statement by the Company that it has complied with the reporting requirements of SEC Rule 144 (at any time after ninety (90) days after the effective date of the registration statement filed by the Company for the IPO), the Securities Act, and the Exchange Act (at any time after the Company has become subject to such reporting requirements), or that it qualifies as a registrant whose securities may be resold pursuant to Form S-3 (at any time after the Company so qualifies) and (ii) such other information as may be reasonably requested in availing any Holder of any rule or regulation of the SEC that permits the selling of any such securities without registration (at any time after the Company has become subject to the reporting requirements under the Exchange Act) or pursuant to Form S-3 (at any time after the Company so qualifies to use such form).

2.10 Limitations on Subsequent Registration Rights. From and after the date of this Agreement, the Company shall not, without the prior written consent of the Holders of a majority of the Registrable Securities then outstanding, enter into any agreement with any holder or prospective holder of any securities of the Company that would (a) allow such holder or prospective holder to include such securities in any registration unless, under the terms of such agreement, such holder or prospective holder may include such securities in any such registration only to the extent that the inclusion of such securities will not reduce the number of the Registrable Securities of the Holders that are included or (b) allow such holder or prospective holder to initiate a demand for registration of any securities held by such holder or prospective holder; provided that this limitation shall not apply to any additional Investor who becomes a party to this Agreement in accordance with Section 6.9.

2.11 “Market Stand off” Agreement. Each Holder hereby agrees that it will not, without the prior written consent of the managing underwriter, during the period commencing on the date of the final prospectus relating to the registration by the Company of shares of its Common Stock or any other equity securities under the Securities Act on a registration statement on Form S-1 or Form S-3, and ending on the date specified by the Company and the managing underwriter, such period not to exceed one hundred eighty (180) days in the case of the IPO: (a) lend; offer; pledge; sell; contract to sell; sell any option or contract to purchase; purchase any option or contract to sell; grant any option, right, or warrant to purchase; or otherwise transfer or dispose of, directly or indirectly, any shares of Common Stock or any securities convertible into or exercisable or exchangeable (directly or indirectly) for Common Stock held immediately before the effective date of the registration statement for such offering or (b) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of such securities, whether any such transaction described in clause (a) or (b) above is to be settled by delivery of Common Stock or other securities, in cash, or otherwise. The foregoing provisions of this Section 2.11 shall apply only to the IPO, shall not apply to the sale of any shares to an underwriter pursuant to an underwriting agreement and shall be applicable to the Holders only if all officers and directors are subject to the same restrictions and the Company uses commercially reasonable efforts to obtain a similar agreement from all stockholders individually owning more than one percent (1%) of the Company’s outstanding Common Stock (after giving effect to the conversion into Common Stock of all outstanding Preferred Stock). The underwriters in connection with such registration are intended third-party beneficiaries of this Section 2.11 and shall have the right, power and authority to enforce the
provisions hereof as though they were a party hereto. Each Holder further agrees to execute such agreements as may be reasonably requested by the underwriters in connection with such registration that are consistent with this Section 2.11 or that are necessary to give further effect thereto. Any discretionary waiver or termination of the restrictions of any or all of such agreements by the Company or the underwriters shall apply pro rata to all Holders subject to such agreements, based on the number of shares subject to such agreements.

2.12 Restrictions on Transfer.

(a) The Preferred Stock and the Registrable Securities shall not be sold, pledged, or otherwise transferred, and the Company shall not recognize and shall issue stop-transfer instructions to its transfer agent with respect to any such sale, pledge, or transfer, except upon the conditions specified in this Agreement, which conditions are intended to ensure compliance with the provisions of the Securities Act. A transferring Holder will cause any proposed purchaser, pledgee, or transferee of the Preferred Stock and the Registrable Securities held by such Holder to agree to take and hold such securities subject to the provisions and upon the conditions specified in this Agreement.

(b) Each certificate, instrument or book entry representing (i) the Preferred Stock, (ii) the Registrable Securities, and (iii) any other securities issued in respect of the securities referenced in clauses (i) and (ii), upon any stock split, stock dividend, recapitalization, merger, consolidation, or similar event, shall (unless otherwise permitted by the provisions of Section 2.12(c)) be notated with a legend substantially in the following form:

THE SECURITIES REPRESENTED HEREBY HAVE BEEN ACQUIRED FOR INVESTMENT AND HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933. SUCH SHARES MAY NOT BE SOLD, PLEDGED, OR TRANSFERRED IN THE ABSENCE OF SUCH REGISTRATION OR A VALID EXEMPTION FROM THE REGISTRATION AND PROSPECTUS DELIVERY REQUIREMENTS OF SAID ACT.

THE SECURITIES REPRESENTED HEREBY MAY BE TRANSFERRED ONLY IN ACCORDANCE WITH THE TERMS OF AN AGREEMENT BETWEEN THE COMPANY AND THE STOCKHOLDER, A COPY OF WHICH IS ON FILE WITH THE SECRETARY OF THE COMPANY.

The Holders consent to the Company making a notation in its records and giving instructions to any transfer agent of the Restricted Securities in order to implement the restrictions on transfer set forth in this Section 2.12.

(c) The holder of such Restricted Securities, by acceptance of ownership thereof, agrees to comply in all respects with the provisions of this Section 2. Before any proposed sale, pledge, or transfer of any Restricted Securities, unless there is in effect a registration statement under the Securities Act covering the proposed transaction, the Holder thereof shall give notice to the Company of such Holder’s intention to effect such sale, pledge, or transfer. Each such notice shall describe the manner and circumstances of the proposed sale, pledge, or transfer in sufficient detail and, if reasonably requested by the Company, shall be accompanied at such Holder’s expense by either (i) a written opinion of legal counsel who shall, and whose legal opinion shall, be reasonably satisfactory to the Company, addressed to the Company, to the effect that the proposed transaction may be effected without registration under the Securities Act; (ii) a “no action” letter from the SEC to the effect that the proposed sale, pledge, or transfer of such Restricted Securities without registration will not result in a recommendation by the staff of the SEC that action be taken with respect thereto; or (iii) any other evidence reasonably satisfactory to counsel.
to the Company to the effect that the proposed sale, pledge, or transfer of the Restricted Securities may be effected without registration under the Securities Act, whereupon the Holder of such Restricted Securities shall be entitled to sell, pledge, or transfer such Restricted Securities in accordance with the terms of the notice given by the Holder to the Company. The Company will not require such a legal opinion or “no action” letter (1) in any transaction in compliance with SEC Rule 144 or (2) in any transaction in which such Holder distributes Restricted Securities to an Affiliate of such Holder for no consideration; provided that each transferee agrees in writing to be subject to the terms of this Section 2.12. Each certificate, instrument, or book entry representing the Restricted Securities transferred as above provided shall bear, except if such transfer is made pursuant to SEC Rule 144, the appropriate restrictive legend set forth in Section 2.12(b), except that such certificate, instrument, or book entry shall not bear such restrictive legend if, in the opinion of counsel for such Holder and the Company, such legend is not required in order to establish compliance with any provisions of the Securities Act.

2.13 Termination of Registration Rights. The right of any Holder to request registration or inclusion of Registrable Securities in any registration pursuant to Section 2.1 or Section 2.2 shall terminate upon the earliest to occur of: (a) seven (7) years after the effective date of the Company’s Registration Statement filed in connection with the Company’s IPO, (b) at such time as Rule 144 or another similar exemption under the Securities Act is available for the sale of all of such Holder’s shares without limitation during a three-month period without registration and (c) the closing of a Deemed Liquidation Event, as such term is defined in the Company’s Amended and Restated Certificate of Incorporation.


3.1 Delivery of Financial Statements. The Company shall deliver to each Major Investor, provided that the Board has not reasonably determined that such Major Investor is a Competitor:

(a) as soon as practicable, but in any event within one hundred twenty (120) days after the end of each fiscal year of the Company, (i) an unaudited balance sheet as of the end of such year, (ii) unaudited statements of income and of cash flows for such year and (iii) a statement of stockholders’ equity as of the end of such year, all such financial statements shall be prepared in accordance with GAAP, consistently applied, and setting forth in comparative form the figures for the previous fiscal year, in reasonable detail.

(b) as soon as practicable, but in any event within forty-five (45) days after the end of each of the first three (3) quarters of each fiscal year of the Company, unaudited statements of income and of cash flows for such fiscal quarter, and an unaudited balance sheet and a statement of stockholders’ equity as of the end of such fiscal quarter, all prepared in accordance with GAAP (except that such financial statements may (i) be subject to normal year-end audit adjustments and (ii) not contain all notes thereto that may be required in accordance with GAAP).

(c) as soon as practicable, but in any event within 45 days after the end of each quarter of each fiscal year of the Company, a statement showing the number of shares of each class and series of capital stock and securities convertible into or exercisable for shares of capital stock outstanding at the end of the applicable period, the Common Stock issuable upon conversion or exercise of any outstanding securities convertible or exercisable for Common Stock and the exchange ratio or exercise price applicable thereto, and the number of shares of issued stock options and stock options not yet issued but reserved for issuance, if any, all in sufficient detail as to permit the Major Investors to calculate their respective percentage equity ownership in the Company, and certified by the chief financial officer or chief executive officer of the Company as being true, complete, and correct.
such other information relating to the financial condition, business, prospects, or corporate affairs of the Company as any Major Investor may from time to time reasonably request; provided, however, that the Company shall not be obligated under this Section 3.1 to provide information (i) that the Company reasonably determines in good faith to be a trade secret or confidential information (unless covered by an enforceable confidentiality agreement, in form acceptable to the Company) or (ii) the disclosure of which would adversely affect the attorney-client privilege between the Company and its counsel.

If, for any period, the Company has any subsidiary whose accounts are consolidated with those of the Company, then in respect of such period the financial statements delivered pursuant to the foregoing sections shall be the consolidated and consolidating financial statements of the Company and all such consolidated subsidiaries.

3.2 Inspection. The Company shall permit each Major Investor, or any of its authorized representatives, at such Major Investor’s expense (provided that the Board has not reasonably determined that such Major Investor is a Competitor), to visit and inspect the Company’s properties; examine its corporate and financial records; and discuss the Company’s affairs, finances, and accounts with its officers, during normal business hours of the Company as may be reasonably requested by the Major Investor; provided, however, that the Company shall not be obligated pursuant to this Section 3.2 to provide access to any information that it reasonably and in good faith considers to be a trade secret or confidential information (unless covered by an enforceable confidentiality agreement, in form acceptable to the Company) or the disclosure of which would adversely affect the attorney-client privilege between the Company and its counsel.

3.3 Termination of Information and Inspection Rights. The covenants set forth in Section 3.1 and Section 3.2 shall terminate and be of no further force or effect (a) immediately before the consummation of the IPO; (b) when the Company first becomes subject to the periodic reporting requirements of Section 12(g) or 15(d) of the Exchange Act; or (c) upon a Deemed Liquidation Event, as such term is defined in the Company’s Amended and Restated Certificate of Incorporation, whichever event occurs first.

3.4 Confidentiality. Each Investor agrees that such Investor will keep confidential and will not disclose, divulge, or use for any purpose (other than to monitor its investment in the Company) any confidential information obtained from the Company pursuant to the terms of this Agreement (including notice of the Company’s intention to file a registration statement), unless such confidential information (a) is known or becomes known to the public in general (other than as a result of a breach of this Section 3.4 by such Investor), (b) is or has been independently developed or conceived by the Investor without use of the Company’s confidential information, or (c) is or has been made known or disclosed to the Investor by a third party without a breach of any obligation of confidentiality such third party may have to the Company; provided, however, that an Investor may disclose confidential information (i) to its attorneys, accountants, consultants, and other professionals to the extent necessary to obtain their services in connection with monitoring its investment in the Company, if such person is bound by an ethical duty to keep such information confidential or such person agrees to be bound by the provisions of this Section 3.4; (ii) to any prospective purchaser of any Registrable Securities from such Investor, if such prospective purchaser agrees to be bound by the provisions of this Section 3.4; (iii) to any existing or prospective Affiliate, partner, member, stockholder, or wholly owned subsidiary of such Investor in the ordinary course of business, provided that such Investor informs such Person that such information is confidential and directs such Person to maintain the confidentiality of such information; or (iv) as may otherwise be required by law, provided that the Investor promptly notifies the Company of such disclosure and takes reasonable steps to minimize the extent of any such required disclosure.
4. Rights to Future Stock Issuances.

4.1 Right of First Offer. Subject to the terms and conditions of this Section 4 and applicable securities laws, if the Company proposes to offer or sell any New Securities, the Company shall first offer such New Securities to each of the Investors. The Investors shall be entitled to apportion the right of first offer hereby granted to them in such proportions as the Investors deem appropriate, among (a) the Investors, (b) Affiliates of the Investors and (c) the beneficial interest holders, such as limited partners, members or any other Person having “beneficial ownership,” as such term is defined in Rule 13d-3 promulgated under the Exchange Act, of any Investor (“Investor Beneficial Owners”); provided that, each such Affiliate or Investor Beneficial Owner (x) is not a Competitor, unless such party’s purchase of New Securities is otherwise consented to by the Board, and (y) agrees to enter into this Agreement and each of the Voting Agreement and Right of First Refusal and Co-Sale Agreement of even date herewith among the Company, the Investors and the other parties named therein, as an “Investor” under each such agreement (provided that any Competitor shall not be entitled to any rights as an Investor under Subsections 3.1, 3.2, and 4.1 hereof).

4.2 Offer Notice. Prior to offering or selling any New Securities, the Company shall give notice (the “Offer Notice”) to each Investor, stating (a) its bona fide intention to offer such New Securities, (b) the number of such New Securities to be offered, and (c) the price and terms, if any, upon which it proposes to offer such New Securities.

4.3 Election to Purchase. By notification to the Company within twenty (20) days after the Offer Notice is given, each Investor may elect to purchase or otherwise acquire, at the price and on the terms specified in the Offer Notice, up to that portion of such New Securities which equals the proportion that the Common Stock then held by such Investor (including all shares of Common Stock then outstanding or issuable (directly or indirectly) upon conversion and/or exercise, as applicable, of the Preferred Stock and any other Derivative Securities then held by such Investor) bears to the total Common Stock of the Company then outstanding, or issuable (directly or indirectly) upon conversion and/or exercise, as applicable, of the Preferred Stock and any other Derivative Securities then outstanding. At the expiration of such twenty (20) day period, the Company shall promptly notify each Investor that elects to purchase or acquire all the shares available to it (each, a “Fully Exercising Investor”) of any other Investor’s failure to do likewise. During the ten (10) day period commencing after the Company has given such notice, each Fully Exercising Investor may, by giving notice to the Company, elect to purchase or acquire, in addition to the number of shares specified above, up to that portion of the New Securities for which Investors were entitled to subscribe but that were not subscribed for by the Investors which is equal to the proportion that the Common Stock issued and held, or issuable (directly or indirectly) upon conversion and/or exercise, as applicable, of Preferred Stock and any other Derivative Securities then held, by such Fully Exercising Investor bears to the Common Stock issued and held, or issuable (directly or indirectly) upon conversion and/or exercise, as applicable, of the Preferred Stock and any other Derivative Securities then held, by all Fully Exercising Investors who wish to purchase such unsubscribed shares. The closing of any sale pursuant to this Section 4 shall occur within the later of ninety (90) days after the date that the Offer Notice is given and the date of initial sale of New Securities pursuant to this Section 4.

4.4 Failure to Purchase. If all New Securities referred to in the Offer Notice are not elected to be purchased or acquired as provided in this Section 4, the Company may, during the ninety (90) day period following the expiration of the period provided in Section 4.3, offer and sell the remaining unsubscribed portion of such New Securities to any Person or Persons at a price not less than, and upon terms no more favorable to the offeree than, those specified in the Offer Notice. If the Company does not enter into an agreement for the sale of the New Securities within such period, or if such agreement is not consummated within thirty (30) days of the execution thereof, the right provided hereunder shall be deemed to be revived and such New Securities shall not be offered unless first reoffered to the Investors in accordance with this Section 4.
4.5 Exceptions to Right of First Offer. The right of first offer in this Section 4 shall not be applicable to (a) Exempted Securities (as defined in the Company’s Amended and Restated Certificate of Incorporation); (b) shares of Common Stock issued in the IPO; and (c) transactions whereby Investors holding at least sixty percent (60%) of the Preferred Stock and shares of Common Stock issued upon conversion of the Preferred Stock then held by the Investors (the “Requisite Investors”) waive the rights granted by this Section 4 with respect to such transaction; provided that no Investor who shall have consented to such waiver shall purchase any securities in such transaction or any related transaction.

4.6 Termination. The covenants set forth in this Section 4 shall terminate and be of no further force or effect (a) immediately before the consummation of the IPO; (b) when the Company first becomes subject to the periodic reporting requirements of Section 12(g) or 15(d) of the Exchange Act; or (c) upon a Deemed Liquidation Event, as such term is defined in the Company’s Amended and Restated Certificate of Incorporation, whichever event occurs first.

5. Additional Covenants.

5.1 Insurance. The Company shall use its commercially reasonable efforts to maintain, from financially sound and reputable insurers, director and officer liability insurance in an amount and on terms and conditions satisfactory to the Board, until such time as the Board determines that such insurance should be discontinued.

5.2 Proprietary Information and Inventions Agreements. Unless otherwise approved by the Board, the Company will cause each former, current or future employee, consultant or officer of the Company to enter into a Confidential Information Agreement (as defined in the Purchase Agreement).

5.3 Employee Stock. Unless otherwise approved by the Board or the compensation committee of the Board all future employees and consultants of the Company who purchase, receive options to purchase, or receive awards of shares of the Company’s capital stock after the date hereof shall be required to execute restricted stock or option agreements, as applicable, providing for (i) vesting of shares over a four (4) year period, with the first twenty-five percent (25%) of such shares vesting following twelve (12) months of continued employment or service, and the remaining shares vesting in equal monthly installments over the following thirty-six (36) months, and (ii) a market stand-off provision substantially similar to that in Section 2.11. In addition, unless otherwise approved by the Board, the Company shall retain a “right of first refusal” on employee transfers until the Company’s IPO and shall have the right to repurchase unvested shares at cost upon termination of employment of a holder of restricted stock.

5.4 Qualified Small Business Stock. The Company shall use commercially reasonable efforts to cause the shares of Preferred Stock, as well as any shares into which such shares are converted, within the meaning of Section 1202(f) of the Internal Revenue Code (the “Code”), to constitute “qualified small business stock” as defined in Section 1202(c) of the Code; provided, however, that such requirement shall not be applicable if the Board determines, in its good-faith business judgment, that such qualification is inconsistent with the best interests of the Company. The Company shall submit to its stockholders (including the Investors) and to the Internal Revenue Service any reports that may be required under Section 1202(d)(1)(C) of the Code and the regulations promulgated thereunder. In addition, within twenty (20) business days after any Investor’s written request therefor, the Company shall, at its option, either (a) deliver to such Investor a written statement indicating whether (and what portion of) such Investor’s interest in the Company constitutes “qualified small business stock” as defined in
Section 1202(c) of the Code or (b) deliver to such Investor such factual information in the Company’s possession as is reasonably necessary to enable such Investor to determine whether (and what portion of) such Investor’s interest in the Company constitutes “qualified small business stock” as defined in Section 1202(c) of the Code.

5.5 Board Matters. Unless otherwise determined by the vote of a majority of the directors then in office, the Board shall meet at least quarterly in accordance with an agreed-upon schedule. The Company shall reimburse the nonemployee directors for all reasonable out-of-pocket travel expenses incurred (consistent with the Company’s travel policy) in connection with attending meetings of the Board. All non-employee directors will be compensated uniformly for service on the Board, except for any grant of stock options or other equity to the independent director which is approved by the Board or the compensation committee of the Board.

5.6 Successor Indemnification. If the Company or any of its successors or assignees consolidates with or merges into any other Person and is not the continuing or surviving corporation or entity of such consolidation or merger, then to the extent necessary, proper provision shall be made so that the successors and assignees of the Company assume the obligations of the Company with respect to indemnification of members of the Board as in effect immediately before such transaction, whether such obligations are contained in the Company’s Bylaws, its Amended and Restated Certificate of Incorporation, or elsewhere, as the case may be.

5.7 Right to Conduct Activities. The Company hereby agrees and acknowledges that certain Investors are professional investment funds, and as such invest in numerous portfolio companies, some of which may be deemed competitive with the Company’s business (as currently conducted or as currently propose to be conducted). The Company hereby agrees that, to the extent permitted under applicable law, each such Investor shall not be liable to the Company for any claim arising out of, or based upon, (i) the investment by either such Investor in any entity competitive with the Company, or (ii) actions taken by any partner, officer or other representative of such Investor to assist any such competitive company, whether or not such action was taken as a member of the board of directors of such competitive company or otherwise, and whether or not such action has a detrimental effect on the Company; provided, however, that the foregoing shall not relieve (x) any of the Investors from liability associated with the unauthorized disclosure of the Company’s confidential information obtained pursuant to this Agreement, or (y) any director or officer of the Company from any liability associated with his or her fiduciary duties to the Company.

5.8 FCPA. The Company represents that it shall not (and shall not permit any of its subsidiaries or affiliates or any of its or their respective directors, officers, managers, employees, independent contractors, representatives or agents to) promise, authorize or make any payment to, or otherwise contribute any item of value to, directly or indirectly, to any third party, including any Non-U.S. Official (as (as such term is defined in the U.S. Foreign Corrupt Practices Act of 1977, as amended (the “FCPA”)), in each case, in violation of the FCPA, the U.K. Bribery Act, or any other applicable anti-bribery or anti-corruption law. The Company further represents that it shall (and shall cause each of its subsidiaries and affiliates to) cease all of its or their respective activities, as well as remEDIATE any actions taken by the Company, its subsidiaries or affiliates, or any of their respective directors, officers, managers, employees, independent contractors, representatives or agents in violation of the FCPA, the U.K. Bribery Act, or any other applicable anti-bribery or anti-corruption law. Upon request, the Company agrees to provide responsive information and/or certifications concerning its compliance with applicable anti-corruption laws. The Company shall promptly notify each Investor if the Company becomes aware of any Enforcement Action (as defined in the Purchase Agreement). The Company shall, and shall cause any direct or indirect subsidiary or entity controlled by it, whether now in existence or formed in the future, to comply with the FCPA. The Company shall use its best efforts to cause any direct or indirect subsidiary, whether now in existence or formed in the future, to comply in all material respects with all applicable laws.
5.9 Relinquished Voting Rights. Notwithstanding anything to the contrary set forth in the Company’s Amended and Restated Certificate of Incorporation, the Company’s Bylaws, applicable law or elsewhere, the Company and the Investors hereby acknowledge and agree that at any time, from time to time, when Nestlé Health Science US Holdings, Inc., Société des Produits Nestlé S.A. and any of their respective Affiliates that is or becomes a Holder (collectively, the “Nestlé Holders”) collectively hold twenty percent (20%) or more of the fully diluted capital stock of the Company, the Nestlé Holders automatically, and without any further action required by any Person, do hereby voluntarily relinquish, and shall not attempt to assert or exercise under any circumstance, any voting rights with respect to any Registrable Securities or other equity securities of the Company held by any Nestlé Holder, in each such case except for any voting rights set forth in Section 3.3 of Article IV(B) of the Company’s Amended and Restated Certificate of Incorporation (which voting rights, for the avoidance of doubt, are not being relinquished and can be freely exercised by any Nestlé Holder, as and when applicable); provided, however, that (a) for the avoidance of doubt, this Section 5.9 shall have no force or effect during any period in which the Nestlé Holders collectively hold less than twenty percent (20%) of the fully diluted capital stock of the Company and (b) this Section 5.9 shall not apply to any transferee of any Registrable Securities or other equity securities of the Company held by any Nestlé Holder.

5.10 Termination of Covenants. The covenants set forth in this Section 5, except for Section 5.5 and Section 5.9, shall terminate and be of no further force or effect (a) immediately before the consummation of the IPO, (b) when the Company first becomes subject to the periodic reporting requirements of Section 12(g) or 15(d) of the Exchange Act, or (c) upon a Deemed Liquidation Event, as such term is defined in the Company’s Amended and Restated Certificate of Incorporation, whichever event occurs first.

6. Miscellaneous.

6.1 Successors and Assigns. The rights under this Agreement may be assigned (but only with all related obligations) by a Holder to a transferee of Registrable Securities that (a) is an Affiliate of a Holder; (b) is a Holder’s Immediate Family Member or trust for the benefit of an individual Holder or one or more of such Holder’s Immediate Family Members; or (c) after such transfer, holds at least 1,000,000 shares of Registrable Securities (subject to appropriate adjustment for stock splits, stock dividends, stock combinations, and other recapitalizations); provided, however, that (i) the Company is, within a reasonable time after such transfer, furnished with written notice of the name and address of such transferee and the Registrable Securities with respect to which such rights are being transferred; and (ii) such transferee agrees in a written instrument delivered to the Company to be bound by and subject to the terms and conditions of this Agreement, including the provisions of Section 2.11. For the purposes of determining the number of shares of Registrable Securities held by a transferee, the holdings of a transferee (1) that is an Affiliate or stockholder of a Holder; (2) who is a Holder’s Immediate Family Member; or (3) that is a trust for the benefit of an individual Holder or such Holder’s Immediate Family Member shall be aggregated together and with those of the transferring Holder; provided further that all transferees who would not qualify individually for assignment of rights shall have a single attorney-in-fact for the purpose of exercising any rights, receiving notices, or taking any action under this Agreement. The terms and conditions of this Agreement inure to the benefit of and are binding upon the respective successors and permitted assignees of the parties. Nothing in this Agreement, express or implied, is intended to confer upon any party other than the parties hereto or their respective successors and permitted assignees any rights, remedies, obligations or liabilities under or by reason of this Agreement, except as expressly provided herein.
6.2 Governing Law. This Agreement and any controversy arising out of or relating to this Agreement shall be governed by and construed in accordance with the internal laws of the State of Delaware, without regard to conflict of law principles that would result in the application of any law other than the laws of the State of Delaware.

6.3 Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Counterparts may be delivered via facsimile, electronic mail (including pdf or any electronic signature complying with the U.S. federal E-SIGN Act of 2000, e.g., www.docusign.com) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.

6.4 Titles and Subtitles. The titles and subtitles used in this Agreement are for convenience only and are not to be considered in construing or interpreting this Agreement.

6.5 Notices. All notices and other communications given or made pursuant to this Agreement shall be in writing and shall be deemed effectively given upon the earlier of actual receipt or: (a) personal delivery to the party to be notified; (b) when sent, if sent by electronic mail or facsimile during the recipient’s normal business hours, and if not sent during normal business hours, then on the recipient’s next business day; (c) five (5) days after having been sent by registered or certified mail, return receipt requested, postage prepaid; or (d) one (1) business day after the business day of deposit with a nationally recognized overnight courier, freight prepaid, specifying next-day delivery, with written verification of receipt. All communications shall be sent to the respective parties at their addresses as set forth on Schedule A hereto, or to the principal office of the Company and to the attention of the Chief Executive Officer, in the case of the Company, or to such email address, facsimile number, or address as subsequently modified by written notice given in accordance with this Section 6.5. If notice is given to the Company, it shall be sent to Prometheus Biosciences, Inc., 9410 Carroll Park Drive, San Diego, CA 92121, Attention: Mark McKenna; and a copy (which shall not constitute notice) shall also be sent to Latham & Watkins LLP, 12670 High Bluff Drive, San Diego, CA 92130, Attention: Cheston J. Larson.

6.6 Amendments and Waivers. Any term of this Agreement may be amended and the observance of any term of this Agreement may be waived (either generally or in a particular instance, and either retroactively or prospectively) only with the written consent of (i) the Company and (ii) the Requisite Investors; provided, however that the Company may in its sole discretion waive compliance with Section 2.12(c) (and the Company’s failure to object promptly in writing after notification of a proposed assignment allegedly in violation of Section 2.12(c) shall be deemed to be a waiver); and provided further that any provision hereof may be waived by any waiving party on such party’s own behalf, without the consent of any other party. Notwithstanding the foregoing, this Agreement may not be amended or terminated and the observance of any term hereof may not be waived with respect to any Investor without the written consent of such Investor, unless such amendment, termination, or waiver applies to all Investors in the same fashion (it being agreed that a waiver of the provisions of Section 4 with respect to a particular transaction shall be deemed to apply to all Investors in the same fashion if such waiver does so by its terms, notwithstanding the fact that certain Investors may nonetheless, by agreement with the Company, purchase securities in such transaction). The Company shall give prompt notice of any amendment or termination hereof or waiver hereunder to any party hereto that did not consent in writing to such amendment, termination, or waiver. Any amendment, termination, or waiver effected in accordance with this Section 6.6 shall be binding on all parties hereto, regardless of whether any such party has consented thereto. No waivers of or exceptions to any term, condition, or provision of this Agreement, in any one or more instances, shall be deemed to be or construed as a further or continuing waiver of any such term, condition, or provision.
6.7 **Severability.** In case any one or more of the provisions contained in this Agreement is for any reason held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality, or unenforceability shall not affect any other provision of this Agreement, and such invalid, illegal, or unenforceable provision shall be reformed and construed so that it will be valid, legal, and enforceable to the maximum extent permitted by law.

6.8 **Aggregation of Stock.** All shares of Registrable Securities held or acquired by Affiliates shall be aggregated together for the purpose of determining the availability of any rights under this Agreement and such Affiliated persons may apportion such rights as among themselves in any manner they deem appropriate.

6.9 **Additional Investors.** Notwithstanding anything to the contrary contained herein, if the Company issues additional shares of Series C Preferred Stock after the date hereof, whether pursuant to the Purchase Agreement or otherwise, any purchaser of such shares of Series C Preferred Stock may become a party to this Agreement by executing and delivering an additional counterpart signature page to this Agreement, and thereafter shall be deemed an “Investor” for all purposes hereunder. No action or consent by the Investors shall be required for such joinder to this Agreement by such additional Investor, so long as such additional Investor has agreed in writing to be bound by all of the obligations as an “Investor” hereunder.

6.10 **Entire Agreement.** This Agreement (including any Schedules and Exhibits hereto) constitutes the full and entire understanding and agreement among the parties with respect to the subject matter hereof, and any other written or oral agreement relating to the subject matter hereof existing between the parties is expressly canceled.

6.11 **Dispute Resolution.** The parties (a) hereby irrevocably and unconditionally submit to the jurisdiction of the state courts of Delaware and to the jurisdiction of the United States District Court for the District of Delaware for the purpose of any suit, action or other proceeding arising out of or based upon this Agreement, and (c) hereby waive, and agree not to assert, by way of motion, as a defense, or otherwise, in any such suit, action or proceeding, any claim that it is not subject personally to the jurisdiction of the above-named courts, that its property is exempt or immune from attachment or execution, that the suit, action or proceeding is brought in an inconvenient forum, that the venue of the suit, action or proceeding is improper or that this Agreement or the subject matter hereof may not be enforced in or by such court.

6.12 **WAIVER OF JURY TRIAL:** EACH PARTY HEREBY WAIVES ITS RIGHTS TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION BASED UPON OR ARISING OUT OF THIS AGREEMENT, THE OTHER TRANSACTION DOCUMENTS, THE SECURITIES OR THE SUBJECT MATTER HEREOF OR THEREOF. THE SCOPE OF THIS WAIVER IS INTENDED TO BE ALL-ENCOMPASSING OF ANY AND ALL DISPUTES THAT MAY BE FILED IN ANY COURT AND THAT RELATE TO THE SUBJECT MATTER OF THIS TRANSACTION, INCLUDING, WITHOUT LIMITATION, CONTRACT CLAIMS, TORT CLAIMS (INCLUDING NEGLIGENCE), BREACH OF DUTY CLAIMS, AND ALL OTHER COMMON LAW AND STATUTORY CLAIMS. THIS SECTION HAS BEEN FULLY DISCUSSED BY EACH OF THE PARTIES HERETO AND THESE PROVISIONS WILL NOT BE SUBJECT TO ANY EXCEPTIONS. EACH PARTY HERETO HEREBY FURTHER WARRANTS AND REPRESENTS THAT SUCH PARTY HAS REVIEWED THIS WAIVER WITH ITS LEGAL COUNSEL, AND THAT SUCH PARTY KNOWINGLY AND VOLUNTARILY WAIVES ITS JURY TRIAL RIGHTS FOLLOWING CONSULTATION WITH LEGAL COUNSEL.
6.13 Delays or Omissions. No delay or omission to exercise any right, power, or remedy accruing to any party under this Agreement, upon any breach or default of any other party under this Agreement, shall impair any such right, power, or remedy of such nonbreaching or nondefaulting party, nor shall it be construed to be a waiver of or acquiescence to any such breach or default, or to any similar breach or default thereafter occurring, nor shall any waiver of any single breach or default be deemed a waiver of any other breach or default theretofore or thereafter occurring. All remedies, whether under this Agreement or by law or otherwise afforded to any party, shall be cumulative and not alternative.

6.14 Acknowledgment. The Company acknowledges that the Investors are in the business of venture capital investing and therefore review the business plans and related proprietary information of many enterprises, including enterprises which may have products or services which compete directly or indirectly with those of the Company. Nothing in this Agreement shall preclude or in any way restrict the Investors from investing or participating in any particular enterprise whether or not such enterprise has products or services which compete with those of the Company.

6.15 Amendment and Restatement of Prior Agreement; Waiver of Right of First Offer. Upon execution of this Agreement by the Company and Existing Investors holding a majority of the Registrable Securities under the Prior Agreement, the Prior Agreement shall thereafter be of no further force and effect and is hereby amended in its entirety and restated herein, and all provisions of rights granted and covenants made in the Prior Agreement are hereby waived, released and superseded in their entirety and shall have no further force or effect including, without limitation, all rights and any notice period associated therewith otherwise applicable to the transactions contemplated by the Purchase Agreement.

[SIGNATURE PAGES FOLLOW]
IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

COMPANY:

PROMETHEUS BIOSCIENCES, INC.

By: /s/ Mark McKenna
Name: Mark McKenna
Title: President and CEO
IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

INVESTORS:

NESTLÉ HEALTH SCIENCE US HOLDINGS, INC.

By: /s/ James Pepin
Name: James Pepin
Title: President

SIGNATURE PAGE – AMENDED AND RESTATED INVESTORS RIGHTS AGREEMENT
IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

INVESTORS:

SOCIÉTÉ DES PRODUITS NESTLÉ S.A.

By: /s/ Claudio Kuoni
Name: Claudio Kuoni
Title: General Counsel NHSc

SIGNATURE PAGE – AMENDED AND RESTATED INVESTORS RIGHTS AGREEMENT
IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

INVESTORS:

CEDARS-SINAI MEDICAL CENTER

By: /s/ James D. Laur  
Name: James D. Laur  
Title: Vice President, Intellectual Property

CEDARS-SINAI MEDICAL CENTER

By: /s/ Edward M. Prunchunas  
Name: Edward M. Prunchunas  
Title: Executive Vice President and CFO
IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

INVESTORS:
ASCEND GLOBAL INVESTMENT FUND SPC-
STRATEGIC SEGREGATED PORTFOLIO

By: /s/ Shierley Widjaja
Name: Shierley Widjaja
Title: 

SIGNATURE PAGE – AMENDED AND RESTATED INVESTORS RIGHTS AGREEMENT
IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

INVESTORS:

LIFE VENTURES 1 LP

By:  /s/ Douglas F. Wall
Name:  Douglas F. Wall
Title:  Managing Director

SIGNATURE PAGE – AMENDED AND RESTATED INVESTORS RIGHTS AGREEMENT
IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above:

INVESTORS:

LIFE VENTURES II, LP

By: /s/ Douglas F. Wall
Name: Douglas F. Wall
Title: Managing Director

SIGNATURE PAGE – AMENDED AND RESTATED INVESTORS RIGHTS AGREEMENT
IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

INVESTORS:

GLENN HOLDINGS, L.P.

By: /s/ Scott L. Glenn
Name: Scott L. Glenn
Title: General Partner

SIGNATURE PAGE – AMENDED AND RESTATED INVESTORS RIGHTS AGREEMENT
IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

INVESTORS:

MAHLBERG FAMILY TRUST

By:  /s/ Barry Mahlberg
Name: Barry Mahlberg
Title: Trustee

SIGNATURE PAGE – AMENDED AND RESTATED INVESTORS RIGHTS AGREEMENT
IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

INVESTORS:

IRAR TRUST: ERIC JOSEPH ZIMMER IRA 35-37926

By:  /s/ Cecila Guerra  
Name:  Cecila Guerra  
Title:  Authorized Signer  

READ AND APPROVED:

/s/ Eric Joseph Zimmer  
 Eric Joseph Zimmer  

SIGNATURE PAGE – AMENDED AND RESTATED INVESTORS RIGHTS AGREEMENT
IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

INVESTORS:

WS INVESTMENT COMPANY, LLC (20A)

By: /s/ James Terranova
Name: James Terranova
Title: Managing Director

SIGNATURE PAGE – AMENDED AND RESTATED INVESTORS RIGHTS AGREEMENT
IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

INVESTORS:

ROLF J. BENIRSCHKE AND MARY P. BENIRSCHKE
FAMILY TRUST DATED JULY 15, 1990

By: /s/ Rolf J. Benirschke
Name: Rolf J. Benirschke
Title: Trustee

SIGNATURE PAGE – AMENDED AND RESTATE[l. RIGHTS AGREEMENT
IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

INVESTORS:

By: /s/ Mike Dee  
Name: Mike Dee

SIGNATURE PAGE – AMENDED AND RESTATED INVESTORS RIGHTS AGREEMENT
IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

INVESTORS:

By: /s/ Kathy May
Name: Kathy May

SIGNATURE PAGE – AMENDED AND RESTATED INVESTORS RIGHTS AGREEMENT
IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

INVESTORS:

LORD WILMORE PARTNERS LLC.

By:  /s/ James Panoff
Name:  James Panoff
Title:  President

SIGNATURE PAGE – AMENDED AND RESTATED INVESTORS RIGHTS AGREEMENT
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<td>1522 West Lane</td>
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<td>Del Mar, CA 92014</td>
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<td>Cedars-Sinai Medical Center</td>
<td>4326 Vista de la Tierra</td>
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<tr>
<td>Mike Dee</td>
<td>8700 Beverly Blvd.</td>
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<tr>
<td></td>
<td>Los Angeles, CA 90048-1865</td>
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<td>IRA Resources, Inc. FBO: Bradley Davis Foltz IRA 35-37634</td>
<td>1342 Monk Road</td>
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<td>Gladwyne, PA 19035</td>
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<td>Kathy May</td>
<td>16376 Nicole Ridge Road</td>
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<td>Glenn Holdings, L.P.</td>
<td>451 Curtis Ave.</td>
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<td>Telluride, CO 81435</td>
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<td>Harlan and Debra Jacobs Family Trust dated September 17, 1999</td>
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<td>La Jolla, CA 92037</td>
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<td>Christopher D. Hazuka, J.D., Ph.D.</td>
<td>c/o Latham &amp; Watkins LLP</td>
</tr>
<tr>
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<td>140 Scott Drive</td>
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<td>Menlo Park, CA 94025</td>
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The Entrust Group FBO Richard Jaffe IRA 7230004599
La Jolla, CA 92037
350 Dane Road
Jay S. Johnson Revocable Trust
Owatonna, MN 55060
Cheston J. Larson
c/o Latham & Watkins LLP
12670 High Bluff Drive
San Diego, CA 92130
Pensco Trust Company Custodian FBO Gary Levine Roth IRA
10505 Sorrento Valley Road, Suite 200
San Diego, CA 92121
Mahlberg Family Trust
San Diego, CA 92131
Barry Mahlberg
10791 Birch Bluff Avenue
Mossy Family Trust, UTD 6/30/05, Peter B. Mossy, TTEE, Sandra M Mossy, TTEE
P.O. Box 7181
6025 Mimulus
Rancho Santa Fe, CA 92067
Christopher Paben
1522 S. Saltair Avenue, Unit 302
Los Angeles, CA 90025
Kyle Paben
1522 S. Saltair Avenue, Unit 302
Los Angeles, CA 90025
Brian Pidgeon
10075 Mesa Rim Road
San Diego, CA 92121
Life Ventures 1 LP
13635 Melissa Lane
Poway, CA 92064
Attn: Doug Wall
VP Company Investments 2018, LLC
55 W. Fifth Street
Los Angeles, CA 90013-1010
IRAR Trust: Eric Joseph Zimmer IRA 35-37926
1000 Broadway, Suite 350
Oakland, CA 94607
EIN: 33-6305812
Eric Joseph Zimmer
434 Loma Larga Dr.
Solana Beach, CA 92075
Ascend Global Investment Fund SPC – Strategic Segregated Portfolio
Registered Address of the Fund:
Ascend Global Investment Fund SPC
Cricket Square, Hutchins Drive
PO Box 2681, Grand Cayman,
KY1-1111, Cayman Islands
Correspondence/Mailing Address:
Ascend Global Investment Fund SPC
C/O Ascend Capital Advisors (S) Pte. Ltd.
1, Kim Seng Promenade, #10-01,
East Tower, Great World City
Singapore 237994
Proehl Investment Ventures LLC
7908 Entrada De Luz E.
San Diego, CA 92127
This warrant and the shares issuable hereunder have not been registered under the Securities Act of 1933, as amended (the "Act"), or the securities laws of any state and, except as set forth in sections 5.3 and 5.4 below, may not be offered, sold, pledged or otherwise transferred unless and until registered under said Act and laws or, in the opinion of legal counsel in form and substance satisfactory to the company, such offer, sale, pledge or other transfer is exempt from such registration.

WARRANT TO PURCHASE STOCK

Company: PROMETHEUS BIOSCIENCES, INC., a Delaware corporation
Number of Shares: 112,500 (Subject to Section 1.7)
Type/Series of Stock: Series C Preferred (Subject to Section 1.7)
Warrant Price: $1.00 per share (Subject to Section 1.7)
Issue Date: January 24, 2020
Expiration Date: January 24, 2030 (See also Section 5.1(b))

Credit Facility: This Warrant to Purchase Stock ("Warrant") is issued in connection with that certain Loan and Security Agreement of even date herewith among Oxford Finance LLC, as Lender and Collateral Agent, the Lenders from time to time party thereto, and the Company (as modified, amended and/or restated from time to time, the "Loan Agreement").

This warrant certifies that, for good and valuable consideration, OXFORD FINANCE LLC ("Oxford" and, together with any successor or permitted assignee or transferee of this Warrant or of any shares issued upon exercise hereof, "Holder") is entitled to purchase the number of fully paid and non-assessable shares (the "Shares") of the above-stated Type/Series of Stock (the "Class") of the above-named company (the "Company") at the above-stated Warrant Price, all as set forth above and as adjusted pursuant to Section 2 of this Warrant, subject to the provisions and upon the terms and conditions set forth in this Warrant.

SECTION 1. EXERCISE.

1.1 Method of Exercise. Holder may at any time and from time to time exercise this Warrant, in whole or in part, by delivering to the Company the original of this Warrant together with a duly executed Notice of Exercise in substantially the form attached hereto as Appendix 1 and, unless Holder is exercising this Warrant pursuant to a cashless exercise set forth in Section 1.2, a check, wire transfer of same-day funds (to an account designated by the Company), or other form of payment acceptable to the Company for the aggregate Warrant Price for the Shares being purchased.

1.2 Cashless Exercise. On any exercise of this Warrant, in lieu of payment of the aggregate Warrant Price in the manner as specified in Section 1.1 above, but otherwise in accordance with the requirements of Section 1.1, Holder may elect to receive Shares equal to the value of this Warrant, or portion hereof as to which this Warrant is being exercised. Thereupon, the Company shall issue to the Holder such number of fully paid and non-assessable Shares as are computed using the following formula:

\[ X = \frac{Y(A-B)}{A} \]

where:

\[ X = \] the number of Shares to be issued to the Holder;
\[ Y = \] the number of Shares with respect to which this Warrant is being exercised (inclusive of the Shares surrendered to the Company in payment of the aggregate Warrant Price);
A = the fair market value (as determined pursuant to Section 1.3 below) of one Share; and

B = the Warrant Price.

1.3 Fair Market Value. If the Company’s common stock is then traded or quoted on a nationally recognized securities exchange, inter-dealer quotation system or over-the-counter market (a “Trading Market”) and the Class is common stock, the fair market value of a Share shall be the closing price or last sale price of a share of common stock reported for the Business Day immediately before the date on which Holder delivers this Warrant together with its Notice of Exercise to the Company. If the Company’s common stock is then traded in a Trading Market and the Class is a series of the Company’s convertible preferred stock, the fair market value of a Share shall be the closing price or last sale price of a share of the Company’s common stock reported for the Business Day immediately before the date on which Holder delivers this Warrant together with its Notice of Exercise to the Company multiplied by the number of shares of the Company’s common stock into which a Share is then convertible. If the Company’s common stock is not traded in a Trading Market, the Board of Directors of the Company shall determine the fair market value of a Share in its reasonable good faith judgment.

1.4 Delivery of Certificate and New Warrant. Within a reasonable time after Holder exercises this Warrant in the manner set forth in Section 1.1 or 1.2 above, the Company shall deliver to Holder a certificate representing the Shares issued to Holder upon such exercise (or, if such Shares are not certificated, the Company shall reflect Holder’s ownership of such Shares by book entry in the Company’s books and records) and, if this Warrant has not been fully exercised and has not expired, the Company shall deliver to Holder a new warrant of like tenor representing the Shares not so acquired.

1.5 Replacement of Warrant. On receipt of evidence reasonably satisfactory to the Company of the loss, theft, destruction or mutilation of this Warrant and, in the case of loss, theft or destruction, on delivery of an indemnity agreement reasonably satisfactory in form, substance and amount to the Company or, in the case of mutilation, on surrender of this Warrant to the Company for cancellation, the Company shall, within a reasonable time, execute and deliver to Holder, in lieu of this Warrant, a new warrant of like tenor and amount.

1.6 Treatment of Warrant Upon Acquisition of Company.

(a) Acquisition. For the purpose of this Warrant, “Acquisition” means any transaction or series of related transactions involving: (i) the sale, lease, exclusive license, or other disposition of all or substantially all of the assets of the Company (ii) any merger or consolidation of the Company into or with another person or entity (other than a merger or consolidation effected exclusively to change the Company’s domicile), or any other corporate reorganization, in which the stockholders of the Company in their capacity as such immediately prior to such merger, consolidation or reorganization, own less than a majority of the Company’s (or the surviving or successor entity’s) outstanding voting power immediately after such merger, consolidation or reorganization (or, if such Company stockholders beneficially own a majority of the outstanding voting power of the surviving or successor entity as of immediately after such merger, consolidation or reorganization, such surviving or successor entity is not the Company); or (iii) any sale or other transfer by the stockholders of the Company of shares representing at least a majority of the Company’s then-total outstanding combined voting power (other than a bona fide equity financing exclusively for capital raising purposes in which the Company sells and issues equity securities to institutional investors and is the surviving and continuing entity in such transaction).

(b) Treatment of Warrant at Acquisition. In the event of an Acquisition in which the consideration to be received by the Company’s stockholders consists solely of cash, solely of Marketable Securities or a combination of cash and Marketable Securities (a “Cash/Public Acquisition”), either (i) Holder shall exercise this Warrant pursuant to Section 1.1 and/or 1.2 and such exercise will be deemed effective immediately prior to and contingent upon the consummation of such Acquisition or (ii) if Holder elects not to exercise the Warrant, this Warrant will expire immediately prior to the consummation of such Acquisition.

(c) The Company shall provide Holder with written notice of its request relating to the Cash/Public Acquisition (together with such reasonable information as Holder may reasonably require regarding the treatment of this Warrant in connection with such contemplated Cash/Public Acquisition giving rise to such notice),
which is to be delivered to Holder not less than seven (7) Business Days prior to the closing of the proposed Cash/Public Acquisition. In the event the Company does not provide such notice, then if, immediately prior to the Cash/Public Acquisition, the fair market value of one Share (or other security issuable upon the exercise hereof) as determined in accordance with Section 1.3 above would be greater than the Warrant Price in effect on such date, then this Warrant shall automatically be deemed on and as of such date to be exercised pursuant to Section 1.2 above as to all Shares (or such other securities) for which it shall not previously have been exercised, and the Company shall promptly notify the Holder of the number of Shares (or such other securities) issued upon such exercise to the Holder and Holder shall be deemed to have restated each of the representations and warranties in Section 4 of the Warrant as the date thereof. If, immediately prior to the Cash/Public Acquisition, the fair market value of one Share (or other security issuable upon the exercise hereof) as determined in accordance with Section 1.3 above would not be greater than the Warrant Price in effect on such date, then this Warrant shall terminate without exercise or conversion immediately prior to, and subject to, the closing of such Cash/Public Acquisition.

(d) Upon the closing of any Acquisition other than a Cash/Public Acquisition defined above, the acquiring, surviving or successor entity shall assume the obligations of this Warrant, and this Warrant shall thereafter be exercisable for the same securities and/or other property as would have been paid for the Shares issuable upon exercise of the unexercised portion of this Warrant as if such Shares were outstanding on and as of the closing of such Acquisition, subject to further adjustment from time to time in accordance with the provisions of this Warrant.

(e) As used in this Warrant, “Marketable Securities” means securities meeting all of the following requirements: (i) the issuer thereof is then subject to the reporting requirements of Section 13 or Section 15(d) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and is then current in its filing of all required reports and other information under the Act and the Exchange Act; (ii) the class and series of shares or other security of the issuer that would be received by Holder in connection with the Acquisition were Holder to exercise this Warrant on or prior to the closing thereof is then traded in a Trading Market, and (iii) following the closing of such Acquisition, Holder would not be restricted from publicly re-selling all of the issuer’s shares and/or other securities that would be received by Holder in such Acquisition were Holder to exercise or convert this Warrant in full on or prior to the closing of such Acquisition, except to the extent that any such restriction (x) arises solely under federal or state securities laws, rules or regulations, or a contractual lock-up provision that is generally applicable to the other former securityholders of the Company receiving such securities, and (y) does not extend beyond six (6) months from the closing of such Acquisition.

SECTION 2. ADJUSTMENTS TO THE SHARES AND WARRANT PRICE.

2.1 Stock Dividends, Splits, Etc. If the Company declares or pays a dividend or distribution on the outstanding shares of the Class payable in common stock or other securities or property (other than cash), then upon exercise of this Warrant, for each Share acquired, Holder shall receive, without additional cost to Holder,
the total number and kind of securities and property which Holder would have received had Holder owned the Shares of record as of the date the dividend or distribution occurred. If the Company subdivides the outstanding shares of the Class by reclassification or otherwise into a greater number of shares, the number of Shares purchasable hereunder shall be proportionately increased and the Warrant Price shall be proportionately decreased. If the outstanding shares of the Class are combined or consolidated, by reclassification or otherwise, into a lesser number of shares, the Warrant Price shall be proportionately increased and the number of Shares shall be proportionately decreased.

2.2 Reclassification, Exchange, Combinations or Substitution. Upon any event whereby all of the outstanding shares of the Class are reclassified, exchanged, combined, substituted, or replaced for, into, with or by Company securities of a different class and/or series, then from and after the consummation of such event, this Warrant will be exercisable for the number, class and series of Company securities that Holder would have received had the Shares been outstanding on and as of the consummation of such event, and subject to further adjustment thereafter from time to time in accordance with the provisions of this Warrant. The provisions of this Section 2.2 shall similarly apply to successive reclassifications, exchanges, combinations, substitutions, replacements or other similar events.

2.3 Conversion of Preferred Stock. If the Class is a class and series of the Company’s convertible preferred stock, in the event that all outstanding shares of the Class are converted, automatically or by action of the holders thereof, into common stock pursuant to the provisions of the Company’s Amended and Restated Certificate of Incorporation (as the same may be amended and/or restated from time to time, the “Certificate of Incorporation”), including, without limitation, in connection with the Company’s initial, underwritten public offering and sale of its common stock pursuant to an effective registration statement under the Act (the “IPO”), then from and after the date on which all outstanding shares of the Class have been so converted, this Warrant shall be exercisable for such number of shares of common stock into which the Shares would have been converted had the Shares been outstanding on the date of such conversion, and the Warrant Price shall equal the Warrant Price in effect as of immediately prior to such conversion divided by the number of shares of common stock into which one Share would have been converted, all subject to further adjustment thereafter from time to time in accordance with the provisions of this Warrant.

2.4 Adjustments for Diluting Issuances. Without duplication of any adjustment otherwise provided for in this Section 2, the number of shares of common stock issuable upon conversion of the Shares shall be subject to anti-dilution adjustment from time to time in the manner set forth in the Certificate of Incorporation (including giving effect to any waiver of such required adjustment effected in accordance with the terms of the Certificate of Incorporation) as if the Shares were issued and outstanding on and as of the date of any such required adjustment.

2.5 No Fractional Share. No fractional Share shall be issuable upon exercise of this Warrant and the number of Shares to be issued shall be rounded down to the nearest whole Share. If a fractional Share interest arises upon any exercise of the Warrant, the Company shall eliminate such fractional Share interest by paying Holder in cash the amount computed by multiplying the fractional interest by (i) the fair market value (as determined in accordance with Section 1.3 above) of a full Share, less (ii) the then-effective Warrant Price.

2.6 Notice/Certificate as to Adjustments. Upon each adjustment of the Warrant Price, Class and/or number of Shares, the Company, at the Company’s expense, shall notify Holder in writing within a reasonable time setting forth the adjustments to the Warrant Price, Class and/or number of Shares and facts upon which such adjustment is based. The Company shall, upon written request from Holder, furnish Holder with a certificate of its Chief Financial Officer, including computations of such adjustment and the Warrant Price, Class and number of Shares in effect upon the date of such adjustment.

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3.1 **Representations and Warranties.** The Company represents and warrants to, and agrees with, the Holder as follows as of the Issue Date:

(a) The initial Warrant Price referenced on the first page of this Warrant is not greater than the price per share at which shares of the Class were last sold and issued prior to the Issue Date hereof in an arms-length transaction in which at least Five Hundred Thousand Dollars ($500,000.00) of such shares were sold.

(b) All Shares which may be issued upon the exercise of this Warrant, and all securities, if any, issuable upon conversion of the Shares, shall, upon issuance, be duly authorized, validly issued, fully paid and non-assessable, and free of any liens and encumbrances except for restrictions on transfer provided for herein or under applicable federal and state securities laws. The Company covenants that it shall at all times cause to be reserved and kept available out of its authorized and unissued capital stock such number of shares of the Class, common stock and other securities as will be sufficient to permit the exercise in full of this Warrant and the conversion of the Shares into common stock or such other securities.

(c) The Company’s capitalization table attached hereto as Schedule 1 is true and complete, in all material respects, as of the Issue Date.

3.2 **Notice of Certain Events.** If the Company proposes at any time to:

(a) declare any dividend or distribution upon the outstanding shares of the Class or common stock, whether in cash, property, stock, or other securities and whether or not a regular cash dividend;

(b) offer for subscription or sale pro rata to the holders of the outstanding shares of the Class any additional shares of any class or series of the Company’s stock (other than pursuant to contractual pre-emptive rights);

(c) effect any reclassification, exchange, combination, substitution, reorganization or recapitalization of the outstanding shares of the Class;

(d) effect an Acquisition or to liquidate, dissolve or wind up; or

(e) effect an IPO;

then, in connection with each such event, the Company shall give Holder:

(1) at least five (5) Business Days prior written notice of the date on which a record will be taken for such dividend, distribution, or subscription rights (and specifying the date on which the holders of outstanding shares of the Class will be entitled thereto) or for determining rights to vote, if any, in respect of the matters referred to in (a) and (b) above;

(2) in the case of the matters referred to in (c) and (d) above at least five (5) Business Days prior written notice of the date when the same will take place (and specifying the date on which the holders of outstanding shares of the Class will be entitled to exchange their shares for the securities or other property deliverable upon the occurrence of such event); and

(3) with respect to the IPO, written notice no later than the date on which the Company files its registration statement in connection therewith.

Reference is made to Section 1.6(c) whereby this Warrant will be deemed to be exercised pursuant to Section 1.2 hereof if the Company does not give written notice to Holder of a Cash/Public Acquisition as required by the terms hereof. Company will also provide information requested by Holder that is reasonably necessary to enable Holder to comply with Holder’s accounting or reporting requirements. Holder agrees that in handling any confidential information of the Company, Holder shall handle such information in accordance with the provisions of Section 12.9 of the Loan Agreement (regardless of whether the Obligations (as defined in the Loan Agreement) have been repaid in full).
The Holder represents and warrants to the Company, as of the Issue Date and as of the date of issuance of any of the Shares issuable upon exercise of this Warrant, as follows:

4.1 **Purchase for Own Account.** This Warrant and the securities to be acquired upon exercise of this Warrant by Holder are being acquired for investment for Holder’s account, not as a nominee or agent, and not with a view to the public resale or distribution within the meaning of the Act. Holder also represents that it has not been formed for the specific purpose of acquiring this Warrant or the Shares. By executing this Warrant, Holder further represents that as of the Issue Date, Holder does not have any contract, undertaking, agreement or arrangement with any person to sell, transfer or grant participations to such person or to any third person with respect to this Warrant, the Shares issuable upon exercise of this Warrant or any shares of common stock issuable upon conversion of such Shares, except for the transfer from Oxford to one or more of Oxford’s affiliates (each an “Oxford Affiliate”), as contemplated and allowed by Section 5.4.

4.2 **Disclosure of Information.** Holder is aware of the Company’s business affairs and financial condition and has received or has had full access to all the information it considers necessary or appropriate to make an informed investment decision with respect to the acquisition of this Warrant and its underlying securities. Holder further has had an opportunity to ask questions and receive answers from the Company regarding the terms and conditions of the offering of this Warrant and its underlying securities and to obtain additional information (to the extent the Company possessed such information or could acquire it without unreasonable effort or expense) necessary to verify any information furnished to Holder or to which Holder has access.

4.3 **Investment Experience.** Holder understands that the purchase of this Warrant and its underlying securities involves substantial risk. Holder has experience as an investor in securities of companies in the development stage and acknowledges that Holder can bear the economic risk of such Holder's investment in this Warrant and its underlying securities and has such knowledge and experience in financial or business matters that Holder is capable of evaluating the merits and risks of its investment in this Warrant and its underlying securities and/or has a preexisting personal or business relationship with the Company and certain of its officers, directors or controlling persons of a nature and duration that enables Holder to be aware of the character, business acumen and financial circumstances of such persons.

4.4 **Accredited Investor Status.** Holder is an “accredited investor” within the meaning of Regulation D promulgated under the Act.

4.5 **The Act.** Holder understands that this Warrant and the Shares issuable upon exercise hereof have not been registered under the Act in reliance upon a specific exemption therefrom, which exemption depends upon, among other things, the bona fide nature of the Holder’s investment intent as expressed herein. Holder understands that this Warrant and the Shares issued upon any exercise hereof must be held indefinitely unless subsequently registered under the Act and qualified under applicable state securities laws, or unless exemption from such registration and qualification are otherwise available. Holder understands that this Warrant and the Shares issuable upon exercise of this Warrant are “restricted securities” under the federal securities laws inasmuch as they are being acquired from the Company in a transaction not involving a public offering and that under such federal securities laws and applicable regulations such securities may be resold without registration under the Act only in certain limited circumstances and absent such circumstances Holder may be required to hold this Warrant and the Shares to be issued upon any exercise hereof indefinitely. Holder is aware of the provisions of Rule 144 promulgated under the Act.

4.6 **Market Stand-off Agreement.** The Holder agrees that the Shares (or, if the Shares are convertible into shares of common stock of the Company, such shares of common stock) shall be subject to the market stand-off provisions in Section 2.11 of the Amended and Restated Investors’ Rights Agreement, dated as of June 30, 2019, by and among the Company and the investors party thereto, as the same may be amended and/or restated from time to time (the “Investors’ Rights Agreement”), or a similar agreement.
4.7 **No Stockholder Rights.** Holder, as a Holder of this Warrant, will not have any voting rights, rights to receive dividends, rights to receive notice of meetings, subscription rights or any other stockholder rights until the exercise of this Warrant.

4.8 **Company Agreements.** If upon exercise or conversion of this Warrant (other than in connection with an Acquisition) Holder continues to hold the Shares, upon the request of the Company, Holder shall execute a counterpart signature page to the investor and stockholder agreements governing the obligations with respect to the shares of the Class.

SECTION 5. **MISCELLANEOUS.**

5.1 **Term; Automatic Cashless Exercise Upon Expiration.**

(a) **Term.** Subject to the provisions of Section 1.6 above, this Warrant is exercisable in whole or in part at any time and from time to time on or before 6:00 PM, Eastern time, on the Expiration Date and shall be void thereafter.

(b) **Automatic Cashless Exercise upon Expiration.** In the event that, upon the Expiration Date, the fair market value of one Share (or other security issuable upon the exercise hereof) as determined in accordance with Section 1.3 above is greater than the Warrant Price in effect on such date, then this Warrant shall automatically be deemed on and as of such date to be exercised pursuant to Section 1.2 above as to all Shares (or such other securities) for which it shall not previously have been exercised, and the Company shall, within a reasonable time, deliver a certificate representing the Shares (or such other securities) issued upon such exercise to Holder.

5.2 **Legends.** Each certificate evidencing Shares (and each certificate evidencing the securities issued upon conversion of any Shares, if any) shall be imprinted with a legend in substantially the following form:

THE SHARES EVIDENCED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE “ACT”), OR THE SECURITIES LAWS OF ANY STATE AND, EXCEPT AS SET FORTH IN THAT CERTAIN WARRANT TO PURCHASE STOCK ISSUED BY THE ISSUER TO OXFORD FINANCE LLC DATED JANUARY 24, 2020, MAY NOT BE OFFERED, SOLD, PLEDGED OR OTHERWISE TRANSFERRED UNLESS AND UNTIL REGISTERED UNDER SAID ACT AND LAWS OR, IN THE OPINION OF LEGAL COUNSEL IN FORM AND SUBSTANCE SATISFACTORY TO THE ISSUER, SUCH OFFER, SALE, PLEDGE OR OTHER TRANSFER IS EXEMPT FROM SUCH REGISTRATION.

5.3 **Compliance with Securities Laws on Transfer.** This Warrant and the Shares issued upon exercise of this Warrant (and the securities issuable, directly or indirectly, upon conversion of the Shares, if any) may not be transferred or assigned in whole or in part except in compliance with applicable federal and state securities laws by the transferor and the transferee (including, without limitation, the delivery of investment representation letters and legal opinions reasonably satisfactory to the Company, as reasonably requested by the Company) and in compliance with the terms of this Warrant. The Company shall not require Holder to provide an opinion of counsel if the transfer is to an affiliate of Holder; provided that any such transferee is an “accredited investor” as defined in Regulation D promulgated under the Act. Additionally, the Company shall also not require an opinion of counsel if there is no material question as to the availability of Rule 144 promulgated under the Act.

5.4 **Transfer Procedure.** After receipt by Oxford of the executed Warrant, Oxford may transfer all or part of this Warrant to one or more Oxford Affiliates, by execution of an Assignment substantially in the form of Appendix 2. Subject to the provisions of Section 5.3 and upon providing the Company with written notice, Oxford, any such Oxford Affiliate and any subsequent Holder, may transfer all or part of this Warrant or the
Shares issuable upon exercise of this Warrant (or the Shares issuable directly or indirectly, upon conversion of the Shares, if any) to any other transferee, provided, however, in connection with any such transfer, the Oxford Affiliate(s) or any subsequent Holder will give the Company notice of the portion of the Warrant being transferred with the name, address and taxpayer identification number of the transferee and Holder will surrender this Warrant to the Company for reissuance to the transferee(s) (and Holder if applicable). Notwithstanding any contrary provision herein, at all times prior to the IPO, Holder may not, without the Company’s prior written consent, transfer this Warrant or any portion hereof, or any Shares issued upon any exercise hereof, or any shares or other securities issued upon any conversion of any Shares issued upon any exercise hereof, to any person or entity who directly competes with the Company, except in connection with an Acquisition of the Company by such a direct competitor.

5.5 Notices. All notices and other communications hereunder from the Company to the Holder, or vice versa, shall be deemed delivered and effective (i) when given personally, (ii) on the third (3rd) Business Day after being mailed by first-class registered or certified mail, postage prepaid, (iii) upon actual receipt if given by facsimile or electronic mail and such receipt is confirmed in writing by the recipient, or (iv) on the first Business Day following delivery to a reliable overnight courier service, courier fee prepaid, in any case at such address as may have been furnished to the Company or Holder, as the case may be, in writing by the Company or such Holder from time to time in accordance with the provisions of this Section 5.5. All notices to Holder shall be addressed as follows until the Company receives notice of a change of address in connection with a transfer or otherwise:

Oxford Finance LLC
133 N. Fairfax Street
Alexandria, VA 22314
Attn: Legal Department

Notice to the Company shall be addressed as follows until Holder receives notice of a change in address:

PROMETHEUS BIOSCIENCES, INC.
9410 Carroll Park Drive
San Diego, CA 92121
Attn: Vika Brough, VP Finance

With a copy (which shall not constitute notice) to:

LATHAM & WATKINS LLP
12670 High Bluff Drive
San Diego, CA 92130
Attn: Cheston Larson

5.6 Waiver. This Warrant and any term hereof may be changed, waived, discharged or terminated (either generally or in a particular instance and either retroactively or prospectively) only by an instrument in writing signed by the party against which enforcement of such change, waiver, discharge or termination is sought.

5.7 Attorneys’ Fees. In the event of any dispute between the parties concerning the terms and provisions of this Warrant, the party prevailing in such dispute shall be entitled to collect from the other party all costs incurred in such dispute, including reasonable attorneys’ fees.

5.8 Counterparts; Facsimile/Electronic Signatures. This Warrant may be executed in counterparts, all of which together shall constitute one and the same agreement. Any signature page delivered electronically or by facsimile shall be binding to the same extent as an original signature page with regards to any agreement subject to the terms hereof or any amendment thereto.

5.9 Governing Law. This Warrant shall be governed by and construed in accordance with the laws of the State of California, without giving effect to its principles regarding conflicts of law.
5.10 **Headings.** The headings in this Warrant are for purposes of reference only and shall not limit or otherwise affect the meaning of any provision of this Warrant.

5.11 **Business Days.** "**Business Day**" is any day that is not a Saturday, Sunday or a day on which banks in California are closed.

[Remainder of page left blank intentionally]

[Signature page follows]

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IN WITNESS WHEREOF, the parties have caused this Warrant to Purchase Stock to be executed by their duly authorized representatives effective as of the Issue Date written above.

“COMPANY”

PROMETHEUS BIOSCIENCES, INC.

By: /s/ Mark McKenna

Name: Mark McKenna  
(Print)
Title: President and Chief Executive Officer

“HOLDER”

OXFORD FINANCE LLC

By: /s/ Colette H. Featherly

Name: Colette H. Featherly  
(Print)
Title: Senior Vice President
NOTICE OF EXERCISE

1. The undersigned Holder hereby exercises its right to purchase shares of the Common/Series Preferred [circle one] Stock of PROMETHEUS BIOSCIENCES, INC. (the "Company") in accordance with the attached Warrant To Purchase Stock, and tenders payment of the aggregate Warrant Price for such shares as follows:

☐ check in the amount of $ payable to order of the Company enclosed herewith
☐ Wire transfer of immediately available funds to the Company’s account
☐ Cashless Exercise pursuant to Section 1.2 of the Warrant
☐ Other [Describe]

2. Please issue a certificate or certificates representing the Shares in the name specified below:

_________________________
Holder’s Name

_________________________
(Address)

3. By its execution below and for the benefit of the Company, Holder hereby restates each of the representations and warranties in Section 4 of the Warrant to Purchase Stock as of the date hereof.

HOLDER:

_________________________
By:
Name:_____________________
Title:___________________
Date:____________________
APPENDIX 2

ASSIGNMENT

For value received, Oxford Finance LLC hereby sells, assigns and transfers unto

Name: [OXFORD TRANSFEREE]
Address: __________________________
Tax ID: __________________________

that certain Warrant to Purchase Stock issued by PROMETHEUS BIOSCIENCES, INC. (the “Company”), on January __, 2020 (the “Warrant”) together with all rights, title and interest therein.

OXFORD FINANCE LLC

By: ________________________________
Name: ______________________________
Title: ______________________________

Date: ________________________________

By its execution below, and for the benefit of the Company, [OXFORD TRANSFEREE] makes each of the representations and warranties set forth in Article 4 of the Warrant and agrees to all other provisions of the Warrant as of the date hereof.

[OXFORD TRANSFEREE]

By: ________________________________
Name: ______________________________
Title: ______________________________
1. **Purpose.**
   
The purpose of the Plan is to advance the interests of the Company’s stockholders by enhancing the Company’s ability to attract, retain and motivate persons who make (or are expected to make) important contributions to the Company by providing such persons with equity ownership opportunities and thereby better aligning the interests of such persons with those of the Company’s stockholders. Capitalized terms used in the Plan are defined in Section 11 below.

2. **Eligibility.**
   
   Service Providers are eligible to be granted Awards under the Plan, subject to the limitations described herein.

3. **Administration and Delegation.**
   
   (a) **Administration.** The Plan will be administered by the Administrator. The Administrator shall have authority to determine which Service Providers will receive Awards, to grant Awards and to set all terms and conditions of Awards (including, but not limited to, vesting, exercise and forfeiture provisions). In addition, the Administrator shall have the authority to take all actions and make all determinations contemplated by the Plan and to adopt, amend and repeal such administrative rules, guidelines and practices relating to the Plan as it shall deem advisable. The Administrator may correct any defect or ambiguity, supply any omission or reconcile any inconsistency in the Plan or any Award in the manner and to the extent it shall deem necessary or appropriate to carry the Plan and any Awards into effect, as determined by the Administrator. The Administrator shall make all determinations under the Plan in the Administrator’s sole discretion and all such determinations shall be final and binding on all persons having or claiming any interest in the Plan or in any Award.

   (b) **Appointment of Committees.** To the extent permitted by Applicable Laws, the Board may delegate any or all of its powers under the Plan to one or more Committees. The Board may abolish any Committee at any time and re-vest in itself any previously delegated authority.

4. **Stock Available for Awards.**
   
   (a) **Number of Shares.** Subject to adjustment under Section 8 hereof, Awards may be made under the Plan covering up to 4,000,000 shares of Common Stock. If any Award expires or lapses or is terminated, surrendered or canceled without having been fully exercised or is forfeited in whole or in part (including as the result of shares of Common Stock subject to such Award being repurchased by the Company at or below the original issuance price), in any case in a manner that results in any shares of Common Stock covered by such Award not being issued or being so reacquired by the Company, the unused Common Stock covered by such Award shall again be available for the grant of Awards under the Plan. Further, shares of Common Stock delivered (either by actual delivery or attestation) to the Company by a Participant to satisfy the applicable exercise or purchase price of Award and/or to satisfy any applicable tax withholding obligation (including shares retained by the Company from the Award being exercised or purchased and/or creating the tax obligation) shall be added to the number of shares of Common Stock available for the grant of Awards under the Plan. However, in the case of Incentive Stock Options (as hereinafter defined), the foregoing provisions shall be subject to any limitations under the Code. Shares of Common Stock issued under the Plan may consist in whole or in part of authorized but unissued shares, shares purchased on the open market or treasury shares.
5. **Stock Options.**

(a) **General.** The Administrator may grant Options to any Service Provider, subject to the limitations on Incentive Stock Options described below. The Administrator shall determine the number of shares of Common Stock to be covered by each Option, the exercise price of each Option and the conditions and limitations applicable to the exercise of each Option, including conditions relating to Applicable Laws, as it considers necessary or advisable.

(b) **Incentive Stock Options.** The Administrator may grant Options intended to qualify as Incentive Stock Options only to employees of the Company, any of the Company’s present or future “parent corporations” or “subsidiary corporations” as defined in Sections 424(e) or (f) of the Code, respectively, and any other entities the employees of which are eligible to receive Incentive Stock Options under the Code. All Options intended to qualify as Incentive Stock Options shall be subject to and shall be construed consistently with the requirements of Section 422 of the Code. Neither the Company nor the Administrator shall have any liability to a Participant, or any other party, (i) if an Option (or any part thereof) which is intended to qualify as an Incentive Stock Option fails to qualify as an Incentive Stock Option or (ii) for any action or omission by the Administrator that causes an Option not to qualify as an Incentive Stock Option, including without limitation, the conversion of an Incentive Stock Option to a Non-Qualified Stock Option or the grant of an Option intended as an Incentive Stock Option that fails to satisfy the requirements under the Code applicable to an Incentive Stock Option. Any Option that is intended to qualify as an Incentive Stock Option, but fails to so qualify for any reason, including without limitation, the portion of any Option becoming exercisable in excess of the $100,000 limitation described in Treasury Regulation Section 1.422-4, shall be treated as a Non-Qualified Stock Option for all purposes.

(c) **Exercise Price.** The Administrator shall establish the exercise price of each Option and specify the exercise price in the applicable Award Agreement. The exercise price shall be not less than 100% of the Fair Market Value on the date the Option is granted. In the case of an Incentive Stock Option granted to an employee who, at the time of grant of the Option, owns (or is treated as owning under Section 424 of the Code) stock representing more than 10% of the voting power of all classes of stock of the Company (or a “parent corporation” or “subsidiary corporation” thereof within the meaning of Sections 424(e) or 424(f) of the Code, respectively), the per share exercise price shall be no less than 110% of the Fair Market Value on the date the Option is granted.

(d) **Duration of Options.** Each Option shall be exercisable at such times and subject to such terms and conditions as the Administrator may specify in the applicable Award Agreement, provided that the term of any Option shall not exceed ten years. In the case of an Incentive Stock Option granted to an employee who, at the time of grant of the Option, owns (or is treated as owning under Section 424 of the Code) stock representing more than 10% of the voting power of all classes of stock of the Company (or a “parent corporation” or “subsidiary corporation” thereof within the meaning of Sections 424(e) or 424(f) of the Code, respectively), the term of the Option shall not exceed five years.
(e) Exercise of Option; Notification of Disposition. Options may be exercised by delivery to the Company of a written notice of exercise, in a form approved by the Administrator (which may be an electronic form), signed by the person authorized to exercise the Option, together with payment in full (i) as specified in Section 5(f) hereof for the number of shares for which the Option is exercised and (ii) as specified in Section 9(e) hereof for any applicable withholding taxes. Unless otherwise determined by the Administrator, an Option may not be exercised for a fraction of a share of Common Stock. If an Option is designated as an Incentive Stock Option, the Participant shall give prompt notice to the Company of any disposition or other transfer of any shares of Common Stock acquired from the Option if such disposition or transfer is made (i) within two years from the grant date with respect to such Option or (ii) within one year after the transfer of such shares to the Participant (other than any such disposition made in connection with a Change in Control). Such notice shall specify the date of such disposition or other transfer and the amount realized, in cash, other property, assumption of indebtedness or other consideration, by the Participant in such disposition or other transfer.

(f) Payment Upon Exercise. Common Stock purchased upon the exercise of an Option granted under the Plan shall be paid for in cash or by check, payable to the order of the Company, or, to the extent permitted by the Administrator, by:

(i) (A) delivery of an irrevocable and unconditional undertaking by a broker acceptable to the Company to deliver promptly to the Company sufficient funds to pay the exercise price and any required tax withholding, or (B) delivery by the Participant to the Company of a copy of irrevocable and unconditional instructions to a broker acceptable to the Company to deliver promptly to the Company cash or a check sufficient to pay the exercise price and any required tax withholding;

(ii) delivery (either by actual delivery or attestation) of shares of Common Stock owned by the Participant valued at their Fair Market Value, provided (A) such method of payment is then permitted under Applicable Laws, (B) such Common Stock, if acquired directly from the Company, was owned by the Participant for such minimum period of time, if any, as may be established by the Company at any time, and (C) such Common Stock is not subject to any repurchase, forfeiture, unfulfilled vesting or other similar requirements;

(iii) surrendering shares of Common Stock then issuable upon exercise of the Option valued at their Fair Market Value on the date of exercise;

(iv) delivery of a promissory note of the Participant to the Company on terms determined by the Administrator;

(v) delivery of property of any other kind which constitutes good and valuable consideration as determined by the Administrator; or

(vi) any combination of the above permitted forms of payment (including cash or check).

(g) Early Exercise of Options. The Administrator may provide in the terms of an Award Agreement that the Service Provider may exercise an Option in whole or in part prior to the full vesting of the Option in exchange for unvested shares of Restricted Stock with respect to any unvested portion of the Option so exercised. Shares of Restricted Stock acquired upon the exercise of any unvested portion of an Option shall be subject to such terms and conditions as the Administrator shall determine.
6. **Restricted Stock; Restricted Stock Units.**

(a) **General.** The Administrator may grant Restricted Stock, or the right to purchase Restricted Stock, to any Service Provider, subject to the right of the Company to repurchase all or part of such shares at their issue price or other stated or formula price from the Participant (or to require forfeiture of such shares if issued at no cost) in the event that conditions specified by the Administrator in the applicable Award Agreement are not satisfied prior to the end of the applicable restriction period or periods established by the Administrator for such Award. In addition, the Administrator may grant to Service Providers Restricted Stock Units, which may be subject to vesting and forfeiture conditions during applicable restriction period or periods, as set forth in an applicable Award Agreement.

(b) **Terms and Conditions for All Restricted Stock and Restricted Stock Unit Awards.** The Administrator shall determine and set forth in the applicable Award Agreement the terms and conditions applicable to each Restricted Stock and Restricted Stock Unit Award, including the conditions for vesting and repurchase (or forfeiture) and the issue price, in each case, if any.

(c) **Additional Provisions Relating to Restricted Stock.**

(i) **Dividends.** Participants holding shares of Restricted Stock will be entitled to all ordinary cash dividends paid with respect to such shares, unless otherwise provided by the Administrator in the applicable Award Agreement. In addition, unless otherwise provided by the Administrator, any dividends or distributions paid in shares, or consisting of a dividend or distribution to holders of Common Stock of property other than an ordinary cash dividend, the shares or other property will be subject to the same restrictions on transferability and forfeitability as the shares of Restricted Stock with respect to which they were paid. Each dividend payment will be made as provided in the applicable Award Agreement, but in no event later than the end of the calendar year in which the dividends are paid to stockholders of that class of stock or, if later, the 15th day of the third month following the later of (A) the date the dividends are paid to stockholders of that class of stock, and (B) the date the dividends are no longer subject to forfeiture.

(ii) **Stock Certificates.** The Company may require that any stock certificates issued in respect of shares of Restricted Stock be deposited in escrow by the Participant, together with a stock power endorsed in blank, with the Company (or its designee).

(d) **Additional Provisions Relating to Restricted Stock Units.**

(i) **Settlement.** Upon the vesting of a Restricted Stock Unit, the Participant shall be entitled to receive from the Company one share of Common Stock or an amount of cash or other property equal to the Fair Market Value of one share of Common Stock on the settlement date, as provided in the applicable Award Agreement. The Administrator may provide that settlement of Restricted Stock Units shall occur upon or as soon as reasonably practicable after the vesting of the Restricted Stock Units or shall instead be deferred, on a mandatory basis or at the election of the Participant, in a manner that complies with Section 409A.

(ii) **Voting Rights.** A Participant shall have no voting rights with respect to any Restricted Stock Units unless and until shares are delivered in settlement thereof.

(iii) **Dividend Equivalents.** To the extent provided by the Administrator, a grant of Restricted Stock Units may provide a Participant with the right to receive Dividend Equivalents. Dividend Equivalents may be paid currently or credited to an account for the Participant, may be settled in cash and/or shares of Common Stock and may be subject to the same restrictions on transfer and forfeitability as the Restricted Stock Units with respect to which the Dividend Equivalents are paid, as determined by the Administrator, subject, in each case, to such terms and conditions as the Administrator shall establish and set forth in the applicable Award Agreement.
7. **Other Stock-Based Awards.**

Other Stock-Based Awards may be granted hereunder to Participants, including, without limitation, Awards entitling Participants to receive shares of Common Stock to be delivered in the future. Such Other Stock-Based Awards shall also be available as a form of payment in the settlement of other Awards granted under the Plan, as stand-alone payments and/or as payment in lieu of compensation to which a Participant is otherwise entitled. Other Stock-Based Awards may be paid in shares of Common Stock, cash or other property, as the Administrator shall determine. Subject to the provisions of the Plan, the Administrator shall determine the terms and conditions of each Other Stock-Based Award, including any purchase price, transfer restrictions, vesting conditions and other terms and conditions applicable thereto, which shall be set forth in the applicable Award Agreement.

8. **Adjustments for Changes in Common Stock and Certain Other Events.**

(a) In the event that the Administrator determines that any dividend or other distribution (whether in the form of cash, Common Stock, other securities, or other property), reorganization, merger, consolidation, combination, repurchase, recapitalization, liquidation, dissolution, or sale, transfer, exchange or other disposition of all or substantially all of the assets of the Company, or exchange of Common Stock or other securities of the Company, issuance of warrants or other rights to purchase Common Stock or other securities of the Company, or other similar corporate transaction or event, as determined by the Administrator, affects the Common Stock such that an adjustment is determined by the Administrator to be appropriate in order to prevent dilution or enlargement of the benefits or potential benefits intended by the Company to be made available under the Plan or with respect to any Award, then the Administrator may, in such manner as it may deem equitable, adjust any or all of:

(i) the number and kind of shares of Common Stock (or other securities or property) with respect to which Awards may be granted or awarded (including, but not limited to, adjustments of the limitations in Section 3 hereof on the maximum number and kind of shares which may be issued);

(ii) the number and kind of shares of Common Stock (or other securities or property) subject to outstanding Awards;

(iii) the grant or exercise price with respect to any Award; and

(iv) the terms and conditions of any Awards (including, without limitation, any applicable financial or other performance “targets” specified in an Award Agreement).

(b) In the event of any transaction or event described in Section 8(a) hereof (including without limitation any Change in Control) or any unusual or nonrecurring transaction or event affecting the Company or the financial statements of the Company, or any change in any Applicable Laws or accounting principles, the Administrator, on such terms and conditions as it deems appropriate, either by the terms of the Award or by action taken prior to the occurrence of such transaction or event and either automatically or upon the Participant’s request, is hereby authorized to take any one or more of the following actions whenever the Administrator determines that such action is appropriate in order to (i) prevent dilution or enlargement of the benefits or potential benefits intended by the Company to be made available under the Plan or with respect to any Award, then the Administrator may, in such manner as it may deem equitable, adjust any or all of:

(i) the number and kind of shares of Common Stock (or other securities or property) with respect to which Awards may be granted or awarded (including, but not limited to, adjustments of the limitations in Section 3 hereof on the maximum number and kind of shares which may be issued);

(ii) the number and kind of shares of Common Stock (or other securities or property) subject to outstanding Awards;

(iii) the grant or exercise price with respect to any Award; and

(iv) the terms and conditions of any Awards (including, without limitation, any applicable financial or other performance “targets” specified in an Award Agreement).
Plan or with respect to any Award granted or issued under the Plan, (ii) to facilitate such transaction or event or (iii) give effect to such changes in Applicable Laws or accounting principles:

(i) To provide for the cancellation of any such Award in exchange for either an amount of cash or other property with a value equal to the amount that could have been obtained upon the exercise or settlement of such Award or realization of the Participant’s rights had such Award been currently exercisable, payable and fully vested, as applicable; provided that, if the amount that could have been obtained upon the exercise or settlement of such Award or realization of the Participant’s rights, in any case, is equal to or less than zero, then such Award may be terminated without payment;

(ii) To provide that such Award shall vest and, to the extent applicable, be exercisable as to all shares covered thereby, notwithstanding anything to the contrary in the Plan or the provisions of such Award;

(iii) To provide that such Award be assumed by the successor or survivor corporation, or a parent or subsidiary thereof, or shall be substituted for by awards covering the stock of the successor or survivor corporation, or a parent or subsidiary thereof, with appropriate adjustments as to the number and kind of shares and applicable exercise or purchase price, in all cases, as determined by the Administrator;

(iv) To make adjustments in the number and type of shares of Common Stock (or other securities or property) subject to outstanding Awards, and/or in the terms and conditions of (including the grant or exercise price), and the criteria included in, outstanding Awards which may be granted in the future;

(v) To replace such Award with other rights or property selected by the Administrator; and/or

(vi) To provide that the Award will terminate and cannot vest, be exercised or become payable after the applicable event.

(c) Notwithstanding the provisions of Section 8(b) above, if a Change in Control occurs and a Participant's Awards are not continued, converted, assumed, or replaced with a substantially similar award by (i) the Company, or (ii) a successor entity or its parent or subsidiary (an "Assumption"), and provided that the Participant has not had a Termination of Service, then the Administrator may provide that, immediately prior to the Change in Control, such Awards shall become fully vested, exercisable and/or payable, as applicable, and all forfeiture, repurchase and other restrictions on such Awards shall lapse, in which case, such Awards shall be canceled upon the consummation of the Change in Control in exchange for the right to receive the Change in Control consideration payable to other holders of Common Stock (A) which may be on such terms and conditions as apply generally to holders of Common Stock under the Change in Control documents (including, without limitation, any escrow, earn-out or other deferred consideration provisions) or such other terms and conditions as the Administrator may provide, and (B) determined by reference to the number of shares subject to such Awards and net of any applicable exercise price; provided that to the extent that any Awards constitute “nonqualified deferred compensation” that may not be paid upon the Change in Control under Section 409A without the imposition of taxes thereon under Section 409A, the timing of such payments shall be governed by the applicable Award Agreement (subject to any deferred consideration provisions applicable under the Change in Control documents); and provided, further, that if the amount to which a Participant would be entitled upon the settlement or exercise of such Award at the time of the Change in Control is equal to or less than zero, then such Award may be terminated without payment. The Administrator shall determine whether an Assumption of an Award has occurred in connection with a Change in Control.

(d) In connection with the occurrence of any Equity Restructuring, and notwithstanding anything to the contrary in this Section 8, the Administrator will equitably adjust each
outstanding Award, which adjustments may include adjustments to the number and type of securities subject to each outstanding Award and/or the exercise price or grant price thereof, if applicable, the grant of new Awards to Participants, and/or the making of a cash payment to Participants, as the Administrator deems appropriate to reflect such Equity Restructuring. The adjustments provided under this Section 8(e) shall be nondiscretionary and shall be final and binding on the affected Participant and the Company; provided that whether an adjustment is equitable shall be determined by the Administrator.

(e) In the event of any pending stock dividend, stock split, combination or exchange of shares, merger, consolidation or other distribution (other than normal cash dividends) of Company assets to stockholders, or any other change affecting the shares of Common Stock or the share price of the Common Stock, including any Equity Restructuring, or if necessary to comply with Applicable Laws or the Code, or for reasons of administrative convenience, the Administrator may, in its sole discretion, refuse to permit the exercise of any Award during a period of up to thirty days prior to the consummation of any such transaction; provided, however, that in the event the vested portion of an Award is not exercisable on the date the Award would otherwise expire pursuant to the terms set forth in the Award Agreement governing such Award as a result of the Administrator’s exercise of discretion pursuant to this Section 8(e), then the expiration of the Award shall be extended through the date that is thirty days following the date on which the Administrator first permits the Award to be exercised (but in no event shall the expiration of the Award be extended beyond the tenth anniversary of the date of grant of such Award).

(f) Except as expressly provided in the Plan or pursuant to action of the Administrator under the Plan, no Participant shall have any rights by reason of any subdivision or consolidation of shares of stock of any class, the payment of any dividend, any increase or decrease in the number of shares of stock of any class or any dissolution, liquidation, merger, or consolidation of the Company or any other corporation. Except as expressly provided in the Plan or pursuant to action of the Administrator under the Plan, no issuance by the Company of shares of stock of any class, or securities convertible into shares of stock of any class, shall affect, and no adjustment by reason thereof shall be made with respect to, the number of shares of Common Stock subject to an Award or the grant or exercise price of any Award. The existence of the Plan, any Award Agreements and the Awards granted hereunder shall not affect or restrict in any way the right or power of the Company to make or authorize (i) any adjustment, recapitalization, reorganization or other change in the Company’s capital structure or its business, (ii) any merger, consolidation dissolution or liquidation of the Company or sale of Company assets or (iii) any sale or issuance of securities, including without limitation, securities with rights superior to those of the Common Stock or which are convertible into or exchangeable for Common Stock. The Administrator may treat Participants and Awards (or portions thereof) differently under this Section 8.


(a) Transferability of Awards. Except as the Administrator may otherwise determine or provide in an Award Agreement or otherwise, in any case in accordance with Applicable Laws, Awards shall not be sold, assigned, transferred, pledged or otherwise encumbered by the person to whom they are granted, either voluntarily or by operation of law, except by will or the laws of descent and distribution, and, during the life of the Participant, shall be exercisable only by the Participant. References to a Participant, to the extent relevant in the context, shall include references to authorized transferees.

(b) Documentation. Each Award shall be evidenced in an Award Agreement, which may be in such form (written, electronic or otherwise) as the Administrator shall determine. Each Award may contain terms and conditions in addition to those set forth in the Plan.

(c) Discretion. Except as otherwise provided by the Plan, each Award may be made alone or in addition or in relation to any other Award. The terms of each Award to a Participant need not be identical, and the Administrator need not treat Participants or Awards (or portions thereof) uniformly.
(d) **Termination of Status.** The Administrator shall determine the effect on an Award of the disability, death, retirement, authorized leave of absence or any other change or purported change in a Participant’s Service Provider status and the extent to which, and the period during which, the Participant, the Participant’s legal representative, conservator, guardian or Designated Beneficiary may exercise rights under the Award, if applicable.

(e) **Withholding.** Each Participant shall pay to the Company, or make provision satisfactory to the Administrator for payment of, any taxes required by law to be withheld in connection with Awards to such Participant no later than the date of the event creating the tax liability. Except as the Administrator may otherwise determine, all such payments shall be made in cash or by certified check. Notwithstanding the foregoing, to the extent permitted by the Administrator, Participants may satisfy such tax obligations in whole or in part by delivery of shares of Common Stock, including shares retained from the Award creating the tax obligation, valued at their Fair Market Value. The Company may, to the extent permitted by Applicable Laws, deduct any such tax obligations from any payment of any kind otherwise due to a Participant.

(f) **Amendment of Award.** The Administrator may amend, modify or terminate any outstanding Award, including but not limited to, substituting therefor another Award of the same or a different type, changing the date of exercise or settlement, and converting an Incentive Stock Option to a Non-Qualified Stock Option. The Participant’s consent to such action shall be required unless (i) the Administrator determines that the action, taking into account any related action, would not materially and adversely affect the Participant, or (ii) the change is permitted under Section 8 and 10(f) hereof.

(g) **Conditions on Delivery of Stock.** The Company will not be obligated to deliver any shares of Common Stock pursuant to the Plan or to remove restrictions from shares previously delivered under the Plan until (i) all conditions of the Award have been met or removed to the satisfaction of the Company, (ii) in the opinion of the Company’s counsel, all other legal matters in connection with the issuance and delivery of such shares have been satisfied, including any applicable securities laws and any applicable stock exchange or stock market rules and regulations, and (iii) the Participant has executed and delivered to the Company such representations or agreements as the Administrator deems necessary or appropriate to satisfy the requirements of any Applicable Laws. The inability of the Company to obtain authority from any regulatory body having jurisdiction, which authority is determined by the Administrator to be necessary to the lawful issuance and sale of any securities hereunder, shall relieve the Company of any liability in respect of the failure to issue or sell such shares as to which such requisite authority shall not have been obtained.

(h) **Acceleration.** The Administrator may at any time provide that any Award shall become immediately vested and/or exercisable in full or in part, free of some or all restrictions or conditions, or otherwise realizable in full or in part, as the case may be.
10. Miscellaneous.

(a) **No Right To Employment or Other Status.** No person shall have any claim or right to be granted an Award, and the grant of an Award shall not be construed as giving a Participant the right to continued employment or any other relationship with the Company. The Company expressly reserves the right at any time to dismiss or otherwise terminate its relationship with a Participant free from any liability or claim under the Plan or any Award, except as expressly provided in an applicable Award Agreement.

(b) **No Rights As Stockholder; Certificates.** Subject to the provisions of the applicable Award Agreement, no Participant or Designated Beneficiary shall have any rights as a stockholder with respect to any shares of Common Stock to be distributed with respect to an Award until becoming the record holder of such shares. Notwithstanding any other provision of the Plan, unless otherwise determined by the Administrator or required by any Applicable Laws, the Company shall not be required to deliver to any Participant certificates evidencing shares of Common Stock issued in connection with any Award and instead such shares of Common Stock may be recorded in the books of the Company (or, as applicable, its transfer agent or stock plan administrator). The Company may place legends on stock certificates issued under the Plan deemed necessary or appropriate by the Administrator in order to comply with Applicable Laws.

(c) **Effective Date and Term of Plan.** The Plan shall become effective on the date on which it is adopted by the Board. No Awards shall be granted under the Plan after the completion of ten years from the earlier of (i) the date on which the Plan was adopted by the Board or (ii) the date the Plan was approved by the Company’s stockholders, but Awards previously granted may extend beyond that date in accordance with the terms of the Plan.

(d) **Amendment of Plan.** The Administrator may amend, suspend or terminate the Plan or any portion thereof at any time; provided that no amendment of the Plan shall materially and adversely affect any Award outstanding at the time of such amendment without the consent of the affected Participant. Awards outstanding under the Plan at the time of any suspension or termination of the Plan shall continue to be governed in accordance with the terms of the Plan and the applicable Award Agreement, as in effect prior to such suspension or termination. The Board shall obtain stockholder approval of any Plan amendment to the extent necessary to comply with Applicable Laws.

(e) **Provisions for Foreign Participants.** The Administrator may modify Awards granted to Participants who are foreign nationals or employed outside the United States or establish subplans or procedures under the Plan to address differences in laws, rules, regulations or customs of such foreign jurisdictions with respect to tax, securities, currency, employee benefit or other matters.

(f) **Section 409A.**

(i) **General.** The Company intends that all Awards be structured in compliance with, or to satisfy an exemption from, Section 409A, such that no adverse tax consequences, interest, or penalties under Section 409A apply in connection with any Awards. Notwithstanding anything herein or in any Award Agreement to the contrary, the Administrator may, without a Participant’s prior consent, amend this Plan and/or Awards, adopt policies and procedures, or take any other actions (including amendments, policies, procedures and actions with retroactive effect) as are necessary or appropriate to preserve the intended tax treatment of Awards under the Plan, including without limitation, any such actions intended to (A) exempt this Plan and/or any Award from the application of Section 409A, and/or (B) comply with the requirements of Section 409A, including without limitation any such regulations, guidance, compliance programs and other interpretative authority that may be issued after the date of grant of any Award.
The Company makes no representations or warranties as to the tax treatment of any Award under Section 409A or otherwise. The Company shall have no obligation under this Section 10(f) or otherwise to take any action (whether or not described herein) to avoid the imposition of taxes, penalties or interest under Section 409A with respect to any Award and shall have no liability to any Participant or any other person if any Award, compensation or other benefits under the Plan are determined to constitute non-compliant, “nonqualified deferred compensation” subject to the imposition of taxes, penalties and/or interest under Section 409A.

(ii) Separation from Service. With respect to any Award that constitutes “nonqualified deferred compensation” under Section 409A, any payment or settlement of such Award that is to be made upon a termination of a Participant’s Service Provider relationship shall, to the extent necessary to avoid the imposition of taxes under Section 409A, be made only upon the Participant’s “separation from service” (within the meaning of Section 409A), whether such “separation from service” occurs upon or subsequent to the termination of the Participant’s Service Provider relationship. For purposes of any such provision of this Plan or any Award Agreement relating to any such payments or benefits, references to a “termination,” “termination of employment” or like terms shall mean “separation from service.”

(iii) Payments to Specified Employees. Notwithstanding any contrary provision in the Plan or any Award Agreement, any payment(s) of “nonqualified deferred compensation” that are otherwise required to be made under an Award to a “specified employee” (as defined under Section 409A and determined by the Administrator) as a result of his or her “separation from service” shall, to the extent necessary to avoid the imposition of taxes under Code Section 409A(a)(2)(B)(i), be delayed until the expiration of the six-month period immediately following such “separation from service” (or, if earlier, until the date of death of the specified employee) and shall instead be paid (in a manner set forth in the Award agreement) on the day that immediately follows the end of such six-month period or as soon as administratively practicable thereafter (without interest). Any payments of “nonqualified deferred compensation” under such Award that are, by their terms, payable more than six months following the Participant’s “separation from service” shall be paid at the time or times such payments are otherwise scheduled to be made.

(g) Limitations on Liability. Notwithstanding any other provisions of the Plan, no individual acting as a director, officer, other employee or agent of the Company will be liable to any Participant, former Participant, spouse, beneficiary, or any other person for any claim, loss, liability, or expense incurred in connection with the Plan or any Award, nor will such individual be personally liable with respect to the Plan because of any contract or other instrument he or she executes in his or her capacity as an Administrator, director, officer, other employee or agent of the Company. The Company will indemnify and hold harmless each director, officer, other employee and agent of the Company to whom any duty or power relating to the administration or interpretation of the Plan has been or will be granted or delegated, against any cost or expense (including attorneys’ fees) or liability (including any sum paid in settlement of a claim with the Administrator’s approval) arising out of any act or omission to act concerning this Plan unless arising out of such person’s own fraud or bad faith.

(h) Lock-Up Period. The Company may, at the request of any representative of the underwriters (the “Managing Underwriter”) or otherwise, in connection with any registration of the offering of any securities of the Company under the Securities Act, prohibit Participants from, directly or indirectly, selling or otherwise transferring any shares of Common Stock or other securities of the Company during a period of up to one hundred eighty days following the effective date of a registration statement of the Company filed under the Securities Act.
(i) **Right of First Refusal.**

Before any shares of Common Stock held by a Participant or any permitted transferee (each, a “**Holder**”) may be sold, pledged, assigned, hypothecated, transferred, or otherwise disposed of (each, a “**Transfer**”), the Company or its assignee(s) shall have a right of first refusal to purchase the shares of Common Stock proposed to be Transferred on the terms and conditions set forth in this Section 10(i) (the “**Right of First Refusal**”). In the event that the Company’s charter, bylaws and/or a stockholders’ agreement applicable to the shares of Common Stock contain a right of first refusal with respect to the shares of Common Stock, such right of first refusal shall apply to the shares of Common Stock to the extent such provisions are more restrictive than the Right of First Refusal set forth in this Section 10(i) and the Right of First Refusal set forth in this Section 10(i) shall not in any way restrict the operation of the Company’s charter, bylaws or the operation of any applicable stockholders’ agreement.

(ii) In the event any Holder desires to Transfer any shares of Common Stock, the Holder shall deliver to the Company a written notice (the “**Notice**”) stating: (A) the Holder’s bona fide intention to sell or otherwise Transfer such shares of Common Stock; (B) the name of each proposed purchaser or other transferee (“**Proposed Transferee**”); (C) the number of shares of Common Stock to be Transferred to each Proposed Transferee; and (D) the price for which the Holder proposes to Transfer the shares of Common Stock (the “**Offered Price**”), and the Holder shall offer such shares of Common Stock at the Offered Price to the Company or its assignee(s).

(iii) Within twenty-five days after receipt of the Notice, the Company and/or its assignee(s) may elect in writing to purchase all, but not less than all, of the shares of Common Stock proposed to be Transferred to any one or more of the Proposed Transferees by delivery of a written exercise notice to the Holder (a “**Company Notice**”). The purchase price (“**Purchase Price**”) for the shares of Common Stock repurchased under this Section 10(i) shall be the Offered Price.

(iv) Payment of the Purchase Price shall be made, at the option of the Company or its assignee(s), in cash (by check or wire transfer), by cancellation of all or a portion of any outstanding indebtedness of the Holder to the Company (or, in the case of repurchase by an assignee, to the assignee), or by any combination thereof, within five days after delivery of the Company Notice or in the manner and at the times mutually agreed to by the Company and the Holder. Should the Offered Price specified in the Notice be payable in property other than cash, the Company or its assignee shall have the right to pay the purchase price in the form of cash equal in amount to the value of such property, as determined by the Administrator.

(v) If all or a portion of the shares of Common Stock proposed in the Notice to be Transferred are not purchased by the Company and/or its assignee(s) as provided in this Section 10(i), then the Holder may sell or otherwise Transfer such shares of Common Stock to that Proposed Transferee at the Offered Price or at a higher price; provided that such sale or other Transfer is consummated within sixty days after the date of the Notice; and provided, further, that any such sale or other Transfer is effected in accordance with any Applicable Laws and the Proposed Transferee agrees in writing that the provisions of this Plan and the applicable Award Agreement and any other applicable agreements governing the shares of Common Stock to be Transferred shall continue to apply to the shares of Common Stock in the hands of such Proposed Transferee. If the shares of Common Stock described in the Notice are not Transferred to the Proposed Transferee within such sixty-day period, a new Notice shall be given to the Company, and the Company and/or its assignees shall again be offered the Right of First Refusal, as provided herein, before any shares of Common Stock held by the Holder may be sold or otherwise Transferred.
(vi) Anything to the contrary contained in this Section 10(i) notwithstanding and to the extent permitted by the Administrator, the Transfer of any or all of the shares of Common Stock during a Participant’s lifetime or upon a Participant’s death by will or intestacy to the Participant’s Immediate Family or a trust for the benefit of the Participant’s Immediate Family shall be exempt from the Right of First Refusal. As used herein, “Immediate Family” shall mean spouse, lineal descendant or antecedent, father, mother, brother or sister or stepchild (whether or not adopted). In such case, the transferee or other recipient shall receive and hold the shares of Common Stock so Transferred subject to the provisions of this Plan (including the Right of First Refusal), the applicable Award Agreement and any other applicable agreements governing the shares of Common Stock to be Transferred, and there shall be no further Transfer of such shares of Common Stock except in accordance with the terms of this Section 10(i) (or otherwise as expressly provided under the Plan).

(vii) The Right of First Refusal shall terminate as to all shares of Common Stock if the Company becomes a Publicly Listed Company upon such occurrence.

(j) Data Privacy. As a condition of receipt of any Award, each Participant explicitly and unambiguously consents to the collection, use and transfer, in electronic or other form, of personal data as described in this paragraph by and among, as applicable, the Company and its subsidiaries and affiliates for the exclusive purpose of implementing, administering and managing the Participant’s participation in the Plan. The Company and its subsidiaries and affiliates may hold certain personal information about a Participant, including but not limited to, the Participant’s name, home address and telephone number, date of birth, social security or insurance number or other identification number, salary, nationality, job title(s), any shares of stock held in the Company or any of its subsidiaries and affiliates, details of all Awards, in each case, for the purpose of implementing, managing and administering the Plan and Awards (the “Data”). The Company and its subsidiaries and affiliates may transfer the Data amongst themselves as necessary for the purpose of implementation, administration and management of a Participant’s participation in the Plan, and the Company and its subsidiaries and affiliates may each further transfer the Data to any third parties assisting the Company in the implementation, administration and management of the Plan. These recipients may be located in the Participant’s country, or elsewhere, and the Participant’s country may have different data privacy laws and protections than the recipients’ country. Through acceptance of an Award, each Participant authorizes such recipients to receive, possess, use, retain and transfer the Data, in electronic or other form, for the purposes of implementing, administering and managing the Participant’s participation in the Plan, including any requisite transfer of such Data as may be required to a broker or other third party with whom the Company or the Participant may elect to deposit any shares of Common Stock. The Data related to a Participant will be held only as long as is necessary to implement, administer, and manage the Participant’s participation in the Plan. A Participant may, at any time, view the Data held by the Company with respect to such Participant, request additional information about the storage and processing of the Data with respect to such Participant, recommend any necessary corrections to the Data with respect to the Participant or refuse or withdraw the consents herein in writing, in any case without cost, by contacting his or her local human resources representative. The Company may cancel Participant’s ability to participate in the Plan and, in the Administrator’s discretion, the Participant may forfeit any outstanding Awards if the Participant refuses or withdraws his or her consents as described herein. For more information on the consequences of refusal to consent or withdrawal of consent, Participants may contact their local human resources representative.

(k) Severability. In the event any portion of the Plan or any action taken pursuant thereto shall be held illegal or invalid for any reason, the illegality or invalidity shall not affect the remaining parts of the Plan, and the Plan shall be construed and enforced as if the illegal or invalid provisions had not been included, and the illegal or invalid action shall be null and void.
Governing Documents. In the event of any contradiction between the Plan and any Award Agreement or any other written agreement between a Participant and the Company or any Subsidiary of the Company that has been approved by the Administrator, the terms of the Plan shall govern, unless it is expressly specified in such Award Agreement or other written document that a specific provision of the Plan shall not apply.

Governing Law. The provisions of the Plan and all Awards made hereunder shall be governed by and interpreted in accordance with the laws of the State of Delaware, disregarding choice-of-law principles of the law of any state that would require the application of the laws of a jurisdiction other than such state.

Restrictions on Shares; Claw-Back Provisions. Shares of Common Stock acquired in respect of Awards shall be subject to such terms and conditions as the Administrator shall determine, including, without limitation, restrictions on the transferability of shares of Common Stock, the right of the Company to repurchase shares of Common Stock, the right of the Company to require that shares of Common Stock be transferred in the event of certain transactions, tag-along rights, bring-along rights, redemption and co-sale rights and voting requirements. Such terms and conditions may be additional to those contained in the Plan and may, as determined by the Administrator, be contained in the applicable Award Agreement or in an exercise notice, stockholders’ agreement or in such other agreement as the Administrator shall determine, in each case in a form determined by the Administrator. The issuance of such shares of Common Stock shall be conditioned on the Participant’s consent to such terms and conditions and the Participant’s entering into such agreement or agreements. All Awards (including any proceeds, gains or other economic benefit actually or constructively received by Participant upon any receipt or exercise of any Award or upon the receipt or resale of any shares of Common Stock underlying the Award) shall be subject to the provisions of any claw-back policy implemented by the Company, including, without limitation, any claw-back policy adopted to comply with the requirements of the Dodd-Frank Wall Street Reform and Consumer Protection Act and any rules or regulations promulgated thereunder, to the extent set forth in such claw-back policy and/or in the applicable Award Agreement. Notwithstanding the foregoing, it shall be a condition to the issuance of any shares of Common Stock pursuant to an Award under this Plan that the Participant shall agree in writing to be bound by the terms and conditions of, and become a party to, any stockholders’ agreement of the Company.

Titles and Headings. The titles and headings of the Sections in the Plan are for convenience of reference only and, in the event of any conflict, the text of the Plan, rather than such titles or headings, shall control.

Conformity to Securities Laws. Participant acknowledges that the Plan is intended to conform to the extent necessary with all provisions of the Securities Act and the Exchange Act and any and all regulations and rules promulgated by the Securities and Exchange Commission thereunder, and state securities laws and regulations. Notwithstanding anything herein to the contrary, the Plan and all Awards granted hereunder shall be administered only in such a manner as to conform to such laws, rules and regulations. To the extent permitted by Applicable Laws, the Plan and all Award Agreements shall be deemed amended to the extent necessary to conform to such laws, rules and regulations.

Definitions. As used in the Plan, the following words and phrases shall have the following meanings:

(a) “Administrator” means the Board or a Committee to the extent that the Board’s powers or authority under the Plan have been delegated to such Committee.

(b) “Applicable Laws” means the requirements relating to the administration of equity incentive plans under U.S. federal and state securities, tax and other applicable laws, rules and regulations,
the applicable rules of any stock exchange or quotation system on which the Common Stock is listed or quoted and the applicable laws and rules of any foreign country or other jurisdiction where Awards are granted or issued under the Plan.

(c) “Award” means, individually or collectively, a grant under the Plan of Options, Restricted Stock, Restricted Stock Units or Other Stock-Based Awards.

(d) “Award Agreement” means a written agreement evidencing an Award, which agreements may be in electronic medium and shall contain such terms and conditions with respect to an Award as the Administrator shall determine, consistent with and subject to the terms and conditions of the Plan.

(e) “Board” means the Board of Directors of the Company.

(f) “Cause,” with respect to a Participant, means “Cause” (or any term of similar effect) as defined in such Participant’s employment agreement with the Company if such an agreement exists and contains a definition of Cause (or term of similar effect), or, if no such agreement exists or such agreement does not contain a definition of Cause (or term of similar effect), then Cause shall include, but not be limited to: (i) the Participant’s unauthorized use or disclosure of confidential information or trade secrets of the Company or any material breach of a written agreement between the Participant and the Company, including without limitation a material breach of any employment, confidentiality, non-compete, non-solicit or similar agreement; (ii) the Participant’s commission of, indictment for or the entry of a plea of guilty or nolo contendere by the Participant to, a felony under the laws of the United States or any state thereof or any crime involving dishonesty or moral turpitude (or any similar crime in any jurisdiction outside the United States); (iii) the Participant’s gross negligence or willful misconduct or the Participant’s willful or repeated failure or refusal to substantially perform assigned duties; (iv) any act of fraud, embezzlement, material misappropriation or dishonesty committed by the Participant against the Company; or (v) any acts, omissions or statements by a Participant which the Company reasonably determines to be materially detrimental or damaging to the reputation, operations, prospects or business relations of the Company.

(g) “Change in Control” means (i) a merger or consolidation of the Company with or into any other corporation or other entity or person, (ii) a sale, lease, exchange or other transfer in one transaction or a series of related transactions of all or substantially all of the Company’s assets, or (iii) any other transaction, including the sale by the Company of new shares of its capital stock or a transfer of existing shares of capital stock of the Company, the result of which is that a third party that is not an affiliate of the Company or its stockholders (or a group of third parties not affiliated with the Company or its stockholders) immediately prior to such transaction acquires or holds capital stock of the Company representing a majority of the Company’s outstanding voting power immediately following such transaction; provided that the following events shall not constitute a “Change in Control”: (A) a transaction (other than a sale of all or substantially all of the Company’s assets) in which the holders of the voting securities of the Company immediately prior to the merger or consolidation hold, directly or indirectly, at least a majority of the voting securities in the successor corporation or its parent immediately after the merger or consolidation; (B) a sale, lease, exchange or other transaction in one transaction or a series of related transactions of all or substantially all of the Company’s assets to an affiliate of the Company; (C) an initial public offering of any of the Company’s securities; (D) a reincorporation of the Company solely to change its jurisdiction; or (E) a transaction undertaken for the primary purpose of creating a holding company that will be owned in substantially the same proportion by the persons who held the Company’s securities immediately before such transaction. Notwithstanding the foregoing, if a Change in Control would give rise to a payment or settlement event with respect to any Award that constitutes “nonqualified deferred compensation,” the transaction or event constituting the Change in Control must also constitute a “change in control event” (as defined in Treasury Regulation §1.409A-3(i)(5)) in order to give rise to the payment or settlement event for such Award, to the extent required by Section 409A.

(i) “Committee” means one or more committees or subcommittees of the Board, which may be comprised of one or more directors and/or executive officers of the Company, in either case, to the extent permitted in accordance with Applicable Laws.

(j) “Common Stock” means the common stock of the Company.

(k) “Company” means Prometheus Biosciences, Inc., a Delaware corporation, or any successor thereto. Except where the context otherwise requires, the term “Company” includes any of the Company’s present or future parent or subsidiary corporations as defined in Sections 424(e) or (f) of the Code and any other business venture (including, without limitation, joint venture or limited liability company) in which the Company has a significant interest, as determined by the Administrator.

(l) “Consultant” means any person, including any advisor, engaged by the Company or a parent or subsidiary of the Company to render services to such entity.

(m) “Designated Beneficiary” means the beneficiary or beneficiaries designated, in a manner determined by the Administrator, by a Participant to receive amounts due or exercise rights of the Participant in the event of the Participant’s death or incapacity. In the absence of an effective designation by a Participant, “Designated Beneficiary” shall mean the Participant’s estate.

(n) “Director” means a member of the Board.

(o) “Disability” means a permanent and total disability within the meaning of Section 22(e)(3) of the Code, as it may be amended from time to time.

(p) “Dividend Equivalents” means a right granted to a Participant pursuant to Section 6(d)(3) hereof to receive the equivalent value (in cash or shares of Common Stock) of dividends paid on shares of Common Stock.

(q) “Employee” means any person, including officers and Directors, employed by the Company (within the meaning of Section 3401(c) of the Code) or any parent or subsidiary of the Company.

(r) “Equity Restructuring” means, as determined by the Administrator, a non-reciprocal transaction between the Company and its stockholders, such as a stock dividend, stock split, spin-off or recapitalization through a large, nonrecurring cash dividend, that affects the shares of Common Stock (or other securities of the Company) or the share price of Common Stock (or other securities of the Company) and causes a change in the per share value of the Common Stock underlying outstanding Awards.


(t) “Fair Market Value” means, as of any date, the value of Stock determined as follows: (i) if the Common Stock is listed on any established stock exchange, its Fair Market Value shall be the closing sales price for such Common Stock as quoted on such exchange for such date, or if no sale occurred on such date, the first market trading day immediately prior to such date during which a sale occurred, as reported in The Wall Street Journal or such other source as the Administrator deems reliable; (ii) if the Common Stock is not traded on a stock exchange but is quoted on a national market or other...
quotation system, the last sales price on such date, or if no sales occurred on such date, then on the date immediately prior to such date on which sales prices are reported, as reported in The Wall Street Journal or such other source as the Administrator deems reliable; or (iii) in the absence of an established market for the Common Stock, the Fair Market Value thereof shall be determined by the Administrator.

(u) “Good Reason” shall mean (a) a change in the Participant’s position with the Company (or its subsidiary employing the Participant) that materially reduces the Participant’s authority, duties or responsibilities, (b) a material diminution in the Participant’s level of base compensation, except in connection with a general reduction in the base compensation of the Company’s personnel with similar status and responsibilities or (c) a relocation of the Participant’s place of employment by more than 50 miles, provided that such change, reduction or relocation is effected by the Company (or its subsidiary employing the Participant) without the Participant’s consent. Notwithstanding the foregoing, Good Reason shall only exist if Participant shall have provided the Company with written notice within sixty (60) days of the initial occurrence of any of the foregoing events or conditions, and the Company or any successor or affiliate fails to eliminate the conditions constituting Good Reason within thirty (30) days after receipt of written notice of such event or condition from Participant. Participant’s resignation from employment with the Company for “Good Reason” must occur within six (6) months following the initial occurrence of one of the foregoing events or conditions. Notwithstanding the foregoing, if Participant is a party to a written employment or consulting agreement with the Company (or its subsidiary) in which the term “good reason” is defined, then “Good Reason” shall be as such term is defined in the applicable written employment or consulting agreement.

(v) “Incentive Stock Option” means an “incentive stock option” as defined in Section 422 of the Code.

(w) “Non-Qualified Stock Option” means an Option that is not intended to be or otherwise does not qualify as an Incentive Stock Option.

(x) “Option” means an option to purchase Common Stock.

(y) “Other Stock-Based Awards” means other Awards of shares of Common Stock, and other Awards that are valued in whole or in part by reference to, or are otherwise based on, shares of Common Stock or other property.

(z) “Participant” means a Service Provider who has been granted an Award under the Plan.

(aa) “Plan” means this 2017 Equity Incentive Plan.

(bb) “Publicly Listed Company” means that the Company or its successor (i) is required to file periodic reports pursuant to Section 12 of the Exchange Act and (ii) the Common Stock is listed on one or more National Securities Exchanges (within the meaning of the Exchange Act) or is quoted on NASDAQ or a successor quotation system.

(cc) “Restricted Stock” means Common Stock awarded to a Participant pursuant to Section 6 hereof that is subject to certain vesting conditions and other restrictions.

(dd) “Restricted Stock Unit” means an unfunded, unsecured right to receive, on the applicable settlement date, one share of Common Stock or an amount in cash or other consideration determined by the Administrator equal to the value thereof as of such payment date, which right may be subject to certain vesting conditions and other restrictions.
(ee) "Section 409A" means Section 409A of the Code and all regulations, guidance, compliance programs and other interpretative authority thereunder.

(ff) "Securities Act" means the Securities Act of 1933, as amended from time to time.

(gg) "Service Provider" means an Employee, Consultant or Director.

(hh) "Termination of Service" means the date the Participant ceases to be a Service Provider.
The Administrator has adopted this supplement for purposes of satisfying the requirements of Section 25102(o) of the California Corporations Code and the regulations issued thereunder ("Section 25102(o)"). Notwithstanding anything to the contrary contained in the Plan and except as otherwise determined by the Administrator, the provisions set forth in this supplement shall apply, to the extent required by applicable California securities laws, to all Awards granted under the Plan to a Participant who is a resident of the State of California on the date of grant (a "California Participant") and which are intended to be exempt from registration in California pursuant to Section 25102(o). Any Awards granted under the Plan to a California Participant that does not comply with this supplement for any reason as determined by the Administrator shall be automatically be deemed to have been granted pursuant to the Plan or pursuant to a sub-plan separate and apart from the Plan that is not intended to be exempt from registration in California pursuant to Section 25102(o). This supplement shall not apply to Awards granted to California Participants or after the date on which the Company becomes a Publicly Listed Company. Definitions in the Plan are applicable to this supplement.

1. **Additional Limitations On Options.**
   
   (a) **Maximum Duration of Options.** No Options granted to California Participants will be granted for a term in excess of 10 years.

   (b) **Minimum Exercise Period Following Termination.** Unless a California Participant’s Service Provider relationship is terminated for Cause, in the event of termination of such Participant’s Service Provider relationship, to the extent required by Applicable Laws, he or she shall have the right to exercise an Option, to the extent that he or she was otherwise entitled to exercise such Option on the date employment terminated, as follows: (i) at least six months from the date of termination, if termination was caused by such Participant’s death or Disability and (ii) at least 30 days from the date of termination, if termination was caused other than by such Participant’s death or Disability.

2. **Additional Limitations For Restricted Stock Awards, Restricted Stock Units and Other Stock-Based Awards.** The terms of all Restricted Stock Awards, Restricted Stock Units and Other Stock-Based Awards granted to California Participants shall comply, to the extent applicable, with Section 260.140.41 or Section 260.140.42 of the California Code of Regulations.

3. **Adjustments.** The Administrator will make such adjustments to an Award held by a California Participant as may be required by Section 260.140.41 or Section 260.140.42 of the California Code of Regulations.

4. **Additional Requirement To Provide Information To California Participants.** To the extent required by Section 260.140.46 of the California Code of Regulations, the Company shall provide to each California Participant and to each California Participant who acquires Common Stock pursuant to the Plan, not less frequently than annually, copies of annual financial statements (which need not be audited). The Company shall not be required to provide such statements to key persons whose duties in connection with the Company assure their access to equivalent information. In addition, this information requirement shall not apply to the Plan to the extent that it complies with all conditions of Rule 701 of the Securities Act ("Rule 701") as determined by the Administrator; provided that for purposes of determining such compliance, any registered domestic partner shall be considered a “family member” as that term is defined in Rule 701.
5. **Stockholder Approval; Additional Limitations On Timing Of Awards.** The Plan will be submitted for the approval of the Company’s stockholders within twelve (12) months after the date of the Board’s adoption of the Plan. Awards may be granted or awarded prior to such stockholder approval; provided that no Award granted to a California Participant shall become exercisable, vested or realizable, as applicable to such Award, unless the Plan has been approved by the Company’s stockholders within twelve months before or after the date the Plan was adopted by the Administrator; and provided, further, that if such approval has not been obtained at the end of said twelve-month period, all Awards previously granted or awarded under the Plan to California Participants shall thereupon be canceled and become null and void.
PROMETHEUS BIOSCIENCES, INC.

2017 EQUITY INCENTIVE PLAN

STOCK OPTION GRANT NOTICE AND
STOCK OPTION AGREEMENT

Prometheus Biosciences, Inc. (the “Company”), pursuant to its 2017 Equity Incentive Plan (the “Plan”), hereby grants to Participant an Option to purchase the number of shares of the Company’s Common Stock (referred to herein as “Shares”) set forth below. This Option is subject to all of the terms and conditions as set forth herein and in the Stock Option Agreement attached hereto as Exhibit A (the “Agreement”) and the Plan, each of which is incorporated herein by reference. Unless otherwise defined herein, the terms defined in the Plan shall have the same defined meanings in this Stock Option Grant Notice (“Grant Notice”) and the Agreement.

Participant: [Insert Participant Name]
Grant Date: [Insert Grant Date]
Vesting Commencement Date: [Insert Vesting Commencement Date]
Exercise Price per Share: $[Insert Exercise Price Per Share]
Total Exercise Price: $[Insert Aggregate Exercise Price]
Total Number of Shares Subject to Option: [Insert Number of Shares]
Expiration Date: [Insert Tenth Anniversary of Grant Date]
Type of Option: ☐ Incentive Stock Option ☐ Non-Qualified Stock Option
Vesting Schedule: [To be specified in individual agreements.]

By his or her signature and the Company’s signature below, Participant agrees to be bound by the terms and conditions of the Plan, the Agreement and this Grant Notice. Participant has reviewed the Agreement, the Plan and this Grant Notice in their entirety, has had an opportunity to obtain the advice of counsel prior to executing this Grant Notice and fully understands all provisions of this Grant Notice, the Agreement and the Plan. Participant hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Administrator of the Plan upon any questions arising under the Plan or the Agreement.

PROMETHEUS BIOSCIENCES, INC.

By: ____________________________
Print Name: Scott L. Glenn
Title: President and CEO

PARTICIPANT

By: ____________________________
Print Name: ____________________________
State of ____________________________
Residence: ____________________________
TO STOCK OPTION GRANT NOTICE

STOCK OPTION AGREEMENT

Pursuant to the Grant Notice to which this Agreement is attached, the Company has granted to Participant an Option under the Plan to purchase the number of Shares indicated in the Grant Notice.

1. Grant of Option. In consideration of Participant’s past and/or continued employment with or service to the Company and for other good and valuable consideration, effective as of the Grant Date set forth in the Grant Notice, the Company irrevocably grants to Participant an Option to purchase any part or all of an aggregate of the number of Shares set forth in the Grant Notice at the Exercise Price per Share set forth in the Grant Notice, upon the terms and conditions set forth in the Plan and this Agreement.

2. Vesting. The Option shall become vested in such amounts and at such times as are set forth in the vesting schedule in the Grant Notice, except that any Share as to which the Option would be fractionally vested will be accumulated and will vest and become exercisable only when a whole Share has accumulated. The installments provided for in the vesting schedule are cumulative. No portion of the Option which has not become vested at the date Participant incurs a Termination of Service shall thereafter become vested, except as may be otherwise provided by the Administrator or as set forth in another written agreement between the Company and Participant.

3. Exercise.

(a) Duration of Exercisability. Any vested portion of the Option may be exercised in whole or in part at any time prior to the time when the Option or portion thereof becomes unexercisable under Section 4.

(b) Person Eligible to Exercise. During the lifetime of Participant, only Participant may exercise the Option or any portion thereof. After the death of Participant, any exercisable portion of the Option may, prior to the time when the Option becomes unexercisable under Section 4, be exercised by Participant’s personal representative or by any person empowered to do so under the deceased Participant’s will or under the then Applicable Laws of descent and distribution.

(c) Manner of Exercise. The Option, or any portion thereof, may be exercised solely by delivery to the Secretary of the Company or the Secretary’s office, or such other place as may be determined by the Administrator, of all of the following prior to the time when the Option or such portion thereof becomes unexercisable under Section 4:

(i) A written exercise notice in substantially in the form attached as Exhibit B to the Grant Notice (or such other form as is prescribed by the Administrator, which may be an electronic form) (the “Exercise Notice”) signed by Participant or any other person then entitled to exercise the Option or portion thereof, stating that the Option or portion thereof is thereby exercised, such Exercise Notice complying with all applicable rules established by the Administrator; and

(ii) Subject to Section 5(f) of the Plan, full payment for the Shares with respect to which the Option or portion thereof is exercised by:
(A) Cash or check, payable to the order of the Company; or
(B) With the consent of the Administrator, surrendering shares of Common Stock then issuable upon exercise of the Option valued at their Fair Market Value on the date of exercise; or
(C) On and after the date the Company becomes a Publicly Listed Company, through the (A) delivery by Participant to the Company of an irrevocable and unconditional undertaking by a creditworthy broker to deliver promptly to the Company sufficient funds to pay the exercise price or (B) delivery by Participant to the Company of a copy of irrevocable and unconditional instructions to a creditworthy broker to deliver promptly to the Company cash or a check sufficient to pay the exercise price; or
(D) With the consent of the Administrator, any other form of payment permitted under Section 5(f) of the Plan; or
(E) any combination of the above permitted forms of payment; and
(iii) Subject to Section 9(e) of the Plan, full payment for any applicable withholding taxes in cash or by check or in the form of consideration permitted by the Administrator for the payment of the exercise price pursuant to Section 3(c)(ii) above or pursuant to Section 3(d) below, which, following the date the Company becomes a Publicly Listed Company shall include the method provided for in Section 3(c)(ii)(C) above; and
(iv) In the event the Option or portion thereof shall be exercised pursuant to Section 3(b) by any person or persons other than Participant, appropriate proof of the right of such person or persons to exercise the Option.

(d) Tax Withholding. The Company shall have the authority and the right to deduct or withhold, or require Participant to remit to the Company, an amount sufficient to satisfy federal, state, local and foreign taxes (including Participant’s employment tax obligation) required by law to be withheld with respect to any taxable event concerning Participant arising as a result of the Option or otherwise under this Agreement, including, without limitation, the authority to deduct such amounts from other compensation payable to Participant by the Company.

(e) Fractional Shares. The Option may only be exercised for whole shares of Common Stock. Any fractional Shares shall be rounded down to the nearest whole share.

4. Expiration of Option. The Option may not be exercised to any extent by anyone after the first to occur of the following events:

(a) The Expiration Date set forth in the Grant Notice;
(b) The expiration of three months following the date of Participant’s Termination of Service, unless such Termination of Service occurs by reason of Participant’s death or Disability or Participant’s discharge by the Company for Cause;
(c) The expiration of one year following the date of Participant’s Termination of Service by reason of Participant’s death or Disability;
(d) The date of Participant’s Termination of Service as a result of Participant’s discharge by the Company for Cause; or

(e) With respect to any unvested portion of the Option, the date that is thirty days following Participant’s Termination of Service for any reason other than as a result of Participant’s discharge by the Company for Cause, or such shorter period as may be determined by the Administrator.

Participant acknowledges that an Incentive Stock Option exercised more than three months after Participant’s termination of status as an Employee, other than by reason of death or Disability, will be taxed as a Non-Qualified Stock Option.

5. Transferability. The Option shall not be sold, assigned, transferred, pledged or otherwise encumbered by Participant, either voluntarily or by operation of law, except by will or the laws of descent and distribution, and, during the life of the Participant, the Option shall be exercisable only by the Participant.

6. Restrictive Legends and Stop-Transfer Orders.

(a) Legends. Participant understands and agrees that the Company shall cause any certificates issued evidencing the Shares to have the legends set forth below or legends substantially equivalent thereto, together with any other legends that may be required by Applicable Laws:

THE SHARES REPRESENTED HEREBY HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (“ACT”), NOR HAVE THEY BEEN REGISTERED OR QUALIFIED UNDER THE SECURITIES LAWS OF ANY STATE. NO TRANSFER OF SUCH SECURITIES WILL BE PERMITTED UNLESS A REGISTRATION STATEMENT UNDER THE ACT IS IN EFFECT AS TO SUCH TRANSFER, THE TRANSFER IS MADE IN ACCORDANCE WITH RULE 144 UNDER THE ACT, OR IN THE OPINION OF COUNSEL (WHICH MAY BE COUNSEL FOR THE COMPANY) REGISTRATION UNDER THE ACT IS UNNECESSARY IN ORDER FOR SUCH TRANSFER TO COMPLY WITH THE ACT AND WITH APPLICABLE STATE SECURITIES LAWS.

THE SHARES REPRESENTED BY THIS CERTIFICATE MAY BE TRANSFERRED ONLY IN ACCORDANCE WITH THE TERMS OF AN AGREEMENT BETWEEN THE COMPANY AND THE STOCKHOLDER, A COPY OF WHICH IS ON FILE WITH THE SECRETARY OF THE COMPANY. SUCH TRANSFER RESTRICTIONS ARE BINDING ON TRANSFEREES OF THESE SHARES.

(b) Stop Transfer Orders. Participant agrees that, in order to ensure compliance with the restrictions referred to in the Plan and this Agreement, the Company may issue appropriate “stop transfer” instructions to its transfer agent, if any, and that, if the Company transfers its own securities, it may make appropriate notations to the same effect in its own records.

(c) Impermissible Transfers Void. The Company shall not be required (i) to transfer on its books any Shares that have been sold or otherwise transferred in violation of any of the provisions of this Agreement or (ii) to treat as owner of such Shares or to accord the right to vote or pay dividends to any purchaser or other transferee to whom such Shares shall have been so transferred.
7. Taxes. Participant understands that Participant may suffer adverse tax consequences as a result of Participant’s purchase or disposition of the Shares. Participant represents that Participant has consulted with any tax consultants Participant deems advisable in connection with the purchase or disposition of the Shares and that Participant is not relying on the Company for any tax advice. Participant is relying solely on such advisors and not on any statements or representations of the Company or any of its agents. Participant understands that Participant (and not the Company) shall be responsible for Participant’s tax liability that may arise as a result of the transactions contemplated by this Agreement.

8. Miscellaneous.

(a) No Right To Employment or Other Status. No person shall have any claim or right to be granted an Award, and the grant of an Award shall not be construed as giving a Participant the right to continued employment or any other relationship with the Company. The Company expressly reserves the right at any time to dismiss or otherwise terminate its relationship with a Participant free from any liability or claim under the Plan or this Agreement.

(b) Notices. Any notice to be given under the terms of this Agreement to the Company shall be addressed to the Company in care of the Secretary of the Company at the Company’s principal office or to the then-current email address for the Secretary of the Company, and any notice to be given to Participant shall be addressed to Participant at the most-recent physical or email address for Participant listed in the Company’s personnel records. By a notice given pursuant to this Section 8(b), either party may hereafter designate a different address for notices to be given to that party. Any notice which is required to be given to Participant shall, if Participant is then deceased, be given to the person entitled to exercise his or her Option by written notice under this Section 8(b). Any notice shall be deemed duly given when sent via email or when sent by certified mail (return receipt requested) and deposited (with postage prepaid) in a post office or branch post office regularly maintained by the United States Postal Service.

(c) Successors and Assigns. The Company may assign any of its rights under this Agreement and the Exercise Notice to single or multiple assignees, and this Agreement shall inure to the benefit of the successors and assigns of the Company. Subject to the restrictions on transfer herein set forth, this Agreement shall be binding upon Participant and his or her heirs, executors, administrators, successors and assigns.

(d) Severability. In the event any portion of the Plan or this Agreement or any action taken pursuant thereto shall be held illegal or invalid for any reason, the illegality or invalidity shall not affect the remaining parts of the Plan and this Agreement, and the Plan and this Agreement shall be construed and enforced as if the illegal or invalid provisions had not been included, and the illegal or invalid action shall be null and void.

(e) Entire Agreement; Governing Documents. The Plan, the Grant Notice and this Agreement (including all Exhibits thereto) constitute the entire agreement of the parties and supersede in their entirety all prior undertakings and agreements of the Company and Participant with respect to the subject matter hereof. In the event of any contradiction between the Plan and any Award Agreement or any other written agreement between a Participant and the Company that has been approved by the Administrator, the terms of the Plan shall govern, unless it is expressly specified in such Award Agreement or other written document that a specific provision of the Plan shall not apply.
(f) **Governing Law.** The provisions of the Plan and all Awards made thereunder, including the Option, shall be governed by and interpreted in accordance with the laws of the State of Delaware, disregarding choice-of-law principles of the law of any state that would require the application of the laws of a jurisdiction other than such state.

(g) **Titles and Headings.** The titles and headings of the Sections in this Agreement are for convenience of reference only and, in the event of any conflict, the text of this Agreement, rather than such titles or headings, shall control.
Effective as of today, __________, ______ the undersigned ("Participant") hereby elects to exercise Participant’s option to purchase _______ Shares of Prometheus Biosciences, Inc. (the “Company”) under and pursuant to the Prometheus Biosciences, Inc. 2017 Equity Incentive Plan (the “Plan”) and the Stock Option Grant Notice and Stock Option Agreement dated __________, ____ (the “Agreement”). Capitalized terms used herein without definition shall have the meanings given in the Agreement.

Grant Date:

Number of Shares as to which Option is Exercised:

Exercise Price per Share: $___________

Total Exercise Price: $___________

Certificate to be issued in name of:

Cash Payment delivered herewith: $___________ (Representing the full Exercise Price for the Shares, as well as any applicable withholding tax)

Type of Option: ☐ Incentive Stock Option ☐ Non-Qualified Stock Option

1. **Representations of Participant.** Participant acknowledges that Participant has received, read and understood the Plan and the Agreement. Participant agrees to abide by and be bound by their terms and conditions. Participant further acknowledges that it is a condition to the issuance of the Shares to Participant upon exercise of the Option listed above that Participant agree to be bound by the terms and conditions of, and become a party to, any stockholders’ agreement of the Company. Participant hereby agrees to be so bound and to execute any additional documents as may be deemed necessary or advisable by the Company in order to effectuate the foregoing agreement.

2. **Tax Consultation.** Participant understands that Participant may suffer adverse tax consequences as a result of Participant’s purchase or disposition of the Shares. Participant represents that Participant has consulted with any tax consultants Participant deems advisable in connection with the purchase or disposition of the Shares and that Participant is not relying on the Company for any tax advice. Participant is relying solely on such advisors and not on any statements or representations of the Company or any of its agents. Participant understands that Participant (and not the Company) shall be responsible for Participant’s tax liability that may arise as a result of this investment or the transactions contemplated by this Agreement.

3. **Participant Representations.** Participant hereby makes the following certifications and representations with respect to the Shares listed above:

   (a) Participant is aware of the Company’s business affairs and financial condition and has acquired sufficient information about the Company to reach an informed and knowledgeable decision to acquire the Shares. Participant is acquiring these Shares for investment for Participant’s own account only and not with a view to, or for resale in connection with, any “distribution” thereof within the meaning of the Securities Act.
(b) Participant acknowledges and understands that the Shares constitute "restricted securities" under the Securities Act and have not been registered under the Securities Act in reliance upon a specific exemption therefrom, which exemption depends upon, among other things, the bona fide nature of Participant’s investment intent as expressed herein. Participant understands that the Shares must be held indefinitely unless they are subsequently registered under the Securities Act or an exemption from such registration is available. Participant further acknowledges and understands that the Company is under no obligation to register the Shares. Participant understands that the certificate evidencing the Shares will be imprinted with a legend which prohibits the transfer of the Shares unless they are registered or such registration is not required in the opinion of counsel satisfactory to the Company and any other legend required under Applicable Laws.

(c) Participant is familiar with the provisions of Rule 701 and Rule 144, each promulgated under the Securities Act, which, in substance, permit limited public resale of “restricted securities” acquired, directly or indirectly from the issuer thereof, in a non-public offering subject to the satisfaction of certain conditions. Rule 701 provides that if the issuer qualifies under Rule 701 at the time of the grant of the Option to Participant, the exercise will be exempt from registration under the Securities Act. In the event the Company becomes subject to the reporting requirements of Section 13 or 15(d) of the Exchange Act, ninety days thereafter (or such longer period as any market stand-off agreement may require) the securities exempt under Rule 701 may be resold, subject to the satisfaction of certain of the conditions specified by Rule 144.

(d) In the event that the Company does not qualify under Rule 701 at the time of grant of the Option, then the securities may be resold in certain limited circumstances subject to the provisions of Rule 144.

(e) Participant further understands that in the event all of the applicable requirements of Rule 701 or 144 are not satisfied, registration under the Securities Act, compliance with Regulation A, or some other registration exemption will be required; and that, notwithstanding the fact that Rules 144 and 701 are not exclusive, the Staff of the Securities and Exchange Commission has expressed its opinion that persons proposing to sell private placement securities other than in a registered offering and otherwise than pursuant to Rules 144 or 701 will have a substantial burden of proof in establishing that an exemption from registration is available for such offers or sales, and that such persons and their respective brokers who participate in such transactions do so at their own risk. Participant understands that no assurances can be given that any such other registration exemption will be available in such event.

4. Notices. Any notice required or permitted hereunder shall be given in accordance with the provisions set forth in Section 8(b) of the Agreement.

5. Entire Agreement. The Plan and Agreement are incorporated herein by reference. This Notice, the Plan and the Agreement constitute the entire agreement of the parties and supersede in their entirety all prior undertakings and agreements of the Company and Participant with respect to the subject matter hereof.

ACCEPTED BY: PROMETHEUS BIOSCIENCES, INC.

By: Print Name: Title: 

SUBMITTED BY PARTICIPANT:

By: Print Name: 

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PROMETHEUS BIOSCIENCES, INC.

2017 EQUITY INCENTIVE PLAN

STOCK OPTION GRANT NOTICE AND
STOCK OPTION AGREEMENT

Prometheus Biosciences, Inc. (the “Company”), pursuant to its 2017 Equity Incentive Plan (the “Plan”), hereby grants to Participant an Option to purchase the number of shares of the Company’s Common Stock (referred to herein as “Shares”) set forth below. This Option is subject to all of the terms and conditions as set forth herein and in the Stock Option Agreement attached hereto as Exhibit A (the “Agreement”) and the Plan, each of which is incorporated herein by reference. Unless otherwise defined herein, the terms defined in the Plan shall have the same defined meanings in this Stock Option Grant Notice (“Grant Notice”) and the Agreement.

Participant: [Insert Participant Name]
Grant Date: [Insert Grant Date]
Vesting Commencement Date: [Insert Vesting Commencement Date]
Exercise Price per Share: $[Insert Exercise Price Per Share]
Total Exercise Price: $[Insert Aggregate Exercise Price]
Total Number of Shares Subject to Option: [Insert Number of Shares]
Expiration Date: [Insert tenth anniversary of Grant Date]
Type of Option: ☐ Incentive Stock Option ☐ Non-Qualified Stock Option
Exercise Schedule: ☒ Early Exercise Permitted

Vesting Schedule: This Option is exercisable immediately, in whole or in part, at such times as are established by the Administrator, conditioned upon Participant entering into a Restricted Stock Purchase Agreement with respect to any unvested shares of Stock. The shares subject to this Option shall vest and/or be released from the Company Repurchase Right, as set forth in Section 5 of the Agreement, according to the following schedule:

[To be specified in individual agreements.]

By his or her signature and the Company’s signature below, Participant agrees to be bound by the terms and conditions of the Plan, the Agreement and this Grant Notice. Participant has reviewed the Agreement, the Plan and this Grant Notice in their entirety, has had an opportunity to obtain the advice of counsel prior to executing this Grant Notice and fully understands all provisions of this Grant Notice, the Agreement and the Plan. Participant hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Administrator of the Plan upon any questions arising under the Plan or the Agreement.

PROMETHEUS BIOSCIENCES, INC.

By: Scott L. Glenn
Print Name: President and CEO
Title: State of Residence:

PARTICIPANT:

By: Print Name:
Title: Residence:
Pursuant to the Grant Notice to which this Agreement is attached, the Company has granted to Participant an Option under the Plan to purchase the number of Shares indicated in the Grant Notice.

1. **Grant of Option.** In consideration of Participant’s past and/or continued employment with or service to the Company and for other good and valuable consideration, effective as of the Grant Date set forth in the Grant Notice, the Company irrevocably grants to Participant an Option to purchase any part or all of an aggregate of the number of Shares set forth in the Grant Notice at the Exercise Price per Share set forth in the Grant Notice, upon the terms and conditions set forth in the Plan and this Agreement.

2. **Vesting.** The Option shall become vested in such amounts and at such times as are set forth in the vesting schedule in the Grant Notice, except that any Share as to which the Option would be fractionally vested will be accumulated and will vest and become exercisable only when a whole Share has accumulated. The installments provided for in the vesting schedule are cumulative. No portion of the Option which has not become vested at the date Participant incurs a Termination of Service shall thereafter become vested, except as may be otherwise provided by the Administrator or as set forth in another written agreement between the Company and Participant.

3. **Exercise.**

   (a) **Exercisability.** Any portion of the Option or the entire Option may be exercised in whole or in part at any time prior to the time when the Option or portion thereof becomes unexercisable under Section 4, provided that each unvested Share with respect to which the Option is exercised (each a “Restricted Share”) shall be subject to the Company Repurchase Right (as defined in Section 5 below) for so long as the Option shall remain unvested with respect to such Share under the terms of this Agreement. The Restricted Shares shall be released from the Company Repurchase Right as set forth in Section 5. For the avoidance of doubt, all Shares with respect to which the Option is exercised shall at all times be assumed to be Restricted Shares to the fullest extent possible under the terms of this Agreement, unless otherwise provided by the Administrator.

   (b) **Person Eligible to Exercise.** During the lifetime of Participant, only Participant may exercise the Option or any portion thereof. After the death of Participant, any exercisable portion of the Option may, prior to the time when the Option becomes unexercisable under Section 4, be exercised by Participant’s personal representative or by any person empowered to do so under the deceased Participant’s will or under the then Applicable Laws of descent and distribution.

   (c) **Manner of Exercise.** The Option, or any portion thereof, may be exercised solely by delivery to the Secretary of the Company or the Secretary’s office, or such other place as may be determined by the Administrator, of all of the following prior to the time when the Option or such portion thereof becomes unexercisable under Section 4:

      (i) A written exercise notice in substantially in the form attached as Exhibit B to the Grant Notice (or such other form as is prescribed by the Administrator, which may be an electronic form) (the “Exercise Notice”) signed by Participant or any other person then entitled to exercise the Option or portion thereof, stating that the Option or portion thereof is thereby exercised, such Exercise Notice complying with all applicable rules established by the Administrator; and
Subject to Section 5(f) of the Plan, full payment for the Shares with respect to which the Option or portion thereof is exercised by:

(A) Cash or check, payable to the order of the Company; or
(B) With the consent of the Administrator, surrendering shares of Common Stock then issuable upon exercise of the Option valued at their Fair Market Value on the date of exercise; or
(C) On and after the date the Company becomes a Publicly Listed Company, through the (A) delivery by Participant to the Company of an irrevocable and unconditional undertaking by a creditworthy broker to deliver promptly to the Company sufficient funds to pay the exercise price or (B) delivery by Participant to the Company of a copy of irrevocable and unconditional instructions to a creditworthy broker to deliver promptly to the Company cash or a check sufficient to pay the exercise price; or
(D) With the consent of the Administrator, any other form of payment permitted under Section 5(f) of the Plan; or
(E) any combination of the above permitted forms of payment; and

Subject to Section 9(e) of the Plan, full payment for any applicable withholding taxes in cash or by check or in the form of consideration permitted by the Administrator for the payment of the exercise price pursuant to Section 3(c)(ii) above or pursuant to Section 3(d) below, which, following the date the Company becomes a Publicly Listed Company shall include the method provided for in Section 3(c)(ii)(C) above; and

In the event the Option or portion thereof shall be exercised pursuant to Section 3(b) by any person or persons other than Participant, appropriate proof of the right of such person or persons to exercise the Option; and

In the event the Option or portion thereof shall be exercised as to Restricted Shares, the following (collectively, the "Additional Documents"):

(A) the stock assignment duly endorsed in blank, attached as Exhibit C to the Grant Notice (the “Stock Assignment”), executed by Participant; and

(B) if Participant has a spouse of Participant, the Consent of Spouse attached as Exhibit D to the Grant Notice, executed by Participant’s spouse.

Tax Withholding. The Company shall have the authority and the right to deduct or withhold, or require Participant to remit to the Company, an amount sufficient to satisfy federal, state, local and foreign taxes (including Participant’s employment tax obligation) required by law to be withheld with respect to any taxable event concerning Participant arising as a result of the Option or otherwise under this Agreement, including, without limitation, the authority to deduct such amounts from other compensation payable to Participant by the Company.
(e) Fractional Shares. The Option may only be exercised for whole shares of Common Stock. Any fractional Shares shall be rounded down to the nearest whole share.

4. Expiration of Option. The Option may not be exercised to any extent by anyone after the first to occur of the following events:
   (a) The Expiration Date set forth in the Grant Notice;
   (b) The expiration of three months following the date of Participant’s Termination of Service, unless such Termination of Service occurs by reason of Participant’s death or Disability or Participant’s discharge by the Company for Cause;
   (c) The expiration of one year following the date of Participant’s Termination of Service by reason of Participant’s death or Disability;
   (d) The date of Participant’s Termination of Service as a result of Participant’s discharge by the Company for Cause; or
   (e) With respect to any unvested portion of the Option, the date that is thirty days following Participant’s Termination of Service for any reason other than as a result of Participant’s discharge by the Company for Cause, or such shorter period as may be determined by the Administrator.

Participant acknowledges that an Incentive Stock Option exercised more than three months after Participant’s termination of status as an Employee, other than by reason of death or Disability, will be taxed as a Non-Qualified Stock Option.

5. Company Repurchase Right.
   (a) Company Repurchase Right. Upon Participant’s Termination of Service for any reason, the Company shall have the right and option to repurchase all of the Restricted Shares from Participant, or Participant’s transferee or legal representative, as the case may be, for a purchase price equal to the price per Share paid for such Restricted Shares (the “Company Repurchase Right”).
   (b) Exercise of Company Repurchase Right. The Company may exercise the Company Repurchase Right by delivering to Participant (or his or her transferee or legal representative, as the case may be), within ninety days of the date of Participant’s Termination of Service, a written notice indicating the Company’s intention to exercise the Company Repurchase Right and setting forth a date for closing not later than thirty days from the issuance of such notice. The closing shall take place at the Company’s office. At the closing, the holder of the certificates for the Restricted Shares shall deliver the stock certificate or certificates evidencing the Restricted Shares, and the Company shall deliver the purchase price therefore. At its option, the Company may elect to make payment for the Restricted Shares to a bank selected by the Company. The Company shall avail itself of this option by a written notice to Participant stating the name and address of the bank, date of closing, and waiving the closing at the Company’s office. If the Company does not elect to exercise the Company Repurchase Right by giving the requisite notice within ninety days following the date of Participant’s Termination of Service, the Company Repurchase Right shall terminate.
   (c) Release of Restricted Shares. The Restricted Shares shall be released from the Company Repurchase Right upon vesting of the Option with respect to such Shares in accordance with the terms of this Agreement. For the avoidance of doubt, all Shares with respect to which the Option is exercised shall at all times be assumed to be Restricted Shares to the fullest extent possible under the terms of this Agreement, unless otherwise provided by the Administrator. Fractional Shares shall be rounded down to the nearest whole share.
6. Escrow. To insure the availability for delivery of the Restricted Shares upon repurchase by the Company pursuant to the Company Repurchase Right, Participant appoints the Secretary of the Company, or such other person designated by the Administrator from time to time as escrow agent, as its attorney-in-fact to sell, assign and transfer unto the Company, such Restricted Shares, if any, repurchased by the Company pursuant to the Company Repurchase Right and shall, upon execution of the applicable Exercise Notice, deliver and deposit with the Secretary of the Company, or such other person designated by the Administrator from time to time, the share certificate(s) representing the Restricted Shares, together with the Stock Assignment. The Restricted Shares and Stock Assignment shall be held by the Secretary, or such other person designated by the Administrator from time to time, in escrow, until the Company exercises the Company Repurchase Right, until such Restricted Shares are released from the Company Repurchase Right as set forth in Section 5 or until such time as this Agreement no longer is in effect. Upon release of the Restricted Shares from the Company’s Repurchase Right, the escrow agent shall as soon as reasonably practicable deliver to Participant the certificate or certificates representing such Shares in the escrow agent’s possession belonging to Participant, and the escrow agent shall be discharged of all further obligations hereunder. The Company, or its designee, shall not be liable for any act it may do or omit to do with respect to holding the Restricted Shares in escrow and while acting in good faith and in the exercise of its judgment.

7. Transferability.

(a) Transferability of Option and Restricted Shares. Neither the Option nor the Restricted Shares shall be sold, assigned, transferred, pledged or otherwise encumbered by Participant, either voluntarily or by operation of law, except by will or the laws of descent and distribution, and, during the life of the Participant, the Option shall be exercisable only by the Participant.

(b) Transferees Subject to Restrictions. Any transferee of the Shares shall hold such Shares subject to all of the provisions hereof and the Plan and the Exercise Notice and Additional Documents executed by Purchaser with respect to such Shares.

8. Rights as a Stockholder. Except as otherwise provided herein, upon exercise of the Option and the issuance of the Shares to Participant (as evidenced by the appropriate entry on the books of the Company or of a duly authorized transfer agent of the Company), Participant shall have all the rights of a stockholder with respect to the Restricted Shares, including the right to receive any cash or stock dividends or other distributions paid to or made with respect to the Restricted Shares, subject to the restrictions described in the following sentence, which restrictions shall lapse when the Restricted Shares are released from the Company Repurchase Right as set forth in Section 5. Unless otherwise provided by the Administrator, if any dividends or distributions are paid in shares, or consist of a dividend or distribution to holders of Common Stock of property other than an ordinary cash dividend, the shares or other property will be subject to same restrictions on transferability as the Restricted Shares with respect to which they were paid and shall automatically be forfeited to the Company for no consideration in the event the Company exercises the Company Repurchase Right for the Restricted Shares with respect to which they were paid. In no event shall a dividend or distribution be paid with respect to Restricted Shares later than the end of the calendar year in which the dividends are paid to holders of Common Stock or, if later, the 15th day of the third month following the later of (a) the date the dividends are paid to holders of Common Stock and (b) the date the Restricted Shares with respect to which the dividends are paid vest. Participant shall enjoy rights as a stockholder until such time as Participant disposes of the Shares or the Company and/or its assignee(s) exercises the Right of First Refusal hereunder. Upon such exercise, Participant shall have no further rights as a holder of the Shares purchased except the right to receive payment for the Shares so purchased in accordance with the provisions of this Agreement, and Participant shall forthwith cause the certificate(s), if any issued, evidencing the Shares so purchased to be surrendered to the Company for transfer or cancellation.
9. **Restrictive Legends and Stop-Transfer Orders.**

(a) **Legends.** Participant understands and agrees that the Company shall cause any certificates issued evidencing the Shares to have the legends set forth below or legends substantially equivalent thereto, together with any other legends that may be required by Applicable Laws:

THE SHARES REPRESENTED HEREBY HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (“ACT”), NOR HAVE THEY BEEN REGISTERED OR QUALIFIED UNDER THE SECURITIES LAWS OF ANY STATE. NO TRANSFER OF SUCH SECURITIES WILL BE PERMITTED UNLESS A REGISTRATION STATEMENT UNDER THE ACT IS IN EFFECT AS TO SUCH TRANSFER, THE TRANSFER IS MADE IN ACCORDANCE WITH RULE 144 UNDER THE ACT, OR IN THE OPINION OF COUNSEL, (WHICH MAY BE COUNSEL FOR THE COMPANY) REGISTRATION UNDER THE ACT IS UNNECESSARY IN ORDER FOR SUCH TRANSFER TO COMPLY WITH THE ACT AND WITH APPLICABLE STATE SECURITIES LAWS.

THE SHARES REPRESENTED BY THIS CERTIFICATE MAY BE SUBJECT TO REPURCHASE PURSUANT TO, AND MAY BE TRANSFERRED ONLY IN ACCORDANCE WITH, THE TERMS OF AN AGREEMENT BETWEEN THE COMPANY AND THE STOCKHOLDER, A COPY OF WHICH IS ON FILE WITH THE SECRETARY OF THE COMPANY. SUCH REPURCHASE AND/OR TRANSFER RESTRICTIONS ARE BINDING ON TRANSFEREES OF THESE SHARES.

(b) **Stop Transfer Orders.** Participant agrees that, in order to ensure compliance with the restrictions referred to in the Plan and this Agreement, the Company may issue appropriate “stop transfer” instructions to its transfer agent, if any, and that, if the Company transfers its own securities, it may make appropriate notations to the same effect in its own records.

(c) **Impermissible Transfers Void.** The Company shall not be required (i) to transfer on its books any Shares that have been sold or otherwise transferred in violation of any of the provisions of this Agreement or (ii) to treat as owner of such Shares or to accord the right to vote or pay dividends to any purchaser or other transferee to whom such Shares shall have been so transferred. Any transfer or attempted transfer of the Option or any of the Restricted Shares not in accordance with the terms of this Agreement shall be void.

10. **Taxes.**

(a) **Tax Consequences of Award.** Participant understands that Participant may suffer adverse tax consequences as a result of Participant’s purchase or disposition of the Shares. Participant represents that Participant has consulted with any tax consultants Participant deems advisable in connection with the purchase or disposition of the Shares and that Participant is not relying on the Company for any tax advice. Participant is relying solely on such advisors and not on any statements or representations of the Company or any of its agents. Participant understands that Participant (and not the Company) shall be responsible for Participant’s tax liability that may arise as a result of the transactions contemplated by this Agreement.
Section 83(b) Election for Restricted Shares Purchased Pursuant to a Non-Qualified Stock Option. Participant acknowledges that, with respect to the exercise of a Non-Qualified Stock Option for Restricted Shares, unless an election is filed by Participant with the Internal Revenue Service and, if necessary, the proper state taxing authorities, within thirty days of the purchase of the Shares, electing pursuant to Section 83(b) of the Code (and similar state tax provisions if applicable) to be taxed currently on any difference between the purchase price of the Shares and their Fair Market Value on the date of purchase, there will be a recognition of taxable income to the Purchaser, measured by the excess, if any, of the Fair Market Value of the Shares, at the time the Company Repurchase Right lapses over the purchase price for the Shares. Participant represents that Participant has consulted any tax consultant(s) Participant deems advisable in connection with the purchase of the Shares or the filing of the election under Section 83(b) of the Code and similar tax provisions.

Section 83(b) Election for Restricted Shares Purchased Pursuant to an Incentive Stock Option. Participant hereby acknowledges that he or she has been informed that, with respect to the exercise of an Incentive Stock Option for Restricted Shares, unless an election is filed by Participant with the Internal Revenue Service and, if necessary, the proper state taxing authorities, within thirty days of the purchase of the Shares, electing pursuant to Section 83(b) of the Code (and similar state tax provisions if applicable) to be taxed currently on any difference between the purchase price of the Shares and their Fair Market Value on the date of purchase, there will be a recognition of income to the Participant, for alternative minimum tax purposes measured by the excess, if any, of the Fair Market Value of the Shares at the time the Company’s Repurchase Option lapses over the purchase price for the Shares. Participant further acknowledges that if an election is filed under Section 83(b) of the Code for the Unvested Shares and such shares are sold or transferred prior to the date two years following the Grant Date and one year following the purchase date of such shares, there will be a recognition of income to the Participant, for ordinary income, measured by the excess, if any, of the Fair Market Value of the Shares at the time the Company’s Repurchase Option lapses over the purchase price for the Shares. Participant represents that Participant has consulted any tax consultant(s) Participant deems advisable in connection with the purchase of the Shares or the filing of the election under Section 83(b) and similar tax provisions.

PARTICIPANT ACKNOWLEDGES THAT IT IS PARTICIPANT’S SOLE RESPONSIBILITY AND NOT THE COMPANY’S TO FILE TIMELY THE ELECTION UNDER SECTION 83(B) OF THE CODE, EVEN IF PARTICIPANT REQUESTS THE COMPANY OR ITS REPRESENTATIVE TO MAKE THIS FILING ON PARTICIPANT’S BEHALF.

11. Miscellaneous.

(a) No Right To Employment or Other Status. No person shall have any claim or right to be granted an Award, and the grant of an Award shall not be construed as giving a Participant the right to continued employment or any other relationship with the Company. The Company expressly reserves the right at any time to dismiss or otherwise terminate its relationship with a Participant free from any liability or claim under the Plan or this Agreement.

(b) Notices. Any notice to be given under the terms of this Agreement to the Company shall be addressed to the Company in care of the Secretary of the Company at the Company’s principal office or to the then-current email address for the Secretary of the Company, and any notice to be given to Participant shall be addressed to Participant at the most-recent physical or email address for
Participant listed in the Company’s personnel records. By a notice given pursuant to this Section 11(b), either party may hereafter designate a different address for notices to be given to that party. Any notice which is required to be given to Participant shall, if Participant is then deceased, be given to the person entitled to exercise his or her Option by written notice under this Section 11(b). Any notice shall be deemed duly given when sent via email or when sent by certified mail (return receipt requested) and deposited (with postage prepaid) in a post office or branch post office regularly maintained by the United States Postal Service.

(c) Successors and Assigns. The Company may assign any of its rights under this Agreement and the Exercise Notice to single or multiple assignees, and this Agreement shall inure to the benefit of the successors and assigns of the Company. Subject to the restrictions on transfer herein set forth, this Agreement shall be binding upon Participant and his or her heirs, executors, administrators, successors and assigns.

(d) Severability. In the event any portion of the Plan or this Agreement or any action taken pursuant thereto shall be held illegal or invalid for any reason, the illegality or invalidity shall not affect the remaining parts of the Plan and this Agreement, and the Plan and this Agreement shall be construed and enforced as if the illegal or invalid provisions had not been included, and the illegal or invalid action shall be null and void.

(e) Entire Agreement; Governing Documents. The Plan, the Grant Notice and this Agreement (including all Exhibits thereto) constitute the entire agreement of the parties and supersede in their entirety all prior undertakings and agreements of the Company and Participant with respect to the subject matter hereof. In the event of any contradiction between the Plan and any Award Agreement or any other written agreement between a Participant and the Company that has been approved by the Administrator, the terms of the Plan shall govern, unless it is expressly specified in such Award Agreement or other written document that a specific provision of the Plan shall not apply.

(f) Governing Law. The provisions of the Plan and all Awards made thereunder, including the Option, shall be governed by and interpreted in accordance with the laws of the State of Delaware, disregarding choice-of-law principles of the law of any state that would require the application of the laws of a jurisdiction other than such state.

(g) Titles and Headings. The titles and headings of the Sections in this Agreement are for convenience of reference only and, in the event of any conflict, the text of this Agreement, rather than such titles or headings, shall control.
EXHIBIT B

TO STOCK OPTION GRANT NOTICE

FORM OF EXERCISE NOTICE

Effective as of today, _______, ________, the undersigned ("Participant") hereby elects to exercise Participant’s option to purchase ________ Shares of Prometheus Biosciences, Inc. (the “Company”) under and pursuant to the Prometheus Biosciences, Inc. 2017 Equity Incentive Plan (the “Plan”) and the Stock Option Grant Notice and Stock Option Agreement dated ________, 20___ (the “Agreement”). Capitalized terms used herein without definition shall have the meanings given in the Agreement.

Grant Date: ________________________________

Number of Shares as to which Option is Exercised: ________________________________

Exercise Price per Share: $ ________________________________

Total Exercise Price: $ ________________________________

Certificate to be issued in name of: ________________________________

Cash Payment delivered herewith: $ ________________________________ (Representing the full Exercise Price for the Shares, as well as any applicable withholding tax)

Type of Option: ☐ Incentive Stock Option ☐ Non-Qualified Stock Option

1. **Representations of Participant.** Participant acknowledges that Participant has received, read and understood the Plan and the Agreement. Participant agrees to abide by and be bound by their terms and conditions.

2. **Tax Consultation.** Participant understands that Participant may suffer adverse tax consequences as a result of Participant’s purchase or disposition of the Shares. Participant represents that Participant has consulted with any tax consultants Participant deems advisable in connection with the purchase or disposition of the Shares and that Participant is not relying on the Company for any tax advice. Participant is relying solely on such advisors and not on any statements or representations of the Company or any of its agents. Participant understands that Participant (and not the Company) shall be responsible for Participant’s tax liability that may arise as a result of this investment or the transactions contemplated by this Agreement.

3. **Participant Representations.** Participant hereby makes the following certifications and representations with respect to the Shares listed above:

   (a) Participant is aware of the Company’s business affairs and financial condition and has acquired sufficient information about the Company to reach an informed and knowledgeable decision to acquire the Shares. Participant is acquiring these Shares for investment for Participant’s own account only and not with a view to, or for resale in connection with, any “distribution” thereof within the meaning of the Securities Act.
(b) Participant acknowledges and understands that the Shares constitute “restricted securities” under the Securities Act and have not been registered under the Securities Act in reliance upon a specific exemption therefrom, which exemption depends upon, among other things, the bona fide nature of Participant’s investment intent as expressed herein. Participant understands that the Shares must be held indefinitely unless they are subsequently registered under the Securities Act or an exemption from such registration is available. Participant further acknowledges and understands that the Company is under no obligation to register the Shares. Participant understands that the certificate evidencing the Shares will be imprinted with a legend which prohibits the transfer of the Shares unless they are registered or such registration is not required in the opinion of counsel satisfactory to the Company and any other legend required under Applicable Laws.

(c) Participant is familiar with the provisions of Rule 701 and Rule 144, each promulgated under the Securities Act, which, in substance, permit limited public resale of “restricted securities” acquired, directly or indirectly from the issuer thereof, in a non-public offering subject to the satisfaction of certain conditions. Rule 701 provides that if the issuer qualifies under Rule 701 at the time of the grant of the Option to Participant, the exercise will be exempt from registration under the Securities Act. In the event the Company becomes subject to the reporting requirements of Section 13 or 15(d) of the Exchange Act, ninety days thereafter (or such longer period as any market stand-off agreement may require) the securities exempt under Rule 701 may be resold, subject to the satisfaction of certain of the conditions specified by Rule 144.

(d) In the event that the Company does not qualify under Rule 701 at the time of grant of the Option, then the securities may be resold in certain limited circumstances subject to the provisions of Rule 144.

(e) Participant further understands that in the event all of the applicable requirements of Rule 701 or 144 are not satisfied, registration under the Securities Act, compliance with Regulation A, or some other registration exemption will be required; and that, notwithstanding the fact that Rules 144 and 701 are not exclusive, the Staff of the Securities and Exchange Commission has expressed its opinion that persons proposing to sell private placement securities other than in a registered offering and otherwise than pursuant to Rules 144 or 701 will have a substantial burden of proof in establishing that an exemption from registration is available for such offers or sales, and that such persons and their respective brokers who participate in such transactions do so at their own risk. Participant understands that no assurances can be given that any such other registration exemption will be available in such event.

4. Notices. Any notice required or permitted hereunder shall be given in accordance with the provisions set forth in Section 11(b) of the Agreement.

5. Entire Agreement. The Plan and Agreement are incorporated herein by reference. This Notice, the Plan and the Agreement constitute the entire agreement of the parties and supersede in their entirety all prior undertakings and agreements of the Company and Participant with respect to the subject matter hereof.

ACCEPTED BY: PROMETHEUS BIOSCIENCES, INC.

By: 
Print Name: 
Title: 

SUBMITTED BY PARTICIPANT:

By: 
Print Name: 
Title: 

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FOR VALUE RECEIVED I, ____________, hereby sell, assign and transfer unto ____________ the shares of the Common Stock of Prometheus Biosciences, Inc. registered in my name on the books of said corporation represented by Certificate No. ______ and do hereby irrevocably constitute and appoint ____________ to transfer the said stock on the books of the within named corporation with full power of substitution in the premises.

This Assignment Separate from Certificate may be used only in accordance with the Stock Option Grant Notice and Stock Option Agreement between Prometheus Biosciences, Inc. and the undersigned dated

_______________, 20__.  
Dated: ________________, __

Signature: __________________________________________

INSTRUCTIONS: Please do not fill in any blanks other than the signature line. The purpose of this assignment is to enable the Company to exercise the Company Repurchase Right, as set forth in the Stock Option Grant Notice and Stock Option Agreement, without requiring additional signatures on the part of Purchaser.
TO STOCK OPTION GRANT NOTICE

CONSENT OF SPOUSE

I, __________, spouse of ____________, have read and approve the Stock Option Grant Notice and Stock Option Agreement dated __________, 20__, between my spouse and Prometheus Biosciences, Inc. In consideration of granting of the right to my spouse to purchase shares of Prometheus Biosciences, Inc. set forth in the Stock Option Grant Notice and Stock Option Agreement, I hereby appoint my spouse as my attorney-in-fact in respect to the exercise of any rights under the Stock Option Grant Notice and Stock Option Agreement and agree to be bound by the provisions of the Stock Option Grant Notice and Stock Option Agreement insofar as I may have any rights in said Stock Option Grant Notice and Stock Option Agreement or any shares issued pursuant thereto under the community property laws or similar laws relating to marital property in effect in the state of our residence as of the date of the signing of the Stock Option Grant Notice and Stock Option Agreement or the exercise of the option granted thereunder.

Dated: _______________, __

________________________________________
Signature of Spouse

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These instructions are provided to assist you if you choose to make an election under Section 83(b) of the Internal Revenue Code, as amended, with respect to the shares of common stock of Prometheus Biosciences, Inc. transferred to you. **Please consult with your personal tax advisor as to whether an election of this nature will be in your best interests in light of your personal tax situation.**

The executed original of the Section 83(b) election must be filed with the Internal Revenue Service not later than 30 days after the date the shares were transferred to you. **There is no remedy for failure to file on time.** The steps outlined below should be followed to ensure the election is mailed and filed correctly and in a timely manner. **If you make the Section 83(b) election, the election is irrevocable.**

Complete the Section 83(b) election form (attached as Attachment 1) and make four (4) copies of the signed election form. Your spouse, if any, should sign the Section 83(b) election form as well.

Prepare the cover letter to the Internal Revenue Service (sample letter attached as Attachment 2).

Send the cover letter with the originally executed Section 83(b) election form and one (1) copy via certified mail, return receipt requested to the Internal Revenue Service at the address of the Internal Revenue Service where you file your personal tax returns. We suggest that you have the package date-stamped at the post office. The post office will provide you with a certified receipt that includes a dated postmark. Enclose a self-addressed, stamped envelope so that the Internal Revenue Service may return a date-stamped copy to you. However, your postmarked receipt is your proof of having timely filed the Section 83(b) election if you do not receive confirmation from the Internal Revenue Service.

One (1) copy must be sent to Prometheus Biosciences, Inc. for its records.

Retain the Internal Revenue Service file stamped copy (when returned) for your records.

Please consult your personal tax advisor for the address of the office of the Internal Revenue Service to which you should mail your election form.
ATTACHMENT 1

ELECTION UNDER INTERNAL REVENUE CODE SECTION 83(B)

The undersigned taxpayer hereby elects, pursuant to Section 83(b) of the Internal Revenue Code of 1986, as amended, to include in taxpayer’s gross income for the current taxable year the amount of any compensation taxable to taxpayer in connection with taxpayer’s receipt of shares (the “Shares”) of Common Stock of Prometheus Biosciences, Inc., a Delaware corporation (the “Company”).

The name, address and taxpayer identification number of the undersigned taxpayer are:

________________________

________________________

SSN: ______________________

The name, address and taxpayer identification number of the Taxpayer’s spouse are (complete if applicable):

________________________

________________________

SSN: ______________________

Description of the property with respect to which the election is being made:

________________________ shares of Common Stock of the Company.

The date on which the property was transferred was ______________. The taxable year to which this election relates is calendar year ____.

Nature of restrictions to which the property is subject:

The Shares are subject to repurchase by the Company or its assignee upon the occurrence of certain events. This repurchase right lapses based upon the continued performance of services by the taxpayer over time.

The fair market value at the time of transfer (determined without regard to any lapse restrictions, as defined in Treasury Regulation Section 1.83-3(i)) of the Shares was $___________ per Share.

The amount paid by the taxpayer for the Shares was per share.

A copy of this statement has been furnished to the Company.

Dated: ______________________ Taxpayer Signature: ______________________

The undersigned spouse of Taxpayer joins in this election. (Complete if applicable).

Dated: ______________________ Spouse’s Signature: ______________________
SAMPLE COVER LETTER TO INTERNAL REVENUE SERVICE

[Address where taxpayer files returns]

Re: Election under Section 83(b) of the Internal Revenue Code of 1986

Taxpayer: _____________________________
Taxpayer’s Social Security Number: _____________________________
Taxpayer’s Spouse: _____________________________
Taxpayer’s Spouse’s Social Security Number: _____________________________

Enclose please find an original and one copy of an Election under Section 83(b) of the Internal Revenue Code of 1986, as amended, being made by the taxpayer referenced above. Please acknowledge receipt of the enclosed materials by stamping the enclosed copy of the Election and returning it to me in the self-addressed stamped envelope provided herewith.

Very truly yours,

Enclosures

cc: Prometheus Biosciences, Inc.
THIS AMENDMENT NO. 1 TO THE PROMETHEUS BIOSCIENCES, INC. 2017 EQUITY INCENTIVE PLAN (this “Amendment”), dated as of May 23, 2018, is made and adopted by PROMETHEUS BIOSCIENCES, INC., a Delaware corporation (the “Company”). Capitalized terms used but not otherwise defined herein shall have the meanings ascribed to them in the Plan (as defined below).

RECITALS

WHEREAS, the Company has adopted the Prometheus Biosciences, Inc. 2017 Equity Incentive Plan (the “Plan”);

WHEREAS, the Company desires to amend the Plan as set forth below;

WHEREAS, pursuant to Section 10(d) of the Plan, the Plan may be amended by the Board of Directors of the Company; and

WHEREAS, the Board of Directors of the Company has approved this Amendment pursuant to resolutions adopted on May 23, 2018, and the stockholders of the Company have approved this Amendment pursuant to resolutions adopted on June 7, 2018.

NOW, THEREFORE, in consideration of the foregoing, the Company hereby amends the Plan as follows:

1. The first sentence of Section 4 of the Plan is hereby amended to read as follows:

   “Subject to adjustment under Section 8 hereof, Awards may be made under the Plan covering up to 6,000,000 shares of Common Stock.”

2. This Amendment shall be and is hereby incorporated in and forms a part of the Plan. All other terms and provisions of the Plan shall remain unchanged except as specifically modified herein. The Plan, as amended by this Amendment, is hereby ratified and confirmed.

[REMAINDER OF PAGE LEFT INTENTIONALLY BLANK]
I hereby certify that the foregoing Amendment was duly adopted by the Board of Directors of Prometheus Biosciences, Inc. on May 23, 2018, and duly approved by the stockholders of Prometheus Biosciences, Inc. on June 7 2018.

By: /s/ Scott L. Glenn
Name: Scott L. Glenn
Title: President and CEO

[Signature Page – Amendment No. 1 to the 2017 Equity Incentive Plan]
AMENDMENT NO. 2
TO THE
PROMETHEUS BIOSCIENCES, INC. 2017 EQUITY INCENTIVE PLAN

THIS AMENDMENT NO. 2 TO THE PROMETHEUS BIOSCIENCES, INC. 2017 EQUITY INCENTIVE PLAN (this “Amendment”), dated as of October 24, 2018, is made and adopted by PROMETHEUS BIOSCIENCES, INC., a Delaware corporation (the “Company”). Capitalized terms used but not otherwise defined herein shall have the meanings ascribed to them in the Plan (as defined below).

RECITALS

WHEREAS, the Company has adopted the Prometheus Biosciences, Inc. 2017 Equity Incentive Plan (the “Plan”);

WHEREAS, the Company desires to amend the Plan as set forth below;

WHEREAS, pursuant to Section 10(d) of the Plan, the Plan may be amended by the Board of Directors of the Company; and

WHEREAS, the Board of Directors of the Company has approved this Amendment pursuant to resolutions adopted on October 24, 2018, and the stockholders of the Company have approved this Amendment pursuant to resolutions adopted on November 14, 2018.

NOW, THEREFORE, in consideration of the foregoing, the Company hereby amends the Plan as follows:

1. The first sentence of Section 4 of the Plan is hereby amended to read as follows:

   “Subject to adjustment under Section 8 hereof, Awards may be made under the Plan covering up to 10,000,000 shares of Common Stock.”

2. This Amendment shall be and is hereby incorporated in and forms a part of the Plan. All other terms and provisions of the Plan shall remain unchanged except as specifically modified herein. The Plan, as amended by this Amendment, is hereby ratified and confirmed.

[REMAINDER OF PAGE LEFT INTENTIONALLY BLANK]
I hereby certify that the foregoing Amendment was duly adopted by the Board of Directors of Prometheus Biosciences, Inc. on October 24, 2018, and duly approved by the stockholders of Prometheus Biosciences, Inc. on November 14, 2018.

By: /s/ Scott L. Glenn
Name: Scott L. Glenn
Title: President and CEO

[Signature Page – Amendment No. 2 to the 2017 Equity Incentive Plan]
THIS AMENDMENT NO. 3 TO THE PROMETHEUS BIOSCIENCES, INC. 2017 EQUITY INCENTIVE PLAN (this “Amendment”), dated as of June 30, 2019, is made and adopted by PROMETHEUS BIOSCIENCES, INC., a Delaware corporation (the “Company”). Capitalized terms used but not otherwise defined herein shall have the meanings ascribed to them in the Plan (as defined below).

RECITALS

WHEREAS, the Company has adopted the Prometheus Biosciences, Inc. 2017 Equity Incentive Plan (the “Plan”);

WHEREAS, the Company desires to amend the Plan as set forth below;

WHEREAS, pursuant to Section 10(d) of the Plan, the Plan may be amended by the Board of Directors of the Company; and

WHEREAS, the Board of Directors of the Company has approved this Amendment pursuant to resolutions adopted on June 28, 2019, and the stockholders of the Company have approved this Amendment pursuant to resolutions adopted on June 28, 2019.

NOW, THEREFORE, in consideration of the foregoing, the Company hereby amends the Plan as follows:

1. The first sentence of Section 4 of the Plan is hereby amended to read as follows:

   “Subject to adjustment under Section 8 hereof, Awards may be made under the Plan covering up to 17,500,000 shares of Common Stock.”

2. This Amendment shall be and is hereby incorporated in and forms a part of the Plan. All other terms and provisions of the Plan shall remain unchanged except as specifically modified herein. The Plan, as amended by this Amendment, is hereby ratified and confirmed.

[REMAINDER OF PAGE LEFT INTENTIONALLY BLANK]
I hereby certify that the foregoing Amendment was duly adopted by the Board of Directors of Prometheus Biosciences, Inc. on June 28, 2019, and duly approved by the stockholders of Prometheus Biosciences, Inc. on June 28, 2019.

By: /s/ Scott L. Glenn
Name: Scott L. Glenn
Title: President and CEO

[Signature Page – Amendment No. 3 to the 2017 Equity Incentive Plan]
AMENDMENT NO. 4
TO THE
PROMETHEUS BIOSCIENCES, INC. 2017 EQUITY INCENTIVE PLAN

THIS AMENDMENT NO. 4 TO THE PROMETHEUS BIOSCIENCES, INC. 2017 EQUITY INCENTIVE PLAN (this “Amendment”), dated as of March 27, 2020, is made and adopted by PROMETHEUS BIOSCIENCES, INC., a Delaware corporation (the “Company”). Capitalized terms used but not otherwise defined herein shall have the meanings ascribed to them in the Plan (as defined below).

RECITALS

WHEREAS, the Company has adopted the Prometheus Biosciences, Inc. 2017 Equity Incentive Plan (the “Plan”);

WHEREAS, the Company desires to amend the Plan as set forth below;

WHEREAS, pursuant to Section 10(d) of the Plan, the Plan may be amended by the Board of Directors of the Company; and

WHEREAS, the Board of Directors of the Company has approved this Amendment pursuant to resolutions adopted on March 27, 2020, and the stockholders of the Company have approved this Amendment pursuant to resolutions adopted on March 27, 2020.

NOW, THEREFORE, in consideration of the foregoing, the Company hereby amends the Plan as follows:

1. The first sentence of Section 4 of the Plan is hereby amended to read as follows:

   “Subject to adjustment under Section 8 hereof, Awards may be made under the Plan covering up to 22,500,000 shares of Common Stock.”

2. This Amendment shall be and is hereby incorporated in and forms a part of the Plan. All other terms and provisions of the Plan shall remain unchanged except as specifically modified herein. The Plan, as amended by this Amendment, is hereby ratified and confirmed.

[REMAINDER OF PAGE LEFT INTENTIONALLY BLANK]
I hereby certify that the foregoing Amendment was duly adopted by the Board of Directors of Prometheus Biosciences, Inc. on March 27, 2020, and duly approved by the stockholders of Prometheus Biosciences, Inc. on March 27, 2020.

By: /s/ Mark McKenna

Name: Mark McKenna
Title: President and CEO

[Signature Page – Amendment No. 4 to the 2017 Equity Incentive Plan]
THIS LOAN AND SECURITY AGREEMENT (as the same may from time to time be amended, modified, supplemented or restated, this “Agreement”) dated as of January 24, 2020 (the “Effective Date”) among OXFORD FINANCE LLC, a Delaware limited liability company with an office located at 133 North Fairfax Street, Alexandria, Virginia 22314 (“Oxford”), as collateral agent (in such capacity, “Collateral Agent”), the Lenders listed on Schedule 1.1 hereof or otherwise a party hereto from time to time including Oxford in its capacity as a Lender (each a “Lender” and collectively, the “Lenders”), and PROMETHEUS BIOSCIENCES, INC., a Delaware corporation (“Parent”) and PROMETHEUS LABORATORIES INC., a California corporation, each with offices located at 9410 Carroll Park Drive, San Diego, CA 92121 (individually and collectively, jointly and severally, “Borrower”), provides the terms on which the Lenders shall lend to Borrower and Borrower shall repay the Lenders. The parties agree as follows:

1. ACCOUNTING AND OTHER TERMS

1.1 Accounting terms not defined in this Agreement shall be construed in accordance with GAAP. Calculations and determinations must be made in accordance with GAAP, except as otherwise noted herein. Capitalized terms not otherwise defined in this Agreement shall have the meanings set forth in Section 13. All other terms contained in this Agreement, unless otherwise indicated, shall have the meaning provided by the Code to the extent such terms are defined therein. All references to “Dollars” or “$” are United States Dollars, unless otherwise noted.

2. LOANS AND TERMS OF PAYMENT

2.1 Promise to Pay. Borrower hereby unconditionally promises to pay each Lender, the outstanding principal amount of all Term Loans advanced to Borrower by such Lender and accrued and unpaid interest thereon and any other amounts due hereunder as and when due in accordance with this Agreement.

2.2 Term Loans.

(a) Availability. (i) Subject to the terms and conditions of this Agreement, the Lenders agree, severally and not jointly, to make term loans to Borrower on the Effective Date in an aggregate amount of Seven Million Five Hundred Thousand Dollars ($7,500,000.00) according to each Lender’s Term A Loan Commitment as set forth on Schedule 1.1 hereto (such term loans are hereinafter referred to singly as a “Term A Loan”, and collectively as the “Term A Loans”). After repayment, no Term A Loan may be re-borrowed.

(ii) Subject to the terms and conditions of this Agreement, the Lenders agree, severally and not jointly, during the Second Draw Period, to make one (1) term loan to Borrower in an amount of not less than Five Million Dollars ($5,000,000.00) and up to Seventeen Million Five Hundred Thousand Dollars ($17,500,000.00) according to each Lender’s Term B Loan Commitment as set forth on Schedule 1.1 hereto (such term loans are hereinafter referred to singly as a “Term B Loan”, and collectively as the “Term B Loans”; each Term A Loan or Term B Loan is hereinafter referred to singly as a “Term Loan” and the Term A Loans and the Term B Loans are hereinafter referred to collectively as the “Term Loans”). After repayment, no Term B Loan may be re-borrowed.

(b) Repayment. Borrower shall make monthly payments of interest only commencing on the first (1st) Payment Date following the Funding Date of each Term Loan, and continuing on the Payment Date of each successive month thereafter through and including the Payment Date immediately preceding the Amortization Date. Borrower agrees to pay, on the Funding Date of each Term Loan, any initial partial monthly interest payment otherwise due for the period between the Funding Date of such Term Loan and the first Payment Date thereof. Commencing on the Amortization Date, and continuing on the Payment Date of each month thereafter, Borrower shall make consecutive equal monthly payments of principal, together with applicable interest, in arrears, to each Lender, as calculated by Collateral Agent (which calculations shall be deemed correct absent manifest error) based upon: (1) the amount of such Lender’s Term Loan, (2) the effective rate of interest, as determined in Section 2.3(a), and (3) a repayment schedule equal to twenty-four (24) months. All unpaid principal and accrued and unpaid interest with respect to each Term Loan is due and payable in full on the Maturity Date. Each Term Loan may only be prepaid in accordance with Sections 2.2(c) and 2.2(d).
(c) **Mandatory Prepayments.** If the Term Loans are accelerated following the occurrence of an Event of Default, Borrower shall immediately pay to Lenders, payable to each Lender in accordance with its respective Pro Rata Share, an amount equal to the sum of: (i) all outstanding principal of the Term Loans plus accrued and unpaid interest thereon through the prepayment date, (ii) the Final Payment, (iii) the Prepayment Fee, plus (iv) all other Obligations that are due and payable, including Lenders’ Expenses and interest at the Default Rate with respect to any past due amounts. Notwithstanding (but without duplication with) the foregoing, on the Maturity Date, if the Final Payment had not previously been paid in full in connection with the prepayment of the Term Loans in full, Borrower shall pay to Collateral Agent, for payment to each Lender in accordance with its respective Pro Rata Share, the Final Payment in respect of the Term Loan(s).

(d) **Permitted Prepayment of Term Loans.**

(i) Borrower shall have the option to prepay all, but not less than all, of the Term Loans advanced by the Lenders under this Agreement, provided Borrower (i) provides written notice to Collateral Agent of its election to prepay the Term Loans at least five (5) Business Days prior to such prepayment, and (ii) pays to the Lenders on the date of such prepayment, payable to each Lender in accordance with its respective Pro Rata Share, an amount equal to the sum of (A) all outstanding principal of the Term Loans plus accrued and unpaid interest thereon through the prepayment date, (B) the Final Payment, (C) the Prepayment Fee, plus (D) all other Obligations that are due and payable, including Lenders’ Expenses and interest at the Default Rate with respect to any past due amounts.

(ii) Notwithstanding anything herein to the contrary, Borrower shall also have the option to prepay part of Term Loans advanced by the Lenders under this Agreement, provided Borrower (i) provides written notice to Collateral Agent of its election to prepay the Term Loans at least five (5) Business Days prior to such prepayment, (ii) prepays such part of the Term Loans in a denomination that is a whole number multiple of Five Million Dollars ($5,000,000.00), and (iii) pays to the Lenders on the date of such prepayment, payable to each Lender in accordance with its respective Pro Rata Share, an amount equal to the sum of (A) the portion of outstanding principal of such Term Loans plus all accrued and unpaid interest thereon through the prepayment date, (B) the applicable Final Payment, and (C) all other Obligations that are then due and payable, including Lenders’ Expenses and interest at the Default Rate with respect to any past due amounts, and (D) the applicable pro-rated Prepayment Fee with respect to the portion of such Term Loans being prepaid. For the purposes of clarity, any partial prepayment shall be applied pro-rata to all outstanding amounts under each Term Loan, and shall be applied pro-rata within each Term Loan tranche to reduce amortization payments under Section 2.2(b) on a pro-rata basis.

2.3 **Payment of Interest on the Credit Extensions.**

(a) **Interest Rate.** Subject to Section 2.3(b), the principal amount outstanding under the Term Loans shall accrue interest at a floating per annum rate equal to the Basic Rate, determined by Collateral Agent on the Funding Date of the applicable Term Loan and monthly thereafter, which interest shall be payable monthly in arrears in accordance with Sections 2.2(b) and 2.3(e). Interest shall accrue on each Term Loan commencing on, and including, the Funding Date of such Term Loan, and shall accrue on the principal amount outstanding under such Term Loan through and including the day on which such Term Loan is paid in full.

(b) **Default Rate.** Immediately upon the occurrence and during the continuance of an Event of Default, Obligations shall accrue interest at a floating per annum rate equal to the rate that is otherwise applicable thereto plus five percentage points (5.00%) (the “Default Rate”). Payment or acceptance of the increased interest rate provided in this Section 2.3(b) is not a permitted alternative to timely payment and shall not constitute a waiver of any Event of Default or otherwise prejudice or limit any rights or remedies of Collateral Agent.

(c) **360-Day Year.** Interest shall be computed on the basis of a three hundred sixty (360) day year, and the actual number of days elapsed.
Debit of Accounts. Collateral Agent and each Lender may debit (or ACH) any deposit accounts, maintained by Borrower or any of its Subsidiaries, starting with the Designated Deposit Account, for principal and interest payments or any other amounts Borrower owes the Lenders under the Loan Documents when due. Any such debits (or ACH activity) shall not constitute a set-off. Without limiting the foregoing, Collateral Agent and each Lender shall use commercially reasonable efforts to notify Borrower for the reasons of debiting of any amounts (other than principal and interest payments) debited from Borrower’s deposit accounts in respect of this Agreement after such debit has been made; provided, however, failure to provide such notice shall not be considered a breach of any provision hereof by Collateral Agent or any Lender.

Payments. Except as otherwise expressly provided herein, all payments by Borrower under the Loan Documents shall be made to the respective Lender to which such payments are owed, at such Lender’s office in immediately available funds on the date specified herein. Unless otherwise provided, interest is payable monthly on the Payment Date of each month. Payments of principal and/or interest received after 2:00 p.m. Eastern time are considered received at the opening of business on the next Business Day. When a payment is due on a day that is not a Business Day, the payment is due the next Business Day and additional fees or interest, as applicable, shall continue to accrue until paid. All payments to be made by Borrower hereunder or under any other Loan Document, including payments of principal and interest, and all fees, expenses, indemnities and reimbursements, shall be made without set-off, recoupment or counterclaim, in lawful money of the United States and in immediately available funds.

2.4 Secured Promissory Notes. The Term Loans shall be evidenced by a Secured Promissory Note or Notes in the form attached as Exhibit D hereto (each a “Secured Promissory Note”), and shall be repayable as set forth in this Agreement. Borrower irrevocably authorizes each Lender to make or cause to be made, on or about the Funding Date of any Term Loan or at the time of receipt of any payment of principal on such Lender’s Secured Promissory Note, an appropriate notation on such Lender’s Secured Promissory Note Record reflecting the making of such Term Loan or (as the case may be) the receipt of such payment. The outstanding amount of each Term Loan set forth on such Lender’s Secured Promissory Note Record shall be prima facie evidence of the principal amount thereof owing and unpaid to such Lender, but the failure to record, or any error in so recording, any such amount on such Lender’s Secured Promissory Note Record shall not limit or otherwise affect the obligations of Borrower under any Secured Promissory Note or any other Loan Document to make payments of principal of or interest on any Secured Promissory Note when due. Upon receipt of an affidavit of an officer of a Lender as to the loss, theft, destruction, or mutilation of its Secured Promissory Note, Borrower shall issue, in lieu thereof, a replacement Secured Promissory Note in the same principal amount thereof and of like tenor.

2.5 Fees. Borrower shall pay to Collateral Agent:

(a) Good Faith Deposit. Borrower has remitted to Collateral Agent Thirty Thousand Dollars ($30,000.00) as a good faith deposit, which amount shall be applied towards the facility fee due under Section 2.5(b) hereof on the Effective Date. For the sake of clarity, Borrower shall be responsible for the entire amount of the facility fee payable pursuant to Section 2.5(b) hereof and the Lenders’ Expenses payable under Section 2.5(e).

(b) FacilityFee. A fully earned, non-refundable facility fee equal to one-half of one percent (0.50%) of the funded Term Loans, to be shared between the Lenders pursuant to their respective Commitment Percentages payable as follows: (i) Thirty-Seven Thousand Five Hundred Dollars ($37,500.00) of the facility fee shall be due and payable on account of the Term A Loan on the Effective Date and (ii) one-half of one percent (0.50%) of the funded amount of the Term B Loan shall be due and payable on the Funding Date of the Term B Loan;

(c) Final Payment. The Final Payment, when due hereunder, to be shared between the Lenders in accordance with their respective Pro Rata Shares;

(d) Prepayment Fee. The Prepayment Fee, when due hereunder, to be shared between the Lenders in accordance with their respective Pro Rata Shares;
Lenders’ Expenses. All Lenders’ Expenses (including reasonable attorneys’ fees and expenses for documentation and negotiation of this Agreement) incurred through and after the Effective Date, when due.

2.6 Withholding. Payments received by the Lenders from Borrower hereunder will be made free and clear of and without deduction for any and all present or future taxes, levies, imposts, duties, deductions, withholdings, assessments, fees or other charges imposed by any governmental authority (including any interest, additions to tax or penalties applicable thereto). Specifically, however, if at any time any Governmental Authority, applicable law, regulation or international agreement requires Borrower to make any withholding or deduction from any such payment or other sum payable hereunder to the Lenders, Borrower hereby covenants and agrees that the amount due from Borrower with respect to such payment or other sum payable hereunder will be increased to the extent necessary to ensure that, after the making of such required withholding or deduction, each Lender receives a net sum equal to the sum which it would have received had no withholding or deduction been required and Borrower shall pay the full amount withheld or deducted to the relevant Governmental Authority. Borrower will, upon request, furnish the Lenders with proof reasonably satisfactory to the Lenders indicating that Borrower has made such withholding payment; provided, however, that Borrower need not make any withholding payment if the amount or validity of such withholding payment is contested in good faith by appropriate and timely proceedings and as to which payment in full is bonded or reserved against by Borrower. The agreements and obligations of Borrower contained in this Section 2.6 shall survive the termination of this Agreement.

3. CONDITIONS OF LOANS

3.1 Conditions Precedent to Initial Credit Extension. Each Lender’s obligation to make a Term A Loan is subject to the condition precedent that Collateral Agent and each Lender shall consent to or shall have received, in form and substance satisfactory to Collateral Agent and each Lender, such documents, and completion of such other matters, as Collateral Agent and each Lender may reasonably deem necessary or appropriate, including, without limitation:

(a) original Loan Documents, each duly executed by Borrower and each Subsidiary, as applicable;

(b) duly executed original Control Agreements with respect to any Collateral Accounts maintained by Borrower or any of its Subsidiaries to the extent required under Section 6.6;

(c) duly executed original Secured Promissory Notes in favor of each Lender according to its Term A Loan Commitment Percentage;

(d) the certificate(s) for the Shares, together with Assignment(s) Separate from Certificate, duly executed in blank;

(e) the Operating Documents and good standing certificates of Borrower and its Subsidiaries certified by the Secretary of State (or equivalent agency) of Borrower’s and such Subsidiaries’ jurisdiction of organization or formation and each jurisdiction in which Borrower and each Subsidiary is qualified to conduct business, each as of a date no earlier than thirty (30) days prior to the Effective Date;

(f) a completed Perfection Certificate for Borrower and each of its Subsidiaries;

(g) the Annual Projections, for the current calendar year;

(h) duly executed original officer’s certificate for Borrower and each Subsidiary that is a party to the Loan Documents, in a form acceptable to Collateral Agent and the Lenders;

(i) certified copies, dated as of date no earlier than thirty (30) days prior to the Effective Date, of financing statement searches, as Collateral Agent shall request, accompanied by written evidence (including any UCC termination statements) that the Liens indicated in any such financing statements either constitute Permitted Liens or have been or, in connection with the initial Credit Extension, will be terminated or released;
(j) a landlord’s consent executed in favor of Collateral Agent in respect of Borrower’s headquarters locations, and each other of Borrower’s and each Subsidiaries’ leased locations where Borrower or any Subsidiary maintains Collateral having a book value in excess of Five Hundred Thousand Dollars ($500,000.00);

(k) a bailee waiver executed in favor of Collateral Agent in respect of each third party bailee where Borrower or any Subsidiary maintains Collateral having a book value in excess of Five Hundred Thousand Dollars ($500,000.00);

(l) a duly executed legal opinion of counsel to Borrower dated as of the Effective Date;

(m) evidence satisfactory to Collateral Agent and the Lenders that the insurance policies required by Section 6.5 hereof are in full force and effect, together with appropriate evidence showing loss payable and/or additional insured clauses or endorsements in favor of Collateral Agent, for the ratable benefit of the Lenders;

(n) a copy of any applicable Registration Rights Agreement or Investors’ Rights Agreement and any amendments thereto; and

(o) payment of the fees and Lenders’ Expenses then due as specified in Section 2.5 hereof.

3.2 Conditions Precedent to all Credit Extensions. The obligation of each Lender to make each Credit Extension, including the initial Credit Extension, is subject to the following conditions precedent:

(a) receipt by Collateral Agent of an executed Disbursement Letter in the form of Exhibit B attached hereto;

(b) the representations and warranties in Section 5 hereof shall be true, accurate and complete in all material respects on the date of the Disbursement Letter and on the Funding Date of each Credit Extension; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true, accurate and complete in all material respects as of such date, and no Event of Default shall have occurred and be continuing or result from the Credit Extension. Each Credit Extension is Borrower’s representation and warranty on that date that the representations and warranties in Section 5 hereof are true, accurate and complete in all material respects; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true, accurate and complete in all material respects as of such date;

(c) in such Lender’s sole but reasonable discretion, there has not been a Material Adverse Change or any material adverse deviation by Borrower from the Annual Projections of Borrower presented to and accepted by Collateral Agent and each Lender;

(d) to the extent not delivered at the Effective Date, duly executed original Secured Promissory Notes and Warrants, in number, form and content acceptable to each Lender, and in favor of each Lender according to its Commitment Percentage, with respect to each Credit Extension made by such Lender after the Effective Date; and

(e) payment of the fees and Lenders’ Expenses then due as specified in Section 2.5 hereof.

3.3 Covenant to Deliver. Borrower agrees to deliver to Collateral Agent and the Lenders each item required to be delivered to Collateral Agent under this Agreement as a condition precedent to any Credit Extension. Borrower expressly agrees that a Credit Extension made prior to the receipt by Collateral Agent or any Lender of any such item shall not constitute a waiver by Collateral Agent or any Lender of Borrower’s obligation to deliver such item, and any such Credit Extension in the absence of a required item shall be made in each Lender’s sole discretion.
3.4 Procedures for Borrowing. Subject to the prior satisfaction of all other applicable conditions to the making of a Term Loan set forth in this Agreement, to obtain a Term Loan (other than the Term A Loan), Borrower shall notify the Lenders (which notice shall be irrevocable) by electronic mail, facsimile, or telephone by 2:00 p.m. Eastern time five (5) Business Days prior to the date the Term Loan is to be made. Together with any such electronic, facsimile or telephonic notification, Borrower shall deliver to the Lenders by electronic mail or facsimile a completed Disbursement Letter executed by a Responsible Officer or his or her designee. The Lenders may rely on any telephone notice given by a person whom a Lender reasonably believes is a Responsible Officer or designee. On the Funding Date, each Lender shall credit and/or transfer (as applicable) to the Designated Deposit Account, an amount equal to its Term Loan Commitment.

4. CREATION OF SECURITY INTEREST

4.1 Grant of Security Interest. Borrower hereby grants Collateral Agent, for the ratable benefit of the Lenders, to secure the payment and performance in full of all of the Obligations, a continuing security interest in, and pledges to Collateral Agent, for the ratable benefit of the Lenders, the Collateral, wherever located, whether now owned or hereafter acquired or arising, and all proceeds and products thereof. Borrower represents, warrants, and covenants that the security interest granted herein is and shall at all times continue to be a first priority perfected security interest in the Collateral, subject only to Permitted Liens that are permitted by the terms of this Agreement to have priority to Collateral Agent’s Lien. If Borrower shall acquire a commercial tort claim (as defined in the Code) greater than Fifty Thousand Dollars ($50,000.00), Borrower shall promptly notify Collateral Agent in a writing signed by Borrower, as the case may be, of the general details thereof (and further details as may be required by Collateral Agent) and grant to Collateral Agent, for the ratable benefit of the Lenders, in such writing a security interest therein and in the proceeds thereof, all upon the terms of this Agreement, with such writing to be in form and substance reasonably satisfactory to Collateral Agent.

If this Agreement is terminated, Collateral Agent’s Lien in the Collateral shall continue until the Obligations (other than inchoate indemnity obligations) are repaid in full in cash. Upon payment in full in cash of the Obligations (other than inchoate indemnity obligations) and at such time as the Lenders’ obligation to make Credit Extensions has terminated, Collateral Agent shall, at the sole cost and expense of Borrower, release its Liens in the Collateral and all rights therein shall revert to Borrower.

4.2 Authorization to File Financing Statements. Borrower hereby authorizes Collateral Agent to file financing statements or take any other action required to perfect Collateral Agent’s security interests in the Collateral, without notice to Borrower, with all appropriate jurisdictions to perfect or protect Collateral Agent’s interest or rights under the Loan Documents, including a notice that any disposition of the Collateral, except to the extent permitted by the terms of this Agreement, by Borrower, or any other Person, shall be deemed to violate the rights of Collateral Agent under the Code.

4.3 Pledge of Collateral. Borrower hereby pledges, assigns and grants to Collateral Agent, for the ratable benefit of the Lenders, a security interest in all the Shares, together with all proceeds and substitutions thereof, all cash, stock and other moneys and property paid thereon, all rights to subscribe for securities declared or granted in connection therewith, and all other cash and noncash proceeds of the foregoing, as security for the performance of the Obligations. On the Effective Date, or, to the extent not certificated as of the Effective Date, within ten (10) Business Days of the certification of any Shares, the certificate or certificates for the Shares will be delivered to Collateral Agent, accompanied by an instrument of assignment duly executed in blank by Borrower. To the extent a pledge of the Shares to the Collateral Agent is required by the terms and conditions governing such Shares to be reflected on the books of the applicable Issuer, Borrower shall cause the books of each entity whose Shares are part of the Collateral and any transfer agent to reflect the pledge of such Shares. Upon the occurrence and during the continuance of an Event of Default hereunder, Collateral Agent may effect the transfer of any securities included in the Collateral (including but not limited to the Shares) into the name of Collateral Agent and cause new (as applicable) certificates representing such securities to be issued in the name of Collateral Agent or its transferee. Borrower will execute and deliver such documents, and take or cause to be taken such actions, as
Collateral Agent may reasonably request to perfect or continue the perfection of Collateral Agent’s security interest in the Shares. Unless an Event of Default shall have occurred and be continuing, Borrower shall be entitled to (i) exercise any voting rights with respect to the Shares and to give consents, waivers and ratifications in respect thereof, provided that no vote shall be cast or consent, waiver or ratification given or action taken which would be inconsistent with any of the terms of this Agreement or which would constitute or create any violation of any of such terms and (ii) to receive and retain any and all dividends, interest and other distributions paid in respect of the Shares to the extent that the payment thereof is not otherwise inconsistent with the terms of this Agreement. All such rights to vote and give consents, waivers and ratifications shall terminate upon the occurrence and continuance of an Event of Default. After all Events of Default have been waived in writing by Collateral Agent and the Lenders, Borrower shall regain the exclusive right to exercise the voting and/or consensual rights and powers that Borrower would otherwise be entitled to exercise and the right to receive and retain any dividends and interest payments from and after the effective date of such waiver that Borrower would otherwise be entitled to receive and retain.

5. REPRESENTATIONS AND WARRANTIES

Borrower represents and warrants to Collateral Agent and the Lenders as follows:

5.1 Due Organization, Authorization: Power and Authority. Borrower and each of its Subsidiaries is duly existing and in good standing as a Registered Organization in its jurisdictions of organization or formation and Borrower and each of its Subsidiaries is qualified and licensed to do business and is in good standing in any jurisdiction in which the conduct of its businesses or its ownership of property requires that it be qualified except where the failure to do so could not reasonably be expected to have a Material Adverse Change. In connection with this Agreement, Borrower and each of its Subsidiaries has delivered to Collateral Agent a completed perfection certificate signed by an officer of Borrower or such Subsidiary (each a “Perfection Certificate” and collectively, the “Perfection Certificates”). Borrower represents and warrants that (a) Borrower and each of its Subsidiaries’ exact legal name is that which is indicated on its respective Perfection Certificate and on the signature page of each Loan Document to which it is a party; (b) Borrower and each of its Subsidiaries is an organization of the type and is organized in the jurisdiction set forth on its respective Perfection Certificate; (c) each Perfection Certificate accurately sets forth each of Borrower’s and its Subsidiaries’ organizational identification number or accurately states that Borrower or such Subsidiary has none; (d) each Perfection Certificate accurately sets forth Borrower’s and each of its Subsidiaries’ place of business, or, if more than one, its chief executive office as well as Borrower’s and each of its Subsidiaries’ mailing address (if different than its chief executive office); (e) Borrower and each of its Subsidiaries (and each of its respective predecessors) have not, in the past five (5) years, changed its jurisdiction of organization, organizational structure or type, or any organizational number assigned by its jurisdiction; and (f) all other information set forth on the Perfection Certificates pertaining to Borrower and each of its Subsidiaries, is accurate and complete (it being understood and agreed that Borrower and each of its Subsidiaries may from time to time update certain information in the Perfection Certificates (including the information set forth in clause (d) above) after the Effective Date to the extent permitted by one or more specific provisions in this Agreement); such updated Perfection Certificates subject to the review and approval of Collateral Agent unless such facts, events or circumstances being updated first arose or occurred after the Effective Date and do not constitute a breach, default, or Event of Default under this Agreement or any other Loan Document. If Borrower or any of its Subsidiaries is not now a Registered Organization but later becomes one, Borrower shall notify Collateral Agent of such occurrence and provide Collateral Agent with such Person’s organizational identification number within five (5) Business Days of receiving such organizational identification number.

The execution, delivery and performance by Borrower and each of its Subsidiaries of the Loan Documents to which it is a party have been duly authorized, and do not (i) conflict with any of Borrower’s or such Subsidiaries’ Operating Documents, (ii) contravene, conflict with, constitute a default under or violate any material Requirement of Law applicable thereto, (iii) contravene, conflict or violate any applicable order, writ, judgment, injunction, decree, determination or award of any Governmental Authority by which Borrower or such Subsidiary, or any of their property or assets may be bound or affected, (iv) require any action by, filing, registration, or qualification with, or Governmental Approval from, any Governmental Authority (except such Governmental Approvals which have already been obtained and are in full force and effect or are being obtained pursuant to Section 6.1(b)), or (v) constitute an event of default under any material agreement by which Borrower or any of such Subsidiaries, or their respective properties, is bound. Neither Borrower nor any of its Subsidiaries is in default under any agreement to which it is a party or by which it or any of its assets is bound in which such default could reasonably be expected to have a Material Adverse Change.
5.2 Collateral.

(a) Borrower and each of its Subsidiaries have good title to, have rights in, and the power to transfer each item of the Collateral upon which it purports to grant a Lien under the Loan Documents, free and clear of any and all Liens except Permitted Liens, and neither Borrower nor any of its Subsidiaries have any Deposit Accounts, Securities Accounts, Commodity Accounts or other investment accounts other than the Collateral Accounts or the other investment accounts, if any, described in the Perfection Certificates delivered to Collateral Agent in connection herewith with respect of which Borrower or such Subsidiary has given Collateral Agent notice and taken such actions as are necessary to give Collateral Agent a perfected security interest therein, pursuant to the terms of Section 6.6(b). The Accounts are bona fide, existing obligations of the Account Debtors.

(b) On the Effective Date, and except as disclosed on the Perfection Certificate or as permitted under Section 6.11, (i) the Collateral is not in the possession of any third party bailee (such as a warehouse), and (ii) no such third party bailee possesses components of the Collateral in excess of Five Hundred Thousand Dollars ($500,000.00). None of the components of the Collateral shall be maintained at locations other than as disclosed in the Perfection Certificates on the Effective Date or as permitted pursuant to Section 6.11.

(c) All Inventory held and released for commercial sale by or for the benefit of Borrower or any Subsidiary is in all material respects of good and marketable quality, free from material defects.

(d) Borrower and each of its Subsidiaries is the sole owner of the Intellectual Property each respectively purports to own, free and clear of all Liens other than Permitted Liens. Except as noted on the Perfection Certificates (it being understood and agreed that Borrower and each of its Subsidiaries may from time to time update certain information in the Perfection Certificates after the Effective Date to the extent permitted by one or more specific provisions in this Agreement; such updated Perfection Certificates subject to the review and approval of Collateral Agent unless such facts, events or circumstances being updated first arose or occurred after the Effective Date and do not constitute a breach, default, or Event of Default under this Agreement or any other Loan Document), neither Borrower nor any of its Subsidiaries is a party to, nor is bound by, any material license or other material agreement with respect to which Borrower or such Subsidiary is the licensee that (i) prohibits or otherwise restricts Borrower or its Subsidiaries from granting a security interest in Borrower's or such Subsidiary's interest in such material license or material agreement or any other property, or (ii) for which a default under or termination of could interfere with Collateral Agent's or any Lender's right to sell any Collateral. Borrower shall provide written notice to Collateral Agent and each Lender within ten (10) days of Borrower or any of its Subsidiaries entering into or becoming bound by any license or agreement with respect to which Borrower or any Subsidiary is the licensee (other than over-the-counter software that is commercially available to the public).

5.3 Litigation. Except as disclosed (i) on the Perfection Certificates, or (ii) in accordance with Section 6.9 hereof, there are no actions, suits, investigations, or proceedings pending or, to the knowledge of the Responsible Officers, threatened in writing by or against Borrower or any of its Subsidiaries involving more than Two Hundred Fifty Thousand Dollars ($250,000.00) or in which a likely adverse decision could reasonably be expected to have a Material Adverse Change.

5.4 No Material Deterioration in Financial Condition; Financial Statements. All consolidated financial statements for Borrower and its Subsidiaries, delivered to Collateral Agent fairly present, in conformity with GAAP, in all material respects the consolidated financial condition of Borrower and its Subsidiaries, and the consolidated results of operations of Borrower and its Subsidiaries (subject, in the case of unaudited financial statements, to normal year-end non-cash adjustments to reflect actual expenses incurred and merger consolidation adjustments and the absence of footnotes). There has not been any event or circumstance that could reasonably be expected to cause a Material Adverse Change since the date of the most recent financial statements submitted to any Lender.

5.5 Solvency. Borrower is, and Borrower and each of its Subsidiaries, on a consolidated basis, are Solvent.
5.6 Regulatory Compliance. Neither Borrower nor any of its Subsidiaries is an “investment company” or a company “controlled” by an “investment company” under the Investment Company Act of 1940, as amended. Neither Borrower nor any of its Subsidiaries is engaged as one of its important activities in extending credit for margin stock (under Regulations X, T and U of the Federal Reserve Board of Governors). Borrower and each of its Subsidiaries has complied in all material respects with the Federal Fair Labor Standards Act. Neither Borrower nor any of its Subsidiaries is a “holding company” or an “affiliate” of a “holding company” or a “subsidiary company” of a “holding company” as each term is defined and used in the Public Utility Holding Company Act of 2005. Neither Borrower nor any of its Subsidiaries has violated any Requirements of Laws, the violation of which could reasonably be expected to have a Material Adverse Change. Neither Borrower’s nor any of its Subsidiaries’ properties or assets has been used by Borrower or such Subsidiary or, to Borrower’s knowledge, by previous Persons, in disposing, producing, storing, treating, or transporting any hazardous substance other than in material compliance with applicable laws. Borrower and each of its Subsidiaries has obtained all consents, approvals and authorizations of, made all declarations or filings with, and given all notices to, all Governmental Authorities that are necessary to continue their respective businesses as currently conducted.

None of Borrower, any of its Subsidiaries, or any of Borrower’s or its Subsidiaries’ controlled Affiliates or any of their respective agents acting or benefiting in any capacity in connection with the transactions contemplated by this Agreement is (i) in violation of any Anti-Terrorism Law, (ii) engaging in or conspiring to engage in any transaction that evades or avoids, or has the purpose of evading or avoiding or attempts to violate, any of the prohibitions set forth in any Anti-Terrorism Law, or (iii) a Blocked Person. None of Borrower, any of its Subsidiaries, or to the knowledge of Borrower and any of their controlled Affiliates or agents, acting or benefiting in any capacity in connection with the transactions contemplated by this Agreement, (x) conducts any business or engages in making or receiving any contribution of funds, goods or services to or for the benefit of any Blocked Person, or (y) deals in, or otherwise engages in any transaction relating to, any property or interest in property blocked pursuant to Executive Order No. 13224, any similar executive order or other Anti-Terrorism Law.

5.7 Investments. Neither Borrower nor any of its Subsidiaries owns any stock, shares, partnership interests or other equity securities except for Permitted Investments.

5.8 Tax Returns and Payments; Pension Contributions. Borrower and each of its Subsidiaries has timely filed all required foreign, federal, state and material local tax returns and reports, and Borrower and each of its Subsidiaries, has timely paid all foreign, federal, state, and material local taxes, assessments, deposits and contributions owed by Borrower and such Subsidiaries, in all jurisdictions in which Borrower or any such Subsidiary is subject to taxes, including the United States, unless such taxes are being contested in accordance with the following sentence. Borrower and each of its Subsidiaries, may defer payment of any contested taxes, provided that (a) Borrower or such Subsidiary, (i) in good faith contests its obligation to pay the taxes by appropriate proceedings promptly and diligently instituted and conducted, (ii) notifies Collateral Agent in writing of the commencement of, and any material development in, the proceedings, and (iii) posts bonds or takes any other steps required to prevent the Governmental Authority levying such contested taxes from obtaining a Lien upon any of the Collateral that is other than a “Permitted Lien” or (b) such taxes, assessments, deposits and contributions do not, individually or in the aggregate exceed Fifty Thousand Dollars ($50,000.00). Neither Borrower nor any of its Subsidiaries is aware of any claims or adjustments proposed for any of Borrower’s or such Subsidiaries’, prior tax years which could result in additional taxes becoming due and payable by Borrower or its Subsidiaries in excess of Fifty Thousand Dollars ($50,000.00). Borrower and each of its Subsidiaries have paid all amounts necessary to fund all present pension, profit sharing and deferred compensation plans in accordance with their terms, and neither Borrower nor any of its Subsidiaries has been, withdrawn from participation in, and have not permitted partial or complete termination of, or permitted the occurrence of any other event with respect to, any such plan which could reasonably be expected to result in any liability of Borrower or its Subsidiaries, including any liability to the Pension Benefit Guaranty Corporation or its successors or any other Governmental Authority.

5.9 Use of Proceeds. Borrower shall use the proceeds of the Credit Extensions solely as working capital and to fund its general business requirements in accordance with the provisions of this Agreement, and not for personal, family, household or agricultural purposes.

5.10 Shares. Borrower has full power and authority to create a first lien on the Shares and no disability or contractual obligation exists that would prohibit Borrower from pledging the Shares pursuant to this Agreement.
To Borrower’s knowledge, there are no subscriptions, warrants, rights of first refusal or other restrictions on transfer relative to, or options exercisable with respect to the Shares. The Shares have been and will be duly authorized and validly issued, and are fully paid and non-assessable. To Borrower’s knowledge, the Shares are not the subject of any present or threatened suit, action, arbitration, administrative or other proceeding, and Borrower knows of no reasonable grounds for the institution of any such proceedings.

5.11 Full Disclosure. No written representation, warranty or other statement of Borrower or any of its Subsidiaries in any certificate or written statement given to Collateral Agent or any Lender, as of the date such representation, warranty, or other statement was made, taken together with all such written certificates and written statements given to Collateral Agent or any Lender, contains any untrue statement of a material fact or omits to state a material fact necessary to make the statements contained in the certificates or statements not misleading (it being recognized that the projections and forecasts provided by Borrower in good faith and based upon reasonable assumptions are not viewed as facts and that actual results during the period or periods covered by such projections and forecasts may differ from the projected or forecasted results).

5.12 Definition of “Knowledge.” For purposes of the Loan Documents, whenever a representation or warranty is made to Borrower’s knowledge or awareness, to the “best of” Borrower’s knowledge, or with a similar qualification, knowledge or awareness means the actual knowledge, after reasonable investigation, of the Responsible Officers.

6. AFFIRMATIVE COVENANTS

Borrower shall, and shall cause each of its Subsidiaries to, do all of the following:

6.1 Government Compliance.

(a) Maintain its and, except as permitted by Section 7.3 all its Subsidiaries’ legal existence and good standing in their respective jurisdictions of organization and maintain qualification in each jurisdiction in which the failure to so qualify could reasonably be expected to have a Material Adverse Change. Comply with all laws, ordinances and regulations to which Borrower or any of its Subsidiaries is subject, the noncompliance with which could reasonably be expected to have a Material Adverse Change.

(b) Obtain and keep in full force and effect, all of the material Governmental Approvals necessary for the performance by Borrower and its Subsidiaries of their respective businesses and obligations under the Loan Documents and the grant of a security interest to Collateral Agent for the ratable benefit of the Lenders, in all of the Collateral. Borrower shall promptly provide copies to Collateral Agent of any material Governmental Approvals obtained by Borrower or any of its Subsidiaries.

6.2 Financial Statements, Reports, Certificates.

(a) Deliver to each Lender:

(i) as soon as available, but no later than thirty (30) days after the last day of each month, a company prepared consolidated and consolidating balance sheet and income statement, and a consolidated cash flow statement, covering the consolidated (and consolidating, as applicable) operations of Borrower and its Subsidiaries for such month certified by a Responsible Officer and in a form reasonably acceptable to Collateral Agent;

(ii) as soon as available, but no later than one hundred eighty (180) days after the last day of Borrower’s fiscal year or within five (5) days of filing with the SEC, audited consolidated financial statements prepared under GAAP, consistently applied, together with an unqualified opinion on the financial statements (or qualified only as to going concern) from an independent certified public accounting firm acceptable to Collateral Agent in its reasonable discretion;
(iii) as soon as available after approval thereof by Borrower’s Board of Directors, but no later than sixty (60) days after the last day of each of Borrower’s fiscal years, Borrower’s annual financial projections for the entire current fiscal year as approved by Borrower’s Board of Directors, which such annual financial projections shall be set forth in a month-by-month format (such annual financial projections as originally delivered to Collateral Agent and the Lenders are referred to herein as the “Annual Projections”; provided that, any revisions of the Annual Projections approved by Borrower’s Board of Directors shall be delivered to Collateral Agent and the Lenders no later than seven (7) days after such approval);

(iv) within five (5) days of delivery, copies of all written statements, reports and notices generally made available to Borrower’s security holders or holders of Subordinated Debt in their capacities as security holders or holders of Subordinated Debt;

(v) in the event that Borrower becomes subject to the reporting requirements under the Securities Exchange Act of 1934, as amended, within five (5) days of filing, all reports on Form 10-K, 10-Q and 8-K filed with the Securities and Exchange Commission,

(vi) together with the Compliance Certificate delivered pursuant to Section 6.2(b), notice of any material amendments of or other material changes to the capitalization table of Borrower and of any changes to the Operating Documents of Borrower or any of its Subsidiaries, together with any copies reflecting such amendments or changes with respect thereto; provided, however, Borrower shall also upon Collateral Agent’s request, promptly deliver to Collateral Agent its then current capitalization table;

(vii) prompt notice of any event that could reasonably be expected to materially and adversely affect the value of the Intellectual Property;

(viii) as soon as available, but no later than thirty (30) days after the last day of each month, copies of the month-end account statements for each Collateral Account maintained by Borrower or its Subsidiaries, which statements may be provided to Collateral Agent and each Lender by Borrower or directly from the applicable institution(s); and

(ix) other information as reasonably requested by Collateral Agent or any Lender.

Notwithstanding the foregoing, documents required to be delivered pursuant to the terms hereof (to the extent any such documents are included in materials otherwise filed with the SEC) may be delivered electronically and if so delivered, shall be deemed to have been delivered on the date on which Borrower posts such documents, or provides a link thereto, on Borrower’s website on the internet at Borrower’s website address.

(b) Concurrently with the delivery of the financial statements specified in Section 6.2(a)(i) above but no later than thirty (30) days after the last day of each month, deliver to each Lender, a duly completed Compliance Certificate signed by a Responsible Officer.

(c) Keep proper books of record and account in accordance with GAAP in all material respects (subject, in the case of unaudited financial statements, to normal year-end non-cash adjustments to reflect actual expenses incurred and merger consolidation adjustments and the absence of footnotes), in which full, true and correct entries shall be made of all dealings and transactions in relation to its business and activities. Borrower shall, and shall cause each of its Subsidiaries to, allow, at the sole cost of Borrower, Collateral Agent or any Lender, during regular business hours upon reasonable prior notice (provided that no notice shall be required when an Event of Default has occurred and is continuing), to visit and inspect any of its properties, to examine and make abstracts or copies from any of its books and records, and to conduct a collateral audit and analysis of its operations and the Collateral. Such audits shall be conducted no more often than once every year unless (and more frequently if) an Event of Default has occurred and is continuing.

6.3 Inventory; Returns. Keep all Inventory held and released for commercial sale, by or for the benefit of Borrower or any Subsidiary, in good and marketable condition, free from material defects. Returns and allowances between Borrower, or any of its Subsidiaries, and their respective Account Debtors, shall follow
Borrower’s, or such Subsidiary’s, customary practices as they exist on the Effective Date. Borrower must promptly notify Collateral Agent and the Lenders of all returns, recoveries, disputes and claims that involve more than Five Hundred Thousand Dollars ($500,000.00) individually or in the aggregate in any calendar year.

6.4 Taxes; Pensions. Timely file and require each of its Subsidiaries to timely file, all required foreign, federal, state and material local tax returns and reports and timely pay, and require each of its Subsidiaries to timely file, all foreign, federal, state, and material local taxes, assessments, deposits and contributions owed by Borrower or its Subsidiaries, except for deferred payment of any taxes contested pursuant to the terms of Section 5.8 hereof or as otherwise permitted pursuant to Section 5.8 hereof, and shall deliver to Collateral Agent, on demand, appropriate certificates attesting to such payments, and pay all amounts necessary to fund all present pension, profit sharing and deferred compensation plans in accordance with the terms of such plans.

6.5 Insurance. Keep Borrower’s and its Subsidiaries’ business and the Collateral insured for risks and in amounts standard for companies in Borrower’s and its Subsidiaries’ industry and location and as Collateral Agent may reasonably request. Insurance policies shall be in a form, with companies, and in amounts that are reasonably satisfactory to Collateral Agent and Collateral Agent hereby agrees that as of the Effective Date, Borrower’s insurance coverage is satisfactory for the purposes herein. All property policies shall have a lender’s loss payable endorsement showing Collateral Agent as lender loss payee and waive subrogation against Collateral Agent, and all liability policies shall show, or have endorsements showing, Collateral Agent, as additional insured. The Collateral Agent shall be named as lender loss payee and/or additional insured with respect to any such insurance providing coverage in respect of any Collateral, and each provider of any such insurance shall agree, by endorsement upon the policy or policies issued by it or by independent instruments furnished to the Collateral Agent, that it will give the Collateral Agent thirty (30) days’ (or, ten (10) days’ for non-payment of premiums) prior written notice before any such policy or policies shall be canceled. Borrower and its Subsidiaries shall give the Collateral Agent thirty (30) days prior written notice before any insurance policy or policies shall be materially altered (other than to increase or expand coverage); provided, however, that, if such prior written notice cannot be provided in such thirty (30) day period, it must in any event be provided within two (2) Business Days after Borrower’s receipt of notice thereof. At Collateral Agent’s request, Borrower shall deliver certified copies of policies and evidence of all premium payments. Proceeds payable under any policy shall, at Collateral Agent’s option, be payable to Collateral Agent, for the ratable benefit of the Lenders, on account of the Obligations. Notwithstanding the foregoing, (a) so long as no Event of Default has occurred and is continuing, Borrower shall have the option of applying the proceeds of any casualty policy up to Two Hundred Fifty Thousand Dollars ($250,000.00) with respect to any loss, but not exceeding Two Hundred Fifty Thousand Dollars ($250,000.00), in the aggregate for all losses under all casualty policies in any one year, toward the replacement or repair of destroyed or damaged property; provided that any such replaced or repaired property (i) shall be of equal or like value as the replaced or repaired Collateral and (ii) shall be deemed Collateral in which Collateral Agent has been granted a first priority security interest, subject to Permitted Liens, and (b) after the occurrence and during the continuance of an Event of Default, all proceeds payable under such casualty policy shall, at the option of Collateral Agent, be payable to Collateral Agent, for the ratable benefit of the Lenders, on account of the Obligations. If Borrower or any of its Subsidiaries fails to obtain insurance as required under this Section 6.5 or to pay any amount or furnish any required proof of payment to third persons, Collateral Agent and/or any Lender may make, at Borrower’s expense, all or part of such payment or obtain such insurance policies required in this Section 6.5, and take any action under the policies Collateral Agent or such Lender deems prudent.

6.6 Operating Accounts.

(a) Maintain all of Borrower’s and its Subsidiaries’ Collateral Accounts, other than accounts excluded pursuant to Section 6.6(b), in accounts which are subject to a Control Agreement in favor of Collateral Agent; provided, that, all of Borrower’s and its Subsidiaries’ Collateral Accounts maintained at Bank of America (the “B of A Accounts”) shall (i) have an aggregate balance that does not exceed One Hundred Thousand Dollars ($100,000.00) in the aggregate at any time and (ii) in accordance with the Post Closing Letter, such B of A Accounts shall be subject to a Control Agreement in favor of Collateral Agent on and after February 14, 2020.

(b) Borrower shall provide Collateral Agent five (5) days’ prior written notice before Borrower or any of its Subsidiaries establishes any Collateral Account. In addition, for each Collateral Account that Borrower or any of its Subsidiaries, at any time maintains, Borrower or such Subsidiary shall cause the applicable
bank or financial institution at or with which such Collateral Account is maintained to execute and deliver a Control Agreement or other appropriate instrument with respect to such Collateral Account to perfect Collateral Agent’s Lien in such Collateral Account in accordance with the terms hereunder substantially contemporaneously with the establishment of such Collateral Account, which Control Agreement may not be terminated without prior written consent of Collateral Agent. The provisions of the previous sentence shall not apply to deposit accounts exclusively used for payroll, payroll taxes and other employee wage and benefit payments to or for the benefit of Borrower’s, or any of its Subsidiaries’, employees and identified to Collateral Agent by Borrower as such in the Perfection Certificates.

(c) Neither Borrower nor any of its Subsidiaries shall maintain any Collateral Accounts except Collateral Accounts maintained in accordance with Sections 6.6(a) and (b).

6.7 Protection of Intellectual Property Rights. Borrower and each of its Subsidiaries shall: (a) use commercially reasonable efforts to protect, defend and maintain the validity and enforceability of its Intellectual Property that is material to Borrower’s business; (b) promptly after Borrower or any of its Subsidiaries obtains knowledge thereof, advise Collateral Agent in writing of material infringement by a third party of its Intellectual Property; and (c) not allow any owned Intellectual Property to be abandoned, forfeited or dedicated to the public without Collateral Agent’s prior written consent.

6.8 Litigation Cooperation. Commencing on the Effective Date and continuing through the termination of this Agreement, make available to Collateral Agent and the Lenders, without expense to Collateral Agent or the Lenders, Borrower and each of Borrower’s officers, employees and agents and Borrower’s Books, to the extent that Collateral Agent or any Lender may reasonably deem them necessary to prosecute or defend any third-party suit or proceeding instituted by or against Collateral Agent or any Lender with respect to any Collateral or relating to Borrower.

6.9 Notices of Litigation and Default. Borrower will give prompt written notice to Collateral Agent and the Lenders of any litigation or governmental proceedings pending or threatened (in writing) against Borrower or any of its Subsidiaries, which could reasonably be expected to result in damages or costs to Borrower or any of its Subsidiaries of Five Hundred Thousand Dollars ($500,000.00) or more or which could reasonably be expected to have a Material Adverse Change. Without limiting or contradicting any other more specific provision of this Agreement, promptly (and in any event within three (3) Business Days) upon (i) Borrower becoming aware of the existence of any Event of Default or event which, with the giving of notice or passage of time, or both, would constitute an Event of Default, Borrower shall give written notice to Collateral Agent and the Lenders of such occurrence, which such notice shall include a reasonably detailed description of such Event of Default or event which, with the giving of notice or passage of time, or both, would constitute an Event of Default; and (ii) any material developments in any of the litigation disclosed in the Perfection Certificate delivered to Collateral Agent as of the Effective Date, or otherwise pending on or after the Effective Date, but no less frequently than quarterly, Borrower shall give written notice to Collateral Agent and the Lenders of such material developments, with at least the same level of detail as presented in the Perfection Certificate delivered to Collateral Agent as of the Effective Date.

6.10 [Intentionally Omitted.]

6.11 Landlord Waivers; Bailee Waivers. In the event that Borrower or any of its Subsidiaries, after the Effective Date, intends to add any new offices or business locations, including warehouses, or otherwise store any portion of the Collateral with, or deliver any portion of the Collateral to, a bailee, in each case pursuant to Section 7.2, then Borrower or such Subsidiary will provide written notice thereof to Collateral Agent and, in the event that the new location is the chief executive office of the Borrower or such Subsidiary or the Collateral at any such new location is valued in excess of Five Hundred Thousand Dollars ($500,000.00) in the aggregate, such bailee or landlord, as applicable, must execute and deliver a bailee waiver or landlord waiver, as applicable, in form and substance reasonably satisfactory to Collateral Agent prior to the addition of any new offices or business locations, or any such storage with or delivery to any such bailee, as the case may be; provided, that, in accordance with this Section 6.11 and with respect to any offices or business locations located in a foreign jurisdiction, where Borrower or any its Subsidiaries (including Foreign Subsidiaries) store any portion of the Collateral, Borrower or any its Subsidiaries shall deliver and execute a bailee waiver or landlord waiver, as applicable, in form and substance reasonably satisfactory to Collateral Agent, to the extent such bailee waiver or landlord waiver is accepted and recognized in such foreign jurisdiction.
6.12 Creation/Acquisition of Subsidiaries. In the event Borrower, or any of its Subsidiaries creates or acquires any Subsidiary, Borrower shall provide prior written notice to Collateral Agent and each Lender of the creation or acquisition of such new Subsidiary and take all such action as may be reasonably required by Collateral Agent or any Lender to cause each such Subsidiary to become a co-Borrower hereunder or to guarantee the Obligations of Borrower under the Loan Documents and, in each case, grant a continuing pledge and security interest in and to the assets of such Subsidiary (substantially as described on Exhibit A hereeto); and Borrower (or its Subsidiary, as applicable) shall grant and pledge to Collateral Agent, for the rable benefit of the Lenders, a perfected security interest in the Shares of each such newly created Subsidiary; provided, however, that solely in the circumstance in which Borrower or any Subsidiary creates or acquires a Foreign Subsidiary in an acquisition permitted by Section 7.3 hereof or otherwise approved by the Required Lenders, (i) such Foreign Subsidiary shall not be required to guarantee the Obligations of Borrower under the Loan Documents and grant a continuing pledge and security interest in and to the assets of such Foreign Subsidiary, and (ii) Borrower shall not be required to grant and pledge to Collateral Agent, for the rable benefit of Lenders, a perfected security interest in more than sixty-five percent (65%) of the Shares of such Foreign Subsidiary, if (A) Borrower demonstrates to the reasonable satisfaction of Collateral Agent that such Foreign Subsidiary providing such guarantee or pledge and security interest or Borrower providing a perfected security interest in more than sixty-five percent (65%) of the Shares would create a present and existing adverse tax consequence to Borrower under the U.S. Internal Revenue Code; (B) no Intellectual Property is held or maintained by such Foreign Subsidiary at any time; and (C) the aggregate value of cash and Cash Equivalents held or maintained by such Foreign Subsidiary does not exceed Two Hundred Fifty Thousand Dollars ($250,000.00) at any time.

6.13 Further Assurances.

(a) Execute any further instruments and take further action as Collateral Agent or any Lender reasonably requests to perfect or continue Collateral Agent’s Lien in the Collateral or to effect the purposes of this Agreement.

(b) Deliver to Collateral Agent and Lenders, within five (5) days after the same are sent or received, copies of all material correspondence, reports, documents and other filings with any Governmental Authority that could reasonably be expected to have a material adverse effect on any of the Governmental Approvals material to Borrower’s business or otherwise could reasonably be expected to have a Material Adverse Change.

7. NEGATIVE COVENANTS

Borrower shall not, and shall not permit any of its Subsidiaries to, do any of the following without the prior written consent of the Required Lenders:

7.1 Dispositions. Convey, sell, lease, transfer, assign, or otherwise dispose of (collectively, “Transfer”), or permit any of its Subsidiaries to Transfer, all or any part of its business or property, except for Transfers (a) of Inventory in the ordinary course of business; (b) of worn out or obsolete Equipment; (c) in connection with Permitted Liens, Permitted Investments and Permitted Licenses; (d) of cash and Cash Equivalents in connection with transactions not prohibited hereunder in the ordinary course of business; (e) consisting of the abandonment, forfeiture or dedication to the public of any Intellectual Property that is not material to Borrower’s business to the extent not otherwise prohibited by the terms of Section 6.7(c); and (f) of other property (other than Intellectual Property) not to exceed Two Hundred Fifty Thousand Dollars ($250,000.00) in the aggregate in any fiscal year.

7.2 Changes in Business, Management, Ownership, or Business Locations. (a) Engage in or permit any of its Subsidiaries to engage in any business other than the businesses engaged in by Borrower as of the Effective Date or reasonably related thereto; (b) liquidate or dissolve, except as permitted under Section 7.3; or (c) (i) any Key Person shall cease to be actively engaged in the management of Borrower unless written notice thereof is provided to Collateral Agent within ten (10) days of such change, or (ii) enter into any transaction or series of related transactions in which the stockholders of Borrower who were not stockholders immediately prior to the
first such transaction own more than forty nine percent (49%) of the voting stock of Borrower immediately after giving effect to such transaction or related series of such transactions (other than by the sale of Borrower’s equity securities in a public offering, a private placement of public equity or to venture capital investors so long as Borrower identifies to Collateral Agent the venture capital investors prior to the closing of the transaction). Borrower shall not, without at least twenty (20) days’ prior written notice to Collateral Agent: (A) add any new offices or business locations, including warehouses (unless such new offices or business locations (i) contain less than Five Hundred Thousand Dollars ($500,000.00) in assets or property of Borrower or any of its Subsidiaries and (ii) are not Borrower’s or its Subsidiaries’ chief executive office); (B) change its jurisdiction of organization, (C) change its organizational structure or type, (D) change its legal name, or (E) change any organizational number (if any) assigned by its jurisdiction of organization.

7.3 **Mergers or Acquisitions.** Merge or consolidate, or permit any of its Subsidiaries to merge or consolidate, with any other Person, or acquire, or permit any of its Subsidiaries to acquire, all or substantially all of the capital stock, shares or property of another Person. A Subsidiary may merge or consolidate into another Subsidiary (provided such surviving Subsidiary is a “co-Borrower” hereunder or has provided a secured Guaranty of Borrower’s Obligations hereunder) or with (or into) Borrower provided Borrower is the surviving legal entity, and as long as no Event of Default is occurring prior thereto or arises as a result therefrom.

7.4 **Indebtedness.** Create, incur, assume, or be liable for any Indebtedness, or permit any Subsidiary to do so, other than Permitted Indebtedness.

7.5 **Encumbrance.** Create, incur, allow, or suffer any Lien on any of its property, or assign or convey any right to receive income, including the sale of any Accounts, or permit any of its Subsidiaries to do so, except for Permitted Liens, or permit any Collateral not to be subject to the first priority security interest granted herein (except for Permitted Liens that are permitted by the terms of this Agreement to have priority over Collateral Agent’s Lien), or enter into any agreement, document, instrument or other arrangement (except with or in favor of Collateral Agent, for the ratable benefit of the Lenders) with any Person which directly or indirectly prohibits or has the effect of prohibiting Borrower, or any of its Subsidiaries, from assigning, mortgaging, pledging, granting a security interest in or upon, or encumbering any of Borrower’s or such Subsidiary’s Intellectual Property, except as is otherwise permitted in Section 7.1 hereof and the definition of “Permitted Liens” herein.

7.6 **Maintenance of Collateral Accounts.** Maintain any Collateral Account except pursuant to the terms of Section 6.6 hereof.

7.7 **Distributions; Investments.** (a) Pay any dividends (other than dividends payable solely in capital stock) or make any distribution or payment in respect of or redeem, retire or purchase any capital stock, in each case other than (i) repurchases pursuant to the terms of employee stock purchase plans, employee restricted stock agreements, stockholder rights plans, director or consultant stock option plans, or similar plans, provided such repurchases do not exceed Two Hundred Fifty Thousand Dollars ($250,000.00) in the aggregate per fiscal year, (ii) repurchases of stock of former employees, officers, consultants or directors pursuant to stock repurchase agreements by the cancellation of indebtedness owed by such former employees or directors to Borrower, (iii) dividends and distributions to Borrower and (iv) conversion to equity of equity securities and Subordinated Debt or (b) directly or indirectly make any Investment other than Permitted Investments, or permit any of its Subsidiaries to do so.

7.8 **Transactions with Affiliates.** Directly or indirectly enter into or permit to exist any material transaction with any Affiliate of Borrower or any of its Subsidiaries, except for (a) transactions that are in the ordinary course of Borrower’s or such Subsidiary’s business, upon fair and reasonable terms that are no less favorable to Borrower or such Subsidiary than would be obtained in an arm’s length transaction with a non-affiliated Person, (b) transaction explicitly permitted or required to be made hereunder between Affiliates, (c) compensation related arrangements in the ordinary course of business or otherwise approved by Borrower’s board or by the Required Lenders in writing, (d) (i) intercompany sales and distribution agreements and (ii) intercompany cost-plus plans or similar arrangements; in each case of (d)(i) and (ii), in the ordinary course of business, and (f) Subordinated Debt or equity investments by Borrower’s investors in Borrower or its Subsidiaries.

7.9 **Subordinated Debt.** (a) Make or permit any payment on any Subordinated Debt, except under the terms of the subordination, intercreditor, or other similar agreement to which such Subordinated Debt is subject, or (b) amend any provision in any document relating to the Subordinated Debt which would increase the amount thereof or adversely affect the subordination thereof to Obligations owed to the Lenders.
7.10 **Compliance.** Become an “investment company” or a company controlled by an “investment company”, under the Investment Company Act of 1940, as amended, or undertake as one of its important activities extending credit to purchase or carry margin stock (as defined in Regulation U of the Board of Governors of the Federal Reserve System), or use the proceeds of any Credit Extension for that purpose; fail to meet the minimum funding requirements of ERISA, permit a Reportable Event or Prohibited Transaction, as defined in ERISA, to occur; fail to comply with the Federal Fair Labor Standards Act or violate any other law or regulation, if the violation could reasonably be expected to have a Material Adverse Change, or permit any of its Subsidiaries to do so; withdraw or permit any Subsidiary to withdraw from participation in, permit partial or complete termination of, or permit the occurrence of any other event with respect to, any present pension, profit sharing and deferred compensation plan which could reasonably be expected to result in any liability of Borrower or any of its Subsidiaries, including any liability to the Pension Benefit Guaranty Corporation or its successors or any other Governmental Authority.

7.11 **Compliance with Anti-Terrorism Laws.** Collateral Agent hereby notifies Borrower and each of its Subsidiaries that pursuant to the requirements of Anti-Terrorism Laws, and Collateral Agent’s policies and practices, Collateral Agent is required to obtain, verify and record certain information and documentation that identifies Borrower and each of its Subsidiaries and their principals, which information includes the name and address of Borrower and each of its Subsidiaries and their principals and such other information that will allow Collateral Agent to identify such party in accordance with Anti-Terrorism Laws. Neither Borrower nor any of its Subsidiaries shall, nor shall Borrower or any of its Subsidiaries permit any controlled Affiliate to, directly or indirectly, knowingly enter into any documents, instruments, agreements or contracts with any Person listed on the OFAC Lists. Borrower and each of its Subsidiaries shall immediately notify Collateral Agent if Borrower or such Subsidiary has knowledge that Borrower, or any Subsidiary or controlled Affiliate of Borrower, is listed on the OFAC Lists or (a) is convicted on, (b) pleads *nolo contendere* to, (c) is indicted on, or (d) is arraigned and held over on charges involving money laundering or predicate crimes to money laundering. Neither Borrower nor any of its Subsidiaries shall, nor shall Borrower or any of its Subsidiaries, permit any controlled Affiliate to, directly or indirectly, (i) conduct any business or engage in any transaction or dealing with any Blocked Person, including, without limitation, the making or receiving of any contribution of funds, goods or services to or for the benefit of any Blocked Person, (ii) deal in, or otherwise engage in any transaction relating to, any property or interests in property blocked pursuant to Executive Order No. 13224 or any similar executive order or other Anti-Terrorism Law, or (iii) engage in or conspire to engage in any transaction that evades or avoids, or has the purpose of evading or avoiding, or attempts to violate, any of the prohibitions set forth in Executive Order No. 13224 or other Anti-Terrorism Law.

8. **EVENTS OF DEFAULT**

Any one of the following shall constitute an event of default (an “Event of Default”) under this Agreement:

8.1 **Payment Default.** Borrower fails to (a) make any payment of principal or interest on any Credit Extension on its due date, or (b) pay any other Obligations within three (3) Business Days after such Obligations are due and payable (which three (3) Business Day grace period shall not apply to payments due on the Maturity Date or the date of acceleration pursuant to Section 9.1 (a) hereof). During the cure period, the failure to cure the payment default is not an Event of Default (but no Credit Extension will be made during the cure period);

8.2 **Covenant Default.**

(a) Borrower or any of its Subsidiaries fails or neglects to perform any obligation in Sections 6.2 (Financial Statements, Reports, Certificates), 6.4 (Taxes), 6.5 (Insurance), 6.6 (Operating Accounts), 6.7 (Protection of Intellectual Property Rights), 6.9 (Notice of Litigation and Default), 6.11 (Landlord Waivers; Bailee Waivers), 6.12 (Creation/Acquisition of Subsidiaries) or 6.13 (Further Assurances) or Borrower violates any covenant in Section 7; or
(b) Borrower, or any of its Subsidiaries, fails or neglects to perform, keep, or observe any other term, provision, condition, covenant or agreement contained in this Agreement or any Loan Documents, and as to any default (other than those specified in this Section 8) under such other term, provision, condition, covenant or agreement that can be cured, has failed to cure the default within fifteen (15) days after the occurrence thereof; provided, however, that if the default cannot by its nature be cured within the fifteen (15) day period or cannot after diligent attempts by Borrower be cured within such fifteen (15) day period, and such default is likely to be cured within a reasonable time, then Borrower shall have an additional period (which shall not in any case exceed thirty (30) days) to attempt to cure such default, and within such reasonable time period the failure to cure the default shall not be deemed an Event of Default (but no Credit Extensions shall be made during such cure period). Grace periods provided under this Section shall not apply, among other things, to financial covenants or any other covenants set forth in subsection (a) above;

8.3 Material Adverse Change. A Material Adverse Change occurs;

8.4 Attachment; Levy; Restraint on Business.

(a) (i) The service of process seeking to attach, by trustee or similar process, any funds of Borrower or any of its Subsidiaries or of any entity under control of Borrower or its Subsidiaries on deposit with any Lender or any Lender’s Affiliate or any bank or other institution at which Borrower or any of its Subsidiaries maintains a Collateral Account, or (ii) a notice of lien, levy, or assessment is filed against Borrower or any of its Subsidiaries or their respective assets by any government agency, and the same under subclauses (i) and (ii) hereof are not, within ten (10) days after the occurrence thereof, discharged or stayed (whether through the posting of a bond or otherwise); provided, however, no Credit Extensions shall be made during any ten (10) day cure period; and

(b) (i) any material portion of Borrower’s or any of its Subsidiaries’ assets is attached, seized, levied on, or comes into possession of a trustee or receiver, or (ii) any court order enjoins, restrains, or prevents Borrower or any of its Subsidiaries from conducting any part of its business;

8.5 Insolvency. (a) Borrower or any of its Subsidiaries is or becomes Insolvent; (b) Borrower or any of its Subsidiaries begins an Insolvency Proceeding; or (c) an Insolvency Proceeding is begun against Borrower or any of its Subsidiaries and not dismissed or stayed within forty-five (45) days (but no Credit Extensions shall be made while Borrower or any Subsidiary is Insolvent and/or until any Insolvency Proceeding is dismissed);

8.6 Other Agreements. There is a default in any agreement to which Borrower or any of its Subsidiaries is a party with a third party or parties resulting in a right by such third party or parties, whether or not exercised, to accelerate the maturity of any Indebtedness in an amount in excess of Five Hundred Thousand Dollars ($500,000.00) or that could reasonably be expected to have a Material Adverse Change;

8.7 Judgments. (a) One or more judgments, orders, or decrees for the payment of money, other than punitive, special, consequential, indirect or like damages (collectively, “Punitive Damages”), in an amount, individually or in the aggregate, of at least Five Hundred Thousand Dollars ($500,000.00) (not covered by independent third-party insurance as to which liability has been accepted by such insurance carrier) shall be rendered against Borrower or any of its Subsidiaries and shall remain unsatisfied, unvacated, or unstayed for a period of ten (10) days after the entry thereof (provided that no Credit Extensions will be made prior to the satisfaction, vacation, or stay of such judgment, order or decree); or (b) one or more judgments, orders, or decrees for the payment of Punitive Damages in an amount, individually or in the aggregate, in excess of Two Million Dollars ($2,000,000.00) shall be rendered against Borrower or any of its Subsidiaries;

8.8 Misrepresentations. Borrower or any of its Subsidiaries or any Person acting for Borrower or any of its Subsidiaries makes any representation, warranty, or other statement now or later in this Agreement, any Loan Document or in any writing delivered to Collateral Agent and/or Lenders, when taken as a whole, or to induce Collateral Agent and/or the Lenders to enter this Agreement or any Loan Document, and such representation, warranty, or other statement, when taken as a whole, is incorrect in any material respect when made;
8.9 Subordinated Debt. A default or breach occurs under any agreement between Borrower or any of its Subsidiaries and any creditor of Borrower or any of its Subsidiaries that signed a subordination, intercreditor, or other similar agreement with Collateral Agent or the Lenders, or any creditor that has signed such an agreement with Collateral Agent or the Lenders breaches any terms of such agreement;

8.10 Guaranty. (a) Any Guaranty terminates or ceases for any reason to be in full force and effect; (b) any Guarantor does not perform any obligation or covenant under any Guaranty; (c) any circumstance described in Sections 8.3, 8.4, 8.5, 8.7, or 8.8 occurs with respect to any Guarantor, or (d) the liquidation, winding up, or termination of existence of any Guarantor;

8.11 Governmental Approvals. Any Governmental Approval shall have been revoked, rescinded, suspended, modified in an adverse manner, or not renewed in the ordinary course for a full term and such revocation, rescission, suspension, modification or non-renewal has resulted in or could reasonably be expected to result in a Material Adverse Change; or

8.12 Lien Priority. Except as the result of any action or inaction by Collateral Agent or any Lender, any Lien created hereunder or by any other Loan Document shall at any time fail to constitute a valid and perfected Lien on any of the Collateral purported to be secured thereby, subject to no prior or equal Lien, other than Permitted Liens which are permitted to have priority in accordance with the terms of this Agreement.

9. RIGHTS AND REMEDIES

9.1 Rights and Remedies.

(a) Upon the occurrence and during the continuance of an Event of Default, Collateral Agent may, and at the written direction of Required Lenders shall, without notice or demand, do any or all of the following: (i) deliver notice of the Event of Default to Borrower, (ii) by notice to Borrower declare all Obligations immediately due and payable (but if an Event of Default described in Section 8.5 occurs all Obligations shall be immediately due and payable without any action by Collateral Agent or the Lenders) or (iii) by notice to Borrower suspend or terminate the obligations, if any, of the Lenders to advance money or extend credit for Borrower’s benefit under this Agreement or under any other agreement between Borrower and Collateral Agent and/or the Lenders (but if an Event of Default described in Section 8.5 occurs all obligations, if any, of the Lenders to advance money or extend credit for Borrower’s benefit under this Agreement or under any other agreement between Borrower and Collateral Agent and/or the Lenders shall be immediately terminated without any action by Collateral Agent or the Lenders).

(b) Without limiting the rights of Collateral Agent and the Lenders set forth in Section 9.1(a) above, upon the occurrence and during the continuance of an Event of Default, Collateral Agent shall have the right at the written direction of the Required Lenders, without notice or demand, to do any or all of the following:

(i) foreclose upon and/or sell or otherwise liquidate, the Collateral;

(ii) apply to the Obligations any (a) balances and deposits of Borrower that Collateral Agent or any Lender holds or controls, or (b) any amount held or controlled by Collateral Agent or any Lender owing to or for the credit or the account of Borrower; and/or

(iii) commence and prosecute an Insolvency Proceeding or consent to Borrower commencing any Insolvency Proceeding.

(c) Without limiting the rights of Collateral Agent and the Lenders set forth in Sections 9.1(a) and (b) above, upon the occurrence and during the continuance of an Event of Default, Collateral Agent shall have the right, without notice or demand, to do any or all of the following:

(i) settle or adjust disputes and claims directly with Account Debtors for amounts on terms and in any order that Collateral Agent considers advisable, notify any Person owing Borrower money of Collateral Agent’s security interest in such funds, and verify the amount of such account;
(ii) make any payments and do any acts it considers necessary or reasonable to protect the Collateral and/or its security interest in the Collateral. Borrower shall assemble the Collateral if Collateral Agent requests and make it available in a location as Collateral Agent reasonably designates. Collateral Agent may enter premises where the Collateral is located, take and maintain possession of any part of the Collateral, and pay, purchase, contest, or compromise any Lien which appears to be prior or superior to its security interest and pay all expenses incurred. Borrower grants Collateral Agent a license to enter and occupy any of its premises, without charge, to exercise any of Collateral Agent’s rights or remedies;

(iii) ship, reclaim, recover, store, finish, maintain, repair, prepare for sale, and/or advertise for sale, the Collateral. Collateral Agent is hereby granted a non-exclusive, royalty-free license or other right to use, without charge, Borrower’s and each of its Subsidiaries’ labels, patents, copyrights, mask works, rights of use of any name, trade secrets, trade names, trademarks, service marks, and advertising matter, or any similar property as it pertains to the Collateral, in completing production of, advertising for sale, and selling any Collateral and, in connection with Collateral Agent’s exercise of its rights under this Section 9.1, Borrower’s and each of its Subsidiaries’ rights under all licenses and all franchise agreements inure to Collateral Agent, for the benefit of the Lenders;

(iv) place a “hold” on any account maintained with Collateral Agent or the Lenders and/or deliver a notice of exclusive control, any entitlement order, or other directions or instructions pursuant to any Control Agreement or similar agreements providing control of any Collateral;

(v) demand and receive possession of Borrower’s Books;

(vi) appoint a receiver to seize, manage and realize any of the Collateral, and such receiver shall have any right and authority as any competent court will grant or authorize in accordance with any applicable law, including any power or authority to manage the business of Borrower or any of its Subsidiaries; and

(vii) subject to clauses 9.1(a) and (b), exercise all rights and remedies available to Collateral Agent and each Lender under the Loan Documents or at law or equity, including all remedies provided under the Code (including disposal of the Collateral pursuant to the terms thereof).

Notwithstanding any provision of this Section 9.1 to the contrary, upon the occurrence of any Event of Default, Collateral Agent shall have the right to exercise any and all remedies referenced in this Section 9.1 without the written consent of Required Lenders following the occurrence of an Exigent Circumstance. As used in the immediately preceding sentence, “Exigent Circumstance” means any event or circumstance that, in the reasonable judgment of Collateral Agent, imminently threatens the ability of Collateral Agent to realize upon all or any material portion of the Collateral, such as, without limitation, fraudulent removal, concealment, or abscondment thereof, destruction or material waste thereof, or failure of Borrower or any of its Subsidiaries after reasonable demand to maintain or reinstate adequate casualty insurance coverage, or which, in the judgment of Collateral Agent, could reasonably be expected to result in a material diminution in value of the Collateral.

9.2 Power of Attorney. Borrower hereby irrevocably appoints Collateral Agent as its lawful attorney-in-fact, exercisable upon the occurrence and during the continuance of an Event of Default, to: (a) endorse Borrower’s or any of its Subsidiaries’ name on any checks or other forms of payment or security; (b) sign Borrower’s or any of its Subsidiaries’ name on any invoice or bill of lading for any Account or drafts against Account Debtors; (c) settle and adjust disputes and claims about the Accounts directly with Account Debtors, for amounts and on terms Collateral Agent determines reasonable; (d) make, settle, and adjust all claims under Borrower’s insurance policies; (e) pay, contest or settle any Lien, charge, encumbrance, security interest, and adverse claim in or to the Collateral, or any judgment based thereon, or otherwise take any action to terminate or discharge the same; and (f) transfer the Collateral into the name of Collateral Agent or a third party as the Code or any applicable law permits. Borrower hereby appoints Collateral Agent as its lawful attorney-in-fact to sign Borrower’s or any of its Subsidiaries’ name on any documents necessary to perfect or continue the perfection of
Collateral Agent’s security interest in the Collateral regardless of whether an Event of Default has occurred until all Obligations (other than inchoate indemnity obligations) have been satisfied in full and Collateral Agent and the Lenders are under no further obligation to make Credit Extensions hereunder. Collateral Agent’s foregoing appointment as Borrower’s or any of its Subsidiaries’ attorney in fact, and all of Collateral Agent’s rights and powers, coupled with an interest, are irrevocable until all Obligations (other than inchoate indemnity obligations) have been fully repaid and performed and Collateral Agent’s and the Lenders’ obligation to provide Credit Extensions terminates.

9.3 Protective Payments. If Borrower or any of its Subsidiaries fail to obtain the insurance called for by Section 6.5 or fails to pay any premium thereon or fails to pay any other amount which Borrower or any of its Subsidiaries is obligated to pay under this Agreement or any other Loan Document, Collateral Agent may obtain such insurance or make such payment, and all amounts so paid by Collateral Agent are Lenders’ Expenses and immediately due and payable, bearing interest at the Default Rate, and secured by the Collateral. Collateral Agent will make reasonable efforts to provide Borrower with notice of Collateral Agent obtaining such insurance or making such payment at the time it is obtained or paid or within a reasonable time thereafter. No such payments by Collateral Agent are deemed an agreement to make similar payments in the future or Collateral Agent’s waiver of any Event of Default.

9.4 Application of Payments and Proceeds. Notwithstanding anything to the contrary contained in this Agreement, upon the occurrence and during the continuance of an Event of Default, (a) Borrower irrevocably waives the right to direct the application of any and all payments at any time or times thereafter received by Collateral Agent from or on behalf of Borrower or any of its Subsidiaries of all or any part of the Obligations, and, as between Borrower on the one hand and Collateral Agent and Lenders on the other, Collateral Agent shall have the continuing and exclusive right to apply and to reapply any and all payments received against the Obligations in such manner as Collateral Agent may deem advisable notwithstanding any previous application by Collateral Agent, and (b) the proceeds of any sale of, or other realization upon all or any part of the Collateral shall be applied: first, to the Lenders’ Expenses; second, to accrued and unpaid interest on the Obligations (including any interest which, but for the provisions of the United States Bankruptcy Code, would have accrued on such amounts); third, to the principal amount of the Obligations outstanding; and fourth, to any other indebtedness or obligations of Borrower owing to Collateral Agent or any Lender under the Loan Documents. Any balance remaining shall be delivered to Borrower or to whoever may be lawfully entitled to receive such balance or as a court of competent jurisdiction may direct. In carrying out the foregoing, (x) amounts received shall be applied in the numerical order provided until exhausted prior to the application to the next succeeding category, and (y) each of the Persons entitled to receive a payment in any particular category shall receive an amount equal to its pro rata share of amounts available to be applied pursuant thereto for such category. Any reference in this Agreement to an allocation between or sharing by the Lenders of any right, interest or obligation “ratably,” “proportionally” or in similar terms shall refer to Pro Rata Share unless expressly provided otherwise. Collateral Agent, if applicable, each Lender, shall promptly remit to the other Lenders such sums as may be necessary to ensure the ratable repayment of each Lender’s portion of any Term Loan and the ratable distribution of interest, fees and reimbursements paid or made by Borrower. Notwithstanding the foregoing, a Lender receiving a scheduled payment shall not be responsible for determining whether the other Lenders also received their scheduled payment on such date; provided, however, if it is later determined that a Lender received more than its ratable share of scheduled payments made on any date or dates, then such Lender shall remit to Collateral Agent or other Lenders such sums as may be necessary to ensure the ratable payment of such scheduled payments, as instructed by Collateral Agent. If any payment or distribution of any kind or character, whether in cash, properties or securities, shall be received by a Lender in excess of its ratable share, then the portion of such payment or distribution in excess of such Lender’s ratable share shall be received by such Lender in trust for and shall be promptly paid over to the other Lender for application to the payments of amounts due on the other Lenders’ claims. To the extent any payment for the account of Borrower is required to be returned as a voidable transfer or otherwise, the Lenders shall contribute to one another as is necessary to ensure that such return of payment is on a pro rata basis. If any Lender shall obtain possession of any Collateral, it shall hold such Collateral for itself and as agent and bailee for Collateral Agent and other Lenders for purposes of perfecting Collateral Agent’s security interest therein.

9.5 Liability for Collateral. So long as Collateral Agent and the Lenders comply with reasonable banking practices regarding the safekeeping of the Collateral in the possession or under the control of Collateral Agent and the Lenders, Collateral Agent and the Lenders shall not be liable or responsible for: (a) the safekeeping of
the Collateral; (b) any loss or damage to the Collateral; (c) any diminution in the value of the Collateral; or (d) any act or default of any carrier, warehouseman, bailee, or other Person. Borrower bears all risk of loss, damage or destruction of the Collateral.

9.6 **No Waiver; Remedies Cumulative.** Failure by Collateral Agent or any Lender, at any time or times, to require strict performance by Borrower of any provision of this Agreement or any other Loan Document shall not waive, affect, or diminish any right of Collateral Agent or any Lender thereafter to demand strict performance and compliance herewith or therewith. No waiver hereunder shall be effective unless signed by Collateral Agent and the Required Lenders and then is only effective for the specific instance and purpose for which it is given. The rights and remedies of Collateral Agent and the Lenders under this Agreement and the other Loan Documents are cumulative. Collateral Agent and the Lenders have all rights and remedies provided under the Code, any applicable law, by law, or in equity. The exercise by Collateral Agent or any Lender of one right or remedy is not an election, and Collateral Agent’s or any Lender’s waiver of any Event of Default is not a continuing waiver. Collateral Agent’s or any Lender’s delay in exercising any remedy is not a waiver, election, or acquiescence.

9.7 **Demand Waiver.** Borrower waives, to the fullest extent permitted by law, demand, notice of default or dishonor, notice of payment and nonpayment, notice of any default, nonpayment at maturity, release, compromise, settlement, extension, or renewal of accounts, documents, instruments, chattel paper, and guarantees held by Collateral Agent or any Lender on which Borrower or any Subsidiary is liable.

10. **NOTICES**

All notices, consents, requests, approvals, demands, or other communication (collectively, "Communication") by any party to this Agreement or any other Loan Document must be in writing and shall be deemed to have been validly served, given, or delivered: (a) upon the earlier of actual receipt and three (3) Business Days after deposit in the U.S. mail, first class, registered or certified mail return receipt requested, with proper postage prepaid; (b) upon transmission, when sent by facsimile transmission; (c) one (1) Business Day after deposit with a reputable overnight courier with all charges prepaid; or (d) when delivered, if hand-delivered by messenger, all of which shall be addressed to the party to be notified and sent to the address, facsimile number, or email address indicated below. Any of Collateral Agent, Lender or Borrower may change its mailing address or facsimile number by giving the other party written notice thereof in accordance with the terms of this Section 10.

If to any Borrower: c/o PROMETHEUS BIOSCIENCES, INC.
9410 Carroll Park Drive
San Diego, CA 92121
Attn: Vika Brough, VP Finance

with a copy (which shall not constitute notice) to: Latham & Watkins
505 Montgomery Street, Suite 2000
San Francisco, CA 94111-6538
Attn: Haim Zaltzman

If to Collateral Agent: OXFORD FINANCE LLC
133 North Fairfax Street
Alexandria, Virginia 22314
Attention: Legal Department

with a copy (which shall not constitute notice) to: Barnes & Thornburg LLP
655 W. Broadway, Suite 900
San Diego, California 92101
11. CHOICE OF LAW, VENUE AND JURY TRIAL WAIVER, AND JUDICIAL REFERENCE

California law governs the Loan Documents without regard to principles of conflicts of law. Borrower, Collateral Agent and each Lender each submit to the exclusive jurisdiction of the State and Federal courts in Santa Clara County, California; provided, however, that nothing in this Agreement shall be deemed to operate to preclude Collateral Agent or any Lender from bringing suit or taking other legal action in any other jurisdiction to realize on the Collateral or any other security for the Obligations, or to enforce a judgment or other court order in favor of Collateral Agent or any Lender. Borrower expressly submits and consents in advance to such jurisdiction in any action or suit commenced in any such court, and Borrower hereby waives any objection that it may have based upon lack of personal jurisdiction, improper venue, or forum non conveniens and hereby consents to the granting of such legal or equitable relief as is deemed appropriate by such court. Borrower hereby waives personal service of the summons, complaints, and other process issued in such action or suit and agrees that service of such summons, complaints, and other process may be made by registered or certified mail addressed to Borrower at the address set forth in, or subsequently provided by Borrower in accordance with, Section 10 of this Agreement and that service so made shall be deemed completed upon the earlier to occur of Borrower’s actual receipt thereof or three (3) days after deposit in the U.S. mails, proper postage prepaid.

TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, BORROWER, COLLATERAL AGENT AND EACH LENDER EACH WAIVE THEIR RIGHT TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION ARISING OUT OF OR BASED UPON THIS AGREEMENT, THE LOAN DOCUMENTS OR ANY CONTEMPLATED TRANSACTION, INCLUDING CONTRACT, TORT, BREACH OF DUTY AND ALL OTHER CLAIMS. THIS WAIVER IS A MATERIAL INDUCEMENT FOR EACH PARTY TO ENTER INTO THIS AGREEMENT. EACH PARTY HAS REVIEWED THIS WAIVER WITH ITS COUNSEL.

WITHOUT INTENDING IN ANY WAY TO LIMIT THE PARTIES’ AGREEMENT TO WAIVE THEIR RESPECTIVE RIGHT TO A TRIAL BY JURY, if the above waiver of the right to a trial by jury is not enforceable, the parties hereto agree that any and all disputes or controversies of any nature between them arising at any time shall be decided by a reference to a private judge, mutually selected by the parties (or, if they cannot agree, by the Presiding Judge of the Santa Clara County, California Superior Court) appointed in accordance with California Code of Civil Procedure Section 638 (or pursuant to comparable provisions of federal law if the dispute falls within the exclusive jurisdiction of the federal courts), sitting without a jury, in Santa Clara County, California; and the parties hereby submit to the jurisdiction of such court. The reference proceedings shall be conducted pursuant to and in accordance with the provisions of California Code of Civil Procedure §§ 638 through 645.1, inclusive. The private judge shall have the power, among others, to grant provisional relief, including without limitation, entering temporary restraining orders, issuing preliminary and permanent injunctions and appointing receivers. All such proceedings shall be closed to the public and confidential and all records relating thereto shall be permanently sealed. If during the course of any dispute, a party desires to seek provisional relief, but a judge has not been appointed at that point pursuant to the judicial reference procedures, then such party may apply to the Santa Clara County, California Superior Court for such relief. The proceeding before the private judge shall be conducted in the same manner as it would be before a court under the rules of evidence applicable to judicial proceedings. The parties shall be entitled to discovery which shall be conducted in the same manner as it would be before a court under the rules of discovery applicable to judicial proceedings. The private judge shall oversee discovery and may enforce all discovery rules and orders applicable to judicial proceedings in the same manner as a trial court judge. The parties agree that the selected or appointed private judge shall have the power to decide all issues in the action or proceeding, whether of fact or of law, and shall report a statement of decision thereon pursuant to California Code of Civil Procedure § 644(a). Nothing in this paragraph shall limit the right of any party at any time to exercise self-help remedies, foreclose against collateral, or obtain provisional remedies. The private judge shall also determine all issues relating to the applicability, interpretation, and enforceability of this paragraph.

12. GENERAL PROVISIONS

12.1 Successors and Assigns. This Agreement binds and is for the benefit of the successors and permitted assigns of each party. Borrower may not transfer, pledge or assign this Agreement or any rights or obligations under it without Collateral Agent’s and each Lender’s prior written consent (which may be granted or withheld in Collateral Agent’s and each Lender’s discretion, subject to Section 12.6). The Lenders have the right,
without the consent of or notice to Borrower, to sell, transfer, assign, pledge, collateralize, or grant participation in (any such sale, transfer, assignment, collateralization, or grant of a participation, a “Lender Transfer”) all or any part of, or any interest in, the Lenders’ obligations, rights, and benefits under this Agreement and the other Loan Documents; provided, however, that any such Lender Transfer (other than a transfer, pledge, sale or assignment to an Eligible Assignee) of its obligations, rights, and benefits under this Agreement and the other Loan Documents shall require the prior written consent of the Required Lenders (such approved assignee, an “Approved Lender”). Borrower and Collateral Agent shall be entitled to continue to deal solely and directly with such Lender in connection with the interests so assigned until Collateral Agent shall have received and accepted an effective assignment agreement in form satisfactory to Collateral Agent executed, delivered and fully completed by the applicable parties thereto, and shall have received such other information regarding such Eligible Assignee or Approved Lender as Collateral Agent reasonably shall require. Notwithstanding anything to the contrary contained herein, so long as no Event of Default has occurred and is continuing, no Lender Transfer (other than a Lender Transfer (i) in respect of the Warrants or (ii) in connection with (x) assignments by a Lender due to a forced divestiture at the request of any regulatory agency; or (y) upon the occurrence of a default, event of default or similar occurrence with respect to a Lender’s own financing or securitization transactions) shall be permitted, without Borrower’s consent, to any Person which is an Affiliate or Subsidiary of Borrower, a direct competitor of Borrower or a vulture hedge fund, each as determined by Collateral Agent.

12.2 Indemnification. Borrower agrees to indemnify, defend and hold Collateral Agent and the Lenders and their respective directors, officers, employees, agents, attorneys, or any other Person affiliated with or representing Collateral Agent or the Lenders (each, an “Indemnified Person”) harmless against: (a) all obligations, demands, claims, and liabilities (collectively, “Claims”) asserted by any other party in connection with; related to; following; or arising from, out of or under, the transactions contemplated by the Loan Documents; and (b) all losses or Lenders’ Expenses incurred, or paid by Indemnified Person in connection with; related to; following; or arising from, out of or under, the transactions contemplated by the Loan Documents between Collateral Agent, and/or the Lenders and Borrower (including reasonable and documented attorneys’ fees and expenses), except for Claims and/or losses directly caused by such Indemnified Person’s gross negligence or willful misconduct. Borrower hereby further indemnifies, defends and holds each Indemnified Person harmless from and against any and all liabilities, obligations, losses, damages, penalties, actions, judgments, suits, claims, costs, expenses and disbursements of any kind or nature whatsoever (including the reasonable and documented fees and disbursements of counsel for such Indemnified Person) in connection with any investigative, response, remedial, administrative or judicial matter or proceeding, whether or not such Indemnified Person shall be designated a party thereto and including any such proceeding initiated by or on behalf of Borrower, and the reasonable expenses of investigation by engineers, environmental consultants and similar technical personnel and any commission, fee or compensation claimed by any broker (other than any broker retained by Collateral Agent or Lenders) asserting any right to payment for the transactions contemplated hereby which may be imposed on, incurred by or asserted against such Indemnified Person as a result of or in connection with the transactions contemplated hereby and the use or intended use of the proceeds of the loan provided hereunder, in each case except for liabilities, obligations, losses, damages, penalties, actions, judgments, suits, claims, costs, expenses and disbursements directly caused by such Indemnified Person’s gross negligence or willful misconduct.

12.3 Time of Essence. Time is of the essence for the performance of all Obligations in this Agreement.

12.4 Severability of Provisions. Each provision of this Agreement is severable from every other provision in determining the enforceability of any provision.

12.5 Correction of Loan Documents. Collateral Agent and the Lenders may correct patent errors and fill in any blanks in this Agreement and the other Loan Documents consistent with the agreement of the parties so long as Collateral Agent provides Borrower with written notice of such correction and allows Borrower at least ten (10) days to object to such correction. In the event of such objection, such correction shall not be made except by an amendment signed by Collateral Agent, the Lenders and Borrower.

12.6 Amendments in Writing: Integration. (a) No amendment, modification, termination or waiver of any provision of this Agreement or any other Loan Document, no approval or consent thereunder, or any consent
to any departure by Borrower or any of its Subsidiaries therefrom, shall in any event be effective unless the same shall be in writing and signed by Borrower, Collateral Agent and the Required Lenders provided that:

(i) no such amendment, waiver or other modification that would have the effect of increasing or reducing a Lender’s Term Loan Commitment or Commitment Percentage shall be effective as to such Lender without such Lender’s written consent;

(ii) no such amendment, waiver or modification that would affect the rights and duties of Collateral Agent shall be effective without Collateral Agent’s written consent or signature;

(iii) no such amendment, waiver or other modification shall, unless signed by all the Lenders directly affected thereby, (A) reduce the principal of, rate of interest on or any fees with respect to any Term Loan or forgive any principal, interest (other than default interest) or fees (other than late charges) with respect to any Term Loan (B) postpone the date fixed for, or waive, any payment of principal of any Term Loan or of interest on any Term Loan (other than default interest) or any fees provided for hereunder (other than late charges or for any termination of any commitment); (C) change the definition of the term “Required Lenders” or the percentage of Lenders which shall be required for the Lenders to take any action hereunder; (D) release all or substantially all of any material portion of the Collateral, authorize Borrower to sell or otherwise dispose of all or substantially all or any material portion of the Collateral or release any Guarantor of all or any portion of the Obligations or its guaranty obligations with respect thereto, except, in each case with respect to this clause (D), as otherwise may be expressly permitted under this Agreement or the other Loan Documents (including in connection with any disposition permitted hereunder); (E) amend, waiver or otherwise modify this Section 12.6 or the definitions of the terms used in this Section 12.6 insofar as the definitions affect the substance of this Section 12.6; (F) consent to the assignment, delegation or other transfer by Borrower of any of its rights and obligations under any Loan Document or release Borrower of its payment obligations under any Loan Document, except, in each case with respect to this clause (F), pursuant to a merger or consolidation permitted pursuant to this Agreement; (G) amend any of the provisions of Section 9.4 or amend any of the definitions of Pro Rata Share, Term Loan Commitment, Commitment Percentage or that provide for the Lenders to receive their Pro Rata Shares of any fees, payments, setoffs or proceeds of Collateral hereunder; (H) subordinate the Liens granted in favor of Collateral Agent securing the Obligations; or (I) amend any of the provisions of Section 12.10. It is hereby understood and agreed that all Lenders shall be deemed directly affected by an amendment, waiver or other modification of the type described in the preceding clauses (C), (D), (E), (F), (G) and (H) of the preceding sentence;

(iv) the provisions of the foregoing clauses (i), (ii) and (iii) are subject to the provisions of any interlender or agency agreement among the Lenders and Collateral Agent pursuant to which any Lender may agree to give its consent in connection with any amendment, waiver or other modification of the Loan Documents only in the event of the unanimous agreement of all Lenders.

(b) Other than as expressly provided for in Section 12.6(a)(i)-(iii), Collateral Agent may, if requested by the Required Lenders, from time to time designate covenants in this Agreement less restrictive by notification to a Responsible Officer.

(c) This Agreement and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements. All prior agreements, understandings, representations, warranties, and negotiations between the parties about the subject matter of this Agreement and the Loan Documents merge into this Agreement and the Loan Documents.

12.7 Counterparts. This Agreement may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, is an original, and all taken together, constitute one Agreement.

12.8 Survival. All covenants, representations and warranties made in this Agreement continue in full force and effect until this Agreement has terminated pursuant to its terms and all Obligations (other than inchoate indemnity obligations and any other obligations which, by their terms, are to survive the termination of this Agreement) have been satisfied. The obligation of Borrower in Section 12.2 to indemnify each Lender and Collateral Agent, as well as the confidentiality provisions in Section 12.9 below, shall survive until the statute of limitations with respect to such claim or cause of action shall have run.
12.9 Confidentiality. In handling any confidential information of Borrower or any of its Subsidiaries, the Lenders and Collateral Agent shall exercise the same degree of care that it exercises for their own proprietary information, but disclosure of information may be made: (a) subject to the terms and conditions of this Agreement, to the Lenders’ and Collateral Agent’s Subsidiaries or Affiliates that are subject to confidentiality provisions of this Section 12.9, or in connection with a Lender’s own financing or securitization transactions and upon the occurrence of a default, event of default or similar occurrence with respect to such financing or securitization transaction; (b) to prospective transferees (other than those identified in (a) above) or purchasers of any interest in the Credit Extensions (provided, however, the Lenders and Collateral Agent shall, except upon the occurrence and during the continuance of an Event of Default, obtain such prospective transferee’s or purchaser’s agreement to the terms of this provision or to similar confidentiality terms); (c) as required by law, regulation, subpoena, or other order; (d) to Lenders’ or Collateral Agent’s regulators or in connection with any examination or audit; (e) as Collateral Agent reasonably considers appropriate in exercising remedies under the Loan Documents; and (f) to third party service providers of the Lenders and/or Collateral Agent so long as such service providers have executed a confidentiality agreement with the Lenders and Collateral Agent with terms no less restrictive than those contained herein. Confidential information does not include information that either: (i) is in the public domain or in the Lenders’ and/or Collateral Agent’s possession when disclosed to the Lenders and/or Collateral Agent, or becomes part of the public domain after disclosure to the Lenders and/or Collateral Agent (other than as a result of its disclosure by Collateral Agent or any Lender in violation of this Agreement); or (ii) is disclosed to the Lenders and/or Collateral Agent by a third party, if the Lenders and/or Collateral Agent does not know that the third party is prohibited from disclosing the information. Collateral Agent and the Lenders may use confidential information for any purpose, including, without limitation, for the development of client databases, reporting purposes, and market analysis so long as Collateral Agent and the Lenders do not disclose Borrower’s identity or the identity of any person associated with Borrower unless otherwise expressly permitted by this Agreement. The provisions of this Section 12.9 shall survive the termination of this Agreement. The agreements provided under this Section 12.9 supersede all prior agreements, understanding, representations, warranties, and negotiations between the parties about the subject matter of this Section 12.9.

12.10 Right of Set Off. Borrower hereby grants to Collateral Agent and to each Lender, a lien, security interest and right of set off as security for all Obligations to Collateral Agent and each Lender hereunder, whether now existing or hereafter arising upon and against all deposits, credits, collateral and property, now or hereafter in the possession, custody, safekeeping or control of Collateral Agent or the Lenders or any entity under the control of Collateral Agent or the Lenders (including a Collateral Agent affiliate) or in transit to any of them. At any time after the occurrence and during the continuance of an Event of Default, without demand or notice, Collateral Agent or the Lenders may set off the same or any part thereof and apply the same to any liability or obligation of Borrower even though unmatured and regardless of the adequacy of any other collateral securing the Obligations. ANY AND ALL RIGHTS TO REQUIRE COLLATERAL AGENT TO EXERCISE ITS RIGHTS OR REMEDIES WITH RESPECT TO ANY OTHER COLLATERAL WHICH SECURES THE OBLIGATIONS, PRIOR TO EXERCISING ITS RIGHT OF SETOFF WITH RESPECT TO SUCH DEPOSITS, CREDITS OR OTHER PROPERTY OF BORROWER ARE HEREBY KNOWINGLY, VOLUNTARILY AND IRREVOCABLY WAIVED.

12.11 Cooperation of Borrower. If necessary, Borrower agrees to (i) execute any documents (including new Secured Promissory Notes) reasonably required to effectuate and acknowledge each assignment of a Term Loan Commitment or Loan to an assignee in accordance with Section 12.1, (ii) make Borrower’s management available to meet with Collateral Agent and prospective participants and assignees of Term Loan Commitments or Credit Extensions (which meetings shall be conducted no more often than twice every twelve months unless an Event of Default has occurred and is continuing), and (iii) assist Collateral Agent or the Lenders in the preparation of information relating to the financial affairs of Borrower as any prospective participant or assignee of a Term Loan Commitment or Term Loan reasonably may request. Subject to the provisions of Section 12.9, Borrower authorizes each Lender to disclose to any prospective participant or assignee of a Term Loan Commitment, any and all information in such Lender’s possession concerning Borrower and its financial affairs which has been delivered to such Lender by or on behalf of Borrower pursuant to this Agreement, or which has been delivered to such Lender by or on behalf of Borrower in connection with such Lender’s credit evaluation of Borrower prior to entering into this Agreement.
12.12 Borrower Liability. Either Borrower may, acting singly, request Credit Extensions hereunder. Each Borrower hereby appoints the other as agent for the other for all purposes hereunder, including with respect to requesting Credit Extensions hereunder. Each Borrower hereunder shall be jointly and severally obligated to repay all Credit Extensions made hereunder, regardless of which Borrower actually receives said Credit Extension, as if each Borrower hereunder directly received all Credit Extensions. Each Borrower waives (a) any suretyship defenses available to it under the Code or any other applicable law, including, without limitation, the benefit of California Civil Code Section 2815 permitting revocation as to future transactions and the benefit of California Civil Code Sections 1432, 2809, 2810, 2819, 2839, 2845, 2847, 2848, 2849, 2850, and 2899 and 3433, and (b) any right to require Collateral Agent or any Lender to: (i) proceed against any Borrower or any other person; (ii) proceed against or exhaust any security; or (iii) pursue any other remedy. Collateral Agent and or any Lender may exercise or not exercise any right or remedy it has against any Borrower or any security it holds (including the right to foreclose by judicial or non-judicial sale) without affecting any Borrower’s liability. Notwithstanding any other provision of this Agreement or other related document, each Borrower irrevocably waives all rights that it may have at law or in equity (including, without limitation, any law subrogating Borrower to the rights of Collateral Agent and the Lenders under this Agreement) to seek contribution, indemnification or any other form of reimbursement from any other Borrower, or any other Person now or hereafter primarily or secondarily liable for any of the Obligations, for any payment made by Borrower with respect to the Obligations in connection with this Agreement or otherwise and all rights that it might have to benefit from, or to participate in, any security for the Obligations as a result of any payment made by Borrower with respect to the Obligations in connection with this Agreement or otherwise. Any agreement providing for indemnification, reimbursement or any other arrangement prohibited under this Section shall be null and void. If any payment is made to a Borrower in contravention of this Section, such Borrower shall hold such payment in trust for Collateral Agent and the Lenders and such payment shall be promptly delivered to Collateral Agent for application to the Obligations, whether matured or unmatured.

13. DEFINITIONS

13.1 Definitions. As used in this Agreement, the following terms have the following meanings:

"Account" is any “account” as defined in the Code with such additions to such term as may hereafter be made, and includes, without limitation, all accounts receivable and other sums owing to Borrower.

"Account Debtor" is any “account debtor” as defined in the Code with such additions to such term as may hereafter be made.

"Affiliate" of any Person is a Person that owns or controls directly or indirectly the Person, any Person that controls or is controlled by or is under common control with the Person, and each of that Person’s senior executive officers, directors, partners and, for any Person that is a limited liability company, that Person’s managers and members.

"Agreement" is defined in the preamble hereof.

"Amortization Date" is March 1, 2023.

"Annual Projections" is defined in Section 6.2(a).

"Anti-Terrorism Laws" are any laws relating to terrorism or money laundering, including Executive Order No. 13224 (effective September 24, 2001), the USA PATRIOT Act, the laws comprising or implementing the Bank Secrecy Act, and the laws administered by OFAC.

"Approved Fund" is any (i) investment company, fund, trust, securitization vehicle or conduit that is (or will be) engaged in making, purchasing, holding or otherwise investing in commercial loans and similar extensions of credit in the ordinary course of its business or (ii) any Person (other than a natural person) which temporarily warehouses loans for any Lender or any entity described in the preceding clause (i) and that, with respect to each of the preceding clauses (i) and (ii), is administered or managed by (a) a Lender, (b) an Affiliate of a Lender or (c) a Person (other than a natural person) or an Affiliate of a Person (other than a natural person) that administers or manages a Lender.
“Approved Lender” is defined in Section 12.1.

“Basic Rate” is the per annum rate of interest (based on a year of three hundred sixty (360) days) equal to the sum of (I) the greater of (a) the thirty (30) day U.S. LIBOR rate reported in The Wall Street Journal on the last Business Day of the month that immediately precedes the month in which the interest will accrue, and (b) two and one hundredths percent (2.01%), plus (II) five and ninety-eight hundredths percent (5.98%). Notwithstanding the foregoing, (x) the Basic Rate from the period of the Effective Date through and including January 31, 2020, shall be 7.99%; and (y) the Basic Rate shall at no time be less than seven and ninety-nine one hundredths percent (7.99%). If The Wall Street Journal (or another nationally recognized rate reporting source acceptable to Collateral Agent) no longer reports the U.S. LIBOR Rate or if such interest rate no longer exists or if The Wall Street Journal no longer publishes the U.S. LIBOR Rate or ceases to exist, Collateral Agent may in good faith, and with reference to the margin above such interest rate in this definition, select a replacement interest rate and replacement margin above such interest rate that results in a substantially similar interest rate floor and total rate in effect immediately prior to the effectiveness of such replacement interest rate and replacement margin, or replacement publication, as the case may be, and shall notify Borrower of such replacement interest rate and replacement margin or replacement publication.

“Blocked Person” is any Person: (a) listed in the annex to, or is otherwise subject to the provisions of, Executive Order No. 13224, (b) a Person owned or controlled by, or acting for or on behalf of, any Person that is listed in the annex to, or is otherwise subject to the provisions of, Executive Order No. 13224, (c) a Person with which any Lender is prohibited from dealing or otherwise engaging in any transaction by any Anti-Terrorism Law, (d) a Person that commits, threatens or conspires to commit or supports “terrorism” as defined in Executive Order No. 13224, or (e) a Person that is named a “specially designated national” or “blocked person” on the most current list published by OFAC or other similar list.

“Borrower” is defined in the preamble hereof.

“Borrower’s Books” are Borrower’s or any of its Subsidiaries’ books and records including ledgers, federal, and state tax returns, records regarding Borrower’s or its Subsidiaries’ assets or liabilities, the Collateral, business operations or financial condition, and all computer programs or storage or any equipment containing such information.

“Business Day” is any day that is not a Saturday, Sunday or a day on which Collateral Agent is closed.

“Cash Equivalents” are (a) marketable direct obligations issued or unconditionally guaranteed by the United States or any agency or any State thereof having maturities of not more than one (1) year from the date of acquisition; (b) commercial paper maturing no more than one (1) year after its creation and having the highest rating from either Standard & Poor’s Ratings Group or Moody’s Investors Service, Inc., (c) certificates of deposit maturing no more than one (1) year after issue provided that the account in which any such certificate of deposit is maintained is subject to a Control Agreement in favor of Collateral Agent and (d) money market funds at least 95% of which constitute Cash Equivalents of the kinds described in clauses (a) through (c) herein. For the avoidance of doubt, the direct purchase by Borrower or any of its Subsidiaries of any Auction Rate Securities, or purchasing participations in, or entering into any type of swap or other derivative transaction, or otherwise holding or engaging in any ownership interest in any type of Auction Rate Security by Borrower or any of its Subsidiaries shall be conclusively determined by the Lenders as an ineligible Cash Equivalent, and any such transaction shall expressly violate each other provision of this Agreement governing Permitted Investments. Notwithstanding the foregoing, Cash Equivalents does not include and Borrower, and each of its Subsidiaries, are prohibited from purchasing, purchasing participations in, entering into any type of swap or other equivalent derivative transaction, or otherwise holding or engaging in any ownership interest in any type of debt instrument, including, without limitation, any corporate or municipal bonds with a long term nominal maturity for which the interest rate is reset through a dutch auction and more commonly referred to as an auction rate security (each, an “Auction Rate Security”).

“Claims” are defined in Section 12.2.
“Code” is the Uniform Commercial Code, as the same may, from time to time, be enacted and in effect in the State of California; provided, that, to
the extent that the Code is used to define any term herein or in any Loan Document and such term is defined differently in different Articles or Divisions of
the Code, the definition of such term contained in Article or Division 9 shall govern; provided further, that in the event that, by reason of mandatory
provisions of law, any or all of the attachment, perfection, or priority of, or remedies with respect to, Collateral Agent’s Lien on any Collateral is
governed by the Uniform Commercial Code in effect in a jurisdiction other than the State of California, the term “Code” shall mean the Uniform
Commercial Code as enacted and in effect in such other jurisdiction solely for purposes of the provisions thereof relating to such attachment, perfection,
priority, or remedies and for purposes of definitions relating to such provisions.

“Collateral” is any and all properties, rights and assets of Borrower described on Exhibit A.

“Collateral Account” is any Deposit Account, Securities Account, or Commodity Account, or any other bank account maintained by Borrower or
any Subsidiary which is a Borrower or Guarantor at any time.

“Collateral Agent” is, Oxford, not in its individual capacity, but solely in its capacity as agent on behalf of and for the benefit of the Lenders.

“Commitment Percentage” is set forth in Schedule 1.1, as amended from time to time.

“Commodity Account” is any “commodity account” as defined in the Code with such additions to such term as may hereafter be made.

“Communication” is defined in Section 10.

“Compliance Certificate” is that certain certificate in the form attached hereto as Exhibit C.

“Contingent Obligation” is, for any Person, any direct or indirect liability, contingent or not, of that Person for (a) any indebtedness, lease,
dividend, letter of credit or other obligation of another such as an obligation directly or indirectly guaranteed, endorsed, co-made, discounted or sold
with recourse by that Person, or for which that Person is directly or indirectly liable; (b) any obligations for undrawn letters of credit for the account of
that Person; and (c) all obligations from any interest rate, currency or commodity swap agreement, interest rate cap or collar agreement, or other
agreement or arrangement designated to protect a Person against fluctuation in interest rates, currency exchange rates or commodity prices; but
“Contingent Obligation” does not include endorsements in the ordinary course of business. The amount of a Contingent Obligation is the stated or
determined amount of the primary obligation for which the Contingent Obligation is made or, if not determinable, the maximum reasonably anticipated
liability for it determined by the Person in good faith; but the amount may not exceed the maximum of the obligations under any guarantee or other
support arrangement.

“Control Agreement” is any control agreement entered into among the depository institution at which Borrower or any of its Subsidiaries
maintains a Deposit Account or the securities intermediary or commodity intermediary at which Borrower or any of its Subsidiaries maintains a
Securities Account or a Commodity Account, Borrower or such Subsidiary, and Collateral Agent pursuant to which Collateral Agent obtains control
(within the meaning of the Code) for the benefit of the Lenders over such Deposit Account, Securities Account, or Commodity Account.

“Copyrights” are any and all copyright rights, copyright applications, copyright registrations and like protections in each work or authorship and
derivative work thereof, whether published or unpublished and whether or not the same also constitutes a trade secret.

“Credit Extension” is any Term Loan or any other extension of credit by Collateral Agent or Lenders for Borrower’s benefit.

“Default Rate” is defined in Section 2.3(b).
“Deposit Account” is any “deposit account” as defined in the Code with such additions to such term as may hereafter be made.

“Designated Deposit Account” is Borrower’s deposit account, account number ending in 4420, maintained with Union Bank.

“Disbursement Letter” is that certain form attached hereto as Exhibit B.

“Dollars,” “dollars” and “$” each mean lawful money of the United States.

“Effective Date” is defined in the preamble of this Agreement.

“Eligible Assignee” is (i) a Lender, (ii) an Affiliate of a Lender, (iii) an Approved Fund and (iv) any commercial bank, savings and loan association or savings bank or any other entity which is an “accredited investor” (as defined in Regulation D under the Securities Act of 1933, as amended) and which extends credit or buys loans as one of its businesses, including insurance companies, mutual funds, lease financing companies and commercial finance companies, in each case, which either (A) has a rating of BBB or higher from Standard & Poor’s Rating Group and a rating of Baa2 or higher from Moody’s Investors Service, Inc. at the date that it becomes a Lender or (B) has total assets in excess of Five Billion Dollars ($5,000,000,000.00), and in each case of clauses (i) through (iv), which, through its applicable lending office, is capable of lending to Borrower without the imposition of any withholding or similar taxes; provided that notwithstanding the foregoing, “Eligible Assignee” shall not include, unless an Event of Default has occurred and is continuing, (i) Borrower or any of Borrower’s Affiliates or Subsidiaries or (ii) a direct competitor of Borrower or a vulture hedge fund, each as determined by Collateral Agent. Notwithstanding the foregoing, (x) in connection with assignments by a Lender due to a forced divestiture at the request of any regulatory agency, the restrictions set forth herein shall not apply and Eligible Assignee shall mean any Person or party and (y) in connection with a Lender’s own financing or securitization transactions, the restrictions set forth herein shall not apply and Eligible Assignee shall mean any Person or party providing such financing or formed to undertake such securitization transaction and any transferee of such Person or party upon the occurrence of a default, event of default or similar occurrence with respect to such financing or securitization transaction; provided that no such sale, transfer, pledge or assignment under this clause (y) shall release such Lender from any of its obligations hereunder or substitute any such Person or party for such Lender as a party hereto until Collateral Agent shall have received and accepted an effective assignment agreement from such Person or party in form satisfactory to Collateral Agent executed, delivered and fully completed by the applicable parties thereto, and shall have received such other information regarding such Eligible Assignee as Collateral Agent reasonably shall require.

“Equipment” is all “equipment” as defined in the Code with such additions to such term as may hereafter be made, and includes without limitation all machinery, fixtures, goods, vehicles (including motor vehicles and trailers), and any interest in any of the foregoing.

“Equity Event” is the receipt by Borrower on or after the Effective Date of unrestricted net cash proceeds of not less than Thirty Million Dollars ($30,000,000.00) from the issuance and sale by Borrower of its Series C Preferred equity securities on terms and conditions reasonably acceptable to Collateral Agent.

“ERISA” is the Employee Retirement Income Security Act of 1974, as amended, and its regulations.

“Event of Default” is defined in Section 8.

“Final Payment” is a payment (in addition to and not a substitution for the regular monthly payments of principal plus accrued interest) due on the earliest to occur of (a) the Maturity Date, or (b) the acceleration of any Term Loan, or (c) the prepayment of a Term Loan pursuant to Section 2.2(c) or (d), equal to the original principal amount of such funded Term Loan multiplied by the Final Payment Percentage, payable to Lenders in accordance with their respective Pro Rata Shares. For the avoidance of doubt, the calculation of any Final Payment shall not include the principal amount prepaid in accordance with Section 2.2(d)(ii) if a Final Payment based on such principal amount was made at the time of such prepayment.

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“Final Payment Percentage” is (i) four percent (4.00%) with respect to the Term A Loan, plus (ii) three percent (3.00%) of the funded amount of the Term B Loan.

“Foreign Subsidiary” is a Subsidiary that is not an entity organized under the laws of the United States or any territory thereof.

“Funding Date” is any date on which a Credit Extension is made to or on account of Borrower which shall be a Business Day.

“GAAP” is generally accepted accounting principles set forth in the opinions and pronouncements of the Accounting Principles Board of the American Institute of Certified Public Accountants and statements and pronouncements of the Financial Accounting Standards Board or in such other statements by such other Person as may be approved by a significant segment of the accounting profession in the United States, which are applicable to the circumstances as of the date of determination.

“General Intangibles” are all “general intangibles” as defined in the Code in effect on the date hereof with such additions to such term as may hereafter be made, and includes without limitation, all copyright rights, copyright applications, copyright registrations and like protections in each work of authorship and derivative work, whether published or unpublished, any patents, trademarks, service marks and, to the extent permitted under applicable law, any applications therefor, whether registered or not, any trade secret rights, including any rights to unpatented inventions, payment intangibles, royalties, contract rights, goodwill, franchise agreements, purchase orders, customer lists, route lists, telephone numbers, domain names, claims, income and other tax refunds, security and other deposits, options to purchase or sell real or personal property, rights in all litigation presently or hereafter pending (whether in contract, tort or otherwise), insurance policies (including without limitation key man, property damage, and business interruption insurance), payments of insurance and rights to payment of any kind.

“Governmental Approval” is any consent, authorization, approval, order, license, franchise, permit, certificate, accreditation, registration, filing or notice, of, issued by, from or to, or other act by or in respect of, any Governmental Authority.

“Governmental Authority” is any nation or government, any state or other political subdivision thereof, any agency, authority, instrumentality, regulatory body, court, central bank or other entity exercising executive, legislative, judicial, taxing, regulatory or administrative functions of or pertaining to government, any securities exchange and any self-regulatory organization.

“Guarantor” is any Person providing a Guaranty in favor of Collateral Agent.

“Guaranty” is any guarantee of all or any part of the Obligations, as the same may from time to time be amended, restated, modified or otherwise supplemented.

“Indebtedness” is (a) indebtedness for borrowed money or the deferred price of property or services, such as reimbursement and other obligations for surety bonds and letters of credit, (b) obligations evidenced by notes, bonds, debentures or similar instruments, (c) capital lease obligations, and (d) Contingent Obligations.

“Indemnified Person” is defined in Section 12.2.

“Insolvency Proceeding” is any proceeding by or against any Person under the United States Bankruptcy Code, or any other bankruptcy or insolvency law, including assignments for the benefit of creditors, compositions, extensions generally with its creditors, or proceedings seeking reorganization, arrangement, or other relief.

“Insolvent” means not Solvent.

“Intellectual Property” means all of Borrower’s or any Subsidiary’s right, title and interest in and to the following:

(a) its Copyrights, Trademarks and Patents;
(b) any and all trade secrets and trade secret rights, including, without limitation, any rights to unpatented inventions, know-how, operating manuals;

(c) any and all source code;

(d) any and all design rights which may be available to Borrower;

(e) any and all claims for damages by way of past, present and future infringement of any of the foregoing, with the right, but not the obligation, to sue for and collect such damages for said use or infringement of the Intellectual Property rights identified above; and

(f) all amendments, renewals and extensions of any of the Copyrights,Trademarks or Patents.

“Inventory” is all “inventory” as defined in the Code in effect on the date hereof with such additions to such term as may hereafter be made, and includes without limitation all merchandise, raw materials, parts, supplies, packing and shipping materials, work in process and finished products, including without limitation such inventory as is temporarily out of any Person’s custody or possession or in transit and including any returned goods and any documents of title representing any of the above.

“Investment” is any beneficial ownership interest in any Person (including stock, partnership interest or other securities), and any loan, advance or capital contribution to any Person.

“Key Person” is each of Borrower’s (i) Chief Executive Officer and President and Treasurer, who is Mark McKenna as of the Effective Date, (ii) Chief Operating Officer, who is Lauren Otsuki as of the Effective Date, (iii) Chief Medical Officer, who is Allison Luo as of the Effective Date and (iv) Chief Scientific Officer, who is Laurens Kruidenier as of the Effective Date.

“Lender” is any one of the Lenders.

“Lenders” are the Persons identified on Schedule 1.1 hereto and each assignee that becomes a party to this Agreement pursuant to Section 12.1.

“Lenders’ Expenses” are all audit fees and expenses, costs, and expenses (including reasonable and documented attorneys’ fees and expenses, as well as appraisal fees, fees incurred on account of lien searches, inspection fees, and filing fees) for preparing, amending, negotiating, administering, defending and enforcing the Loan Documents (including, without limitation, those incurred in connection with appeals or Insolvency Proceedings) or otherwise incurred by Collateral Agent and/or the Lenders in connection with the Loan Documents.

“Lien” is a claim, mortgage, deed of trust, levy, charge, pledge, security interest, or other encumbrance of any kind, whether voluntarily incurred or arising by operation of law or otherwise against any property.

“Loan Documents” are, collectively, this Agreement, the Warrants, the Perfection Certificates, each Compliance Certificate, each Disbursement Letter, the Post Closing Letter, any subordination agreements, any note, or notes or guaranties executed by Borrower or any other Person, and any other present or future agreement entered into by Borrower, any Guarantor or any other Person for the benefit of the Lenders and Collateral Agent in connection with this Agreement; all as amended, restated, or otherwise modified.

“Material Adverse Change” is (a) a material impairment in the perfection or priority of Collateral Agent’s Lien in the Collateral or in the value of such Collateral; (b) a material adverse change in the business, operations or condition (financial or otherwise) of Borrower or Borrower and its Subsidiaries, taken as a whole; or (c) a material impairment of the prospect of repayment of any portion of the Obligations.
“Maturity Date” is January 23, 2025.

“Obligations” are all of Borrower’s obligations to pay when due any debts, principal, interest, Lenders’ Expenses, the Prepayment Fee, the Final Payment, and other amounts Borrower owes the Lenders now or later, in connection with, related to, following, or arising from, out of or under, this Agreement or, the other Loan Documents (other than the Warrants or any other equity instruments), or otherwise, and including interest accruing after Insolvency Proceedings begin (whether or not allowed) and debts, liabilities, or obligations of Borrower assigned to the Lenders and/or Collateral Agent, and the performance of Borrower’s duties under the Loan Documents (other than the Warrants or any other equity instruments).

“OFAC” is the U.S. Department of Treasury Office of Foreign Assets Control.

“OFAC Lists” are, collectively, the Specially Designated Nationals and Blocked Persons List maintained by OFAC pursuant to Executive Order No. 13224, 66 Fed. Reg. 49079 (Sept. 25, 2001) and/or any other list of terrorists or other restricted Persons maintained pursuant to any of the rules and regulations of OFAC or pursuant to any other applicable Executive Orders.

“Operating Documents” are, for any Person, such Person’s formation documents, as certified by the Secretary of State (or equivalent agency) of such Person’s jurisdiction of organization on a date that is no earlier than thirty (30) days prior to the Effective Date, and, (a) if such Person is a corporation, its bylaws in current form, (b) if such Person is a limited liability company, its limited liability company agreement (or similar agreement), and (c) if such Person is a partnership, its partnership agreement (or similar agreement), each of the foregoing with all current amendments or modifications thereto.

“Patents” means all patents, patent applications and like protections including without limitation improvements, divisions, continuations, renewals, reissues, extensions and continuations-in-part of the same.

“Payment Date” is the first (1st) calendar day of each calendar month, commencing on March 1, 2020.

“Perfection Certificate” and “Perfection Certificates” is defined in Section 5.1.

“Permitted Indebtedness” is:

(a) Borrower’s Indebtedness to the Lenders and Collateral Agent under this Agreement and the other Loan Documents;

(b) Indebtedness existing on the Effective Date and disclosed on the Perfection Certificate(s);

(c) Subordinated Debt;

(d) unsecured Indebtedness to trade creditors incurred in the ordinary course of business;

(e) Indebtedness consisting of capitalized lease obligations and purchase money Indebtedness, in each case incurred by Borrower or any of its Subsidiaries to finance the acquisition, repair, improvement or construction of fixed or capital assets of such person, provided that (i) the aggregate outstanding principal amount of all such Indebtedness does not exceed Five Hundred Thousand Dollars ($500,000.00) at any time and (ii) the principal amount of such Indebtedness does not exceed the lower of the cost or fair market value of the property so acquired or built or of such repairs or improvements financed with such Indebtedness (each measured at the time of such acquisition, repair, improvement or construction is made);

(f) Indebtedness incurred as a result of endorsing negotiable instruments received in the ordinary course of Borrower’s business;

(g) Indebtedness of Borrower with respect to corporate credit cards in an aggregate amount not to exceed Two Hundred Thousand Dollars ($200,000.00);
(h) Indebtedness of Borrower with respect to automobile leases in the ordinary course of business in an aggregate amount not to exceed One Million Two Hundred Thousand Dollars ($1,200,000.00) in any fiscal year;

(i) intercompany Indebtedness among Borrower and its Subsidiaries otherwise constituting (and without duplication with any clause of the definition of) “Permitted Investments;”

(j) other unsecured Indebtedness not exceeding One Hundred Thousand Dollars ($100,000.00) in the aggregate outstanding at any time; and

(k) extensions, refinancings, modifications, amendments and restatements of any items of Permitted Indebtedness (a) through (i) above, provided that the principal amount thereof is not increased or the terms thereof are not modified to impose materially more burdensome terms upon Borrower, or its Subsidiary, as the case may be.

“Permitted Investments” are:

(a) Investments disclosed on the Perfection Certificate(s) and existing on the Effective Date;

(b) (i) Investments consisting of cash and Cash Equivalents, and (ii) any other Investments permitted by Borrower’s investment policy, as amended from time to time, provided that such investment policy (and any such amendment thereto) has been approved in writing by Collateral Agent;

(c) Investments consisting of the endorsement of negotiable instruments for deposit or collection or similar transactions in the ordinary course of Borrower;

(d) Investments consisting of Deposit Accounts in which Collateral Agent has a perfected security interest, except to the extent a perfected security interest is not required therein, in accordance with Section 6.6;

(e) Investments in connection with Transfers permitted by Section 7.1 and Investments consisting of the creation of a Subsidiary permitted under Section 6.12 of this Agreement, which is otherwise a Permitted Investment;

(f) Investments (i) by Borrower in Subsidiaries which are Borrowers or Guarantors; (ii) by Borrower in Subsidiaries which are not Borrowers or Guarantors, not to exceed Two Hundred Fifty Thousand Dollars ($250,000.00) in the aggregate per fiscal year or otherwise pursuant to transfer pricing arrangements entered into between Borrower and any Subsidiary in the ordinary course of business; and (iii) of Subsidiaries in or to Borrower or any Guarantor;

(g) Investments consisting of (i) travel advances and employee relocation loans and other employee loans and advances in the ordinary course of business, and (ii) loans to employees, officers or directors relating to the purchase of equity securities of Borrower or its Subsidiaries pursuant to employee stock purchase plans or agreements approved by Borrower’s Board of Directors; not to exceed Two Hundred Fifty Thousand Dollars ($250,000.00) in the aggregate for (i) and (ii) in any fiscal year;

(h) Investments (including debt obligations) received in connection with the bankruptcy or reorganization of customers or suppliers and in settlement of delinquent obligations of, and other disputes with, customers or suppliers arising in the ordinary course of business;

(i) Investments consisting of notes receivable of, or prepaid royalties and other credit extensions, to customers and suppliers who are not Affiliates, in the ordinary course of business; provided that this paragraph (h) shall not apply to Investments of Borrower in any Subsidiary;
(j) to the extent constituting Investments, but without duplication with any clause of the definition of, “Permitted Indebtedness;”

(k) cash and non-cash Investments in joint ventures or strategic alliances in the ordinary course of Borrower’s business consisting of the licensing of technology permitted under this Agreement, the development of technology or the providing of technical support; provided that any cash Investments do not exceed Two Hundred Fifty Thousand Dollars ($250,000.00) in the aggregate in any fiscal year; and

(l) other Investments in an amount not to exceed One Hundred Thousand Dollars ($100,000.00) in any fiscal year.

“Permitted Licenses” are (A) licenses of over-the-counter software that is commercially available to the public, and (B) non-exclusive and exclusive licenses for the use of the Intellectual Property of Borrower or any of its Subsidiaries entered into in the ordinary course of business, provided, that, with respect to each such license described in clause (B), (i) no Event of Default has occurred or is continuing at the time of such license; (ii) the license constitutes an arms-length transaction, the terms of which, on their face, do not provide for a sale or assignment of any Intellectual Property and do not restrict the ability of Borrower or any of its Subsidiaries, as applicable, to pledge, grant a security interest in or lien on, or assign or otherwise Transfer any Intellectual Property; (iii) in the case of any exclusive license, (x) Borrower delivers ten (10) days’ prior written notice and a brief summary of the terms of the proposed license to Collateral Agent and the Lenders and delivers to Collateral Agent and the Lenders copies of the final executed licensing documents in connection with the exclusive license promptly upon consummation thereof, and (y) any such license could not result in a legal transfer of title of the licensed property but may be exclusive in respects other than territory and may be exclusive as to territory only as to discrete geographical areas outside of the United States; and (iv) all upfront payments, royalties, milestone payments or other proceeds arising from the licensing agreement that are payable to Borrower or any of its Subsidiaries are paid to a Deposit Account that is governed by a Control Agreement.

“Permitted Liens” are:

(a) Liens existing on the Effective Date and disclosed on the Perfection Certificates or arising under this Agreement and the other Loan Documents;

(b) Liens for taxes, fees, assessments or other government charges or levies, either (i) not due and payable or (ii) being contested in good faith and for which Borrower maintains adequate reserves on its Books, provided that no notice of any such Lien has been filed or recorded under the Internal Revenue Code of 1986, as amended, and the Treasury Regulations adopted thereunder;

(c) liens securing Indebtedness permitted under clause (e) of the definition of “Permitted Indebtedness,” provided that (i) such liens exist prior to the acquisition of, or attach substantially simultaneous with, or within twenty (20) days after the, acquisition, lease, repair, improvement or construction of, such property financed or leased by such Indebtedness and (ii) such liens do not extend to any property of Borrower other than the property (and proceeds thereof) acquired, leased or built, or the improvements or repairs, financed by such Indebtedness;

(d) Liens of carriers, warehousemen, suppliers, or other Persons that are possessory in nature arising in the ordinary course of business so long as such Liens attach only to Inventory, securing liabilities in the aggregate amount not to exceed One Hundred Thousand Dollars ($100,000.00), and which are not delinquent or remain payable without penalty or which are being contested in good faith and by appropriate proceedings which proceedings have the effect of preventing the forfeiture or sale of the property subject thereto;

(e) Liens to secure payment of workers’ compensation, employment insurance, old-age pensions, social security and other like obligations incurred in the ordinary course of business (other than Liens imposed by ERISA);
(f) Liens incurred in the extension, renewal or refinancing of the indebtedness secured by Liens described in (a) through (c), but any extension, renewal or replacement Lien must be limited to the property encumbered by the existing Lien and the principal amount of the indebtedness may not increase;

(g) leases or subleases of real property granted in the ordinary course of Borrower’s business (or, if referring to another Person, in the ordinary course of such Person’s business), and leases, subleases, non-exclusive licenses or sublicenses of personal property (other than Intellectual Property) granted in the ordinary course of Borrower’s business (or, if referring to another Person, in the ordinary course of such Person’s business), if the leases, subleases, licenses and sublicenses do not prohibit granting Collateral Agent or any Lender a security interest therein;

(h) banker’s liens, rights of setoff and Liens in favor of financial institutions incurred in the ordinary course of business arising in connection with Borrower’s deposit accounts or securities accounts held at such institutions solely to secure payment of fees and similar costs and expenses and provided such accounts are maintained in compliance with Section 6.6(b) hereof;

(i) Liens arising from judgments, decrees or attachments in circumstances not constituting an Event of Default under Section 8.4 or 8.7;

(j) deposits to secure the performance of bids, trade contracts (other than for borrowed money), leases, statutory obligations, surety and appeal bonds, performance bonds and other obligations of a like nature; in each case, incurred in the ordinary course of business and not representing obligations for borrowed money, in an amount not exceeding Two Hundred Fifty Thousand Dollars ($250,000.00) in the aggregate outstanding at any time;

(k) Liens on cash securing obligations permitted under clause (g) of Permitted Indebtedness; and

(l) Liens consisting of Permitted Licenses.

“Person” is any individual, sole proprietorship, partnership, limited liability company, joint venture, company, trust, unincorporated organization, association, corporation, institution, public benefit corporation, firm, joint stock company, estate, entity or government agency.

“Post Closing Letter” is that certain Post Closing Letter dated as of the Effective Date by and between Collateral Agent and Borrower.

“Prepayment Fee” is, with respect to any Term Loan subject to prepayment prior to the Maturity Date, whether by mandatory or voluntary prepayment, acceleration or otherwise, an additional fee payable to the Lenders in amount equal to:

(i) for a prepayment made on or after the Effective Date through and including the first anniversary of the Effective Date, three percent (3.00%) of the principal amount of the Term Loans prepaid;

(ii) for a prepayment made after the first anniversary of the Effective Date through and including the second anniversary of the Effective Date, two percent (2.00%) of the principal amount of the Term Loans prepaid;

(iii) for a prepayment made after the second anniversary of the Effective Date through and including the third anniversary of the Effective Date, one percent (1.00%) of the principal amount of the Term Loans prepaid; and

(iv) for a prepayment made after the third anniversary of the Effective Date and prior to the Maturity Date, no Prepayment Fee shall be applicable.
“Pro Rata Share” is, as of any date of determination, with respect to each Lender, a percentage (expressed as a decimal, rounded to the ninth decimal place) determined by dividing the outstanding principal amount of Term Loans held by such Lender by the aggregate outstanding principal amount of all Term Loans.

“Registered Organization” is any “registered organization” as defined in the Code with such additions to such term as may hereafter be made.

“Required Lenders” means (i) for so long as all of the Persons that are Lenders on the Effective Date (each an “Original Lender”) have not assigned or transferred any of their interests in their Term Loan, Lenders holding one hundred percent (100%) of the aggregate outstanding principal balance of the Term Loan, or (ii) at any time from and after any Original Lender has assigned or transferred any interest in its Term Loan, Lenders holding at least sixty six percent (66%) of the aggregate outstanding principal balance of the Term Loan and, in respect of this clause (ii), (A) each Original Lender that has not assigned or transferred any portion of its Term Loan, (B) each assignee or transferee of an Original Lender’s interest in the Term Loan, but only to the extent that such assignee or transferee is an Affiliate or Approved Fund of such Original Lender, and (C) any Person providing financing to any Person described in clauses (A) and (B) above; provided, however, that this clause (C) shall only apply upon the occurrence of a default, event of default or similar occurrence with respect to such financing.

“Requirement of Law” is as to any Person, the organizational or governing documents of such Person, and any law (statutory or common), treaty, rule or regulation or determination of an arbitrator or a court or other Governmental Authority, in each case applicable to or binding upon such Person or any of its property or to which such Person or any of its property is subject.

“Responsible Officer” is any of the President, Chief Executive Officer, or Chief Financial Officer of Borrower acting alone.

“Second Draw Period” is the period commencing on the date of the occurrence of the Equity Event and ending on the earliest of (i) ninety (90) days after the occurrence of the Equity Event; (ii) September 30, 2020; and (iii) the occurrence of an Event of Default; provided, however, that the Second Draw Period shall not commence if on the date of the occurrence of the Equity Event an Event of Default has occurred and is continuing.

“Second Draw Promissory Note” is defined in Section 2.4.

“Secured Promissory Note Record” is a record maintained by each Lender with respect to the outstanding Obligations owed by Borrower to Lender and credits made thereto.

“Securities Account” is any “securities account” as defined in the Code with such additions to such term as may hereafter be made.

“Shares” is one hundred percent (100%) of the issued and outstanding capital stock, membership units or other securities owned or held of record by Borrower or Borrower’s Subsidiary, in any Subsidiary; provided that, in the event Borrower, demonstrates to Collateral Agent’s reasonable satisfaction, that a pledge of more than sixty five percent (65%) of the Shares of such Subsidiary which is a Foreign Subsidiary, creates a present and existing adverse tax consequence to Borrower under the U.S. Internal Revenue Code, “Shares” shall mean sixty-five percent (65%) of the issued and outstanding capital stock, membership units or other securities owned or held of record by Borrower or its Subsidiary in such Foreign Subsidiary.

“Solvent” is, with respect to any Person: the fair salable value of such Person’s consolidated assets (including goodwill minus disposition costs) exceeds the fair value of such Person’s liabilities; such Person is not left with unreasonably small capital after the transactions in this Agreement; and such Person is able to pay its debts (including trade debts) as they mature.

“Subordinated Debt” is indebtedness incurred by Borrower or any of its Subsidiaries subordinated to all Indebtedness of Borrower and/or its Subsidiaries to the Lenders (pursuant to a subordination, intercreditor, or other similar agreement in form and substance satisfactory to Collateral Agent and the Lenders entered into between Collateral Agent, Borrower, and/or any of its Subsidiaries, and the other creditor), on terms acceptable to Collateral Agent and the Lenders.
“Subsidiary” is, with respect to any Person, any Person of which more than fifty percent (50%) of the voting stock or other equity interests (in the case of Persons other than corporations) is owned or controlled, directly or indirectly, by such Person or through one or more intermediaries.

“Term A Loan” is defined in Section 2.2(a)(i) hereof.

“Term B Loan” is defined in Section 2.2(a)(ii) hereof.

“Term Loan” is defined in Section 2.2(a)(ii) hereof.

“Term Loan Commitment” is, for any Lender, the obligation of such Lender to make a Term Loan, up to the principal amount shown on Schedule 1.1. “Term Loan Commitments” means the aggregate amount of such commitments of all Lenders.

“Trademarks” means any trademark and servicemark rights, whether registered or not, applications to register and registrations of the same and like protections, and the entire goodwill of the business of Borrower connected with and symbolized by such trademarks.

“Transfer” is defined in Section 7.1.

“Warrants” are those certain Warrants to Purchase Stock dated as of the Effective Date, or any date thereafter, issued by Borrower in favor of each Lender or such Lender’s Affiliates.

[Balance of Page Intentionally Left Blank]
IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed as of the Effective Date.

BORROWER:

PROMETHEUS BIOSCIENCES, INC.

By /s/ Mark McKenna
Name: Mark McKenna
Title: President and Chief Executive Officer

PROMETHEUS LABORATORIES INC.

By /s/ Mark McKenna
Name: Mark McKenna
Title: President and Chief Executive Officer

COLLATERAL AGENT AND LENDER:

OXFORD FINANCE LLC

By /s/ Colette H. Featherly
Name: Colette H. Featherly
Title: Senior Vice President

[Signature Page to Loan and Security Agreement]
## Lenders and Commitments

### Term A Loans

<table>
<thead>
<tr>
<th>Lender</th>
<th>Term Loan Commitment</th>
<th>Commitment Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>OXFORD FINANCE LLC</td>
<td>$7,500,000.00</td>
<td>100.00%</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>$7,500,000.00</strong></td>
<td><strong>100.00%</strong></td>
</tr>
</tbody>
</table>

### Term B Loans

<table>
<thead>
<tr>
<th>Lender</th>
<th>Term Loan Commitment</th>
<th>Commitment Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>OXFORD FINANCE LLC</td>
<td>$17,500,000.00</td>
<td>100.00%</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>$17,500,000.00</strong></td>
<td><strong>100.00%</strong></td>
</tr>
</tbody>
</table>

### Aggregate (all Term Loans)

<table>
<thead>
<tr>
<th>Lender</th>
<th>Term Loan Commitment</th>
<th>Commitment Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>OXFORD FINANCE LLC</td>
<td>$25,000,000.00</td>
<td>100.00%</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>$25,000,000.00</strong></td>
<td><strong>100.00%</strong></td>
</tr>
</tbody>
</table>
EXHIBIT A

Description of Collateral

The Collateral consists of all of Borrower’s right, title and interest in and to the following personal property:

All goods, Accounts (including health-care receivables), Equipment, Inventory, contract rights or rights to payment of money, leases, license agreements, franchise agreements, General Intangibles (except as noted below), commercial tort claims, documents, instruments (including any promissory notes), chattel paper (whether tangible or electronic), cash, deposit accounts and other Collateral Accounts, all certificates of deposit, fixtures, letters of credit rights (whether or not the letter of credit is evidenced by a writing), securities, and all other investment property, supporting obligations, and financial assets, whether now owned or hereafter acquired, wherever located; and

All Borrower’s Books relating to the foregoing, and any and all claims, rights and interests in any of the above and all substitutions for, additions, attachments, accessories, accessions and improvements to and replacements, products, proceeds and insurance proceeds of any or all of the foregoing.

Notwithstanding the foregoing, the Collateral does not include (i) any Intellectual Property; provided, however, the Collateral shall include all Accounts and all proceeds of Intellectual Property. If a judicial authority (including a U.S. Bankruptcy Court) would hold that a security interest in the underlying Intellectual Property is necessary to have a security interest in such Accounts and such property that are proceeds of Intellectual Property, then the Collateral shall automatically, and effective as of the Effective Date, include the Intellectual Property to the extent necessary to permit perfection of Collateral Agent’s security interest in such Accounts and such other property of Borrower that are proceeds of the Intellectual Property; (ii) more than sixty-five percent (65%) of the total combined voting power of all classes of stock entitled to vote the shares of capital stock (the “Shares”) of any Foreign Subsidiary, if Borrower demonstrates to Collateral Agent’s reasonable satisfaction that a pledge of more than sixty-five percent (65%) of the Shares of such Subsidiary creates a present and existing adverse tax consequence to Borrower under the U.S. Internal Revenue Code; and (iii) any license or contract, in each case if the granting of a Lien in such license or contract is prohibited by or would constitute a default under the agreement governing such license or contract (but (A) only to the extent such prohibition is enforceable under applicable law and (B) other than to the extent that any such term would be rendered ineffective pursuant to Sections 9-406, 9-408 or 9-409 (or any other Section) of Division 9 of the Code); provided that upon the termination, lapsing or expiration of any such prohibition, such license or contract, as applicable, shall automatically be subject to the security interest granted in favor of Collateral Agent hereunder and become part of the “Collateral.”

Pursuant to the terms of a certain negative pledge arrangement with Collateral Agent and the Lenders, Borrower has agreed not to encumber any of its Intellectual Property.
EXHIBIT B

Form of Disbursement Letter

[see attached]
The undersigned, being the duly elected and acting President and Chief Executive Officer of PROMETHEUS BIOSCIENCES, INC., a Delaware corporation with offices located at 9410 Carroll Park Drive, San Diego, CA 92121, on behalf of itself and each borrower under the Loan Agreement (collectively, “Borrower”), does hereby certify to OXFORD FINANCE LLC (“Oxford” and “Lender”), as collateral agent (the “Collateral Agent”) in connection with that certain Loan and Security Agreement dated as of January 24, 2020, by and among Borrower, Collateral Agent and the Lenders from time to time party thereto (the “Loan Agreement”; with other capitalized terms used below having the meanings ascribed thereto in the Loan Agreement) that:

1. The representations and warranties made by Borrower in Section 5 of the Loan Agreement and in the other Loan Documents are true and correct in all material respects as of the date hereof; provided that those representations and warranties expressly referring to a specific date shall be true and correct in all material respects as of such date.

2. No event or condition has occurred that would constitute an Event of Default under the Loan Agreement or any other Loan Document.

3. Borrower is in compliance with the covenants and requirements contained in Sections 4, 6 and 7 of the Loan Agreement.

4. All conditions referred to in Section 3 of the Loan Agreement to the making of the Loan to be made on or about the date hereof have been satisfied or waived by Collateral Agent.

5. No Material Adverse Change has occurred.

6. The undersigned is a Responsible Officer.

[Balance of Page Intentionally Left Blank]
7. The proceeds of the Term A Loan shall be disbursed as follows:

<table>
<thead>
<tr>
<th>Loan Amount</th>
<th>$ 7,500,000.00</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plus:</td>
<td></td>
</tr>
<tr>
<td>—Deposit Received</td>
<td>$ 30,000.00</td>
</tr>
<tr>
<td>Less:</td>
<td></td>
</tr>
<tr>
<td>—Facility Fee</td>
<td>($ 37,500.00)</td>
</tr>
<tr>
<td>—Interim Interest</td>
<td>($ 13,316.67)</td>
</tr>
<tr>
<td>—Lender’s Legal Fees</td>
<td>($ 86,608.50)*</td>
</tr>
</tbody>
</table>

Net Term A Loan Proceeds due from Oxford: $ 7,392,574.83

8. The Term A Loan shall amortize in accordance with the Amortization Table attached hereto.

9. The aggregate net proceeds of the Term Loans shall be transferred to the Designated Deposit Account as follows:

Account Name: PROMETHEUS BIOSCIENCES, INC.

[Balance of Page Intentionally Left Blank]

* Legal fees and costs are through the Effective Date. Post-closing legal fees and costs, payable after the Effective Date, to be invoiced and paid post-closing.
EXHIBIT C

Compliance Certificate

TO: OXFORD FINANCE LLC, as Collateral Agent and Lender

FROM: PROMETHEUS BIOSCIENCES, INC., for itself and on behalf of all Borrowers under the Loan Agreement

The undersigned authorized officer ("Officer") of PROMETHEUS BIOSCIENCES, INC. ("Borrower"), hereby certifies in [his/her] capacity as an Officer, and not under any individual capacity, that in accordance with the terms and conditions of the Loan and Security Agreement by and among Borrower, Collateral Agent, and the Lenders from time to time party thereto (the "Loan Agreement," capitalized terms used but not otherwise defined herein shall have the meanings given them in the Loan Agreement),

(a) Borrower is in complete compliance for the period ending __________ with all required covenants except as noted below;

(b) There are no Events of Default, except as noted below;

(c) Except as noted below, all representations and warranties of Borrower stated in the Loan Documents are true and correct in all material respects on this date and for the period described in (a), above; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true, accurate and complete in all material respects as of such date.

(d) Borrower, and each of Borrower’s Subsidiaries, has timely filed all required tax returns and reports, Borrower, and each of Borrower’s Subsidiaries, has timely paid all foreign, federal, state, and local taxes, assessments, deposits and contributions owed by Borrower, or Subsidiary, except as otherwise permitted pursuant to the terms of Section 5.8 of the Loan Agreement;

(e) No Liens have been levied or claims made against Borrower or any of its Subsidiaries relating to unpaid employee payroll or benefits of which Borrower has not previously provided written notification to Collateral Agent and the Lenders.

Attached are the required documents, if any, supporting our certification(s). The Officer, on behalf of Borrower, further certifies that the attached financial statements are prepared in accordance with Generally Accepted Accounting Principles (GAAP) and are consistently applied from one period to the next except as explained in an accompanying letter or footnotes and except, in the case of unaudited financial statements, for the absence of footnotes and subject to year-end audit adjustments as to the interim financial statements.

Please indicate compliance status since the last Compliance Certificate by circling Yes, No, or N/A under “Complies” column.

<table>
<thead>
<tr>
<th>Reporting Covenant</th>
<th>Requirement</th>
<th>Actual</th>
<th>Complies</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Financial statements</td>
<td>Monthly within 30 days</td>
<td>Yes</td>
<td>N/A</td>
</tr>
<tr>
<td>2) Annual (CPA Audited) statements</td>
<td>Within 180 days after FYE</td>
<td>Yes</td>
<td>N/A</td>
</tr>
<tr>
<td>3) Annual Financial Projections/Budget (prepared on a monthly basis)</td>
<td>Annually (within 60 days of FYE), and when revised</td>
<td>Yes</td>
<td>N/A</td>
</tr>
</tbody>
</table>
4) A/R & A/P agings
   If applicable
   Yes No N/A

5) 8-K, 10-K and 10-Q Filings
   If applicable, within 5 days of filing
   Yes No N/A

6) Compliance Certificate
   Monthly within 30 days
   Yes No N/A

7) IP Report
   When required
   Yes No N/A

8) Total amount of Borrower’s cash and cash equivalents at the last day of the measurement period
   $______ Yes No N/A

9) Total amount of Borrower’s Subsidiaries’ cash and cash equivalents at the last day of the measurement period
   $______ Yes No N/A

Deposit and Securities Accounts
(Please list all accounts; attach separate sheet if additional space needed)

<table>
<thead>
<tr>
<th>Institution Name</th>
<th>Account Number</th>
<th>New Account?</th>
<th>Account Control Agreement in place?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1)</td>
<td></td>
<td>Yes No Yes No</td>
<td></td>
</tr>
<tr>
<td>2)</td>
<td></td>
<td>Yes No Yes No</td>
<td></td>
</tr>
<tr>
<td>3)</td>
<td></td>
<td>Yes No Yes No</td>
<td></td>
</tr>
<tr>
<td>4)</td>
<td></td>
<td>Yes No Yes No</td>
<td></td>
</tr>
</tbody>
</table>

Other Matters

1) Have there been any changes in management since the last Compliance Certificate? Yes No

2) Have there been any transfers/sales/disposals/retirement of Collateral or IP prohibited by the Loan Agreement? Yes No

3) Have there been any new or pending claims or causes of action against Borrower that involve more than Five Hundred Thousand Dollars ($500,000.00)? Yes No

4) Have there been any amendments of or other changes to the capitalization table of Borrower and to the Operating Documents of Borrower or any of its Subsidiaries? If yes, provide copies of any such amendments or changes with this Compliance Certificate. Yes No
Exceptions

Please explain any exceptions with respect to the certification above: (If no exceptions exist, state "No exceptions." Attach separate sheet if additional space needed.)

PROMETHEUS BIOSCIENCES, INC.,
For itself and on behalf of all Borrowers

By
Name: ________________________________________
Title: ________________________________________
Date: ________________________________________

LENDER USE ONLY

Received by: _______________ Date: ____________

Verified by: _______________ Date: ____________

Compliance Status: Yes No
EXHIBIT D

Form of Secured Promissory Note

[see attached]
SECURED PROMISSORY NOTE
( Term A Loan )

FOR VALUE RECEIVED, the undersigned, PROMETHEUS BIOSCIENCES, INC., a Delaware corporation, and PROMETHEUS LABORATORIES INC., a California corporation, each with offices located at 9410 Carroll Park Drive, San Diego, CA 92121 (individually and collectively, jointly and severally, “Borrower”) HEREBY PROMISES TO PAY to the order of OXFORD FINANCE LLC (“Lender”) the principal amount of SEVEN MILLION FIVE HUNDRED THOUSAND DOLLARS ($7,500,000.00) or such lesser amount as shall equal the outstanding principal balance of the Term A Loan made to Borrower by Lender, plus interest on the aggregate unpaid principal amount of such Term A Loan, at the rates and in accordance with the terms of the Loan and Security Agreement dated January 24, 2020 by and among Borrower, Lender, Oxford Finance LLC, as Collateral Agent, and the other Lenders from time to time party thereto (as amended, restated, supplemented or otherwise modified from time to time, the “Loan Agreement”). If not sooner paid, the entire principal amount and all accrued and unpaid interest hereunder shall be due and payable on the Maturity Date as set forth in the Loan Agreement. Any capitalized term not otherwise defined herein shall have the meaning attributed to such term in the Loan Agreement.

Principal, interest and all other amounts due with respect to the Term A Loan, are payable in lawful money of the United States of America to Lender as set forth in the Loan Agreement and this Secured Promissory Note (this “Note”). The principal amount of this Note and the interest rate applicable thereto, and all payments made with respect thereto, shall be recorded by Lender and, prior to any transfer hereof, endorsed on the grid attached hereto which is part of this Note.

The Loan Agreement, among other things, (a) provides for the making of a secured Term A Loan by Lender to Borrower, and (b) contains provisions for acceleration of the maturity hereof upon the happening of certain stated events.

This Note may not be prepaid except as set forth in Section 2.2 (c) and Section 2.2(d) of the Loan Agreement.

This Note and the obligation of Borrower to repay the unpaid principal amount of the Term A Loan, interest on the Term A Loan and all other amounts due Lender under the Loan Agreement are secured under the Loan Agreement.

Presentment for payment, demand, notice of protest and all other demands and notices of any kind in connection with the execution, delivery, performance and enforcement of this Note are hereby waived.

Borrower shall pay all reasonable fees and expenses, including, without limitation, reasonable attorneys’ fees and costs, incurred by Lender in the enforcement or attempt to enforce any of Borrower’s obligations hereunder not performed when due.

This Note shall be governed by, and construed and interpreted in accordance with, the internal laws of the State of California.

The ownership of an interest in this Note shall be registered on a record of ownership maintained by Lender or its agent. Notwithstanding anything else in this Note to the contrary, the right to the principal of, and stated interest on, this Note may be transferred only if the transfer is registered on such record of ownership and the transferee is identified as the owner of an interest in the obligation. Borrower shall be entitled to treat the registered holder of this Note (as recorded on such record of ownership) as the owner in fact thereof for all purposes and shall not be bound to recognize any equitable or other claim to or interest in this Note on the part of any other person or entity.
IN WITNESS WHEREOF, Borrower has caused this Note to be duly executed by one of its officers thereunto duly authorized on the date hereof.

BORROWER:

PROMETHEUS BIOSCIENCES, INC.
By /s/ Mark McKenna
Name: Mark McKenna
Title: President and Chief Executive Officer

PROMETHEUS LABORATORIES INC.
By /s/ Mark McKenna
Name: Mark McKenna
Title: President and Chief Executive Officer

[Signature Page to Secured Promissory Note]
[Term A Loan Note]
<table>
<thead>
<tr>
<th>Date</th>
<th>Principal Amount</th>
<th>Interest Rate</th>
<th>Scheduled Payment Amount</th>
<th>Notation By</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>
I hereby certify, solely in my capacity as an officer of Borrower, and not in any individual capacity, as follows, as of the date set forth above:

1. I am the Secretary, Assistant Secretary or other officer of Borrower. My title is as set forth below.

2. Borrower’s exact legal name is set forth above. Borrower is a corporation existing under the laws of the State of Delaware.

3. Attached hereto as Exhibit A and Exhibit B, respectively, are true, correct and complete copies of (i) Borrower’s Certificate of Incorporation (including amendments), as filed with the Secretary of State of the state in which Borrower is incorporated as set forth in paragraph 2 above; and (ii) Borrower’s Bylaws. Neither such Certificate of Incorporation nor such Bylaws have been amended, annulled, rescinded, revoked or supplemented, and such Articles/Certificate of Incorporation and such Bylaws remain in full force and effect as of the date hereof.

4. The following resolutions were duly and validly adopted by Borrower’s Board of Directors at a duly held meeting of such directors (or pursuant to a unanimous written consent or other authorized corporate action). Such resolutions are in full force and effect as of the date hereof and have not been in any way modified, repealed, rescinded, amended or revoked, and the Lenders may rely on them until each Lender receives written notice of revocation from Borrower.

[Balance of Page Intentionally Left Blank]
**RESOLVED**, that any one of the following officers or employees of Borrower, whose names, titles and signatures are below, may act on behalf of Borrower:

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
<th>Signature</th>
<th>Authorized to Add or Remove Signatories</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mark McKenna</td>
<td>President and Chief Executive Officer</td>
<td>/s/ Mark McKenna</td>
<td>x</td>
</tr>
<tr>
<td>Christopher Slavinsky</td>
<td>General Counsel and Head of Business Development</td>
<td>/s/ Christopher Slavinsky</td>
<td>x</td>
</tr>
<tr>
<td>Viktoria Brough</td>
<td>Vice President, Finance</td>
<td>/s/ Viktoria Brough</td>
<td>x</td>
</tr>
</tbody>
</table>

**RESOLVED FURTHER**, that any one of the persons designated above with a checked box beside his or her name may, from time to time, add or remove any individuals to and from the above list of persons authorized to act on behalf of Borrower.

**RESOLVED FURTHER**, that such individuals may, on behalf of Borrower:

- **Borrow Money.** Borrow money from the Lenders.
- **Execute Loan Documents.** Execute any loan documents any Lender requires.
- **Grant Security.** Grant Collateral Agent a security interest in substantially all of Borrower’s assets.
- **Negotiate Items.** Negotiate or discount all drafts, trade acceptances, promissory notes, or other indebtedness in which Borrower has an interest and receive cash or otherwise use the proceeds.
- **Issue Warrants.** Issue warrants for Borrower’s capital stock.
- **Further Acts.** Designate other individuals to request advances, pay fees and costs and execute other documents or agreements (including documents or agreement that waive Borrower’s right to a jury trial) they believe to be necessary to effectuate such resolutions.

**RESOLVED FURTHER**, that all acts authorized by the above resolutions and any prior acts relating thereto are ratified.

[Balance of Page Intentionally Left Blank]
5. The persons listed above are Borrower’s officers or employees with their titles and signatures shown next to their names.

PROMETHEUS BIOSCIENCES, INC.

By:  

/s/ Mark McKenna

Name: Mark McKenna

Title: President and Chief Executive Officer

*** If the Secretary, Assistant Secretary or other certifying officer executing above is designated by the resolutions set forth in paragraph 4 as one of the authorized signing officers, this Certificate must also be signed by a second authorized officer or director of Borrower:

I, the General Counsel and Head of Business Development of Borrower, hereby certify as to paragraphs 1 through 5 above, as
[print title]
of the date set forth above.

PROMETHEUS BIOSCIENCES, INC.

By:  

/s/ Christopher Slavinsky

Name: Christopher Slavinsky

Title: General Counsel and Head of Business Development

[Signature Page to Corporate Borrowing Certificate]

[Prometheus Biosciences, Inc.]
I hereby certify, solely in my capacity as an officer of Borrower, and not in any individual capacity, as follows, as of the date set forth above:

1. I am the Secretary, Assistant Secretary or other officer of Borrower. My title is as set forth below.

2. Borrower’s exact legal name is set forth above. Borrower is a corporation existing under the laws of the State of Delaware.

3. Attached hereto as Exhibit A and Exhibit B, respectively, are true, correct and complete copies of (i) Borrower’s Articles of Incorporation (including amendments), as filed with the Secretary of State of the state in which Borrower is incorporated as set forth in paragraph 2 above; and (ii) Borrower’s Bylaws. Neither such Articles of Incorporation nor such Bylaws have been amended, annulled, rescinded, revoked or supplemented, and such Articles/Certificate of Incorporation and such Bylaws remain in full force and effect as of the date hereof.

4. The following resolutions were duly and validly adopted by Borrower’s Board of Directors at a duly held meeting of such directors (or pursuant to a unanimous written consent or other authorized corporate action). Such resolutions are in full force and effect as of the date hereof and have not been in any way modified, repealed, rescinded, amended or revoked, and the Lenders may rely on them until each Lender receives written notice of revocation from Borrower.
**RESOLVED**, that **any one** of the following officers or employees of Borrower, whose names, titles and signatures are below, may act on behalf of Borrower:

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<td>General Counsel and Head of Business Development</td>
<td>/s/ Christopher Slavinsky</td>
<td>x</td>
</tr>
<tr>
<td>Viktoria Brough</td>
<td>Vice President, Finance</td>
<td>/s/ Viktoria Brough</td>
<td>x</td>
</tr>
</tbody>
</table>

**RESOLVED FURTHER**, that **any one** of the persons designated above with a checked box beside his or her name may, from time to time, add or remove any individuals to and from the above list of persons authorized to act on behalf of Borrower.

**RESOLVED FURTHER**, that such individuals may, on behalf of Borrower:

**Borrow Money.** Borrow money from the Lenders.

**Execute Loan Documents.** Execute any loan documents any Lender requires.

**Grant Security.** Grant Collateral Agent a security interest in substantially all of Borrower’s assets.

**Negotiate Items.** Negotiate or discount all drafts, trade acceptances, promissory notes, or other indebtedness in which Borrower has an interest and receive cash or otherwise use the proceeds.

**Further Acts.** Designate other individuals to request advances, pay fees and costs and execute other documents or agreements (including documents or agreement that waive Borrower’s right to a jury trial) they believe to be necessary to effectuate such resolutions.

**RESOLVED FURTHER,** that all acts authorized by the above resolutions and any prior acts relating thereto are ratified.

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*Balance of Page Intentionally Left Blank*
5. The persons listed above are Borrower’s officers or employees with their titles and signatures shown next to their names.

PROMETHEUS LABORATORIES INC.

By: /s/ Mark McKenna

Name: Mark McKenna

Title: President and Chief Executive Officer

*** If the Secretary, Assistant Secretary or other certifying officer executing above is designated by the resolutions set forth in paragraph 4 as one of the authorized signing officers, this Certificate must also be signed by a second authorized officer or director of Borrower:

I, the General Counsel and Head of Business Development of Borrower, hereby certify as to paragraphs 1 through 5 above, as [print title] of the date set forth above.

PROMETHEUS LABORATORIES INC.

By: /s/ Christopher Slavinsky

Name: Christopher Slavinsky

Title: General Counsel and Head of Business Development
EXHIBIT A TO UCC FINANCING STATEMENT

Description of Collateral

The Collateral consists of all of Debtor’s right, title and interest in and to the following personal property:

All goods, Accounts (including health-care receivables), Equipment, Inventory, contract rights or rights to payment of money, leases, license agreements, franchise agreements, General Intangibles (except as noted below), commercial tort claims, documents, instruments (including any promissory notes), chattel paper (whether tangible or electronic), cash, deposit accounts and other Collateral Accounts, all certificates of deposit, fixtures, letters of credit rights (whether or not the letter of credit is evidenced by a writing), securities, and all other investment property, supporting obligations, and financial assets, whether now owned or hereafter acquired, wherever located; and

All Borrower’s Books relating to the foregoing, and any and all claims, rights and interests in any of the above and all substitutions for, additions, attachments, accessories, accessions and improvements to and replacements, products, proceeds and insurance proceeds of any or all of the foregoing.

Notwithstanding the foregoing, the Collateral does not include (i) any Intellectual Property; provided, however, the Collateral shall include all Accounts and all proceeds of Intellectual Property. If a judicial authority (including a U.S. Bankruptcy Court) would hold that a security interest in the underlying Intellectual Property is necessary to have a security interest in such Accounts and such property that are proceeds of Intellectual Property, then the Collateral shall automatically, and effective as of the Effective Date, include the Intellectual Property to the extent necessary to permit perfection of Collateral Agent’s security interest in such Accounts and such other property of Borrower that are proceeds of the Intellectual Property; (ii) more than sixty-five percent (65%) of the total combined voting power of all classes of stock entitled to vote the shares of capital stock (the “Shares”) of any Foreign Subsidiary, if Borrower demonstrates to Collateral Agent’s reasonable satisfaction that a pledge of more than sixty-five percent (65%) of the Shares of such Subsidiary creates a present and existing adverse tax consequence to Borrower under the U.S. Internal Revenue Code; and (iii) any license or contract, in each case if the granting of a Lien in such license or contract is prohibited by or would constitute a default under the agreement governing such license or contract (but (A) only to the extent such prohibition is enforceable under applicable law and (B) other than to the extent that any such term would be rendered ineffective pursuant to Sections 9-406, 9-408 or 9-409 (or any other Section) of Division 9 of the Code); provided that upon the termination, lapsing or expiration of any such prohibition, such license or contract, as applicable, shall automatically be subject to the security interest granted in favor of Collateral Agent hereunder and become part of the “Collateral.”

Pursuant to the terms of a certain negative pledge arrangement with Collateral Agent and the Lenders, Borrower has agreed not to encumber any of its Intellectual Property.

Capitalized terms used but not defined herein have the meanings ascribed in the Uniform Commercial Code in effect in the State of California as in effect from time to time (the “Code”) or, if not defined in the Code, then in the Loan and Security Agreement by and between Debtor, Secured Party and the other Lenders party thereto (as modified, amended and/or restated from time to time).
LEASE
(Single Tenant; Net)

BETWEEN

THE IRVINE COMPANY

AND

PROMETHEUS LABORATORIES INC.
ARTICLE XIII. SUBORDINATION; ESTOPPEL CERTIFICATE; FINANCIALS
SECTION 13.1. SUBORDINATION
SECTION 13.2. ESTOPPEL CERTIFICATE
SECTION 13.3. FINANCIALS

ARTICLE XIV. EVENTS OF DEFAULT AND REMEDIES
SECTION 14.1. TENANT’S DEFAULTS
SECTION 14.2. LANDLORD’S REMEDIES
SECTION 14.3. LATE PAYMENTS
SECTION 14.4. RIGHT OF LANDLORD TO PERFORM
SECTION 14.5. DEFAULT BY LANDLORD
SECTION 14.6. EXPENSES AND LEGAL FEES
SECTION 14.7. WAIVER OF JURY TRIAL
SECTION 14.8. SATISFACTION OF JUDGMENT

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SECTION 15.1. HOLDING OVER
SECTION 15.2. MERGER ON TERMINATION
SECTION 15.3. SURRENDER OF PREMISES; REMOVAL OF PROPERTY

ARTICLE XVI. PAYMENTS AND NOTICES

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ARTICLE XVIII. BROKER’S COMMISSION

ARTICLE XIX. TRANSFER OF LANDLORD’S INTEREST

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SECTION 21.6. EXECUTED COPY
SECTION 21.7. ATTACHMENTS

ARTICLE XXII. MISCELLANEOUS
SECTION 22.1. NONDISCLOSURE OF LEASE TERMS
SECTION 22.2. [INTENTIONALLY DELETED]
SECTION 22.3. CHANGES REQUESTED BY LENDER
SECTION 22.4. MORTGAGEE PROTECTION
SECTION 22.5. [INTENTIONALLY DELETED]
SECTION 22.6. SECURITY MEASURES

EXHIBITS
Exhibit A  Description of Premises
Schedule A  Landlord’s Work
Exhibit B  Environmental Questionnaire
Exhibit C  [Intentionally Deleted]
Exhibit D  Insurance Requirements
Exhibit E  Rules and Regulations
Exhibit F  Location of Generators/Trash Enclosures
Exhibit G  Signage Criteria
Exhibit H  Requirements for Contractors
Exhibit I  Standard Improvements
Exhibit J  Howard’s Rug Proposal Dated June 1, 2005
Exhibit X  Work Letter
Exhibit X-1  Preliminary Plan
Exhibit X-2  Approved Subcontractors
Exhibit Y  Project Site Plan
LEASE
(Single Tenant; Net)

THIS LEASE is made as of the 22nd day of June, 2005, by and between THE IRVINE COMPANY, a Delaware corporation hereafter called “Landlord,” and PROMETHEUS LABORATORIES INC., a California corporation, hereinafter called “Tenant.”

ARTICLE I. BASIC LEASE PROVISIONS

Each reference in this Lease to the “Basic Lease Provisions” shall mean and refer to the following collective terms, the application of which shall be governed by the provisions in the remaining Articles of this Lease.

1. Premises: The Premises are more particularly described in Section 2.1.
   Address of Building: 9410 Carroll Park Drive, San Diego, CA

2. Project Description: Canyon Ridge Technology Park (as more particularly described on Exhibit Y attached hereto)

3. Use of Premises: General office, research and development and all permitted uses under the project zoning: IL-2-1.

4. Commencement Date: January 1, 2006 (subject to “Landlord Delays” as defined in Section 3.1 of this Lease)

5. Expiration Date: December 31, 2012

6. Basic Rent: Commencing on the Commencement Date, the Basic Rent shall be Ninety Four Thousand Eighty-Nine Dollars ($94,089.00) per month, based on $0.95 per rentable square foot.
   Basic Rent is subject to adjustment as follows:
   Commencing January 1, 2007, the Basic Rent shall be Ninety Seven Thousand Sixty Dollars ($97,060.00) per month, based on $0.98 per rentable square foot.
   Commencing January 1, 2008, the Basic Rent shall be One Hundred Thousand Thirty One Dollars ($100,031.00) per month, based on $1.01 per rentable square foot.
   Commencing January 1, 2009, the Basic Rent shall be One Hundred Three Thousand Three Dollars ($103,003.00) per month, based on $1.04 per rentable square foot.
   Commencing January 1, 2010, the Basic Rent shall be One Hundred Five Thousand Nine Hundred Seventy-Four Dollars ($105,974.00) per month, based on $1.07 per rentable square foot.
   Commencing January 1, 2011, the Basic Rent shall be One Hundred Eight Thousand Nine Hundred Forty-Five Dollars ($108,945.00) per month, based on $1.10 per rentable square foot.
   Commencing January 1, 2012, the Basic Rent shall be One Hundred Eleven Thousand Nine Hundred Sixteen Dollars ($111,916.00) per month, based on $1.13 per rentable square foot.

7. Guarantor(s): None

8. Floor Area: Approximately 99,041 rentable square feet

9. Security Deposit: $280,867.00 (subject to reduction as set forth in Section 4.3)

10. Broker(s): Cushman & Wakefield/CREA/Grubb & Ellis/BRE

11. Additional Insureds: None

12. Address for Payments and Notices:

   LANDLORD
   THE IRVINE COMPANY
dba Office Properties
8105 Irvine Center Drive, Suite 300
Irvine, CA 92618
Attn: Vice President, Operations, Technology Portfolio

   TENANT
   PROMETHEUS LABORATORIES INC.
5739 Pacific Center Blvd.
San Diego, CA 92121
Attn: Legal Department
with a copy of notices to:

THE IRVINE COMPANY
dba Office Properties
8105 Irvine Center Drive, Suite 300
Irvine, CA 92618
Attn: Senior Vice President, Operations
Office Properties

Following the Commencement Date:

PROMETHEUS LABORATORIES INC.
9410 Carroll Park Drive
San Diego, CA 92121
Attn: Legal Department

13. Tenant’s Liability Insurance Requirement (as defined in Exhibit D): $2,000,000.00

14. Vehicle Parking Spaces: Two Hundred Seventy-Eight (278)
ARTICLE II. PREMISES

SECTION 2.1. LEASED PREMISES. Landlord leases to Tenant and Tenant leases from Landlord the premises shown in Exhibit A (the “Premises”), containing approximately the rentable square footage set forth as the “Floor Area” in Item 8 of the Basic Lease Provisions. The Premises consist of all of the Floor Area within the building identified in Item 1 of the Basic Lease Provisions. The Premises together with such building, the underlying real property and all improvements outside of such building located on such real property (including, without limitation, the structure housing the boiler room, chiller room and cooling tower (the “Utility Building”)), are collectively called the “Building.” The Building is a portion of the project identified in Item 2 of the Basic Lease Provisions and shown in Exhibit Y (the “Project”). Landlord makes no representation that the Project will not be changed from the Project as shown on Exhibit Y; provided, however, that in the event of such change Tenant’s obligation with respect to Operating Expenses shall be reasonably adjusted to take into account such change. All references to “Floor Area” in this Lease shall mean the rentable square footage set forth in Item 8 of the Basic Lease Provisions. The rentable square footage set forth in Item 8 may include or have been adjusted by various factors, including, without limitation, a load factor for any vertical penetrations, stairwells or similar features or areas of the Building. Tenant agrees that the Floor Area set forth in Item 8 shall be binding on Landlord and Tenant for purposes of this Lease regardless of whether any future or differing measurements of the Premises or the Building are consistent or inconsistent with the Floor Area set forth in Item 8.

SECTION 2.2. ACCEPTANCE OF PREMISES. Except as expressly provided in this Lease, Tenant acknowledges that neither Landlord nor any representative of Landlord has made any representation or warranty with respect to the Premises, the Building or the Project. No representation or warranty is made concerning the suitability or fitness of the Premises, the Building or the Project for any purpose, including without limitation any representations or warranties regarding the compliance of Tenant’s use of the Premises with the applicable zoning or regarding any other land use matters, and Tenant shall be solely responsible as to such matters. Further, neither Landlord nor any representative of Landlord has made any representations or warranties regarding (i) what other tenants or uses may be permitted or intended in the Building or the Project, (ii) any exclusivity of use by Tenant with respect to its permitted use of the Premises as set forth in Item 3 of the Basic Lease Provisions, or (iii) any construction of portions of the Project not yet completed. Except as expressly provided in this Lease, Tenant’s lease of the Premises shall be on an “as is” basis. Landlord shall, at its sole cost and expense, construct, repair and/or replace the items set forth on Schedule A attached to this Lease (collectively, the “Landlord’s Work”). The Landlord’s Work shall be constructed in a good and workmanlike manner in compliance with all applicable building codes and permits, and in accordance with the scheduled completion dates for each component of the Landlord’s Work set forth on attached Schedule A. Landlord shall obtain any customary manufacturers/installers warranties for the Landlord’s Work. Except as expressly provided in this Lease, Tenant shall be conclusively deemed to have accepted the Premises and those portions of the Building and Project in which Tenant has any rights under this Lease as of the “Early Occupancy Date” (as defined in Section 3.2), which acceptance shall mean that it is conclusively established that the Premises and those portions of the Building and Project in which Tenant has any rights under this Lease were in satisfactory condition and in conformity with the provisions of this Lease, subject only to (1) those defective or incomplete portions of the Landlord’s Work which Tenant shall have itemized on a written punch list and delivered to Landlord within forty-five (45) days following Landlord’s written notice(s) that the Landlord’s Work has been substantially completed (or within forty five (45) days following the date of this Lease for items of Landlord’s Work designated as “complete” on the attached Schedule A), and (2) Landlord’s obligations expressly set forth in Section 2.4 below. Landlord shall correct any deficiencies with the Landlord’s Work promptly following delivery of the itemized punch list therefor as provided in the foregoing. Landlord shall also provide two (2) allowances to Tenant as follows: (a) Sixteen Thousand Seven Hundred Dollars ($16,700.00) (the “Access Control Allowance”) towards the cost to repair and/or replace the access control system in the Premises (the “Access Control Work”); and (b) Three Hundred thousand Dollars ($300,000.00) (the “Floor Surface Allowance”) towards the cost of head blasting, repairing and otherwise preparing the surface of the Building’s slab as more particularly provided in that certain proposal from Howard’s Rug dated June 1, 2005, a copy of which proposal is attached hereto as Exhibit J (the “Floor Surfacing Work”). Tenant shall obtain those warranties from the manufacturers/installers for the Access Control Work and for the Floor Surfacing Work satisfactory to Tenant in its sole discretion, and Landlord shall have no liability whatsoever for the Access Control Work and/or for the Floor Surfacing Work beyond payment of the applicable allowance therefor. Sums from each of the allowances shall be paid within thirty (30) days of Landlord’s receipt of an invoice(s) with respect to the covered work. Promptly from and after the full execution and delivery of this Lease, Landlord shall deliver possession of the Premises to Tenant (such date of delivery of possession (the “Delivery Date”) for Tenant’s construction of those tenant improvements (the “Tenant Improvements”) in the Premises as provided in, and subject to the terms and conditions of, the Work Letter attached as Exhibit X hereeto (the “Work Letter”).

SECTION 2.3. BUILDING NAME AND ADDRESS. Except for any names already in use by Tenant prior to such selection and notification by Landlord, Tenant shall not utilize any name selected by Landlord from time to time for the Building and/or the Project as any part of Tenant’s corporate or trade name. Upon not less than sixty (60) days written notice to Tenant, Landlord shall have the right to change the name, address, number or designation of the Building or Project without liability to Tenant. Notwithstanding the foregoing, Landlord shall reimburse Tenant for all reasonable out-of-pocket expenses incurred by Tenant, including without limitation, Tenant’s costs of obtaining new business cards, stationery and informing Tenant’s customers and vendors of Tenant’s new address, not to exceed Ten Thousand Dollars ($10,000.00) in the aggregate, resulting from any changed name, number or designation of the Building or Project initiated by Landlord.
SECTION 2.4. LANDLORD’S RESPONSIBILITIES. Landlord warrants to Tenant that (a) the roof, foundation, footings, slab, structural walls, exterior windows and skylights (including seals), plumbing, fire sprinkler/life safety system, lighting, heating, ventilation and air conditioning systems, electrical systems, and the passenger and freight elevators serving the Premises shall be in good operating condition and repair (except to the extent modified or otherwise impaired by Tenant’s construction of the Tenant Improvements) on the Early Occupancy Date, (b) the Premises, the Building, and Common Areas shall be free of all mold as of the Delivery Date, and (c) the Premises, Building and the Common Areas (except for the Tenant Improvements) shall comply with all laws, codes and regulations (collectively, “Laws”) pertaining thereto, and shall be free of latent defects in the construction thereof, as of the Early Occupancy Date. Provided that Tenant shall notify Landlord of a non-compliance with the foregoing warranty set forth in Subsection 2.4(a) above not later than one hundred twenty (120) days from and after the Early Occupancy Date, or of a non-compliance with the foregoing warranty set forth in Subsection 2.4(b) above not later than sixty (60) days from and after the Delivery Date, then Landlord shall, except as otherwise provided in this Lease, promptly after receipt of written notice from Tenant setting forth the nature and extent of each non-compliance, rectify same at Landlord’s sole cost and expense and not as a Project Cost. Except as otherwise provided in this Lease, promptly after receipt of written notice from Tenant setting forth the nature and extent of each non-compliance, Landlord shall rectify any non-compliance with the foregoing warranty contained in Subsection 2.4(c) above throughout the Term of this Lease at Landlord’s sole cost and expense and not as a Project Cost.

ARTICLE III. TERM

SECTION 3.1. GENERAL. The term of this Lease ("Term") shall commence on the date set forth in Item 4 of the Basic Lease Provisions (the “Commencement Date”), and shall expire on the date set forth in Item 5 of the Basic Lease Provisions (the “Expiration Date”). Notwithstanding the foregoing, the Commencement Date and the Expiration Date shall be extended, on a day-for-day basis, in the event that Tenant’s construction of the Tenant Improvements is actually delayed due to: (i) Landlord’s failure to respond within the time period(s) required for approvals as set forth in the attached Work Letter, or (ii) Landlord’s failure to complete any component of the Landlord’s Work as set forth on Schedule A attached to this Lease (collectively, a “Landlord’s Delay”); provided, however, that no Landlord’s Delay shall be effective unless and until Tenant shall notify Landlord that any such failure is causing, or is likely to cause, an actual delay in Tenant’s construction of the Tenant Improvements, and Landlord shall thereafter fail to cure such failure within two (2) business days thereafter. Any dispute involving a Landlord’s Delay shall be resolved by JAMs as provided in Article III of the attached Work Letter.

SECTION 3.2. EARLY OCCUPANCY. Landlord agrees that Tenant shall be permitted to occupy the Premises for the conduct of its business on that date (the “Early Occupancy Date”) of Tenant’s choosing following the Delivery Date and prior to the Commencement Date of this Lease. Tenant’s occupancy of the Premises prior to the Commencement Date shall be subject to all of the covenants and conditions on Tenant’s part contained in this Lease (including, without limitation, the covenants contained in Sections 5.3, 6.1, 7.1, 7.3, 7.4, 10.1 and 10.3 of the Lease), except for the obligation to pay Basic Rent.

SECTION 3.3. RIGHT TO EXTEND THIS LEASE. Provided that no Event of Default has occurred and is continuing under any provision of this Lease, either at the time of exercise of the extension right granted herein or at the time of the commencement of such extension, and provided further that Tenant is occupying at least fifty percent (50%) of the Premises, then Tenant may extend the Term of this Lease for one (1) period of sixty (60) months at the “Fair Market Rent” (as defined below). Tenant shall exercise its right to extend the Term by and only by delivering to Landlord, not later than ten (10) months or more than thirteen (13) months prior to the Expiration Date, Tenant’s written notice that it desires to so extend the Term of this Lease (the “Extension Notice”). The “Fair Market Rent” shall mean the economic terms (e.g., Basic Rent, tenant improvement allowance, brokerage commission and any other concessions typically granted by landlords of similar buildings/comparable space in the Sorrento Mesa and Sorrento Valley areas to the extent applicable to the proposed extension) secured at that time by landlords of similar buildings/comparable space in the Sorrento Mesa and Sorrento Valley areas for lease extensions. The Fair Market Rent for any extension of the Term shall be determined as provided in the following provisions.

Landlord shall, within thirty (30) days following the Extension Notice, notify Tenant in writing of its determination of the Fair Market Rent including the basis for such determination (“Landlord’s Determination”). Within twenty (20) business days following delivery of the Landlord’s Determination, Tenant shall notify Landlord in writing (“Tenant’s Notice”) that it shall (a) lease the Premises on the terms set forth in Landlord’s Determination, (b) arbitrate Landlord’s Determination as set forth in this Section 3.3 in which case Tenant shall include Tenant’s determination of the Fair Market Rent (“Tenant’s Determination”), or (c) irrevocably withdraw the Extension Notice. If Tenant fails to provide Tenant’s notice as provided herein, Tenant shall be deemed to have irrevocably withdrawn the Extension Notice and waived its extension rights under this Section 3.3. Tenant’s Notice shall serve as its irrevocable notice of its commitment to extend the Term on the terms and conditions herein provided. If applicable, within ten (10) days following delivery of the Tenant’s Determination, the parties shall attempt to agree on an appraiser to determine the Fair Market Rent. If the parties are unable to agree in that time, then each party shall designate an appraiser within ten (10) days thereafter. Should either party fail to so designate an appraiser within that time, then the appraiser designated by the other party shall determine the Fair Market Rent. Should each of the parties timely designate an appraiser, then the two appraisers so designated shall appoint a third appraiser who shall, acting alone, determine the Fair Market Rent for the Premises. Any appraiser designated hereunder shall have an MAI certification with not less than five (5) years experience in the valuation of commercial industrial buildings in the vicinity of the Project.
Within thirty (30) days following the selection of the appraiser and such appraiser’s receipt of the Landlord’s Determination and the Tenant’s Determination, the appraiser shall determine whether the Landlord’s Determination or the Tenant’s Determination more accurately reflects the Fair Market Rent. Accordingly, either the Landlord’s Determination or the Tenant’s Determination shall be selected by the appraiser as the Fair Market Rent for the extension period. In making such determination, the appraiser shall not attribute any factor for brokerage commissions in making its determination of the Fair Market Rent. At any time before the decision of the appraiser is rendered, either party may, by written notice to the other party, accept the rental terms submitted by the other party, in which event such terms shall be deemed adopted as the agreed Fair Market Rent. The fees of the appraiser(s) shall be borne entirely by the party whose determination of the Fair Market Rent was not accepted by the appraiser.

Within twenty (20) days after the determination of the Fair Market Rent, Landlord shall prepare an appropriate and commercially reasonable and mutually agreeable amendment to this Lease for the extension period, and Tenant shall execute and return same to Landlord within ten (10) days after Tenant’s receipt of same. Should the Fair Market Rent not be established by the commencement of the extension period, then Tenant shall continue paying rent at the rate in effect during the last month of the initial Term, and a lump sum adjustment shall be made promptly upon the determination of such new rental rate.

If Tenant fails to timely exercise the extension right granted herein within the time period expressly set forth for exercise by Tenant in the initial paragraph of this Section, Tenant’s right to extend the Term shall be extinguished and the Lease shall automatically terminate as of the expiration date of the Term, without any extension and without any liability to Landlord. Except for a “Permitted Transfer” (as defined in Section 9.4 of this Lease), any attempt to assign or transfer any right or interest created by this paragraph shall be void from its inception. Tenant shall have no other right to extend the Term beyond the single sixty (60) month extension period created by this paragraph. Unless agreed to in a writing signed by Landlord and Tenant, any extension of the Term, whether created by an amendment to this Lease or by a holdover of the Premises by Tenant, or otherwise, shall be deemed a part of, and not in addition to, any duly exercised extension period permitted by this paragraph.

ARTICLE IV. RENT AND OPERATING EXPENSES

SECTION 4.1. BASIC RENT. From and after the Commencement Date, Tenant shall pay to Landlord without deduction or offset, the rental amount for the Premises shown in Item 6 of the Basic Lease Provisions (the “Basic Rent”), including subsequent adjustments, if any. Any rental adjustment to Basic Rent shown in Item 6 shall be deemed to occur on the specified monthly anniversary of the Commencement Date, whether or not the Commencement Date occurs at the end of a calendar month. The rent shall be due and payable in advance commencing on the Commencement Date (as prorated for any partial month) and continuing thereafter on the first day of each successive calendar month of the Term. No demand, notice or invoice shall be required for the payment of Basic Rent. An installment of rent in the amount of one (1) full month’s Basic Rent at the initial rate specified in Item 6 of the Basic Lease Provisions and one (1) month’s estimated Tenant’s Share of Operating Expenses (as defined in Section 4.2) shall be delivered to Landlord concurrently with Tenant’s execution of this Lease and shall be applied against the Basic Rent and Operating Expenses first due hereunder.

SECTION 4.2. OPERATING EXPENSES.

(a) From and after the Early Occupancy Date, Tenant shall pay to Landlord, as additional rent, Tenant’s Share of all Operating Expenses, as defined in Section 4.2(f), incurred by Landlord in the operation of the Building and the Project. The term “Tenant’s Share” means (i) one hundred percent (100%) of Operating Expenses reasonably determined by Landlord to relate specifically to the Building rather than the entire Project or any other building in the Project, plus (ii) that portion of any Operating Expenses determined by multiplying the cost of such item by a fraction, the numerator of which is the Floor Area and the denominator of which is the total rentable square footage intended for lease or occupancy of (A) all of the buildings in the Project for expenses reasonably determined by Landlord to benefit or relate substantially to the entire Project rather than any specific building, or (B) all or some of the buildings within the Project as well as all or a portion of other property owned by Landlord and/or its affiliates for expenses reasonably determined by Landlord to benefit or relate to such buildings within the Project and such other real property. In the event that Landlord reasonably determines that any premises within any building within the Project or any portion of a building or project within a larger area incurs a non-proportional benefit from any expense, or is the non-proportional cause of any such expense, Landlord may, allocate a greater percentage of such Operating Expense to such premises, building or project, as applicable. Notwithstanding the foregoing provision for calculation of the “Tenant’s Share” (but subject to the provisions of Section 4.2(h) “capping” said management fee), the full amount of any management fee for the management of the Premises that is calculated as a percentage of the rent payable by Tenant shall be paid in full by Tenant as additional rent.

(b) Prior to the start of each full Expense Recovery Period (as defined in this Section 4.2), Landlord shall give Tenant a good faith line item written estimate of the amount of Tenant’s Share of Operating Expenses for the applicable Expense Recovery Period. Failure to provide such estimate shall not relieve Tenant from its obligation to pay Tenant’s Share of Operating Expenses or estimated amounts thereof, if and when Landlord provides such estimate or final payment amount. Tenant shall pay the estimated amounts to Landlord in equal monthly installments, in advance concurrently with payments of Basic Rent. If Landlord has not furnished its written estimate for any Expense Recovery Period by the time set forth above, Tenant shall continue to pay monthly the estimated Tenant’s Share of Operating Expenses in effect during the prior Expense Recovery Period; provided that when the new estimate is delivered to Tenant, Tenant shall, at the next monthly payment date(s), pay any accrued estimated Tenant’s Share of Operating Expenses based upon the new estimate or receive a credit against
amounts next due for overpaid amounts. For purposes hereof, “Expense Recovery Period” shall mean every twelve month period during the Term (or portion thereof for the first and last lease years) commencing July 1 and ending June 30, provided that Landlord shall have the right to change the date on which an Expense Recovery Period commences in which event appropriate reasonable adjustments shall be made to Tenant’s Share of Operating Expenses so that the amount payable by Tenant shall not materially vary as a result of such change.

(c) Within one hundred twenty (120) days after the end of each Expense Recovery Period, Landlord shall furnish to Tenant a statement showing in reasonable detail the actual or prorated Tenant’s Share of Operating Expenses incurred by Landlord during the period, and the parties shall within thirty (30) days thereafter make any payment or allowance necessary to adjust Tenant’s estimated payments of Tenant’s Share of Operating Expenses, if any, to the actual Tenant’s Share of Operating Expenses as shown by the annual statement. Any delay or failure by Landlord in delivering any statement hereunder shall not constitute a waiver of Landlord’s right to require Tenant to pay Tenant’s Share of Operating Expenses pursuant hereto. Any amount due Tenant shall be credited against installments next coming due under this Section 4.2, and any deficiency shall be paid by Tenant together with the next installment. Should Tenant fail to object in writing to Landlord’s determination of Tenant’s Share of Operating Expenses within one hundred eighty (180) days following Tenant’s receipt of Landlord’s expense statement (the “Review Period”), Landlord’s determination of Tenant’s Share of Operating Expenses for the applicable Expense Recovery Period shall be conclusive and binding on the parties for all purposes and any future claims to the contrary shall be barred.

Provided no Event of Default (based on Tenant’s failure to pay any sum due under this Lease) has occurred, which has not either been cured by Tenant or waived by Landlord, Tenant shall have the right to cause its own qualified employee(s) or a certified public accountant, in either case engaged on a non-contingency fee basis, to audit Operating Expenses by inspecting Landlord’s general ledger of expenses not more than once for any Expense Recovery Period. However, to the extent that insurance premiums are determined by Landlord on the basis of an internal allocation of costs utilizing information Landlord in good faith deems proprietary, such expense component shall not be subject to audit. Tenant shall give notice to Landlord of Tenant’s intent to audit, if at all, within the Review Period for the applicable Expense Recovery Period. Such audit shall be conducted at a mutually agreeable time during normal business hours at the office of Landlord or its management agent where such accounts are maintained. If Tenant’s audit determines that actual Operating Expenses have been overstated by more than five percent (5%), then subject to Landlord’s right to review and/or contest the audit results, Landlord shall reimburse Tenant for the reasonable out-of-pocket costs of such audit. Tenant’s rent shall be appropriately adjusted to reflect any overstatement in Operating Expenses. In the event of a dispute between Landlord and Tenant regarding such audit, such dispute shall be submitted and resolved by binding arbitration pursuant to the provisions of Article III of the attached Work Letter. All of the information obtained by Tenant and/or its auditor in connection with such audit, as well as any compromise, settlement, or adjustment reached between Landlord and Tenant as a result thereof, shall be held in strict confidence and, except as may be required pursuant to litigation, shall not be disclosed to any third party, directly or indirectly, by Tenant or its auditor or any of their officers, agents or employees. Landlord may require Tenant’s auditor to execute a separate confidentiality agreement affirming the foregoing as a condition precedent to any audit. In the event of a violation of this confidentiality covenant in connection with any audit, then in addition to any other legal or equitable remedy available to Landlord, Tenant shall forfeit its right to any reconciliation or cost reimbursement payment from Landlord due to said audit (and any such payment theretofore made by Landlord shall be promptly returned by Tenant), and Tenant shall have no further audit rights under this Lease.

(d) Even though this Lease has terminated and the Tenant has vacated the Premises, when the final determination is made of Tenant’s Share of Operating Expenses for the Expense Recovery Period in which this Lease terminates, Tenant shall, subject to the audit rights set forth in Section 4.2(c) above, within thirty (30) days of written notice pay the entire increase over the estimated Tenant’s Share of Operating Expenses already paid. Conversely, any overpayment by Tenant shall be rebated by Landlord to Tenant not later than thirty (30) days after such final determination.

(e) If, at any time during any Expense Recovery Period, any one or more of the Operating Expenses are increased to a rate(s) or amount(s) in excess of the rate(s) or amount(s) used in calculating the estimated Tenant’s Share of Operating Expenses for the year, then the estimate of Tenant’s Share of Operating Expenses may be increased by written notice from Landlord for the month in which such rate(s) or amount(s) becomes effective and for all succeeding months by an amount equal to Tenant’s Share of the increase. If Landlord gives Tenant written notice of the amount or estimated amount of the increase, the month in which the increase will or has become effective, then Tenant shall pay the increase to Landlord as a part of Tenant’s monthly payments of the estimated Tenant’s Share of Operating Expenses as provided in Section 4.2(b), commencing with the month following Tenant’s receipt of Landlord’s notice. In addition, Tenant shall pay upon written request any such increases which were incurred prior to the Tenant commencing to pay such monthly increase. Following any such increase, if requested by Tenant, Landlord shall review any possible decreases in other of the Operating Expenses for such year with Tenant, and will implement any such decreases, if warranted.

(f) The term “Operating Expenses” shall mean and include all Project Costs, as defined in subsection (g), and Property Taxes, as defined in subsection (h).

(g) The term “Project Costs” shall include all commercially reasonable expenses of operation, repair and maintenance of the Building and the Project, including without limitation all appurtenant Common Areas (as defined in Section 6.2), and shall include the following charges by way of illustration but not limitation: water and sewer charges; insurance premiums and deductibles and/or reasonable premium and deductible equivalents should
Landlord elect to self-insure all or any portion of any risk that Landlord is authorized to insure hereunder; license, permit, and inspection fees; light; power; window washing; trash pickup; heating, ventilating and air conditioning (to the extent not performed and paid for by Tenant as provided under Section 7.1 below); supplies; materials; equipment; tools; the cost of any commercially reasonable environmental, insurance, tax or other consultant utilized by Landlord in connection with the Building and/or Project; establishment of reasonable reserves for replacements and/or repairs; costs incurred in connection with compliance with any laws or changes in laws applicable to the Building or the Project that become effective after the Early Occupancy Date; the cost of any capital investments or replacements (other than tenant improvements for specific tenants) to the extent of the amortized amount thereof over the useful life of such capital investments or replacements with interest calculated at seven percent (7%) per annum, all as determined by Landlord in accordance with generally accepted accounting principles, consistently applied, for each such year of useful life during the Term; costs associated with the maintenance of an air conditioning, heating and ventilation service agreement (to the extent not performed and paid for by Tenant as provided under Section 7.1 below); third-party labor costs and expenses; reasonably allocated wages and salaries, fringe benefits, and payroll taxes for administrative and other personnel directly applicable to the Building and/or Project, including both Landlord’s personnel and outside personnel; any expense incurred pursuant to Sections 6.1, 6.2, 6.4, 7.2, and 10.2; and a reasonable overhead/management fee for the professional operation of the Project. It is understood and agreed that Project Costs may include competitive charges for direct services (including, without limitation, management and/or operations services) provided by any subsidiary, division or affiliate of Landlord. Tenant shall bear the burden of proof in any challenge to Landlord’s designation of an item as a Project Cost based on the fact Tenant does not consider it to be commercially reasonable.

(h) Notwithstanding the provisions of Section 4.2(g) above, Project Costs shall not include: (i) the cost of capital improvements (except as permitted in Section 4.2(g) above, but subject to Landlord’s obligations contained in Section 2.4 above); (ii) all fees, costs, principal and interest related to any mortgage(s) or deed(s) of trust, all payments made under any ground or underlying lease and all other non-operating debts of Landlord; (iii) the cost of repairs or other work to the extent Landlord is actually reimbursed by insurance or condemnation proceeds, or otherwise actually reimbursed by a third party; (iv) costs in connection with leasing space in the Building (including, without limitation, brokerage commissions, marketing costs, attorneys’ fees, lease concessions, rental abatements and construction allowances granted to specific tenants); (v) costs incurred in connection with the sale, financing or refinancing of the Building or Project; (vi) fines, interest and penalties incurred due to the late payment of Property Taxes or Project Costs not caused to by Tenant’s failure to timely pay Basic Rent, Operating Expenses or Property Taxes; (vii) any penalties or damages that Landlord pays to Tenant under this Lease or to other tenants in the Building or Project under their respective leases; (viii) any costs, fines, or penalties incurred due to violations by Landlord of any governmental rule or authority; (ix) the cost of any service provided to Tenant or other occupants of the Building or Project for which Landlord is actually reimbursed by another tenant in the Building; (x) costs associated with damage or repairs to the Project or Common Areas necessitated by the willful misconduct of Landlord or Landlord’s employees or authorized agents; (xi) salaries and benefits or employees over the level of property manager or building engineer; (xii) legal fees, accountant fees and other expenses incurred in disputes with other tenants or occupants of the Building or Project or associated with the enforcement of any other leases or defense of Landlord’s title to or interest in the Building, Project or any part thereof; (xiii) services or installations furnished to any tenant in the Building or Project that are not also furnished to Tenant; (xiv) the cost of any service provided to Tenant or other occupants of the Building or Project for which Landlord is actually reimbursed; (xv) costs or fees payable to public authorities in connection with any future construction, renovation and/or improvements to the Project (other than the Tenant Improvements or any improvements made to the Premises by or for Tenant) including fees for transit, housing, schools, open space, child care, arts programs, traffic mitigation measures, environmental impact reports, traffic studies, and transportation system management plans (provided, however, any of the foregoing that would be considered part of Property Taxes and/or billed as such may be included in Property Taxes); (xvi) expenditures covered by the “Property Policy” or by the “Liability Policy” (as defined in Section 10.2) should Landlord elect to self-insure such coverage under Section 10.2; (xvii) organizational expenses associated with the creation, maintenance and operation of the entity which constitutes Landlord; (xviii) except as allowed as a capital replacement or investment cost pursuant to Section 4.2(g) above, rentals and other related expenses, if any, incurred in leasing air conditioning systems, elevators or other equipment ordinarily considered capital in nature; (xix) amounts paid to persons or entities affiliated with, controlled by, controlling of, or under common control with, Landlord to the extent such amounts are greater than would have been charged by an unaffiliated third party in an arms-length transaction; (xx) any management fee or administrative cost in excess of the lower of (A) the fee charged by similar landlords in the area of the Project or (B) four percent (4%) of the Basic Rent and Operating Expenses for the period in question for the first five (5) years of the Term; and five percent (5%) for the final two years of the Term; (xxi) any reserves for capital replacements of any item other than a reasonable reserve for the replacement of the roof of the Building and the Utility Building; (xxii) should Landlord elect to self-insure the “Property Policy” and/or the “Liability Policy” (as defined in Section 10.2), the costs of premium and/or deductible equivalents to the extent such costs are in excess of the cost of such coverage if purchased in the insurance marketplace (based on the size of Landlord’s portfolio and its loss history); (xxiii) as determined following each Expense Recovery Period, any item of Project Cost which is duplicative of any other item of Project Costs; and (xxiv) taxes on Landlord's income from all sources.

(i) The term “Property Taxes” as used herein shall include any form of federal, state, county or local government or municipal taxes, fees, charges or other impositions of every kind (whether general, special, ordinary or extraordinary) related to the ownership, leasing or operation of the Premises, Building or Project, including without limitation, the following: (i) all real estate taxes or personal property taxes, as such property taxes may be reassessed from time to time; and (ii) other taxes, charges and assessments which are levied with respect to this Lease or to the Building and/or the Project, and any improvements, fixtures and equipment and other property of Landlord located in the Building and/or the Project, (iii) all assessments and fees for public improvements, services,
and facilities and impacts thereon, including without limitation arising out of any Community Facilities Districts, “Mello Roos” districts, similar assessment districts, and any traffic impact mitigation assessments or fees; (iv) any tax, surcharge or assessment which shall be levied in addition to or in lieu of real estate or personal property taxes, other than taxes covered by Article VIII; and (v) taxes based on the receipt of rent (including gross receipts or sales taxes applicable to the receipt of rent), and (vi) reasonable costs and expenses incurred in good faith in contesting the amount or validity of any Property Tax by proper proceedings. Notwithstanding the foregoing, Property Taxes shall not include: (A) income, capital, stock, succession, transfer, franchise, gift, estate or inheritance tax; (B) any item to the extent otherwise included in Project Costs; (C) any environmental assessments, charges or liens arising in connection with the remediation of Hazardous Materials from the Project, the causation of which arose prior to the Commencement Date or to the extent caused by Landlord, its agents, employees or contractors or any tenant of the Project (other than Tenant or its sublessees or assignees); (D) reserves for future Property Taxes; or (E) penalties or interest on the late payment of any Property Taxes. In no event shall Tenant be obligated to pay that portion of Property Taxes allocated to the Building or Premises by Landlord that is more than five percent (5%) greater than the taxes actually levied against the assessor’s parcel on which the Premises is located. If any Property Taxes are payable in installments over a period of time, Tenant shall be liable only for the payment of those installments falling due and payable during the Term, with appropriate proration for fractional years.

SECTION 4.3. SECURITY DEPOSIT. Concurrently with Tenant’s delivery of this Lease, Tenant shall deposit with Landlord the sum, if any, stated in Item 9 of the Basic Lease Provisions, to be held by Landlord as security for the full and faithful performance of all of Tenant’s obligations under this Lease (the “Security Deposit”). Subject to the last sentence of this Section, the Security Deposit shall be understood and agreed to be the property of Landlord upon Landlord’s receipt thereof, and may be utilized by Landlord in its sole and absolute discretion towards the payment of all expenses by Landlord for which Tenant would be required to reimburse Landlord under this Lease. Upon any Event of Default by Tenant (as defined in Section 14.1), Landlord may, in its sole and absolute discretion, use or apply the whole or any part of the Security Deposit to pay any sum which Tenant is obligated to pay under this Lease including, but not limited to, sums that Landlord may reasonably expend or be required to expend by reason of the Event of Default by Tenant or any loss or damage that Landlord may suffer by reason of the Event of Default or costs incurred by Landlord in connection with the repair or restoration of the Premises pursuant to Section 15.3 of this Lease upon expiration or earlier termination of this Lease. In no event shall Landlord be obligated to apply the Security Deposit upon an Event of Default and Landlord’s rights and remedies resulting from an Event of Default, including without limitation, Tenant’s failure to pay Basic Rent, Tenant’s Share of Operating Expenses or any other amount due to Landlord pursuant to this Lease, shall not be diminished or altered in any respect due to the fact that Landlord is holding the Security Deposit. If any portion of the Security Deposit is applied by Landlord as permitted by this Section, Tenant shall within five (5) business days after written demand by Landlord deposit cash with Landlord in an amount sufficient to restore the Security Deposit to its original amount. If Tenant fully performs its obligations under this Lease, the Security Deposit shall be returned to Tenant within thirty (30) days after the expiration of the Term, provided that Tenant agrees that Landlord may retain the Security Deposit to the extent and until such time as all amounts due from Tenant in accordance with this Lease have been determined (which determination shall not be unreasonably withheld, conditioned or delayed) and paid in full and Tenant agrees that Tenant shall have no claim against Landlord for Landlord’s retaining such Security Deposit to the extent provided in this Section.

Provided that no Event of Default has theretofore occurred under any provision of this Lease, Tenant shall have the right to have the Security Deposit reduced to the amount of One Hundred Twenty-Three Thousand One Hundred Eight Dollars ($123,108.00) by sending written request thereof to Landlord, which request shall be accompanied by Tenant’s audited Statements demonstrating two (2) immediately prior consecutive years of positive net income for Tenant. Following such written request to Landlord, Tenant shall be credited in the amount of the difference between the amount of the Security Deposit stated in Item 9 of the Basic Lease Provisions and the reduced amount of Security Deposit set forth above, against Basic Rent and Operating Expenses next coming due under this Lease.

ARTICLE V. USES

SECTION 5.1. USE. Tenant shall use the Premises only for the purposes stated in Item 3 of the Basic Lease Provisions, all in accordance with applicable laws and restrictions and pursuant to approvals to be obtained by Tenant from all relevant and required governmental agencies and authorities. The parties agree that any contrary use shall be deemed to cause material and irreparable harm to Landlord and shall entitle Landlord to injunctive relief in addition to any other available remedy. Tenant, at its expense, shall procure, maintain and make available for Landlord’s inspection throughout the Term, all governmental approvals, licenses and permits required for the proper and lawful conduct of Tenant’s permitted use of the Premises. Tenant shall not do or permit anything to be done in or about the Premises which will in any way unreasonably interfere with the rights of other occupants of the Project, or use or allow the Premises to be used for any unlawful purpose, nor shall Tenant permit any nuisance or commit any waste in the Premises or the Project. Tenant shall not, without Landlord’s prior written consent conduct its business operations in areas outside the Premises or the Utility Building, including but not limited to storing any property, equipment or trash in such areas except as shown on Exhibit F attached hereto. Tenant shall be responsible for any increased cost of any insurance policy(ies) covering the Project and/or their contents occasioned by its use. Tenant shall comply at its expense with all present and future laws, ordinances, restrictions, regulations, orders, rules and requirements of all governmental authorities that pertain to Tenant or its use of the Premises, including without limitation all federal and state occupational health and safety requirements, whether or not Tenant’s compliance will necessitate expenditures or interfere with its use and enjoyment of the Premises. Tenant shall comply at its expense with all present and future covenants, conditions, easements or restrictions now or
hereafter affecting or encumbering the Building and/or Project, and any amendments or modifications thereto, including without limitation the payment
by Tenant of any periodic or special dues or assessments charged against the Premises or Tenant which may be allocated to the Premises or Tenant in
accordance with the provisions thereof, provided, however, that such future or amended covenants, conditions, easements or restrictions are provided to
Tenant (and, to the extent action is required of Tenant to comply, Tenant has reasonable prior notice) and do not materially impair the rights of Tenant or
materially increase the obligations of Tenant under this Lease. Tenant shall promptly upon demand reimburse Landlord for any additional commercially
reasonable insurance premium charged by reason of Tenant’s failure to comply with the provisions of this Section, and shall indemnify Landlord from
any liability and/or reasonable expense resulting from Tenant’s noncompliance.

SECTION 5.2. SIGNS. Tenant shall have the right to install one (1) exterior building-top sign on the Building, one (1) sign on either side of the
existing monument sign in front of the Building and commercially reasonable signage for Tenant’s name (and for any subtenant’s name) on the
Premises’ entry and exit doors, subject to Landlord’s right of prior approval that such exterior signage is in compliance with the Signage Criteria
(defined below). Except as provided in the foregoing, Tenant shall have no right to maintain signs in any location on or about the Building or the Project
and shall not place or erect any signs that are visible from the exterior of the Building, except to the extent required by law, regulation or government
authority. The size, design, graphics, material, style, color and other physical aspects of any permitted sign shall be subject to Landlord’s written
determination, as determined solely by Landlord, prior to installation, that signage is in compliance with any covenants, conditions or restrictions
covering the Premises and Landlord’s sign program for the Project, in effect and approved by the City of San Diego (the “Signage Criteria”) as
of the date of installation of such signage. A copy of the Signage Criteria in effect as of the date of this Lease is attached as Exhibit G to this Lease. Prior
to placing or erecting any such signs, Tenant shall obtain and deliver to Landlord a copy of any applicable municipal or other governmental permits
and approvals and comply with any applicable insurance requirements for such signage. Tenant shall be responsible for the cost of any permitted sign,
including the fabrication, installation, maintenance and removal thereof and the cost of any permits therefor. If Tenant fails to maintain its sign in good
condition, or if Tenant fails to remove same upon termination of this Lease and repair and restore any damage caused by the sign or its removal,
Landlord may do so at Tenant’s expense. Landlord shall have the right to temporarily remove any signs in connection with any repairs or maintenance in
or upon the Building. The term “sign” as used in this Section shall include all signs, designs, monuments, displays, advertising materials, logos, banners,
projected images, pennants, decals, pictures, notices, lettering, numerals or graphics.

SECTION 5.3. HAZARDOUS MATERIALS.

(a) For purposes of this Lease, the term “Hazardous Materials” includes (i) any “hazardous material” as defined in Section 25501(o) of the
California Health and Safety Code, (ii) hydrocarbons, polychlorinated biphenyls or asbestos, (iii) any toxic or hazardous materials, substances, wastes or
materials as defined pursuant to any other applicable state, federal or local law or regulation, and (iv) any other substance or matter which may result in
liability to any person or entity as a result of such person’s possession, use, release or distribution of such substance or matter and that is considered a
hazardous material under any applicable law or regulation.

(b) Tenant shall not cause or permit any Hazardous Materials to be brought upon, stored, used, generated, released or disposed of on, under, from
or about the Premises (including without limitation the soil and groundwater thereunder) without the prior written consent of Landlord, which shall not
be unreasonably withheld as hereinafter provided. Notwithstanding the foregoing, Tenant shall have the right, without obtaining prior written consent of
Landlord, to utilize within the Premises: (A) a reasonable quantity of standard office or consumer products that may contain Hazardous Materials (such as
photocopy toner, “White Out”, and the like), provided however, that (i) Tenant shall maintain such products in their original retail packaging, shall
follow all instructions on such packaging with respect to the storage, use and disposal of such products, and shall otherwise comply with all applicable
laws with respect to such products, and (ii) all of the other terms and provisions of this Section 5.3 shall apply with respect to Tenant’s storage, use and
disposal of all such products; and (B) those Hazardous Materials (i) in kind and content listed on the Environmental Questionnaire (defined below)
delivered to Landlord prior to the execution of this Lease or otherwise reasonably related to Tenant’s diagnostic business (the “Current HazMats”) to
the extent that the use of such Current HazMats shall comply with all applicable laws and all of the other terms and provisions of this Section 5.3 shall
apply with respect to Tenant’s storage, use and disposal of such Current HazMats, and (ii) reasonably related to any future, non-diagnostic business
which Tenant (each a “Future HazMat”) to the extent (1) the use of such Future HazMats shall comply with all applicable laws and all of the other
terms and provisions of this Section 5.3 shall apply with respect to Tenant’s storage, use and disposal of such Future HazMats, (2) Tenant gives Landlord
prior written notice with regard to its proposed use of any Future HazMat, (3) if Landlord reasonably determines that a Future HazMat is materially
different in type and risk than the Current HazMats, Landlord may require Tenant obtain the insurance described in Exhibit D, Section 2 in amount
commensurate with such different type and risk, and (4) Landlord may place such reasonable conditions with respect to Tenant’s use of any Future
HazMat and may further require that Tenant demonstrate that any such Future HazMats are necessary or useful to Tenant’s business and will be
generated, stored, used and disposed of in a manner that complies with all applicable laws and regulations pertaining thereto and with good business
practices. Tenant understands that Landlord may utilize an environmental consultant to assist in determining conditions of approval in connection with
the storage, generation, release, disposal or use of Future HazMats proposed by Tenant as provided in the foregoing sentence on or about the Premises,
and Tenant agrees that any reasonable costs incurred by Landlord in connection therewith shall be reimbursed by Tenant to Landlord either as a
condition to such consent by Landlord or as additional rent hereunder upon demand.
(c) Prior to the execution of this Lease, Tenant shall complete, execute and deliver to Landlord an Environmental Questionnaire and Disclosure Statement (the "Environmental Questionnaire") in the form of Exhibit B attached hereto. The completed Environmental Questionnaire shall be deemed incorporated into this Lease for all purposes, and Landlord shall be entitled to rely fully on the information contained therein. Tenant shall disclose to Landlord in writing at the time it makes its annual regulatory disclosures regarding its use of Hazardous Materials or, if no such disclosure is made or required, on or about each anniversary of the Commencement Date, the names and amounts of all Hazardous Materials which were stored, generated, used, released and/or disposed of on, under or about the Premises for the twelve-month period prior thereto, and which Tenant expects to store, generate, use, release and/or dispose of on, under or about the Premises for the succeeding twelve-month period. In addition, to the extent Tenant is permitted to utilize Hazardous Materials upon the Premises, Tenant shall, upon reasonable notice, make available for inspection and copying complete and legible copies of all the following environmental documents relating to Hazardous Materials utilized by Tenant on or about the Premises: reports filed pursuant to any self-reporting requirements; permit applications, permits, monitoring reports, emergency response or action plans, workplace exposure and community exposure warnings or notices and all other reports, disclosures, plans or documents (even those which may be characterized as confidential) relating to water discharges, air pollution, waste generation or disposal, and underground storage tanks for Hazardous Materials; orders, reports, notices, listings and correspondence (even those which may be considered confidential) of or concerning the release, investigation of, compliance, cleanup, remedial and corrective actions, and abatement of Hazardous Materials; and all complaints, pleadings and other legal documents filed by or against Tenant related to Tenant’s use, handling, storage, release and/or disposal of Hazardous Materials. Notwithstanding anything to the contrary contained in this Section 5.3, under no circumstances shall (i) any provision in this Section 5.3 require Tenant to disclose to Landlord any document Tenant reasonably believes is attorney-client privileged or attorney work product or (ii) Tenant be required to disclose any confidential materials without such disclosure being subject to the parties’ execution of a commercially reasonable non-disclosure agreement.

(d) Landlord and its agents shall have the right, but not the obligation, after giving Tenant at least 24 hours prior notice (except in an emergency for which no notice shall be required) to inspect, sample and/or monitor the Premises and/or the soil or groundwater thereunder at any time to determine whether Tenant is complying with the terms of this Section 5.3, and in connection therewith Tenant shall provide, with prior reasonable notice, Landlord with full access to all facilities, records and personnel related thereto. If Tenant is not in compliance with any of the provisions of this Section 5.3, or in the event of a release of any Hazardous Material on, under or about the Premises caused or permitted by Tenant, its agents, employees, contractors, licensees or invitees, Landlord and its agents shall have the right, but not the obligation, without limitation upon any of Landlord’s other rights and remedies under this Lease, to immediately enter upon the Premises without notice and to discharge Tenant’s obligations under this Section 5.3 at Tenant’s expense (which expense shall be reasonable under the circumstances), including without limitation the taking of emergency or long-term remedial action. Landlord and its agents shall endeavor to minimize interference with Tenant’s business in connection therewith, but shall not be liable for any such interference. In addition, Landlord, at Tenant’s expense (which expense shall be reasonable under the circumstances), shall have the right, but not the obligation, to join and participate in any legal proceedings or actions initiated in connection with any claims arising out of the storage, generation, use, release and/or disposal by Tenant or its agents, employees, contractors, licensees or invitees of Hazardous Materials on, under, from or about the Premises (provided that Landlord reasonably determines that an actual or potential conflict of interest between Landlord and Tenant exists or may exist that reasonably requires Landlord to retain a separate attorney from Tenant).

(e) If the presence of any Hazardous Materials on, under, from or about the Premises or the Project caused or permitted by Tenant or its agents, employees, contractors, licensees or invitees results in (i) injury to any person, (ii) injury to or any contamination of the Premises or the Project, or (iii) injury to or contamination of any real or personal property wherever situated, Tenant, at its expense, shall promptly take all actions necessary to return the Premises and the Project and any other directly affected real or personal property owned by Landlord to the "Required Condition" (as hereinafter defined). Notwithstanding the foregoing, Tenant shall not, without Landlord’s prior written consent, which consent may be given or withheld in Landlord’s sole and absolute discretion, take any remedial action in response to the presence of any Hazardous Materials on, under or about the Premises or the Project or any other directly affected real or personal property owned by Landlord or enter into any similar agreement to take remedial action, consent, decree or other compromise with any governmental agency with respect to any Hazardous Materials claims; provided however, Landlord’s prior written consent shall not be necessary in the event that the presence of Hazardous Materials on, under or about the Premises or the Project or any other directly affected real or personal property owned by Landlord (i) imposes an immediate threat to the health, safety or welfare of any individual and (ii) is of such a nature that an immediate remedial response is necessary and it is not possible to obtain Landlord’s consent before taking such action. Landlord shall be responsible for any increased costs or liability to the extent they are directly attributable to Landlord’s withholding or delay in providing its consent. As used herein, “Required Condition” shall mean returning the Premises and the Project and any other directly affected real or personal property owned by Landlord to a condition that is both (A) required by applicable federal, state or local law, regulation or order, including without limitation, performing any required cleanup, remediation, removal, disposal, neutralization or other treatment of Hazardous Materials, and (B) wherein Landlord’s marketability, use and leasing thereof as commercial properties is not materially impaired. To the fullest extent permitted by law, Tenant shall indemnify, hold harmless, protect and defend (with attorneys reasonably acceptable to Landlord) Landlord and any successors to all or any portion of Landlord’s interest in the Premises and the Project and any other directly affected real or personal property owned by Landlord from and against any and all liabilities, losses, damages, diminution in value, judgments, fines, demands, claims, recoveries, deficiencies, costs and expenses (including without limitation reasonable attorneys’ fees, court costs and other professional expenses), whether foreseeable or unforeseeable, arising directly or indirectly out of the use, generation, storage, treatment,
release, on- or off-site disposal or transportation of Hazardous Materials on, into, from, under or about the Premises, the Building or the Project and any other directly affected real or personal property owned by Landlord caused or knowingly permitted by Tenant, its agents, employees, contractors, licensees or invitees (each a "Tenant Party"). Such indemnity obligation shall specifically include, without limitation, the cost of any repair, restoration, cleanup or detoxification of the Premises, the Building and the Project and any other directly affected real or personal property owned by Landlord required or necessary to return same to the Required Condition, the preparation of any closure or other required plans, whether or not such action is required or necessary during the Term or after the expiration of this Lease and any loss of rental due to the inability to lease the Premises or any portion of the Building or Project as a result of such Hazardous Material or remediation thereof. If it is at any time discovered that Hazardous Materials have been released on, into, from, under or about the Premises during the Term by Tenant or any Tenant Party, or that Tenant or any Tenant Party may have caused or knowingly permitted the release of a Hazardous Material on, under, from or about the Premises, the Building or the Project or any other directly affected real or personal property owned by Landlord, Tenant shall, at Landlord’s request, immediately prepare and submit to Landlord a comprehensive plan, subject to Landlord’s reasonable approval, specifying the actions to be taken by Tenant to return the Premises, the Building or the Project or any other directly affected real or personal property owned by Landlord to the Required Condition. Upon Landlord’s approval of such cleanup plan, Tenant shall, at its expense, and without limitation of any rights and remedies of Landlord under this Lease or at law or in equity, immediately implement such plan and proceed to cleanup such Hazardous Materials in accordance with all applicable laws and as required by such plan and this Lease. The provisions of this Section 5.3(e) shall expressly survive the expiration or sooner termination of this Lease.

(f) Notwithstanding anything to the contrary contained in this Lease, Tenant shall have no liability or responsibility with respect to any Hazardous Materials in, on, under or around the Building or Project which were not caused or knowingly permitted by Tenant or by any Tenant Party. Notwithstanding the preceding sentence, Tenant agrees to notify its agents, employees, contractors, licensees, and invitees of any exposure or potential exposure to Hazardous Materials at the Premises that Landlord brings to Tenant’s attention. Provided such information is accurate, Tenant hereby acknowledges that this disclosure satisfies any obligation of Landlord to Tenant pursuant to California Health & Safety Code Section 25359.7, or any amendment or substitute thereto or any other disclosure obligations of Landlord. Landlord shall take responsibility, at its sole cost and expense, for any governmental-require clean-up, remediation, removal, disposal, neutralization or other treatment of Hazardous Materials conditions described in this Section 5.3(f). The foregoing obligation on the part of Landlord shall include the reasonable costs (including, without limitation, reasonable attorney’s fees) of defending Tenant from and against any legal action or proceeding instituted by any governmental agency in connection with such clean-up, remediation, removal, disposal, neutralization or other treatment of such conditions, provided that Tenant promptly tenders such defense to Landlord.

(g) Landlord represents that, to "Landlord’s knowledge" (as hereinafter defined), there are no Hazardous Materials in, on, under or about the Premises, the Building, nor have there been Hazardous Materials in, on or about the Premises during the Term, together with any taxes thereon. If any utilities or services are not separately metered or assessed to Tenant, Landlord shall make a reasonable determination of Tenant’s proportionate share of the cost of such utilities and services, and Tenant shall pay such amount to Landlord, as an item of additional rent, within thirty (30) days after receipt of Landlord’s statement or invoice therefor. Alternatively, Landlord may elect to include such cost in the definition of Project Costs in which event Tenant shall pay Tenant’s proportionate share of such costs in the manner set forth in Section 4.2. Landlord shall not be liable for damages or otherwise for any failure or interruption of any utility or other service furnished to the Premises, and no such failure or interruption shall be deemed an eviction or entitle Tenant to terminate this Lease or withhold or abate any rent due hereunder. Notwithstanding the foregoing, if as a result of the direct actions of Landlord, its employees, contractors or authorized agents, for more than three (3) consecutive business days following written notice to Landlord there is no HVAC or electricity services to all or a portion of the Premises, or such an interruption of other essential utilities and building services, such as fire protection or water, so that all or a portion of the Premises cannot be used by Tenant, then Tenant’s Basic Rent (or an equitable portion of such Basic Rent to the extent that less than all of the Premises are affected) shall thereafter be abated until the Premises are again usable by Tenant; provided, however, that if Landlord is diligently pursuing the repair of such utilities or services and Landlord provides substitute services reasonably suitable for Tenant’s purposes, as for example, bringing in portable air-conditioning equipment, then there shall not be an abatement of Basic Rent. Provided Landlord shall diligently pursue the repair of such utilities and services, the foregoing provisions shall be Tenant’s sole recourse and remedy in the event of such an interruption of services. The foregoing provisions shall not apply in case of the actions of parties other than Landlord, its employees, contractors or authorized agents, or in the case of damage to, or destruction of, the Premises (which shall be governed by the provisions of Article XI of the Lease). Any disputes concerning the foregoing provisions shall be submitted to and resolved by JAMS arbitration pursuant to Article III of the Work Letter attached to this Lease.

ARTICLE VI. COMMON AREAS; SERVICES

SECTION 6.1. UTILITIES AND SERVICES. Tenant shall be responsible, at its sole cost and expense, for all charges for water, gas, electricity, sewer, heat, light, power, telephone, telecommunications service, refuse pickup, janitorial service, interior landscape maintenance and all other utilities, materials and services furnished directly to Tenant or the Premises or used by Tenant in, on or about the Premises during the Term, together with any taxes thereon. If any utilities or services are not separately metered or assessed to Tenant, Landlord shall make a reasonable determination of Tenant’s proportionate share of the cost of such utilities and services, and Tenant shall pay such amount to Landlord, as an item of additional rent, within thirty (30) days after receipt of Landlord’s statement or invoice therefor. Alternatively, Landlord may elect to include such cost in the definition of Project Costs in which event Tenant shall pay Tenant’s proportionate share of such costs in the manner set forth in Section 4.2. Landlord shall not be liable for damages or otherwise for any failure or interruption of any utility or other service furnished to the Premises, and no such failure or interruption shall be deemed an eviction or entitle Tenant to terminate this Lease or withhold or abate any rent due hereunder. Notwithstanding the foregoing, if as a result of the direct actions of Landlord, its employees, contractors or authorized agents, for more than three (3) consecutive business days following written notice to Landlord there is no HVAC or electricity services to all or a portion of the Premises, or such an interruption of other essential utilities and building services, such as fire protection or water, so that all or a portion of the Premises cannot be used by Tenant, then Tenant’s Basic Rent (or an equitable portion of such Basic Rent to the extent that less than all of the Premises are affected) shall thereafter be abated until the Premises are again usable by Tenant; provided, however, that if Landlord is diligently pursuing the repair of such utilities or services and Landlord provides substitute services reasonably suitable for Tenant’s purposes, as for example, bringing in portable air-conditioning equipment, then there shall not be an abatement of Basic Rent. Provided Landlord shall diligently pursue the repair of such utilities and services, the foregoing provisions shall be Tenant’s sole recourse and remedy in the event of such an interruption of services. The foregoing provisions shall not apply in case of the actions of parties other than Landlord, its employees, contractors or authorized agents, or in the case of damage to, or destruction of, the Premises (which shall be governed by the provisions of Article XI of the Lease). Any disputes concerning the foregoing provisions shall be submitted to and resolved by JAMS arbitration pursuant to Article III of the Work Letter attached to this Lease.
Landlord shall at all reasonable times have free access to the Building and Premises to install, maintain, repair, replace or remove all electrical and mechanical installations of Landlord. Tenant acknowledges that the costs incurred by Landlord related to providing above-standard utilities to Tenant (which shall only be provided upon Tenant’s request), including, without limitation, telephone lines, shall be charged to Tenant.

SECTION 6.2. OPERATION AND MAINTENANCE OF COMMON AREAS. During the Term, Landlord shall operate all Common Areas within the Project. The term “Common Areas” shall mean all areas which are not held for exclusive use by persons entitled to occupy space, and all other appurtenant areas and improvements within the Projectprovided by Landlord for the common use of Landlord and tenants and their respective employees and invitees, including without limitation parking areas and structures, driveways, sidewalks, landscaped and planted areas, but shall not include any interior spaces within any buildings in the Project.

SECTION 6.3. USE OF COMMON AREAS. The occupancy by Tenant of the Premises shall include the use of the Common Areas in common with Landlord and with all others for whose convenience and use the Common Areas may be provided by Landlord, subject, however, to compliance with the Rules and Regulations (as defined in Article XVII of this Lease). Landlord shall operate and maintain the Common Areas in the manner as determined by Landlord in its reasonable discretion. All costs incurred by Landlord for the maintenance and operation of the Common Areas shall be included in Project Costs except to the extent any particular cost incurred is related to or associated with a specific tenant and can be charged to such tenant of the Project. Landlord shall at all times during the Term have exclusive control of the Common Areas, and may restrain or permit any use or occupancy, or require all persons using the Common Areas to obey the rules and regulations of Landlord. Tenant shall keep the Common Areas clear of any obstruction or unauthorized use related to Tenant’s operations or use of Premises, including without limitation, planters and furniture. Except as expressly provided elsewhere in this Lease, nothing in this Lease shall be deemed to impose liability upon Landlord for any damage to or loss of the property of, or for any injury to, Tenant, its invitees or employees. Landlord may temporarily close any portion of the Common Areas for repairs, remodeling and/or alterations, to prevent a public dedication or the accrual of prescriptive rights, or for any other reason deemed sufficient by Landlord, without liability to Landlord, provided, however, that any such closure shall not unreasonably interfere with Tenant’s access to the Premises or Tenant’s parking rights granted in this Lease.

SECTION 6.4. PARKING. Tenant shall be entitled to the number of vehicle parking spaces set forth in Item 14 of the Basic Lease Provisions, which spaces shall be unreserved and unassigned, on those portions of the Common Areas designated by Landlord for parking. Tenant shall not use more parking spaces than such number. All parking spaces shall be used only for parking of vehicles no larger than full size passenger automobiles, sports utility vehicles or pickup trucks. Tenant shall not permit or allow any vehicles that belong to or are controlled by Tenant or Tenant’s employees, suppliers, shippers, customers or invitees to be loaded, unloaded or parked in areas other than those designated by Landlord for such activities. If Tenant permits or allows any of the prohibited activities described above, then Landlord shall have the right, without notice, in addition to such other rights and remedies that Landlord may have, to remove or tow away the vehicle involved and charge the costs to Tenant. Parking within the Common Areas shall be limited to striped parking stalls, and no parking shall be permitted in any driveways, access ways or in any area which would prohibit or impede the free flow of traffic within the Common Areas. There shall be no parking of any vehicles for longer than seven (7) consecutive days unless otherwise authorized by Landlord, and vehicles which have been abandoned or parked in violation of the terms hereof may be towed away at the owner’s expense. Nothing contained in this Lease shall be deemed to create liability upon Landlord for any damage to motor vehicles of visitors or employees, for any loss of property from within those motor vehicles, or for any injury to Tenant, its visitors or employees, unless ultimately determined to be caused by the active negligence or willful misconduct of Landlord, or Landlord’s employees, authorized agents or contractors. Landlord shall have the right to require, at all reasonable times, that Tenant permit such parking as is necessary and advisable for the proper and efficient operation and maintenance of parking within the Common Areas. Tenant shall have the right to construct, maintain and operate lighting facilities within the parking areas; to change the area, level, location and arrangement of the parking areas and improvements therein; to restrict parking by tenants, their officers, agents and employees to employee parking areas; after the expiration of the initial 84-month Term of this Lease, to enforce parking charges (by operation of meters or otherwise); and to do and perform such other acts in and to the parking areas and improvements therein as, in the use of good business judgment, Landlord shall determine to be advisable. Any person using the parking area shall observe all directional signs and arrows and any posted speed limits. In no event shall Tenant interfere with the use and enjoyment of the parking area by other tenants of the Project or their employees or invitees. Parking areas shall be used only for parking vehicles. Washing, waxing, cleaning or servicing of vehicles, or the storage of vehicles for longer than 48-hours, is prohibited unless otherwise authorized by Landlord. Tenant shall be liable for any damage to the parking areas caused by Tenant or Tenant’s employees, suppliers, shippers, customers or invitees, including without limitation damage from excess oil leakage. Tenant shall have no right to install any fixtures, equipment or personal property in the parking areas.

SECTION 6.5. CHANGES AND ADDITIONS BY LANDLORD. Landlord reserves the right to make alterations or additions to the Building or the Project, or to the attendant fixtures, equipment and Common Areas. Landlord may at any time relocate or remove any of the various buildings, parking areas, and other Common Areas, and may add buildings and areas to the Project from time to time. No change shall entitle Tenant to any abatement of rent or other claim against Landlord, provided that the change does not deprive Tenant of reasonable access to or use of the Premises. Notwithstanding the foregoing, no change by Landlord to the Common Areas shall: (i) materially impair access to and from the Premises from the parking areas, (ii) reduce the number of Tenant’s parking spaces granted under this Lease, or (iii) otherwise unreasonably interfere with Tenant’s access to and use of the Premises, the parking areas and the Common Areas adjacent to the Building in any material manner without Tenant’s prior written consent, which shall not be unreasonably withheld.
ARTICLE VII. MAINTAINING THE PREMISES

SECTION 7.1. TENANT’S MAINTENANCE AND REPAIR. Tenant at its sole expense shall repair and maintain and make all appropriate replacements necessary to keep the Premises in the condition as existed on the Commencement Date (or on any later date that the improvements may have been installed), excepting ordinary wear and tear and casualty, including without limitation all interior glass, doors, door closures, hardware, fixtures, HVAC systems and equipment serving the Premises, electrical, plumbing, fire extinguisher equipment and other equipment installed in the Premises, all Alterations constructed by Tenant pursuant to Section 7.3 below, and all of the “Tenant Improvements” installed by Tenant pursuant to the Work Letter. In no event, however, shall Tenant be responsible for capitalized replacements exceeding the amount of Ten Thousand Dollars ($10,000.00) in cost per replacement, or for any repairs required of Landlord pursuant to Sections 2.2 or 2.4. Any damage or deterioration of the Premises shall not be deemed ordinary wear and tear if the same could have been prevented by good maintenance practices by Tenant. As part of its maintenance obligations hereunder, Tenant shall provide all janitorial services to the Premises and, at Landlord’s request, shall provide Landlord with copies of all maintenance schedules, reports and notices prepared by, for or on behalf of Tenant. All repairs and replacements shall, unless otherwise permitted in this Lease, be at least equal in quality to the original work, taking into account ordinary wear and tear, and shall be made only by a licensed contractor, which contractor, for repairs or replacements exceeding $50,000.00, shall be approved in writing in advance by Landlord, not to be unreasonably withheld or delayed. Any contractor utilized by Tenant shall be subject to Landlord’s standard requirements for contractors attached hereto as Exhibit H, as reasonably modified from time to time. Landlord may impose reasonable restrictions and requirements with respect to repairs, as provided in Section 7.3, and the provisions of Section 7.4 shall apply to all repairs. If Tenant fails to properly maintain and/or repair the Premises as herein provided following Landlord’s notice and the expiration of the applicable cure period (or earlier if Landlord determines that such work must be performed prior to such time in order to avoid damage to the Premises or Building or other detriment), then Landlord may elect, but shall have no obligation, to perform any repair or maintenance required hereunder on behalf of Tenant and at Tenant’s expense, and Tenant shall reimburse Landlord upon demand for all reasonable costs incurred upon submission of an invoice. Notwithstanding anything to the contrary in this Section 7.1, Tenant may, by giving Landlord not less than sixty (60) days prior written notice, elect to have Landlord assume Tenant’s obligations under this Section 7.1 for repair and maintenance of the HVAC systems and equipment serving the Premises.

SECTION 7.2. LANDLORD’S MAINTENANCE AND REPAIR. Subject to Section 7.1 and Article XI, Landlord shall maintain in good operating condition and repair all parts of the Premises that are not Tenant’s obligation under Section 7.1 and all areas outside of the Premises including, without limitation, all portions and elements of the roof (including sky lights and related seals), foundations, footings, the exterior surfaces of the exterior walls of the Building (including exterior glass and doors), structural walls, passenger and freight elevators and the structural, life/safety, electrical and mechanical systems (except for HVAC systems and equipment) in or serving the Building, except that Tenant at its expense shall make all repairs which Landlord deems reasonably necessary as a result of the act or negligence of Tenant, its agents, employees, invitees, subtenants or contractors. Landlord shall have the right to employ or designate any reputable person or firm, including any employee or agent of Landlord or any of Landlord’s affiliates or divisions, to perform any service, repair or maintenance function. Landlord need not make any other improvements or repairs except as specifically required under this Lease, and nothing contained in this Section shall limit Landlord’s right to reimbursement from Tenant for reasonable maintenance, repair costs and replacement costs as provided elsewhere in this Lease (but subject to any limitations therein provided). Tenant understands that it shall not make repairs at Landlord’s expense or by rental offset. Tenant further understands that Landlord shall not be required to make any repairs to the roof, foundations, footings, the exterior surfaces of the exterior walls of the Building (excluding exterior glass), or structural, electrical or mechanical systems unless and until Tenant has notified Landlord in writing of the need for such repair and Landlord shall have a reasonable period of time thereafter to commence and complete said repair, if warranted. Except as set forth in Sections 2.4 and 4.2 of this Lease, all costs of any maintenance, repairs and replacement on the part of Landlord provided hereunder shall be considered part of Project Costs.

SECTION 7.3. ALTERATIONS. Except as otherwise provided in this Section, Tenant shall make no alterations, additions, fixtures or improvements (“Alterations”) to the Premises or the Building without the prior written consent of Landlord, which consent shall not be unreasonably withheld. Notwithstanding the foregoing, Tenant may make Alterations to the Premises costing less than Fifty Thousand Dollars ($50,000.00) during each calendar year of the Term without Landlord’s consent, provided, however, that any Alterations which require a governmental permit as a prerequisite to the construction thereof, shall require Landlord’s prior written consent, which shall not be unreasonably withheld, and Tenant shall supply an itemized summary to Landlord’s property manager, including as-built plans (if applicable), at least annually, of all of the foregoing Alterations made without Landlord’s consent. Notwithstanding anything to the contrary contained in either of the foregoing sentences, without the prior written consent of Landlord which may be withheld in Landlord’s sole and absolute discretion, no Alterations shall: (i) affect the exterior of the Building or outside areas (or be visible from adjoining sites), (ii) adversely affect or penetrate through any of the structural portions of the Building, including but not limited to the roof, (iii) require any change to the basic floor plan of the Premises (including, without limitation, the adding of any additional “office” square footage) or any material change to any structural, electrical or mechanical systems of the Premises, (iv) fail to comply with any applicable governmental requirements or with any governmental permit prerequisite to the construction thereof, (v) result in the Premises requiring building services beyond the level normally provided to other tenants, (vi) interfere in any manner with the proper functioning of, or Landlord’s access...
to, any mechanical, electrical, plumbing or HVAC systems, facilities or equipment located in or serving the Building, or (vii) alter or replace Standard Improvements with a Non-Standard Improvement. In the event that any requested Alteration involves the use of lesser quality materials or less stringent specifications than the building standard materials and specifications attached hereto as Exhibit I (“Standard Improvements”), Landlord may withhold consent to such Alteration in its sole and absolute discretion. In the event that any requested Alteration involves the use of lesser quality materials or less stringent specifications than the Standard Improvements (such use being referred to as a “Non-Standard Improvement”), Tenant shall be responsible for the cost of replacing such Non-Standard Improvement with the applicable Standard Improvement (“Replacements”), which Replacements shall be completed prior to the Expiration Date or earlier termination of this Lease. Landlord may impose any reasonable condition to its consent, including but not limited to reasonable requirements as to the manner and time of performance of such work, but not including a lien and completion bond unless: (A) Tenant’s current Statements show a net worth less than the Statements of Tenant at lease execution, and (B) such Alterations cost in excess of Two Hundred Fifty Thousand Dollars ($250,000.00). Landlord shall in all events, whether or not Landlord’s consent is required, have the right to reasonably approve the contractor performing the installation and removal of Alterations and Replacements and Tenant shall not permit any contractor not approved by Landlord to perform any work on the Premises or on the Building. The restriction set forth in the preceding sentence shall not apply if the cost of such Alteration or Replacement is less than Fifty Thousand Dollars ($50,000.00). Tenant shall obtain all required permits for the installation and removal of Alterations and Replacements and shall perform the installation and removal of Alterations and Replacements in compliance with all applicable laws, regulations and ordinances, including without limitation the Americans with Disabilities Act, all covenants, conditions and restrictions affecting the Project, and the Rules and Regulations as described in Article XVII. Tenant understands and agrees that Landlord shall be entitled to a supervision fee for any Alterations either requiring a permit from the City of San Diego or affecting any mechanical, electrical, plumbing or HVAC systems, facilities or equipment located in or serving the Building, in the following amounts: (i) five percent (5%) of the cost of such Alterations costing less than Fifty Thousand Dollars ($50,000.00), or (ii) for Alterations costing more than Fifty Thousand Dollars ($50,000.00), the sum of Two Thousand Five Hundred Dollars ($2,500.00) plus one percent (1%) of the cost of such Alterations (not to exceed the aggregate amount of Fifteen Thousand Dollars ($15,000.00)), plus Landlord’s actual and reasonable costs of its mechanical and/or electrical engineers to review such Alterations. Under no circumstances shall Tenant make any Alterations or Replacements which incorporate any Hazardous Materials, including without limitation asbestos-containing construction materials into the Premises, the Building or the Common Area. If any governmental entity requires, as a condition to any proposed Alterations by Tenant, that improvements be made to the Common Areas, and if Landlord consents to such improvements to the Common Areas (which consent may be withheld in the sole and absolute discretion of Landlord), then Tenant shall, at Tenant’s sole expense, make such required improvements to the Common Areas in such manner, utilizing such materials, and with such contractors, architects and engineers as Landlord may require in its reasonable discretion. Any request for Landlord’s consent to any proposed Alterations shall be made in writing and shall contain architectural plans describing the work in detail reasonably satisfactory to Landlord. Landlord may elect to cause its architect to review Tenant’s architectural plans, and the reasonable cost of that review shall be reimbursed by Tenant. Should the work proposed by Tenant and consented to by Landlord modify the basic floor plan of the Premises, then Tenant shall, at its expense, furnish Landlord with as-built drawings and CAD disks compatible with Landlord’s systems and standards. Unless Landlord otherwise agrees in writing, all Alterations made or affixed to the Premises, the Building or to the Common Area (but excluding trade fixtures, personal property, equipment and furniture, including, but not limited to, laboratory equipment and benching and emergency generators which shall remain the property of Tenant), shall become the property of Landlord and shall be surrendered with the Premises at the end of the Term; except that Landlord may, as provided in the next succeeding paragraph of this Section 7.3, require Tenant to remove by the Expiration Date or sooner termination date of this Lease, all or any of the Alterations installed either by Tenant or by Landlord at Tenant’s request, and to repair any damage to the Premises, the Building or the Common Area arising from that removal and restore the Premises to their condition prior to making such Alterations, reasonable wear and tear and casualty excepted.

As of the Expiration Date or earlier termination date of this Lease, Landlord shall have the right to require Tenant to remove any Alterations made by Tenant to the Premises and to replace same with the applicable Replacements, whether or not Landlord’s consent was required. Notwithstanding anything to the contrary in this Section 7.3, if at the time of requesting Landlord’s consent to any such Alterations or if prior to commencing any Alterations for which Landlord’s consent is not required, Tenant shall request in writing whether or not Landlord shall require such Alterations to be so removed and replaced as of the Expiration Date or earlier termination date of this Lease, then Landlord’s right to require Tenant to so remove and replace such Alterations shall be exercised, if at all, at the time of Landlord’s consent thereto.

As used in this Section 7.3, “Alterations” do not include the Tenant Improvements to be constructed by Tenant pursuant to the attached Work Letter.

SECTION 7.4. MECHANIC’S LIENS. Tenant shall keep the Premises free from any liens arising out of any work performed, materials furnished, or obligations incurred by or for Tenant. Upon request by Landlord, Tenant shall promptly (but in no event later than ten (10) business days following such request) cause any such lien to be released by posting a bond in accordance with California Civil Code Section 3143 or any successor statute. In the event that Tenant shall not, within thirty (30) days following the imposition of any lien, cause the lien to be released of record by payment or posting of a proper bond, Landlord shall have, in addition to all other available remedies, the right to cause the lien to be released by any means it deems proper, including payment of or defense against the claim giving rise to the lien. All reasonable expenses so incurred by Landlord, including Landlord’s attorneys’ fees, and any direct damages incurred by Landlord proximately caused by such lien, shall be reimbursed by Tenant upon demand, together with interest from the date of payment by Landlord at the per annum rate of ten
SECTION 7.5. ENTRY AND INSPECTION. Landlord shall at all reasonable times, upon at least 24 hours prior written or oral notice (except in emergencies, when no notice shall be required) have the right to enter the Premises to inspect them, to supply services in accordance with this Lease, to have access to install, repair, maintain, replace or remove all electrical and mechanical installations of Landlord and to protect the interests of Landlord in the Premises, and to submit the Premises to prospective or actual purchasers or encumbrance holders (or, during the last one hundred and eighty (180) days of the Term or when an uncured Tenant Event of Default exists, to prospective tenants), all without being deemed to have caused an eviction of Tenant and without abatement of rent except as provided elsewhere in this Lease. Landlord shall have the right, if desired, to retain a key which unlocks all of the doors in the Premises, excluding Tenant’s vaults and safes, and Landlord shall have the right to use any and all means which Landlord may deem proper to open the doors in an emergency in order to obtain entry to the Premises, and any entry to the Premises obtained by Landlord shall not under any circumstances be deemed to be a forcible or unlawful entry into, or a detainer of, the Premises, or any eviction of Tenant from the Premises.

SECTION 7.6. COMMUNICATIONS EQUIPMENT. Landlord hereby grants to Tenant a non-exclusive license (the “License”) to install, maintain and operate on the roof of the Building one or more antenna or satellite dishes not exceeding forty-eight inches (48”) in height (the “Antenna”) in accordance with and subject to the terms and conditions set forth below. The Antenna shall be installed at a location designated by Landlord and reasonably acceptable to Tenant (“Licensed Area”). The Licensed Area shall be considered to be a part of the Premises for all purposes under the Lease, and except as otherwise expressly provided in this Section 7.6 all provisions applicable to the use of the Premises under the Lease shall apply to the Licensed Area and its use by Tenant.

1. The Term of the License shall be coterminous with this Lease;

2. Tenant shall not be obligated to pay any license fee for the use of the Licensed Area pursuant to this Section 7.7 during the Term of this Lease.

3. Tenant shall use the Licensed Area only for the installation, operation, repair, replacement and maintenance of the Antenna and the necessary mechanical and electrical equipment to service said Antenna and for no other use or purpose. The installation of the Antenna and all equipment and facilities related thereto, including any required conduit from the Premises to the Antenna, shall be deemed to constitute an alteration subject to the provisions of Section 7.3 of the Lease, provided that Landlord shall not unreasonably withhold its approval of the same. Landlord may require appropriate screening for the Antenna as a condition of Landlord’s approval of the installation of the Antenna. Tenant may have access to the Licensed Area for such uses during normal business hours and at times upon reasonable prior notice to Landlord and shall reimburse Landlord for any reasonable out-of-pocket expenses incurred by Landlord in connection therewith;

4. The Antenna shall be used only for transmitting and/or receiving data, audio and/or video signals to and from Tenant’s facilities within the Premises for Tenant’s use, and shall not be used or permitted to be used by Tenant for purposes of broadcasting signals to the public or to provide telecommunications or other communications transmitting or receiving services to any third parties as a commercial business;

5. Landlord reserves the right upon reasonable prior written notice to Tenant to require the removal of any and all of such equipment should Landlord reasonably determine that its presence results in material damage to the Building unless Tenant makes satisfactory arrangements to protect Landlord therefrom;

6. Tenant shall require its employees, when using the Licensed Area, to stay within the immediate vicinity thereof. In addition, in the event any communications system or broadcast or receiving facilities are operating in the area, Tenant shall at all times during the term of the License conduct its operations so as to ensure that such system or facilities shall not be subjected to harmful interference as a result of such operations by Tenant. Upon notification from Landlord of any such interference, Tenant agrees to immediately take the necessary steps to correct such situation, and Tenant’s failure to do so shall be deemed a default under the terms of this License, as a result of which Landlord may terminate the License on five (5) days notice, and Tenant shall remove the Antenna.

7. During the term of the License, Tenant shall comply with any standards promulgated by applicable governmental authorities or otherwise reasonably established by Landlord regarding the generation of electromagnetic fields. Should Landlord determine in good faith at any time that the Antenna poses a health or safety hazard to occupants of the Building, Landlord may require Tenant to make arrangements satisfactory to Landlord to mitigate such hazard or, if Tenant either fails or is unable to make such satisfactory arrangements, to remove the Antenna. Any claim or liability resulting from the use of the Antenna or the Licensed Area shall be subject to the indemnification provisions of this Lease applicable to Tenant’s use of the Premises;
ARTICLE VIII. TAXES AND ASSESSMENTS ON TENANT’S PROPERTY

SECTION 9.1. RIGHTS OF PARTIES.

(a) Notwithstanding any provision of this Lease to the contrary, and except as to transfers expressly permitted without Landlord’s consent pursuant to Section 9.4, Tenant will not, either voluntarily or by operation of law, assign, sublet, encumber, or otherwise transfer all or any part of Tenant’s interest in this Lease or the Premises, or permit the Premises to be occupied by anyone other than Tenant, without Landlord’s prior written consent, which consent shall not unreasonably be withheld or conditioned in accordance with the provisions of Section 9.1(b). No assignment (whether voluntary, involuntary or by operation of law) and no subletting shall be valid or effective without Landlord’s prior written consent and, at Landlord’s election, any such assignment or subletting shall be void and of no force and effect and any such attempted assignment or subletting shall constitute an Event of Default of this Lease if not cured within thirty (30) days of written notice from Landlord. Landlord shall not be deemed to have given its consent to any assignment or subletting by any course of action other than written consent. To the extent not prohibited by provisions of the Bankruptcy Code, 11 U.S.C. Section 101 et seq., Tenant on behalf of itself and its creditors, administrators and assigns waives the applicability of Section 365(e) of the Bankruptcy Code unless the proposed assignee of the Trustee for the estate of the bankrupt meets Landlord’s standard for consent as set forth in Section 9.1(b) of this Lease. If this Lease is assigned to any person or entity pursuant to the provisions of the Bankruptcy Code, any and all monies or other considerations to be delivered in connection with the assignment shall be delivered to Landlord, shall be and remain the exclusive property of Landlord and shall not constitute property of Tenant or of the estate of Tenant within the meaning of the Bankruptcy Code. Any person or entity to which this Lease is assigned pursuant to the provisions of the Bankruptcy Code shall be deemed to have assumed all of the obligations arising under this Lease on and after the date of the assignment, and shall upon demand execute and deliver to Landlord an instrument confirming that assumption.

(b) If Tenant desires to transfer an interest in this Lease or the Premises, it shall first notify Landlord of its desire and shall submit in writing to Landlord: (i) the name and address of the proposed transferee; (ii) the nature of any proposed transferee’s business to be carried on in the Premises; (iii) the terms and provisions of any proposed sublease, assignment or other transfer, including a copy of the proposed assignment, sublease or transfer form; (iv) evidence that the proposed assignee, subtenant or transferee will comply with the requirements of Exhibit D hereto; (v) a completed Environmental Questionnaire from the proposed assignee, subtenant or transferee; (vi) any other information requested by Landlord and reasonably related to the transfer and (vii) the fee described in Section 9.1(c). Except as provided in Section 9.1(c), Landlord shall not unreasonably withhold or condition its consent, provided that the parties agree that it shall be reasonable for Landlord to withhold and/or condition its consent if: (1) the use of the Premises will not be consistent with the provisions of this Lease; (2) a proposed subtenant or assignee has not demonstrated to the reasonable satisfaction of Landlord that it is financially responsible or has failed to submit to Landlord all reasonable information as requested by Landlord (following...
execution of a commercially reasonable non-disclosure agreement, if required by the proposed subtenant or assignee) concerning the proposed subtenant or assignee, including, but not limited to, a certified balance sheet of the proposed subtenant or assignee as of a date within one hundred eighty (180) days of the request for Landlord’s consent, statements of income or profit and loss of the proposed subtenant or assignee for the two-year period preceding the request for Landlord’s consent, and/or a certification signed by the proposed subtenant or assignee that it has not been evicted or been in arrears in rent at any other leased premises for the 3-year period preceding the request for Landlord’s consent; (3) the proposed assignee or subtenant is an existing tenant of the Building or Project or a prospect with whom Landlord is actively negotiating to become a tenant at the Building or Project; or (4) the proposed transfer will impose adverse tax effects on Landlord for which Landlord will not be fully compensated. Tenant’s exterior signage rights are personal to Tenant and may not be assigned or transferred to any assignee of this Lease or subtenant of the Premises.

Notwithstanding the foregoing, Tenant may assign its exterior signage rights in connection with an assignment of this Lease or a subletting of more than fifty percent (50%) of the Floor Area of the Premises that is consented to by Landlord or in connection with a Permitted Transfer (as defined below); provided, however, that Landlord shall have the right of prior approval that such signage continues to comply with the Sign Criteria and the other requirements of Section 5.2 of this Lease, and provided further that any name and/or graphics on such signage do not materially devalue the Project as determined by Landlord in its sole and absolute discretion.

If Landlord consents to the proposed transfer, Tenant may within ninety (90) days after the date of the consent effect the transfer upon the terms described in the information furnished to Landlord; provided that any material change in the terms shall be subject to Landlord’s consent as set forth in this Section 9.1. Landlord shall approve or disapprove any requested transfer within fifteen (15) business days following receipt of Tenant’s written request, the information set forth above, and the fee set forth below.

(c) Notwithstanding the provisions of Section 9.1(b) above, in lieu of consenting to a proposed assignment of this Lease or to a proposed subletting of more than fifty percent (50%) of the Floor Area of the Premises for all or substantially all of the then-remaining Term of this Lease, Landlord may elect, within the fifteen (15) business day period permitted for Landlord to approve or disapprove a requested transfer, to (i) sublease the Premises (or the portion proposed to be so subleased), or take an assignment of Tenant’s interest in this Lease, upon substantially the same terms as offered to the proposed subtenant or assignee (excluding terms relating to the purchase of trade fixtures, furniture and equipment, personal property, the use of Tenant’s name or the continuation of Tenant’s business), or (ii) terminate this Lease as to the portion of the Premises proposed to be so subleased or assigned with a proportionate abatement in the rent payable under this Lease in which case Tenant shall have no further liability for Basic Rent or Operating Expenses accruing from and after the effective date of such termination with respect to such portion of the Premises, effective thirty (30) days following written notice by Landlord of its election to so sublease or terminate. Landlord may thereafter, at its option, assign, sublet or re-let any space so sublet, obtained by assignment or obtained by termination to any third party, including without limitation the proposed transferee of Tenant. (d) In the event that Landlord approves the requested assignment or subletting, Tenant agrees that fifty percent (50%) of any amounts actually paid by the assignee or subtenant, however described, in excess of (i) the Basic Rent payable by Tenant hereunder, or in the case of a sublease of a portion of the Premises, in excess of the Basic Rent and Operating Expenses reasonably allocable to such portion as determined by Landlord, plus (ii) Tenant’s direct out-of-pocket costs which Tenant certifies to Landlord have been incurred to provide occupancy related services or other costs to such assignee or subtenant of a nature commonly provided by landlords of similar space (e.g. brokerage commissions, improvement allowances, etc., actually incurred by Tenant), shall be the property of Landlord and such amounts shall be payable directly to Landlord by the assignee or subtenant or, at Landlord’s option, by Tenant within ten (10) days of Tenant’s receipt thereof. Landlord shall have the right to review or audit the books and records of Tenant, or have such books and records reviewed or audited by an outside accountant, to confirm any such direct out-of-pocket costs. In the event that such direct out-of-pocket costs claimed by Tenant are overstated by more than five percent (5%), Tenant shall reimburse Landlord for any of Landlord’s costs related to such review or audit. At Landlord’s request, a commercially reasonable written agreement shall be entered into by and among Tenant, Landlord and the proposed assignee or subtenant confirming the requirements of this Section 9.1(d).

(e) Tenant shall pay to Landlord a fee equal to the greater of (i) Landlord’s actual and reasonable costs related to such assignment, subletting or other transfer or (ii) Five Hundred Dollars ($500.00), to process any request by Tenant for an assignment, subletting or other transfer under this Lease. Tenant shall pay Landlord the sum of Five Hundred Dollars ($500.00) concurrently with Tenant’s request for consent to any assignment, subletting or other transfer, and Landlord shall have no obligation to consider such request unless accompanied by such payment. Tenant shall pay Landlord upon demand any costs in excess of such payment to the extent Landlord’s actual costs related to such request exceeds $500.00. Such fee is hereby acknowledged as a reasonable amount to reimburse Landlord for its costs of review and evaluation of a proposed transfer.

SECTION 9.2. EFFECT OF TRANSFER. Except for a termination elected by Landlord pursuant to Subsection 9.1(c)(ii) above, no subletting or assignment, even with the consent of Landlord, shall relieve Tenant of its obligation to pay rent and to perform all its other obligations under this Lease. Moreover, Tenant shall indemnify and hold Landlord harmless, as provided in Section 10.3, for any act or omission by an assignee or subtenant. Each assignee, other than Landlord, shall assume all obligations of Tenant under this Lease and shall be liable jointly and severally with Tenant for the payment of all rent, and for the due performance of all of Tenant’s obligations, under this Lease. No assignment or subletting shall be effective or binding on Landlord unless documentation in form and
SECTION 9.3. SUBLEASE REQUIREMENTS. The following terms and conditions shall apply to any subletting by Tenant of all or any part of the Premises and shall be deemed included in each sublease:

(a) Except as expressly otherwise agreed by Landlord in its written consent to such sublease, the sublease and/or any subletting by Tenant shall be subject and subordinate to this Lease.

(b) Tenant hereby irrevocably assigns to Landlord all of Tenant’s interest in all rentals and income arising from any sublease of the Premises, and Landlord may collect such rent and income and apply same toward Tenant’s obligations under this Lease during the pendency of any Event of Default; provided, however, that unless there is an uncured Event of Default by Tenant, Tenant shall have the right to receive and collect the sublease rentals. At Tenant’s request, not more frequently than quarterly, Landlord shall supply Tenant with the gross amounts of any such sublease rentals so collected by Landlord to date and the application of such subrentals so collected to amounts then due under the Lease. Landlord shall not, by reason of this assignment or the collection of sublease rentals, be deemed liable to the subtenant for the performance of any of Tenant’s obligations under the sublease. Tenant hereby irrevocably authorizes and directs any subtenant, upon receipt of a written notice from Landlord stating that an uncured Event of Default exists in the performance of Tenant’s obligations under this Lease, to pay to Landlord all sums then and thereafter due under the sublease. Tenant agrees that the subtenant may rely on that notice without any duty of further inquiry and notwithstanding any notice or claim by Tenant to the contrary.

(c) In the event of the termination of this Lease for any reason, including without limitation as the result of an Event of Default by Tenant or by the mutual agreement of Landlord and Tenant, Landlord may, at its sole option, take over Tenant’s entire interest in any sublease and, upon notice from Landlord, the subtenant shall attorn to Landlord. In no event, however, shall Landlord be liable for any previous act or omission by Tenant under the sublease or for the return of any advance rental payments or deposits under the sublease that have not been actually delivered to Landlord, nor shall Landlord be bound by any sublease modification executed without Landlord’s consent or for any advance rental payment by the subtenant in excess of one month’s rent. The general provisions of this Lease, including without limitation those pertaining to insurance and indemnification, shall be deemed incorporated by reference into the sublease despite the termination of this Lease. In the event Landlord does not elect to take over Tenant’s interest in a sublease in the event of any such termination of this Lease, such sublease shall terminate concurrently with the termination of this Lease and such subtenant shall have no further rights under such sublease and Landlord shall have no obligations to such subtenant.

SECTION 9.4. CERTAIN TRANSFERS. The following shall be deemed to constitute an assignment of this Lease: (a) the sale of all or substantially all of Tenant’s assets (other than bulk sales in the ordinary course of business), or (b) the transfer, assignment or hypothecation of any stock or interest in Tenant to a single entity which constitutes more than fifty percent (50%) of Tenant’s voting stock. Notwithstanding the foregoing, Landlord’s consent shall not be required for the assignment of this Lease to: (A) any person(s) or entity who controls, is controlled by or is under common control with Tenant, (B) to any entity resulting from the merger, consolidation or other reorganization with Tenant, whether or not Tenant is the surviving entity, or (C) to any person or legal entity which acquires all or substantially all of the assets or stock of Tenant (each of the foregoing is hereinafter referred to as “Permitted Transfer”), so long as (i) the net worth of the successor or reorganized entity after such Permitted Transfer is at least equal to the net worth of Tenant as of the execution of this Lease by Landlord, evidence of which, reasonably satisfactory to Landlord, shall be presented to Landlord prior to such Permitted Transfer, (ii) Tenant shall provide to Landlord, prior to such Permitted Transfer, written notice of such Permitted Transfer and such assignment documentation and other information as Landlord may reasonably require in connection therewith, and (iii) all of the other terms and requirements Section 9.2 and 9.3 (but not of Section 9.1) shall apply with respect to such assignment. For purposes of this Section 9.4, a public or private offering of Tenant debt or equity shall not be deemed an assignment of this Lease.

ARTICLE X. INSURANCE AND INDEMNITY

SECTION 10.1. TENANT’S INSURANCE. Tenant, at its sole cost and expense, shall provide and maintain in effect the insurance described in Exhibit D. Evidence of that insurance must be delivered to Landlord prior to the Commencement Date.

SECTION 10.2. LANDLORD’S INSURANCE. Landlord shall provide property insurance coverage insuring the full replacement cost of the Building, including all Tenant Improvements constructed pursuant to the attached Work Letter, with or without deductible and in amounts and coverages appropriate and consistent with industry standards as reasonably determined by Landlord and subject to standard exclusions (such as, but not limited to, earthquake and flood exclusions) (the “Property Policy”), and commercial general liability insurance with or without deductible and in amounts and coverages appropriate and consistent with industry standards as reasonably determined by Landlord (the “Liability Policy”). In addition, Landlord may, at its election, obtain insurance for such other risks as Landlord or its mortgages may from time to time deem appropriate in its sole discretion,
including without limitation, coverage for earthquake and flood. Landlord shall not be required to carry insurance of any kind on Tenant’s Alterations or on Tenant’s other property, including, without limitation, Tenant’s trade fixtures, furnishings, equipment, signs and all other items of personal property, and Landlord shall not be obligated to repair or replace that property should damage occur. All proceeds of insurance maintained by Landlord upon the Building and/or Project shall be the property of Landlord, whether or not Landlord is obligated to or elects to make any repairs. At Landlord’s option, Landlord may self-insure all or any portion of the risks for which Landlord is required or elects to provide insurance hereunder; provided, however, that in the event The Irvine Company, or any affiliate thereof, is no longer the “Landlord” under this Lease, such successor Landlord must demonstrate to Tenant a net worth of at least One Hundred Million Dollars ($100,000,000.00) to continue to self-insure such risks.

SECTION 10.3. JOINT INDEMNITY.

(a) To the fullest extent permitted by law, Tenant shall defend, indemnify, protect, save and hold harmless Landlord, its agents, and any and all affiliates of Landlord, including, without limitation, any corporations or other entities controlling, controlled by or under common control with Landlord, from and against any and all claims, liabilities, costs or expenses arising either before or after the Commencement Date from Tenant’s use or occupancy of the Premises, the Building or the Common Areas, or from the conduct of its business, or from any activity, work, or thing done, permitted or suffered by Tenant or its agents, employees, invitees or licensees in or about the Premises, the Building or the Common Areas, or from any act or negligence of Tenant or its agents, employees, invitees or licensees. Tenant shall immediately notify Landlord in case of fire or accident in the Premises or the Building and of matters related to the nature that Landlord had actual knowledge of the condition; or (iii) that is Landlord’s responsibility to indemnify Tenant pursuant to Section 10.3(b) below.

(b) To the fullest extent permitted by law, but subject to the express limitations on liability contained in this Lease, Landlord shall defend, indemnify, protect, save and hold harmless Tenant, its agents and any and all affiliates of Tenant, including without limitation, any corporations, or other entities controlling, controlled by or under common control with Tenant, from and against any and all claims, liabilities, costs or expenses arising either before or after the Commencement Date from Tenant’s conduct of business in the Premises.

SECTION 10.4. LANDLORD’S NONLIABILITY. Subject to the express indemnity obligations contained in Section 10.3(b) of this Lease and such other applicable provisions of this Lease (including, without limitation, Landlord’s right to self-insure pursuant to Section 10.2 above), Landlord shall not be liable to Tenant, its employees, agents and invitees, and Tenant hereby waives all claims against Landlord for personal injury or any other loss, cost, damage, injury or liability whatsoever resulting from fire, explosion, falling plaster, steam, gas, electricity, water or rain which may leak or flow from or into any part of the Premises or from the breakage, leakage, obstruction or other defects of the pipes, sprinklers, wires, appliances, plumbing, air conditioning, electrical works or other fixtures in the Building. Notwithstanding any provision of this Lease to the contrary, including, without limitation, the provisions of Section 10.3(b) of this Lease, Landlord shall in no event be liable to Tenant, its employees, agents, and invitees, and Tenant hereby waives all claims against Landlord, for (i) loss or interruption of Tenant’s business or income (including, without limitation, any consequential damages and lost profit or opportunity costs), or (ii) any other loss, cost, damage, injury or liability resulting from Acts of God (except with respect to restoration obligations pursuant to Article XI below), acts of civil disobedience or insurrection, acts or omissions (criminal or otherwise) of any third parties (other than Landlord’s employees or authorized agents), including without limitation, any other tenants within the Project or their agents, employees, contractors, guests or invitees. It is understood that any such condition may require the temporary evacuation or closure of all or a portion of the Building. Landlord shall have no liability (including without limitation consequential damages and lost profit or opportunity costs) and, except as provided in Sections 6.1, 11.1 and 12.1 below, there shall be no abatement of rent, by reason of any injury to or interference with Tenant’s business arising from the making of any repairs, alterations or improvements to any portion of the Building, including repairs to the Premises, nor shall any related activity by Landlord constitute an actual or constructive eviction; provided, however, that in making repairs, alterations or improvements, Landlord shall interfere as little as reasonably practicable with the conduct of Tenant’s business in the Premises. Should Tenant elect to receive any service or products from a concessioneer, licensee or third party tenant of Landlord, Landlord shall have no liability for any services or products so provided or for any breach of contract by such third party provider. Neither Landlord nor its agents shall be liable for interference with light or other similar intangible interests. Tenant shall immediately notify Landlord in case of fire or accident in the Premises or the Building and of matters related to the condition of the Premises or Building that pose a material threat to the safety or health of persons in or around the Premises or Building.

SECTION 10.5. WAIVER OF SUBROGATION. Notwithstanding anything to the contrary contained in this Lease, Landlord and Tenant each hereby waives all rights of recovery against the other and the other’s agents on account of loss and damage occasioned to the property of such waiving party to the extent that the waiving party is entitled to proceeds for such loss or damage under any property insurance policies carried or required to be carried
by the provisions of this Lease (including, without limitation, the Property Policy carried by Landlord, regardless of whether Landlord self-insures such coverage); provided however, that the foregoing waiver shall not apply to the extent of Tenant’s obligations to pay deductibles under any such policies and this Lease. By this waiver it is the intent of the parties that neither Landlord nor Tenant shall be liable to any insurance company (by way of subrogation or otherwise) insuring the other party for any loss or damage insured against under any property insurance policies contemplated by this Lease, even though such loss or damage might be occasioned by the negligence of such party, its agents, employees, contractors, guests or invitees.

ARTICLE XI. DAMAGE OR DESTRUCTION

SECTION 11.1. RESTORATION.

(a) If the Premises or the Building or a part thereof are materially damaged by any fire, flood, earthquake or other casualty (including but not limited to, the contamination of the Premises and/or the Building by Hazardous Materials not caused or knowingly permitted by Tenant or by any Tenant Party which contamination renders the Premises unsafe for occupancy by Tenant), then Landlord shall have the right to terminate this Lease upon written notice to Tenant if: (i) Landlord reasonably determines that proceeds necessary to pay the full cost of repair is not available from Landlord’s Property Policy (regardless of whether Landlord self-insures such coverage), or from any earthquake insurance carried by Landlord, plus such additional amounts Tenant elects, at its option, to contribute, excluding however the deductible (for which Tenant shall be responsible for Tenant’s Share); (ii) Landlord reasonably determines that the Premises cannot, with reasonable diligence, be fully repaired by Landlord (or cannot be safely repaired because of the presence of hazardous factors, including without limitation Hazardous Materials, earthquake faults, and other similar dangers) within two hundred seventy (270) days after the date of the damage; (iii) an uncured monetary Event of Default by Tenant has occurred; or (iv) the material damage occurs during the final twelve (12) months of the Term. Landlord shall notify Tenant in writing (“Landlord’s Notice”) within sixty (60) days after the damage occurs as to (A) whether Landlord is terminating this Lease as a result of such material damage and (B) if Landlord is not terminating this Lease, the number of days within which Landlord has estimated that the Premises, with reasonable diligence, are likely to be fully repaired. In the event Landlord elects to terminate this Lease, this Lease shall terminate as of the date specified for termination by Landlord’s Notice (which termination date shall in no event be later than sixty (60) days following the date of the damage, or, if no such date is specified, such termination shall be the date of Landlord’s Notice).

(b) If Landlord has the right to terminate this Lease pursuant to Section 11.1(a) and does not elect to so terminate this Lease, and provided that at the time of Landlord’s Notice no uncured monetary Event of Default exists, then within twenty (20) days following delivery of Landlord’s Notice pursuant to Section 11.1(a), Tenant may elect to terminate this Lease by written notice to Landlord, but only if (i) Landlord’s Notice specifies that Landlord has determined that the Premises cannot be repaired, with reasonable diligence, within two hundred seventy (270) days after the date of damage or (ii) the casualty has occurred within the final twelve (12) months of the Term and such material damage has a materially adverse impact on Tenant’s continued use of the Premises. If Tenant fails to provide such termination notice within such twenty (20) day period, Tenant shall be deemed to have waived any termination right under this Section 11.1(b) or any other applicable law.

(c) In the event that neither Landlord nor Tenant terminates this Lease pursuant to this Section 11.1 as a result of material damage to the Building or Premises resulting from a casualty, Landlord shall repair all material damage to the Premises or the Building as soon as reasonably possible and this Lease shall continue in effect for the remainder of the Term. Subject to any provision to the contrary in the Work Letter, such repair by Landlord shall include repair of material damage to the Tenant Improvements constructed pursuant to the Work Letter, so long as insurance proceeds from insurance required to be carried by Tenant are made available to Landlord. Landlord shall have the right, but not the obligation, to repair or replace any other leasehold improvements made by Tenant or any Alterations (as defined in Section 7.3) constructed by Tenant. If Landlord elects to repair or replace such leasehold improvements and/or Alterations, all insurance proceeds available for such repair or replacement shall be made available to Landlord (to the extent expended for such repair and/or replacement by Landlord). Landlord shall have no liability to Tenant in the event that the Premises or the Building has not been fully repaired within the time period specified by Landlord in Landlord’s Notice to Tenant as described in Section 11.1(a). Notwithstanding the foregoing, the repair of damage to the Premises to the extent such damage is not material shall be governed by Sections 7.1 and 7.2.

(d) In the event the Lease is not terminated by Landlord or Tenant as provided in this Article XI, commencing on the date of such material damage to the Building, and ending on the sooner of the date the damage is repaired or the date this Lease is terminated, the Basic Rent and Operating Expenses to be paid under this Lease shall be abated in the same proportion that the Floor Area of the Premises that is rendered unusable by the damage from time to time bears to the total Floor Area of the Premises, as reasonably determined by Landlord, provided that Tenant is then carrying the rental loss insurance required of Tenant pursuant to Exhibit D.

(e) Except as provided in Section 11.1(c), Landlord shall not be required to repair or replace any of Tenant’s furniture, trade fixtures or equipment or any Tenant Improvement or Alteration.

(f) Tenant shall fully cooperate with Landlord in removing Tenant’s personal property and any debris from the Premises to facilitate all inspections of the Premises and the making of any repairs. Notwithstanding anything to the contrary contained in this Lease, if Landlord in good faith believes there is a risk of injury to persons or damage to property from entry into the Building or Premises following any damage or destruction thereto, Landlord may restrict entry into the Building or the Premises by Tenant, its employees, agents and contractors in a
non-discriminatory manner, without being deemed to have violated Tenant’s rights of quiet enjoyment to, or made an unlawful detainer of, or evicted Tenant from, the Premises. Upon request, Landlord shall consult with Tenant to determine if there are safe methods of entry into the Building or the Premises solely in order to allow Tenant to retrieve files, data in computers, and necessary inventory, subject however to all indemnities and waivers of liability from Tenant to Landlord contained in this Lease and any additional indemnities and waivers of liability which Landlord may require.

SECTION 11.2. LEASE GOVERNS. Tenant agrees that the provisions of this Lease, including without limitation Section 11.1, shall govern any damage or destruction and shall accordingly supersede any contrary statute or rule of law.

ARTICLE XII. EMINENT DOMAIN

SECTION 12.1. TOTAL OR PARTIAL TAKING. If all or a material portion of the Building is taken by any lawful authority by exercise of the right of eminent domain, or sold to prevent a taking, either Tenant or Landlord may terminate this Lease effective as of the date possession is required to be surrendered to the authority. For purposes of this Article XII, a material portion of the Building shall be enough that, in Tenant’s good faith judgment, the part of the Building that remains cannot, within a reasonable period of time, be made reasonably suitable for the continued operation of Tenant’s business. In the event title to a portion of the Building or Project, whether or not including a portion of the Premises, is taken or sold in lieu of taking, and if Landlord elects to restore the Building in such a way as to alter the Premises materially, either party may terminate this Lease, by written notice to the other party, effective on the date of vesting of title. In the event neither party has elected to terminate this Lease as provided above, then Landlord shall promptly, after receipt of a sufficient condemnation award, proceed to restore the Premises to substantially their condition prior to the taking, and a proportionate allowance shall be made to Tenant for the Basic Rent and Operating Expenses corresponding to the time during which, and to the part of the Premises of which, Tenant is deprived on account of the taking and restoration. In the event of a taking, Landlord shall be entitled to the entire amount of the condemnation award without deduction for any estate or interest of Tenant; provided that nothing in this Section shall be deemed to give Landlord any interest in, or prevent Tenant from seeking any award against the taking authority for, the taking of personal property and fixtures belonging to Tenant or for relocation or business interruption expenses recoverable from the taking authority.

SECTION 12.2. TEMPORARY TAKING. No temporary taking of the Premises shall terminate this Lease or give Tenant any right to abatement of rent, and any award specifically attributable to a temporary taking of the Premises shall belong entirely to Tenant. A temporary taking shall be deemed to be a taking of the use or occupancy all or any part of the Building for a period of not to exceed thirty (30) days.

SECTION 12.3. TAKING OF PARKING AREA. In the event there shall be a taking of the parking area such that Landlord can no longer provide sufficient parking to comply with this Lease, Landlord may substitute reasonably equivalent parking in a location reasonably close to the Building at no cost to Tenant; provided that if Landlord fails to make that substitution within fifteen (15) days following the taking and if the taking materially impairs Tenant’s use and enjoyment of the Premises, Tenant may, at its option, terminate this Lease by written notice to Landlord. If this Lease is not so terminated by Tenant, there shall be no abatement of rent and this Lease shall continue in effect.

ARTICLE XIII. SUBORDINATION; ESTOPPEL CERTIFICATE; FINANCIALS

SECTION 13.1. SUBORDINATION. At the option of Landlord or any lender of Landlord’s that obtains a security interest in the Building, this Lease shall be either superior or subordinate to all ground or underlying leases, mortgages and deeds of trust, if any, which may hereafter affect the Building, and to all renewals, modifications, consolidations, replacements and extensions thereof; provided, that so long as no Event of Default exists under this Lease, Tenant’s possession and quiet enjoyment of the Premises shall not be disturbed and this Lease shall not terminate in the event of termination of any such ground or underlying lease, or the foreclosure of any such mortgage or deed of trust, to which this Lease has been subordinated pursuant to this Section. Tenant shall execute and deliver any commercially reasonable documents or agreements requested by Landlord or such lessor or lender which provide Tenant with the non-disturbance protections set forth in this Section. In the event of a termination or foreclosure, Tenant shall become a tenant of and attorn to the successor-in-interest to Landlord upon the same terms and conditions as are contained in this Lease, and shall execute any instrument reasonably required by Landlord’s successor for that purpose. Tenant shall also, upon written request of Landlord, execute and deliver all commercially reasonable instruments as may be required from time to time to subordinate the rights of Tenant under this Lease to any ground or underlying lease or to the lien of any mortgage or deed of trust (provided that such instruments include the nondisturbance and attornment provisions set forth above), or, if requested by Landlord, to subordinate, in whole or in part, any ground or underlying lease or the lien of any mortgage or deed of trust to this Lease. Tenant agrees that any purchaser at a foreclosure sale or lender taking title under a deed-in-lieu of foreclosure shall not be responsible for any act or omission of a prior landlord, shall not be subject to any offsets or defenses Tenant may have against a prior landlord, and shall not be liable for the return of the security deposit to the extent it is not actually received by such purchaser or bound by any rent paid for more than the current month in which the foreclosure occurred. Landlord shall use its reasonable diligence to obtain the instrument described in the foregoing from the holder of any ground or underlying lease and/or of any mortgage or deed of trust of record as of the execution of this Lease.
Within sixty (60) days of the execution hereof, as a condition precedent to Tenant’s obligations under this Lease, Landlord shall deliver to Tenant executed and notarized nondisturbance agreements in writing from any lenders whose debt is secured by all or a portion of the Project, in form and content provided for in the applicable underlying financing documents, stating that so long as Tenant is not in default under any of the terms, covenants, conditions, or agreements of this Lease, this Lease and all of the terms, provisions, and conditions of this Lease, shall remain in full force and effect, and neither this Lease, nor Tenant’s rights nor Tenant’s possession of the Premises will be disturbed during the Term of this Lease or any extension thereof. Tenant shall reimburse Landlord for, or shall pay directly, all costs assessed by said lender (in excess of One Thousand Dollars ($1,000.00)) in connection with obtaining such nondisturbance agreement(s).

SECTION 13.2. ESTOPPEL CERTIFICATE.

(a) Tenant shall, at any time upon not less than ten (10) business days prior written notice from Landlord, execute, acknowledge and deliver to Landlord, in any form that Landlord may reasonably require, a statement in writing (i) certifying that this Lease is unmodified and in full force and effect (or, if modified, stating the nature of the modification and certifying that this Lease, as modified, is in full force and effect) and the dates to which the rental, additional rent and other charges have been paid in advance, if any, and (ii) acknowledging that, to Tenant’s knowledge, there are no uncured defaults on the part of Landlord, or specifying each default if any are claimed, and (iii) setting forth all further information regarding this Lease and/or Tenant’s occupancy of the Premises that Landlord or any purchaser or encumbrancer may reasonably require. Tenant’s statement may be relied upon by any prospective purchaser or encumbrancer of all or any portion of the Building or Project.

(b) Notwithstanding any other rights and remedies of Landlord, Tenant’s failure to deliver any estoppel statement required by the provisions of Section 13.2(a) above within the provided time shall be conclusive upon Tenant that (i) this Lease is in full force and effect, without modification except as may be represented by Landlord, (ii) there are no uncured Events of Default in Landlord’s performance, and (iii) not more than one month’s rental (excluding the Security Deposit) has been paid in advance.

SECTION 13.3. FINANCIALS.

(a) Tenant has delivered to Landlord prior to the execution of this Lease, and shall deliver to Landlord at any time upon not less than ten (10) business days prior written notice from Landlord, Tenant’s audited financial statements, including a balance sheet and profit and loss statement for the most recent prior year for which such statements are available (collectively, the “Statements”), which Statements shall accurately and completely reflect the financial condition of Tenant. Landlord agrees that it will keep the Statements confidential, except that Landlord shall have the right to deliver the same to any proposed purchaser of the Building or Project (provided that Landlord shall require that any such proposed purchaser execute a confidentiality agreement, in commercially reasonable form, requiring that the Statement be kept confidential), and to any encumbrancer of all or any portion of the Building or Project (provided that Landlord shall request such encumbrancer to keep such Statements confidential). Notwithstanding the foregoing, in the event Tenant shall become a publicly-traded corporation whose stock is traded on a nationally recognized exchange or on NASDAQ, the “Statements” shall consist of Tenant’s most recently publicly disclosed financial statements.

(b) Tenant acknowledges that Landlord is relying on the Statements in its determination to enter into this Lease, and Tenant represents to Landlord, which representation shall be deemed made on the date of this Lease, that no material adverse change in the financial condition of Tenant, as reflected in the Statements, has occurred since the date Tenant delivered the Statements to Landlord. The Statements are represented and warranted by Tenant to be correct and to accurately and fully reflect Tenant’s true financial condition as of, and for the periods presented in, such Statements provided to Landlord.

ARTICLE XIV. EVENTS OF DEFAULT AND REMEDIES

SECTION 14.1. TENANT’S DEFAULTS. In addition to any other breaches of this Lease which are defined as Events of Default in this Lease, the occurrence of any one or more of the following events shall constitute an Event of Default by Tenant:

(a) The failure by Tenant to make any payment of Basic Rent or additional rent required to be made by Tenant, as and when due, where the failure continues for a period of five (5) days after written notice from Landlord to Tenant; provided, however, that any such notice shall be in lieu of, and not in addition to, any notice required under California Code of Civil Procedure Section 1161 and 1161(a) as amended. For purposes of these Events of Default and remedies provisions, the term “additional rent” shall be deemed to include all amounts of any type whatsoever other than Basic Rent to be paid by Tenant pursuant to the terms of this Lease.

(b) The assignment, sublease, encumbrance or other transfer of this Lease by Tenant, either voluntarily or by operation of law, whether by judgment, execution, transfer by intestacy or testacy, or other means, without the prior written consent of Landlord when consent is required by this Lease.

(c) The discovery by Landlord that any of the Statements provided by Tenant was materially and adversely false.

(d) The failure of Tenant to timely and fully provide any subordination agreement, estoppel certificate or financial statements in accordance with the requirements of Article XIII.
(f) (i) The making by Tenant of any general assignment for the benefit of creditors; (ii) the filing by or against Tenant of a petition to have Tenant adjudged a Chapter 7 debtor under the Bankruptcy Code or to have debts discharged or a petition for reorganization or arrangement under any law relating to bankruptcy (unless, in the case of a petition filed against Tenant, the same is dismissed within sixty (60) days); (iii) the appointment of a trustee or receiver to take possession of substantially all Tenant’s assets located at the Premises or of Tenant’s interest in this Lease, if possession is not restored to Tenant within sixty (60) days; (iv) the attachment, execution or other judicial seizure of substantially all of Tenant’s assets located at the Premises or of Tenant’s interest in this Lease, where the seizure is not discharged within sixty (60) days; or (v) Tenant’s convening of a meeting of its creditors for the purpose of effecting a moratorium upon or composition of its debts. Landlord shall not be deemed to have knowledge of any event described in this Section 14.1(f) unless notification in writing is received by Landlord, nor shall there be any presumption attributable to Landlord of Tenant’s insolvency. In the event that any provision of this Section 14.1(f) is contrary to applicable law, the provision shall be of no force or effect.

SECTION 14.2. LANDLORD’S REMEDIES.

(a) If an Event of Default by Tenant occurs, then in addition to any other remedies available to Landlord, Landlord may exercise the following remedies:

(i) Landlord may terminate Tenant’s right to possession of the Premises by any lawful means, in which case this Lease shall terminate and Tenant shall immediately surrender possession of the Premises to Landlord. Such termination shall not affect any accrued obligations of Tenant under this Lease. Upon termination, Landlord shall have the right to reenter the Premises and remove all persons and property. Landlord shall also be entitled to recover from Tenant:

1. The worth at the time of award of the unpaid Basic Rent and additional rent which had been earned at the time of termination;

2. The worth at the time of award of the amount by which the unpaid Basic Rent and additional rent which would have been earned after termination exceeds the amount of such loss that Tenant proves could have been reasonably avoided;

3. The worth at the time of award of the amount by which the unpaid Basic Rent and additional rent for the balance of the Term after the time of award exceeds the amount of such loss that Tenant proves could be reasonably avoided;

4. Any other amount necessary to compensate Landlord for all the detriment proximately caused by Tenant’s failure to perform its obligations under this Lease or which in the ordinary course of things would be likely to result from Tenant’s Event of Default, including, but not limited to, the cost of recovering possession of the Premises, refurbishment of the Premises, marketing costs, commissions and other expenses of reletting, including necessary repair, the unamortized portion of any tenant improvements and brokerage commissions funded by Landlord in connection with this Lease, reasonable attorneys’ fees, and any other reasonable costs; and

5. The term “rent” as used in the Lease shall be deemed to mean the Basic Rent, Tenant’s Share of Operating Expenses and any other sums required to be paid by Tenant to Landlord pursuant to the terms of this Lease, including, without limitation, any sums that may be owing from Tenant pursuant to Section 4.3 of this Lease. Any sum, other than Basic Rent, shall be computed on the basis of the average monthly amount accruing during the twenty-four (24) month period immediately prior to the Event of Default, except that if it becomes necessary to compute such rental before the twenty-four (24) month period has occurred, then the computation shall be on the basis of the average monthly amount during the shorter period. As used in Sections 14.2(a)(i) (1) and (2) above, the “worth at the time of award” shall be computed by allowing interest at the rate of ten percent (10%) per annum. As used in Section 14.2(a)(i)(3) above, the “worth at the time of award” shall be computed by discounting the amount at the discount rate of the Federal Reserve Bank of San Francisco at the time of award plus one percent (1%).

(ii) Landlord may elect not to terminate Tenant’s right to possession of the Premises, in which event Landlord may continue to enforce all of its rights and remedies under this Lease, including the right to collect all rent as it becomes due. Efforts by the Landlord to maintain, preserve or relet the Premises, or the appointment of a receiver to protect the Landlord’s interests under this Lease, shall not constitute a termination of the Tenant’s right to possession of the Premises. In the event that Landlord elects to avail itself of the remedy provided by this Section 14.2(a)(ii), Landlord shall not unreasonably withhold its consent to an assignment or subletting of the Premises subject to the reasonable standards for Landlord’s consent as are contained in this Lease.
(b) Landlord shall be under no obligation to observe or perform any covenant of this Lease on its part to be observed or performed which accrues after the date of any Event of Default by Tenant unless and until the Event of Default is cured by Tenant, it being understood and agreed that the performance by Landlord of its obligations under this Lease are expressly conditioned upon Tenant’s full and timely performance of its obligations under this Lease. The various rights and remedies reserved to Landlord in this Lease or otherwise shall be cumulative and, except as otherwise provided by California law, Landlord may pursue any or all of its rights and remedies at the same time.

(c) No delay or omission of Landlord to exercise any right or remedy shall be construed as a waiver of the right or remedy of any Event of Default by Tenant. The acceptance by Landlord of rent shall not be a (i) waiver of any preceding Event of Default by Tenant of any provision of this Lease, other than the failure of Tenant to pay the particular rent accepted, regardless of Landlord’s knowledge of the preceding Event of Default at the time of acceptance of rent, or (ii) a waiver of Landlord’s right to exercise any remedy available to Landlord by virtue of the Event of Default. The acceptance of any payment from a debtor in possession, a trustee, a receiver or any other person acting on behalf of Tenant or Tenant’s estate shall not waive or cure an Event of Default under Section 14.1. No payment by Tenant or receipt by Landlord of a lesser amount than the rent required by this Lease shall be deemed to be other than a partial payment on account of the earliest due stipulated rent, nor shall any endorsement or statement on any check or letter be deemed an accord and satisfaction and Landlord shall accept the check or payment without prejudice to Landlord’s right to recover the balance of the rent or pursue any other remedy available to it. No act or thing done by Landlord or Landlord’s agents during the Term shall be deemed an acceptance of a surrender of the Premises, and no agreement to accept a surrender shall be valid unless in writing and signed by Landlord. No employee of Landlord or of Landlord’s agents shall have any power to accept the keys to the Premises prior to the termination of this Lease, and the delivery of the keys to any employee shall not operate as a termination of this Lease or a surrender of the Premises.

SECTION 14.3. LATE PAYMENTS.

(a) Any payment due to Landlord under this Lease, including without limitation Basic Rent, Tenant’s Share of Operating Expenses or any other payment due to Landlord under this Lease, that is not received by Landlord within five (5) days following the date due shall bear interest at the maximum per annum rate of ten percent (10%) not to exceed the rate permitted by law from the date due until fully paid. The payment of interest shall not cure any Event of Default by Tenant under this Lease. In addition, Tenant acknowledges that the late payment by Tenant to Landlord of Basic Rent and Tenant’s Share of Operating Expenses will cause Landlord to incur costs not contemplated by this Lease, the exact amount of which will be extremely difficult and impracticable to ascertain. Those costs may include, but are not limited to, administrative, processing and accounting charges, and late charges which may be imposed on Landlord by the terms of any ground lease, mortgage or trust deed covering the Premises. Accordingly, if any Basic Rent or Tenant’s Share of Operating Expenses due from Tenant shall not be received by Landlord or Landlord’s designee within five (5) days following the date due, then Tenant shall pay to Landlord, in addition to the interest provided above, a late charge, which the Tenant agrees is reasonable, in a sum equal to the greater of five percent (5%) of the amount overdue or Two Hundred Fifty Dollars ($250.00) for each delinquent payment; provided, however, that Landlord shall waive such late fee in connection with the initial late payment by Tenant. Acceptance of a late charge alone by Landlord shall not constitute a waiver of Tenant’s Event of Default with respect to the overdue amount, nor shall it prevent Landlord from exercising any of its other rights and remedies.

(b) Following each second installment of Basic Rent and/or the payment of Tenant’s Share of Operating Expenses within any twelve (12) month period that is not paid within five (5) days following the date due, Landlord shall have the option to require that beginning with the first payment of Basic Rent next due, Basic Rent and the Tenant’s Share of Operating Expenses shall no longer be paid in monthly installments but shall be payable quarterly three (3) months in advance. Should Tenant deliver to Landlord, at any time during the Term, two (2) or more insufficient checks, the Landlord may require that all monies then and thereafter due from Tenant be paid to Landlord by cashier’s check or wire transfer. If any check for any payment to Landlord hereunder is returned by the bank for any reason, such payment shall not be deemed to have been received by Landlord and Tenant shall be responsible for any applicable late charge, interest payment and the charge to Landlord by its bank for such returned check. Nothing in this Section shall be construed to compel Landlord to accept Basic Rent, Tenant’s Share of Operating Expenses or any other payment from Tenant if there exists an Event of Default unless such payment fully cures any and all such Event of Default. Any acceptance of any such payment shall not be deemed to waive any other right of Landlord under this Lease. Any payment by Tenant to Landlord may be applied by Landlord, in its sole and absolute discretion, in any order determined by Landlord to any amounts then due to Landlord.

SECTION 14.4. RIGHT OF LANDLORD TO PERFORM. All covenants and agreements to be performed by Tenant under this Lease shall be performed at Tenant’s sole cost and expense and without any abatement of rent or right of set-off. If Tenant fails to pay any sum of money due under this Lease, other than rent payable to Landlord, or fails to perform any other act on its part to be performed under this Lease, and the failure continues beyond any applicable grace period set forth in Section 14.1, then in addition to any other available remedies, Landlord may, at its election make the payment or perform the other act on Tenant’s part and Tenant hereby grants Landlord the right to enter onto the Premises in order to carry out such performance. Landlord’s election to make the payment or perform the act on Tenant’s part shall not give rise to any responsibility of Landlord to continue making the same or similar payments or performing the same or similar acts nor shall Landlord be responsible to Tenant for any damage caused to Tenant as the result of such performance by Landlord. Tenant shall, promptly upon demand by Landlord, reimburse Landlord for all reasonable sums paid by Landlord and all necessary incidental costs, together with interest at the per annum rate of ten percent (10%) not to exceed the maximum rate permitted by law from the date of the payment by Landlord. Landlord shall provide Tenant with written notice and the appropriate cure period provided in this Lease before performing any act on behalf of Tenant.
SECTION 14.5. DEFAULT BY LANDLORD. Landlord shall not be deemed to be in default in the performance of any obligation under this Lease, and Tenant shall have no rights to take any action against Landlord, unless and until Landlord has failed to perform the obligation within thirty (30) days after written notice by Tenant to Landlord specifying in reasonable detail the nature and extent of the failure; provided, however, that if the nature of Landlord’s obligation is such that more than thirty (30) days are required for its performance, then Landlord shall not be deemed to be in default if it commences performance within the thirty (30) day period and thereafter diligently pursues the cure to completion. In the event of Landlord’s default under this Lease, Tenant’s sole remedies shall be to seek damages or specific performance from Landlord, provided that any damages shall be limited to Tenant’s actual out-of-pocket expenses and shall in no event include any consequential damages, lost profits or opportunity costs; provided, however, if Landlord fails to commence and diligently pursue a cure to its default with respect to an item or condition that threatens the health or safety of persons in or around the Building, Tenant may take all reasonable actions to resolve the issue and seek its actual out-of-pocket damages so incurred against Landlord. Tenant may resort to its sole remedies cumulatively or in the alternative.

SECTION 14.6. EXPENSES AND LEGAL FEES. All sums reasonably incurred by Landlord in connection with any Event of Default by Tenant under this Lease or holding over of possession by Tenant after the expiration or earlier termination of this Lease, or any action related to a filing for bankruptcy or reorganization by Tenant, including without limitation all costs, expenses and actual accountants, appraisers, attorneys and other professional fees, and any reasonable collection agency or other collection charges, shall be due and payable to Landlord on demand, and shall bear interest at the rate of ten percent (10%) per annum not to exceed the maximum rate permitted by law. Should either Landlord or Tenant bring any action in connection with this Lease, the prevailing party shall be entitled to recover as a part of the action its reasonable attorneys’ fees, and all other reasonable costs. The prevailing party for the purpose of this Section shall be determined by the trier of the facts.

SECTION 14.7. WAIVER OF JURY TRIAL. LANDLORD AND TENANT EACH ACKNOWLEDGES THAT IT IS AWARE OF AND HAS HAD THE ADVICE OF COUNSEL OF ITS CHOICE WITH RESPECT TO ITS RIGHTS TO TRIAL BY JURY, AND EACH PARTY DOES HEREBY EXPRESSLY AND KNOWINGLY WAIVE AND RELEASE ALL SUCH RIGHTS TO TRIAL BY JURY IN ANY ACTION, PROCEEDING OR COUNTERCLAIM BROUGHT BY EITHER PARTY HERETO AGAINST THE OTHER (AND/OR AGAINST ITS OFFICERS, DIRECTORS, EMPLOYEES, AGENTS, OR SUBSIDIARY OR AFFILIATED ENTITIES) ON ANY MATTERS WHATSOEVER ARISING OUT OF OR IN ANY WAY CONNECTED WITH THIS LEASE, TENANT’S USE OR OCCUPANCY OF THE PREMISES, AND/OR ANY CLAIM OF INJURY OR DAMAGE. FURTHERMORE, THIS WAIVER AND RELEASE OF ALL RIGHTS TO A JURY TRIAL IS DEEMED TO BE INDEPENDENT OF EACH AND EVERY OTHER PROVISION, COVENANT, AND/OR CONDITION SET FORTH IN THIS LEASE.

SECTION 14.8. SATISFACTION OF JUDGMENT. The respective obligations of Landlord and Tenant do not constitute the personal obligations of the individual partners, trustees, directors, officers or shareholders of Landlord or Tenant, respectively or their constituent partners. Should Tenant recover a money judgment against Landlord, such judgment shall be satisfied only from the interest of Landlord in the Project and out of the rent or other income from such property receivable by Landlord or out of consideration received by Landlord from the sale or other disposition of all or any part of Landlord’s right, title or interest in the Project and no action for any deficiency may be sought or obtained by Tenant. The provisions of the foregoing sentence shall not apply, however, to: (i) proceeds from insurance coverage required of Landlord pursuant to Section 10.2 of this Lease, (ii) Landlord’s obligation to carry insurance coverage pursuant to Section 10.2 to the extent that Landlord elects to “self-insure” such coverage, and (iii) Landlord’s obligation to fund the Access Control Allowance, the Floor Surface Allowance and/or the Landlord’s Contribution (as defined in the Work Letter) pursuant to the applicable provisions of this Lease.

ARTICLE XV. END OF TERM

SECTION 15.1. HOLDING OVER. This Lease shall terminate without further notice upon the expiration of the Term, and any holding over by Tenant after the expiration shall not constitute a renewal or extension of this Lease, or give Tenant any rights under this Lease, except when in writing signed by both parties. Any period of time following the Expiration Date or earlier termination of this Lease required for Tenant to remove its property or to place the Premises in the condition required pursuant to Section 15.3 (or for Landlord to do so if Tenant fails to do so) shall be deemed a holding over by Tenant. If Tenant holds over for any period after the Expiration Date (or earlier termination) of the Term without the prior written consent of Landlord, such possession shall constitute a tenancy at sufferance only and an Event of Default under this Lease; such holding over with the prior written consent of Landlord shall constitute a month-to-month tenancy commencing on the first (1st) day following the termination of this Lease and terminating thirty (30) days following delivery of written notice of termination by either Landlord or Tenant to the other. In either of such events, possession shall be subject to all of the terms of this Lease, except that for the initial two (2) months of holdover the monthly Basic Rent shall be one hundred fifty percent (150%) of the Basic Rent for the month immediately preceding the date of termination, and thereafter the monthly Basic Rent shall be the greater of (a) one hundred fifty percent (150%) of the Basic Rent for the month immediately preceding the date of termination or (b) the then currently scheduled Basic Rent for comparable space in the Project. The acceptance by Landlord of monthly holdover rental in a lesser amount shall not constitute a waiver of Landlord’s right to recover the full amount due for any holdover by Tenant, unless otherwise agreed in writing by Landlord. If Tenant fails to surrender the Premises upon the expiration of this Lease
Despite demand to do so by Landlord, Tenant shall indemnify and hold Landlord harmless from all loss or liability, including without limitation, any claims made by any preceding tenant relating to such failure to surrender. The foregoing provisions of this Section are in addition to and do not affect Landlord’s right of re-entry or any other rights of Landlord under this Lease or at law.

SECTION 15.2. MERGER ON TERMINATION. The voluntary or other surrender of this Lease by Tenant, or a mutual termination of this Lease, shall terminate any or all existing subleases unless Landlord, at its option, elects in writing to treat the surrender or termination as an assignment to it of any or all subleases affecting the Premises.

SECTION 15.3. SURRENDER OF PREMISES; REMOVAL OF PROPERTY. Subject to the provisions of 7.3 of this Lease, upon the Expiration Date or upon any earlier termination of this Lease, Tenant shall quit and surrender possession of the Premises to Landlord in as good order, condition and repair as of the date of substantial completion of the Tenant Improvements by Tenant or as hereafter may be improved by Landlord or Tenant, reasonable wear and tear, casualty and repairs which are Landlord’s obligation excepted, and shall, without expense to Landlord, remove or cause to be removed from the Premises all personal property, trade fixtures (including, without limitation, laboratory benches and equipment and the Generators) and debris, except for any items that Landlord may by written authorization allow to remain. Tenant shall repair all damage to the Premises resulting from the removal, which repair shall include the restoration of all electrical and plumbing facilities caused by such removal, the patching and filling of holes and repair of structural damage, provided that Landlord may instead elect to repair any structural damage and the reasonable costs thereof shall be reimbursed by Tenant. If Tenant shall fail to comply with the provisions of this Section, Landlord may effect the removal and/or make any repairs, and the cost to Landlord shall be additional rent payable by Tenant upon demand. If Tenant fails to remove Tenant’s personal property from the Premises upon the expiration of the Term, Landlord may remove, store, dispose of and/or retain such personal property, at Landlord’s option, in accordance with then applicable laws, all at the expense of Tenant. If requested by Landlord following the Expiration Date or earlier termination of this Lease, Tenant shall execute, acknowledge and deliver to Landlord an instrument in writing releasing and quitclaiming to Landlord all right, title and interest of Tenant in the Premises.

ARTICLE XVI. PAYMENTS AND NOTICES

All sums payable by Tenant to Landlord shall be deemed to be rent under this Lease and shall be paid, without deduction or offset, except as expressly provided in this Lease, in lawful money of the United States to Landlord at its address set forth in Item 12 of the Basic Lease Provisions, or at any other place as Landlord may designate in writing. Unless this Lease expressly provides otherwise, as for example in the payment of Basic Rent and the Tenant’s Share of Operating Expenses pursuant to Sections 4.1 and 4.2, all payments shall be due and payable within five (5) business days after demand. All payments requiring proration shall be prorated on the basis of a thirty (30) day month and a three hundred sixty (360) day year. Any notice, election, demand, consent, approval or other communication to be given or other document to be delivered by either party to the other may be delivered in person or by courier or overnight delivery service to the other party, addressed to the other party at the address set forth in Item 12 of the Basic Lease Provisions. Either party may, by written notice to the other, served in the manner provided in this Article, designate a different address. If more than one person or entity is named as Tenant under this Lease, service of any notice upon any one of them shall be deemed as service upon all of them.

ARTICLE XVII. RULES AND REGULATIONS

Tenant agrees to observe faithfully and comply strictly with the Rules and Regulations, attached as Exhibit E (the “Rules and Regulations”), and any reasonable and nondiscriminatory amendments, modifications and/or additions as may be adopted and published by written notice to tenants by Landlord for the safety, care, security, good order, or cleanliness of the Premises, Building, Project and Common Areas, provided that such additional rules and regulations do not materially decrease Tenant’s rights under this Lease or materially increase Tenant’s obligations under this Lease. Landlord shall use its commercially reasonable efforts to apply the Rules and Regulations uniformly and on a non-discriminatory basis, but Landlord shall not be liable to Tenant for any violation of the Rules and Regulations or the breach of any covenant or condition in any lease by any other tenant or such tenant’s agents, employees, contractors, guests or invitees. One or more waivers by Landlord of any breach of the Rules and Regulations by Tenant or by any other tenant(s) shall not be a waiver of any subsequent breach of that rule or any other. Tenant’s failure to keep and observe the Rules and Regulations, following written notice from Landlord and Tenant’s failure to cure pursuant to the applicable provisions of Section 14.1 above, shall constitute an Event of Default. In the case of any conflict between the Rules and Regulations and this Lease, this Lease shall be controlling.

ARTICLE XVIII. BROKER’S COMMISSION

The parties recognize as the broker(s) who negotiated this Lease the firm(s), if any, whose name(s) is (are) stated in Item 10 of the Basic Lease Provisions, and agree that Landlord shall be responsible for the payment of brokerage commissions to those broker(s) unless otherwise provided in this Lease. Tenant warrants that it has had no dealings with any other real estate broker or agent in connection with the negotiation of this Lease, and Tenant agrees to indemnify and hold Landlord harmless from any cost, expense or liability (including reasonable attorneys’ fees) for any compensation, commissions or charges claimed by any other real estate broker or agent employed or claiming to represent or to have been employed by Tenant in connection with the negotiation of this Lease. The foregoing agreement shall survive the termination of this Lease.
ARTICLE XIX. TRANSFER OF LANDLORD'S INTEREST

In the event of any transfer of Landlord’s interest in the Premises, and the transferee’s assumption of the obligations of the Landlord arising from and after the effective date of such transfer, the transferor shall be automatically relieved of all further obligations on the part of Landlord, (but shall not be relieved of any obligations or liabilities arising during its ownership of such interest in the Building or Project) and the transferor shall be relieved of any obligation to pay any funds in which Tenant has an interest to the extent that such funds have been turned over, subject to that interest, to the transferee and Tenant is notified of the transfer as required by law. No beneficiary of a deed of trust to which this Lease is or may be subordinate, and no landlord under a so-called sale-leaseback, shall be responsible in connection with the Security Deposit, unless the mortgagee or beneficiary under the deed of trust or the landlord actually receives the Security Deposit. It is intended that the covenants and obligations contained in this Lease on the part of Landlord shall, subject to the foregoing, be binding on Landlord, its successors and assigns, only during and in respect to their respective successive periods of ownership.

ARTICLE XX. INTERPRETATION

SECTION 20.1. GENDER AND NUMBER. Whenever the context of this Lease requires, the words “Landlord” and “Tenant” shall include the plural as well as the singular, and words used in neuter, masculine or feminine genders shall include the others.

SECTION 20.2. HEADINGS. The captions and headings of the articles and sections of this Lease are for convenience only, are not a part of this Lease and shall have no effect upon its construction or interpretation.

SECTION 20.3. JOINT AND SEVERAL LIABILITY. If more than one person or entity is named as Tenant, the obligations imposed upon each shall be joint and several and the act of or notice from, or notice or refund to, or the signature of, any one or more of them shall be binding on all of them with respect to the tenancy of this Lease, including, but not limited to, any renewal, extension, termination or modification of this Lease.

SECTION 20.4. SUCCESSORS. Subject to Articles IX and XIX, all rights and liabilities given to or imposed upon Landlord and Tenant shall extend to and bind their respective heirs, executors, administrators, successors and assigns. Nothing contained in this Section is intended, or shall be construed, to grant to any person other than Landlord and Tenant and their successors and assigns any rights or remedies under this Lease.

SECTION 20.5. TIME OF ESSENCE. Time is of the essence with respect to the performance of every provision of this Lease.

SECTION 20.6. CONTROLLING LAW/VENUE. This Lease shall be governed by and interpreted in accordance with the laws of the State of California. Any litigation commenced concerning any matters whatsoever arising out of or in any way connected to this Lease shall be initiated in the Superior Court of the county in which the Project is located.

SECTION 20.7. SEVERABILITY. If any term or provision of this Lease, the deletion of which would not adversely affect the receipt of any material benefit by either party or the deletion of which is consented to by the party adversely affected, shall be held invalid or unenforceable to any extent, the remainder of this Lease shall not be affected and each term and provision of this Lease shall be valid and enforceable to the fullest extent permitted by law.

SECTION 20.8. WAIVER AND CUMULATIVE REMEDIES. One or more waivers by Landlord or Tenant of any breach of any term, covenant or condition contained in this Lease shall not be a waiver of any subsequent breach of the same or any other term, covenant or condition. Consent to any act by one of the parties shall not be deemed to render unnecessary the obtaining of that party’s consent to any subsequent act. No breach by either party of this Lease shall be deemed to have been waived by the other party unless the waiver is in a writing signed by such party. Subject to the express limitations and restrictions contained in this Lease, the rights and remedies of Landlord and Tenant under this Lease shall be cumulative and in addition to any and all other rights and remedies which such party may have.

SECTION 20.9. INABILITY TO PERFORM. In the event that either party shall be delayed or hindered in or prevented from the performance of any work or in performing any act required under this Lease by reason of any cause beyond the reasonable control of that party, other than financial inability, then the performance of the work or the doing of the act shall be excused for the period of the delay and the time for performance shall be extended for a period equivalent to the period of the delay. The provisions of this Section shall not operate to excuse Tenant from the prompt payment of rent, or either party from the timely performance of any of their respective obligations under this Lease within such party’s reasonable control.

SECTION 20.10. ENTIRE AGREEMENT. This Lease and its exhibits and other attachments cover in full each and every agreement of every kind between the parties concerning the Premises, the Building, and the Project, and all preliminary negotiations, oral agreements, understandings and/or practices, except those contained in this Lease, are superseded and of no further effect. Tenant waives its rights to rely on any representations or promises made by Landlord or others which are not contained in this Lease. No verbal agreement or implied covenant shall be held to modify the provisions of this Lease, any statute, law, or custom to the contrary notwithstanding.
SECTION 20.11. QUIET ENJOYMENT. Upon the observance and performance of all the covenants, terms and conditions on Tenant’s part to be observed and performed, and subject to the other provisions of this Lease, Tenant shall have the right of quiet enjoyment and use of the Premises for the Term without hindrance or interruption by Landlord or any other person claiming by or through Landlord.

SECTION 20.12. SURVIVAL. All covenants of Landlord or Tenant which reasonably would be intended to survive the expiration or sooner termination of this Lease, including without limitation any warranty or indemnity hereunder, shall so survive and continue to be binding upon and inure to the benefit of the respective parties and their successors and assigns.

SECTION 20.13. INTERPRETATION. This Lease shall not be construed in favor of or against either party, but shall be construed as if both parties prepared this Lease.

ARTICLE XXI. EXECUTION AND RECORDING

SECTION 21.1. COUNTERPARTS. This Lease may be executed in one or more counterparts, each of which shall constitute an original and all of which shall be one and the same agreement.

SECTION 21.2. CORPORATE, LIMITED LIABILITY COMPANY AND PARTNERSHIP AUTHORITY. The parties hereto represent and warrant that they are duly authorized to execute and deliver this Lease, and that this Lease is binding in accordance with its terms. If this Lease is not signed by two officers as provided in California Corporations Code Section 313, Tenant shall, at Landlord’s request, deliver a certified copy of its board of directors’ resolution, operating agreement or partnership agreement or certificate authorizing or evidencing the execution of this Lease.

SECTION 21.3. EXECUTION OF LEASE; NO OPTION OR OFFER. The submission of this Lease to Tenant shall be for examination purposes only, and shall not constitute an offer to or option for Tenant to lease the Premises. Execution of this Lease by Tenant and its return to Landlord shall not be binding upon Landlord, notwithstanding any time interval, until Landlord has in fact executed and delivered this Lease to Tenant, it being intended that this Lease shall only become effective upon execution by Landlord and delivery of a fully executed counterpart to Tenant.

SECTION 21.4. RECORDING. Tenant shall not record this Lease without the prior written consent of Landlord. Tenant, upon the request of Landlord, shall execute and acknowledge a “short form” memorandum of this Lease for recording purposes.

SECTION 21.5. AMENDMENTS. No amendment or termination of this Lease shall be effective unless in writing signed by authorized signatories of Tenant and Landlord, or by their respective successors in interest. No actions, policies, oral or informal arrangements, business dealings or other course of conduct by or between the parties shall be deemed to modify this Lease in any respect.

SECTION 21.6. EXECUTED COPY. Any fully executed photocopy or similar reproduction of this Lease shall be deemed an original for all purposes.

SECTION 21.7. ATTACHMENTS. All exhibits, amendments, riders and addenda attached to this Lease are hereby incorporated into and made a part of this Lease.

ARTICLE XXII. MISCELLANEOUS

SECTION 22.1. NONDISCLOSURE OF LEASE TERMS. Tenant acknowledges and agrees that the terms of this Lease are confidential and constitute proprietary information of Landlord. Disclosure of the terms could adversely affect the ability of Landlord to negotiate other leases and impair Landlord’s relationship with other tenants. Accordingly, Tenant agrees that it, and its partners, officers, directors, employees and attorneys, shall not intentionally and voluntarily disclose, by public filings or otherwise, the terms and conditions of this Lease (“Confidential Information”) to any third party, either directly or indirectly, without the prior written consent of Landlord, which consent may be given or withheld in Landlord’s sole and absolute discretion. The foregoing restriction shall not apply if either: (i) Tenant is required to disclose the Confidential Information in response to a subpoena or other regulatory, administrative or court order, (ii) independent legal counsel to Tenant advises that Tenant is required to disclose the Confidential Information to, or file a copy of this Lease with, any governmental agency or any stock exchange; provided however, that in such event, Tenant shall, before making any such disclosure (A) provide Landlord with prompt written notice of such required disclosure, (B) at Tenant’s sole cost, take all commercially reasonable steps to resist or narrow such requirement, including without limitation preparing and filing a request for confidential treatment of the Confidential Information and (C) if disclosure of the Confidential Information is required by subpoena or other regulatory, administrative or court order, Tenant shall provide Landlord with as much advance notice of the possibility of such disclosure as practical so that Landlord may attempt to stop such disclosure or obtain an order concerning such disclosure. In addition, Tenant may disclose the terms of this Lease to prospective assignees of this Lease and prospective subtenants under this Lease with whom Tenant is actively negotiating such an assignment or sublease. Notwithstanding anything to the contrary, the restrictions contained in this Section 22.1 shall not apply to the filing of this Lease with the Securities and Exchange Commission in connection with any public offering of securities.

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SECTION 22.3. CHANGES REQUESTED BY LENDER. If, in connection with obtaining financing for the Project, the lender shall request reasonable modifications in this Lease as a condition to the financing, Tenant will not unreasonably withhold or delay its consent, provided that the modifications do not materially increase the obligations nor materially decrease the rights of Tenant, or materially and adversely affect the leasehold interest created by this Lease.

SECTION 22.4. MORTGAGEE PROTECTION. No act or failure to act on the part of Landlord which would otherwise entitle Tenant to be relieved of its obligations hereunder shall result in such a release or termination unless (a) Tenant has given notice by registered or certified mail to any beneficiary of a deed of trust or mortgage covering the Building whose address has been furnished to Tenant and (b) such beneficiary is afforded a reasonable opportunity to cure the default by Landlord (which in no event shall be less than sixty (60) days), including, if necessary to effect the cure, time to obtain possession of the Building by power of sale or judicial foreclosure provided that such foreclosure remedy is diligently pursued. Tenant agrees that each beneficiary of a deed of trust or mortgage covering the Building is an express third party beneficiary hereof, Tenant shall have no right or claim for the collection of any deposit from such beneficiary or from any purchaser at a foreclosure sale unless such beneficiary or purchaser shall have actually received and not refunded the deposit, and Tenant shall comply with any written directions by any beneficiary to pay rent due hereunder directly to such beneficiary without determining whether a default exists under such beneficiary’s deed of trust.

SECTION 22.5. [Intentionally Deleted]

SECTION 22.6. SECURITY MEASURES. Tenant hereby acknowledges that Landlord shall have no obligation whatsoever to provide guard service or other security measures for the benefit of the Premises or the Project. Tenant assumes all responsibility for the protection of Tenant, its employees, agents, invitees and property from acts of third parties. Nothing herein contained shall prevent Landlord, at its sole option, from providing security protection for the Project or any part thereof, in which event the reasonable cost thereof shall be included within the definition of Project Costs.

LANDLORD:

THE IRVINE COMPANY

By: /s/ William R. Halford
William R. Halford
President, Office Properties

By: /s/ Steven M. Case
Steven M. Case, Senior Vice President
Leasing, Office Properties

TENANT:

PROMETHEUS LABORATORIES INC.,
a California corporation

By: /s/ Joseph M. Limber
Joseph M. Limber
President and Chief Executive Officer

By: /s/ Michael V. Swanson
Michael V. Swanson
Vice President, Finance
and Chief Financial Officer
SCHEDULE A

Landlord's Work

Landlord shall repair and/or replace the following items located in or around the Building and Premises, insuring that such items are in good operating condition:

1. Central plant
   a. Cooling tower system, loop chemistry and flow performance – Complete, subject to Note 1 below
   b. Boiler controls, burners and ignition integrity - Complete, subject to Note 1 below
      i. Chiller System #1 – Complete, subject to Note 1 below
      ii. Chiller System #2 – Landlord shall replace with a 180-ton Turbocor McQuay chiller system. Chiller System #2 shall be installed as the “Lead Chiller System”– To be completed within sixteen (16) weeks of Lease execution
   c. All circulating pumps - Complete, subject to Note 1 below
   d. Controls – Landlord has installed a new Siemens Control Panel. All points have been tested & verified. Complete, subject to Note 1 below.

2. Building
   a. Air handlers drives/fans and controllers - Complete, subject to Note 1 below
   b. VAV distribution boxes performance and integrity in Existing Office Areas – Complete, subject to Note 1 below
   c. Reheat coils in Existing Office Areas - Complete, subject to Note 1 below
   d. Siemens Building Automation control system including a new computer & printer, software, supporting documentation including, but not limited to, programming printout with point locations and setpoints, loop control performance integrity in existing office areas - To be completed within four (4) weeks of Lease execution, subject to Note 1 below
   e. ADA Compliance Work as follows, to be completed within eight (8) weeks of Lease Execution:
      i. Lower grab bars in all handicapped stalls. Includes lowering flushometers and wall tile repair
      ii. Lower coat hooks. Plugs will be inserted into removed screw holes
      iii. Add U-shaped pulls
      iv. Lower feminine napkin dispensers. Screw holes to be patched
      v. Add deck-mounted soap dispensers
      vi. Adjust drinking fountains if required.

3. Premises
   a. Provide functional trash/recycle container storage enclosures as set forth in Exhibit F – To be completed by July 30, 2005
   b. Provide functional Hazardous Materials storage enclosures as set forth in Exhibit F – To be completed by July 30, 2005

Note 1 – Landlord shall provide written notice of completion of these items after execution and delivery of the Lease. To ensure that the Premises’ existing HVAC system (consisting of the items in Section 1 above except for Chiller System #2 and the items in Section 2(a)-(d) above and referred to herein as the “Existing HVAC System”) is complete, Landlord shall run the Existing HVAC System for a 72-hour period to verify stable temperature control. Upon the successful completion of this test, Landlord may notify Tenant that the Existing HVAC System is complete. Should the Existing HVAC System fail to remain in good operating condition during the forty-five (45) day period after such written notice, Landlord shall repair this system, provide written notice that it is in good operating condition, and the forty-five (45) day period shall start over.

Schedule A to the Lease
THE FIRST AMENDMENT (the “Amendment”) is made and entered into as of January 25, 2010, by and between THE IRVINE COMPANY LLC, a Delaware limited liability company, (”Landlord”) and PROMETHEUS LABORATORIES INC., a California corporation (“Tenant”).

RECITALS

A. Landlord (formerly known as The Irvine Company, a Delaware corporation) and Tenant are parties to that certain lease dated June 22, 2005 (the “Lease”). Pursuant to the Lease, Landlord has leased to Tenant space currently containing approximately 99,041 rentable square feet (the “Original Premises”) described as the 1st floor of the building located at 9410 Carroll Park Drive, San Diego, California (the “Building”).

B. Tenant has requested that additional space containing approximately 11,000 rentable square feet on the mezzanine level (the “Mezzanine”) of the Building shown on Exhibit A hereto (the “Expansion Space”) be added to the Original Premises and that the Lease be appropriately amended and Landlord is willing to do the same on the following terms and conditions.

NOW, THEREFORE, in consideration of the above recitals which by this reference are incorporated herein, the mutual covenants and conditions contained herein and other valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Landlord and Tenant agree as follows:

I. Expansion and Effective Date. Effective as of November 1, 2009 (the “Expansion Effective Date”), the Premises, as defined in the Lease, is increased from 99,041 rentable square feet on the 1st floor to 110,041 rentable square feet on the 1st floor and the Mezzanine level by the addition of the Expansion Space, and from and after the Expansion Effective Date, the Original Premises and the Expansion Space, collectively, shall be deemed the Premises, as defined in the Lease. The Term for the Expansion Space shall commence on the Expansion Effective Date and end on the Expiration Date (i.e., December 31, 2012). The Expansion Space is subject to all the terms and conditions of the Lease except as expressly modified herein and Tenant shall not be entitled to receive any allowances, abatements or other financial concessions granted with respect to the Original Premises or the Expansion Space, except as set forth herein or in the Lease.

II. Basic Rent. In addition to Tenant’s obligation to pay Basic Rent for the Original Premises, Tenant shall pay Landlord Basic Rent for the Expansion Space as follows:

<table>
<thead>
<tr>
<th>Months of Term or Period</th>
<th>Monthly Rate Per Square Foot</th>
<th>Monthly Basic Rent</th>
</tr>
</thead>
<tbody>
<tr>
<td>11/1/09 – 12/31/09</td>
<td>$0.52</td>
<td>$5,720.00</td>
</tr>
<tr>
<td>1/1/10 – 12/31/10</td>
<td>$0.535</td>
<td>$5,885.00</td>
</tr>
<tr>
<td>1/1/11 – 12/31/11</td>
<td>$0.55</td>
<td>$6,050.00</td>
</tr>
<tr>
<td>1/1/12 – 12/31/12</td>
<td>$0.565</td>
<td>$6,215.00</td>
</tr>
</tbody>
</table>

All such Basic Rent shall be payable by Tenant in accordance with the terms of the Lease.

III. Project Costs and Property Taxes. For the period commencing on the Expansion Effective Date and ending on the Expiration Date, Tenant shall be obligated to pay Tenant’s Share of Property Taxes accruing in connection with the Expansion Space in accordance with the Lease. For the purposes of clarity, Tenant shall be responsible for the payment of supplemental Property Taxes assessed, if any, solely with respect to the addition of the square footage in the Expansion Space and not for any other improvements. Landlord represents and warrants that no other tenant in the Project has expanded its space during the term of this Lease for which Tenant has been assessed additional charges. Landlord acknowledges and agrees that if, in the future, any other tenant in the Project expands its space, Tenant shall not be responsible for any supplemental taxes or charges due to such expansion.

IV. Additional Security Deposit. No additional security deposit shall be required in connection with this Amendment.

V. Improvements to Expansion Space.

A. Condition of Expansion Space. Tenant has inspected the Expansion Space and agrees to accept the same “as is” without any agreements, representations, understandings or obligations on the part of Landlord to perform any alterations, repairs or improvements, except as may be expressly provided otherwise in this Amendment.

B. Any construction, alterations or improvements to the Expansion Space shall be performed by Tenant at its sole cost and expense using contractors selected by Tenant and approved by Landlord and shall be governed in all respects by the provisions of Section 7.3 of the Lease. Landlord, to the best of the actual knowledge of the on-site project manager, Mark Breeden, has no actual knowledge of any failure of Tenant to comply with the terms and provisions contained therein. Nothing contained herein shall be deemed a representation by Landlord that Tenant has fully complied with Section 7.3 of the Lease.
VI. Parking. Tenant shall not be entitled to any additional parking spaces in connection with the Expansion Space.

VII. SDN List. Tenant hereby represents and warrants that, to the best of its knowledge, neither Tenant nor any officer, director, controlling or managing partner, member or other principal of Tenant (collectively, “Tenant Parties”) is listed as a Specially Designated National and Blocked Person (“SDN”) on the list of such persons and entities issued by the U.S. Treasury Office of Foreign Assets Control (OFAC).

VIII. Other Pertinent Provisions. Landlord and Tenant agree that, effective as of the date of this Amendment (unless different effective date(s) is/are specifically referenced in this Section), the Lease shall be amended in the following additional respects:

A. Restoration of Expansion Space. Upon Landlord’s request, Tenant shall restore the Expansion Space on or prior to the Expiration Date to its original condition, reasonable wear and tear excepted. Tenant’s out-of-pocket costs for such restoration shall not exceed $100,000.00. Notwithstanding the foregoing, in the event Tenant renews the Lease for a minimum of 3 years following the Expiration Date, Tenant’s restoration obligation set forth herein shall be waived.

B. Payment and Notice. Landlord’s addresses for payment of rent and notices in accordance with Article I, Item 13 (Basic Lease Provisions) shall be deleted in their entirety and the following substituted in lieu thereof:

“Payment Address:
The Irvine Company LLC
Department #6421
Los Angeles, CA 90084-6421

Notice Address:
The Irvine Company LLC
9171 Towne Center Drive, Suite 140
San Diego, Ca 92122
Attn: Property Manager
with a copy of notices to:
THE IRVINE COMPANY LLC
P.O. Box 6370
Newport Beach, CA 92658-6370
Attn: Vice President, Operations,
Office Properties/San Diego”

IX. GENERAL.

A. Effect of Amendments. The Lease shall remain in full force and effect except to the extent that it is modified by this Amendment.

B. Entire Agreement. This Amendment and the Lease embody the entire understanding between Landlord and Tenant and can be changed only by a writing signed by Landlord and Tenant. There have been no additional oral or written representations or agreements. Under no circumstances shall Tenant be entitled to any rent abatement, improvement allowance, leasehold improvements, or any similar economic incentives that may have been provided Tenant in connection with entering into the Lease, unless specifically set forth in this Amendment.

C. Counterparts. If this Amendment is executed in counterparts, each is hereby declared to be an original; all, however, shall constitute but one and the same amendment. In any action or proceeding, any photographic, photostatic, or other copy of this Amendment may be introduced into evidence without foundation.

D. Defined Terms. All words commencing with initial capital letters in this Amendment and defined in the Lease shall have the same meaning in this Amendment as in the Lease, unless they are otherwise defined in this Amendment.

E. Authority. If Tenant is a corporation, limited liability company or partnership, or is comprised of any of them, each individual executing this Amendment for the corporation, limited liability company or partnership represents that he or she is duly authorized to execute and deliver this Amendment on behalf of such entity and that this Amendment is binding upon such entity in accordance with its terms.
F. **Attorneys’ Fees**. The provisions of the Lease respecting payment of attorneys’ fees shall also apply to this Amendment.

G. **Execution of Amendment**. Submission of this Amendment by Landlord is not an offer to enter into this Amendment but rather is a solicitation for such an offer by Tenant. Neither party shall be bound by this Amendment until the parties have executed and delivered the same to the other party.

H. **Nondisclosure of Terms**. Tenant hereby acknowledges that the provisions of Section 22.1 of the Lease (Nondisclosure of Lease Terms) is hereby restated and in full force and effect relative to the terms and conditions of this Amendment and any other subsequent amendment, agreement, or other modification of the Lease.

**IN WITNESS WHEREOF**, Landlord and Tenant have duly executed this Amendment as of the day and year first above written.

**LANDLORD:**

THE IRVINE COMPANY LLC,
a Delaware limited liability company

By: /s/ Steven M. Case

Steven M. Case
Executive Vice President Office Properties

By: /s/ Michael T. Bennett

Michael T. Bennett
Senior Vice President, Operations Office Properties

**TENANT:**

PROMETHEUS LABORATORIES INC.,
a California corporation

By: /s/ Joseph M. Limber

Printed Name: Joseph M. Limber
Title: President & CEO

By: /s/ Mark E. Spring

Printed Name: Mark E. Spring
Title: Sr VP Finance & CFO

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SECOND AMENDMENT

THIS SECOND AMENDMENT (the “Amendment”) is made and entered into as of October 5, 2011, by and between THE IRVINE COMPANY LLC, a Delaware limited liability company (“Landlord”), and PROMETHEUS LABORATORIES, INC., a California corporation (“Tenant”).

RECITALS

A. Landlord (formerly known as The Irvine Company, a Delaware corporation) and Tenant are parties to that certain lease dated Jun 22, 2005 (“Original Lease”), which lease has been previously amended by a First Amendment dated January 25, 2010 (“First Amendment”, the Original Lease, as amended by the First Amendment, the “Lease”). Pursuant to the Lease, Landlord has leased to Tenant space currently containing approximately 110,041 rentable square feet (the “Premises”) described as the 1st floor and the mezzanine level of the building located at 9410 Carroll Park Drive, San Diego, California (the “Building”).

B. The Lease by its terms shall expire on December 31, 2012 (“Prior Expiration Date”), and the parties desire to extend the Term of the Lease, all on the following terms and conditions.

NOW, THEREFORE, in consideration of the above recitals which by this reference are incorporated herein, the mutual covenants and conditions contained herein and other valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Landlord and Tenant agree as follows:

I. Extension. The Term of the Lease is hereby extended and shall expire on December 31, 2017 (“Extended Expiration Date”), unless sooner terminated in accordance with the terms of the Lease. That portion of the Term commencing the day immediately following the Prior Expiration Date (“Extension Date”) and ending on the Extended Expiration Date shall be referred to herein as the “Extended Term”.

II. Basic Rent. As of the Extension Date, the schedule of Basic Rent payable with respect to the Premises during the Extended Term is the following:

<table>
<thead>
<tr>
<th>Months of Term or Period</th>
<th>Monthly Rate Per Square Foot</th>
<th>Monthly Basic Rent</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/1/13 – 12/31/13</td>
<td>$0.80</td>
<td>$88,033.00</td>
</tr>
<tr>
<td>1/1/14 – 12/31/14</td>
<td>$0.84</td>
<td>$92,434.00</td>
</tr>
<tr>
<td>1/1/15 – 12/31/15</td>
<td>$0.87</td>
<td>$95,736.00</td>
</tr>
<tr>
<td>1/1/16 – 12/31/16</td>
<td>$0.91</td>
<td>$100,137.00</td>
</tr>
<tr>
<td>1/1/17 – 12/31/17</td>
<td>$0.95</td>
<td>$104,539.00</td>
</tr>
</tbody>
</table>

All such Basic Rent shall be payable by Tenant in accordance with the terms of the Lease.

III. Building Costs and Property Taxes. For the period commencing on the Extension Date and ending on the Extended Expiration Date, Tenant shall be obligated to pay Tenant’s Share of Operating Expenses accruing in connection with the Premises in accordance with the terms of the Lease.

IV. Additional Security Deposit. Provided that no Event of Default has occurred under any provision of the Lease, then effective as of the Extension Date, the Security Deposit held by Landlord as provided under Section 4.3 of the Lease as security for payment of rent and the performance of the other terms and conditions of the Lease by Tenant shall be reduced from $123,108.00 to $0.00. Landlord shall return to Tenant the Security Deposit in the amount of $123,108.00 within thirty (30) days after the Extension Date.

V. Improvements to Premises.

A. Condition of Premises. Tenant is in possession of the Premises and accepts the same “as is” without any agreements, representations, understandings or obligations on the part of Landlord to perform any alterations, repairs or improvements, except as may be expressly provided otherwise in this Amendment or the Lease.

B. Tenant Improvements. Effective as of the Extension Date Tenant shall be permitted to construct the Tenant Improvements for the Premises in accordance with the provisions of Exhibit A, Work Letter, attached hereto (“Work Letter”) and may utilize the Landlord Contribution as set forth in the Work Letter.

VI. Parking. Effective as of the Extension Date, Tenant shall continue to be entitled to 278 unreserved parking spaces in accordance with Section 6.4 of the Lease.

VII. SDN List. Tenant hereby represents and warrants that neither Tenant nor any officer, director, employee, partner, member or other principal of Tenant (collectively, “Tenant Parties”) is listed as a Specially Designated National and Blocked Person (“SDN”) on the list of such persons and entities issued by the U.S. Treasury Office of Foreign Assets Control (OFAC). In the event
Tenant or any Tenant Party is or becomes listed as an SDN, Tenant shall be deemed in breach of this Lease and Landlord shall have the right to terminate the Lease immediately upon written notice to Tenant.

VIII. Other Pertinent Provisions. Landlord and Tenant agree that, effective as of the date of this Amendment (unless different effective date(s) is/are specifically referenced in this Section), the Lease shall be amended in the following additional respects:

A. Removal and Restoration. Notwithstanding any contrary provisions in the Lease, Tenant, shall not be required to remove or restore (i) the improvements existing within the Premises as of the date of the full and final execution of this Amendment or (ii) the Tenant Improvements (as defined in Exhibit A of this Amendment), if and to the extent approved in accordance with the terms and conditions set forth in Exhibit A of this Amendment, upon the earlier termination or expiration of this Lease, as amended.

B. Alterations. Effective as of the Extension Date, Section 7.3 (Alterations) shall be amended by deleting the reference to “$50,000.00” in the second sentence and substituting “$60,000.00” in lieu thereof. In addition, Landlord agrees that Tenant shall not be responsible for the 5% supervision/management fee in connection with Cosmetic Alterations and further, Cosmetic Alterations, as defined, shall not be subject to the $60,000.00 annual limit of Alterations not requiring the consent of Landlord, however, they shall be included in the summary of Alterations made without Landlord’s consent as required by Section 7.3. As used herein, “Cosmetic Alterations” includes installing or replacing carpeting (or other types of flooring), or applying or touching up paint.

C. Right to Extend. Tenant shall have an additional one time right to extend the Term of the Lease for an additional sixty (60) month period beyond the Expiration Date, pursuant and subject to the terms and conditions of Section 3.3 (Right to Extend this Lease) of the Lease; except that such right shall be exercised, if at all, not less than nine (9) and not more than twelve (12) months prior to the Extended Expiration Date.

D. Right of First Offer. Provided that no Event of Default has occurred under the Lease, Landlord hereby grants Tenant a right (“First Right”) to lease, during the initial Extended Term each of (i) approximately 23,455 rentable square feet of office space known as Suite No. 100, and/or (ii) approximately 18,351 rentable square feet of office space known as Suite No. 150 in the building located at 9339 Carroll Park Drive, San Diego, California and shown on Exhibit A hereto (each, “First Right Space”) in accordance with and subject to the provisions of this Section; provided that this First Right shall cease to be effective during the final 12 months of the Extended Term unless and until Tenant exercises its extension option set forth in Section VIII.C above (or is then negotiating alternate terms for the extension of the Lease). Except as otherwise provided below, prior to leasing each First Right Space, or any portion thereof, to any other party during the period that this First Right is in effect and after determining that the existing tenant in the applicable First Right Space will not extend or renew the term of its lease, Landlord shall give Tenant written notice of the basic economic terms including but not limited to the Basic Rent, term, operating expense base, security deposit, and tenant improvement allowance (collectively, the “Economic Terms”), upon which Landlord is willing to lease such particular First Right Space to Tenant or to a third party; provided that the Economic Terms shall exclude brokerage commissions and other Landlord payments that do not directly inure to the tenant’s benefit. Further, if the First Right is exercised by Tenant during the first eighteen (18) months of the Extended Term, Tenant shall not be required to provide any security deposit if (i) Tenant is not then otherwise required to provide any security deposit with respect to the then current Premises, and (ii) Tenant’s net worth at the time the First Right is exercised is not less than 90% of its net worth as of the date hereof. If Tenant exercises any First Right during the initial 18 months of the Extended Term, the term for the applicable First Right Space shall be for a term equal to the then unexpired portion of the Term of the Lease and the Economic Terms shall be upon the same economic terms as the original Premises leased hereunder (including without limitation, the applicable Monthly Rate per square foot as set forth in Section II above). If Landlord intends to lease other office space in addition to the First Right Space as part of a single transaction, then Landlord’s notice shall so provide and all such space shall collectively be subject to the provisions of this Section VIII.D. Within 5 business days after receipt of Landlord’s notice, Tenant must give Landlord written notice pursuant to which Tenant shall elect to (i) lease all, but not less than all, of the space specified in Landlord’s notice (the “Designated Space”) upon such Economic Terms and the same non-Economic Terms as set forth in this Lease; (ii) refuse to lease the Designated Space, specifying that such refusal is not based upon the Economic Terms, but upon Tenant’s lack of need for the Designated Space, in which event Landlord may lease the Designated Space upon any terms it deems appropriate; or (iii) refuse to lease the Designated Space, specifying that such refusal is based upon said Economic Terms, in which event Tenant shall also specify revised Economic Terms upon which Tenant shall be willing to lease the Designated Space. In the event that Tenant does not so respond in writing to Landlord’s notice within said period, Tenant shall be deemed to have elected clause (ii) above. In the event Tenant gives Landlord notice pursuant to clause (iii) above, Landlord may elect to either (x) lease the Designated Space to Tenant upon such
revised Economic Terms and the same other non-Economic Terms as set forth in this Lease, or (y) lease the Designated Space to any third party upon Economic Terms which are not materially more favorable to such party than those Economic Terms proposed by Tenant. Should Landlord so elect to lease the Designated Space to Tenant (or if Tenant exercises its right under Section VIII.D(i) above), then Landlord shall promptly prepare and deliver to Tenant an amendment to this Lease consistent with the foregoing, and Tenant shall execute and return same to Landlord within 10 days. If either Tenant or Landlord fails to timely deliver such amendment the other party may specifically enforce their respective rights hereunder, and/or to pursue any other available legal remedy. Notwithstanding the foregoing, it is understood that Tenant’s First Right shall be subject to those certain extension or expansion rights previously granted by Landlord to any third party tenant in the Building, and Landlord shall in no event be obligated to initiate this First Right prior to leasing any portion of the First Right Space to the then-current occupant thereof. Tenant’s rights under this Section shall be personal to the original Tenant named in this Lease and may not be assigned or transferred (except in connection with a Permitted Transfer of this Lease as described in Section 9.4 of the Lease). Any other attempted assignment or transfer shall be void and of no force or effect. Tenant’s election not to lease any Designated Space relating to one First Right Space shall not waive, limit, alter, or impair Tenant’s First Right with respect to the other First Right Space.

E. Deleted Provision. Section VIII.A of the First Amendment (Restoration of Expansion Space) shall be deleted in its entirety and of no further force and effect.

IX. GENERAL.

A. Effect of Amendments. The Lease shall remain in full force and effect except to the extent that it is modified by this Amendment.

B. Entire Agreement. This Amendment embodies the entire understanding between Landlord and Tenant and can be changed only by a writing signed by Landlord and Tenant. There have been no additional oral or written representations or agreements. Under no circumstances shall Tenant be entitled to any rent abatement, improvement allowance, leasehold improvements, or any similar economic incentives that may have been provided Tenant in connection with entering into the Lease, unless specifically set forth in this Amendment.

C. Counterparts. If this Amendment is executed in counterparts, each is hereby declared to be an original; all, however, shall constitute but one and the same amendment. In any action or proceeding, any photographic, photostatic, or other copy of this Amendment may be introduced into evidence without foundation.

D. Defined Terms. All words commencing with initial capital letters in this Amendment and defined in the Lease shall have the same meaning in this Amendment as in the Lease, unless they are otherwise defined in this Amendment.

E. Authority. If Tenant is a corporation, limited liability company or partnership, or is comprised of any of them, each individual executing this Amendment for the corporation, limited liability company or partnership represents that he or she is duly authorized to execute and deliver this Amendment on behalf of such entity and that this Amendment is binding upon such entity in accordance with its terms.

F. Attorneys’ Fees. The provisions of the Lease respecting payment of attorneys’ fees shall also apply to this Amendment.

G. Execution of Amendment. Submission of this Amendment by Landlord is not an offer to enter into this Amendment but rather is a solicitation for such an offer by Tenant. Landlord shall not be bound by this Amendment until Landlord has executed and delivered the same to Tenant.

H. Nondisclosure of Terms. Tenant hereby acknowledges that the provisions of Section 22.1 of the Lease (Nondisclosure of Lease Terms) are hereby restated in full force and effect relative to the terms and conditions of this Amendment and any other subsequent amendment, agreement, or other modification of the Lease (as well as the Lease itself).

(SIGNATURES TO FOLLOW ON NEXT PAGE)
IN WITNESS WHEREOF, Landlord and Tenant have duly executed this Amendment as of the day and year first above written.

LANDLORD:

THE IRVINE COMPANY LLC,
a Delaware limited liability company

By: /s/ Douglas G. Holte
Douglas G. Holte
President
Office Properties

By: /s/ Jeanne M. Lazar
Jeanne M. Lazar
Senior Vice President, Finance
Office Properties

TENANT:

PROMETHEUS LABORATORIES, INC.,
a California corporation

By: /s/ JOSEPH M. LIMBER
Printed Name: JOSEPH M. LIMBER
Title: PRESIDENT & CEO

By: /s/ William Franzblau
Printed Name: William Franzblau
Title: Secretary
I. TENANT IMPROVEMENTS

The tenant improvement work ("Tenant Improvements") shall consist of any work required to complete the Premises pursuant to approved plans and specifications. Tenant shall employ its own architect and general contractor in constructing the Tenant Improvements, subject to Landlord's reasonable prior approval. Notwithstanding the foregoing, if the Tenant Improvement work requires a permit from the City of San Diego, then the general contractor shall be selected and engaged by Tenant on the basis of a competitive bid involving 3 pre-selected general contractors reasonably approved by Landlord and Tenant. The Tenant Improvement work shall be completed by the general contractor with the lowest bid. The work shall be undertaken and prosecuted in accordance with the following requirements (provided that, to the extent Tenant elects to perform Tenant Improvements without applying the Landlord Contribution (defined below) to the payment of such Tenant Improvements, then (except with respect to Tenant's right to apply the Landlord Contribution towards the Basic Rent Credit as set forth below) this Work Letter shall not apply, and Section 7.3 of the Lease shall be solely applicable to such Tenant Improvements, which shall constitute Alterations for all purposes thereunder):

A. Concurrently with approval being granted by Tenant, the space plans, construction drawings and specifications for all improvements and finishes, together with any changes thereto for the Tenant Improvements, shall be submitted to Landlord (with samples as required) for review and approval by Landlord and its architect for the Project (as described in Article I of the Lease). In lieu of disapproving an item, Landlord may approve same on the condition that Tenant pay to Landlord, prior to the start of construction and in addition to all sums otherwise due hereunder, an amount equal to the cost, as reasonably estimated by Landlord, of removing and replacing the item upon the expiration or termination of the Lease. Should Landlord approve work that would necessitate any ancillary Building modification or other expenditure by Landlord, then except to the extent of any remaining balance of the "Landlord Contribution", Tenant shall, in addition to its other obligations herein, promptly fund the cost thereof to Landlord.

B. All construction drawings prepared by Tenant's architect shall follow Landlord’s CAD standards, which standards shall be provided to Tenant or its architect upon request.

C. Tenant shall use the electrical, mechanical, plumbing and fire/life safety engineers and subcontractors designated by Landlord. All other subcontractors shall be subject to Landlord’s reasonable approval.

D. Tenant shall deliver to Landlord a copy of the final application for permit and issued permit for the construction work, if any.

E. Tenant’s general contractor and each of its subcontractors shall comply with Landlord’s requirements as generally imposed on third party contractors, including without limitation all insurance coverage requirements and the obligation to furnish appropriate certificates of insurance to Landlord prior to commencement of construction.

F. A construction schedule shall be provided to Landlord prior to commencement of the construction work, and weekly updates shall be supplied during the progress of the work.

G. Tenant shall give Landlord 10 days prior written notice of the commencement of construction so that Landlord may cause an appropriate notice of non-responsibility to be posted.

H. Tenant and its general contractor shall attend weekly job meetings with Landlord’s construction manager for the Project.

I. Upon substantial completion of the work, Tenant shall cause to be provided to Landlord (i) as-built drawings of the Premises signed by Tenant’s architect, (ii) CAD files of the improved space compatible with Landlord’s CAD standards, (iii) a final punchlist signed by Tenant, (iv) final and unconditional lien waivers from all contractors and subcontractors, (v) a duly recorded Notice of Completion of the improvement work, and (vi) a certificate of occupancy for the Premises (collectively, the "Close-out Package"). Should Tenant fail to provide complete CAD files compatible with Landlord’s standards as required herein, Landlord may cause its architect to prepare same and the cost thereof shall be reimbursed to Landlord by Tenant within ten (10) days of invoice therefor.
K. The work shall be prosecuted at all times in accordance with all state, federal and local laws, regulations and ordinances, including without limitation all OSHA and other safety laws.

L. All of the provisions of the Lease shall apply to any activity of Tenant, its agents and contractors, in the Premises prior to the Extension Date, except for the obligation of Tenant to pay rent.

M. Notwithstanding anything herein to the contrary, Jones Lang Lasalle is hereby approved by Landlord to act as Tenant’s construction manager with respect to the Tenant Improvements.

Landlord shall not be liable in any way for any injury, loss or damage which may occur to any work performed by Tenant, nor shall Landlord be responsible for repairing any defective condition therein. In no event shall Tenant’s failure to complete the Tenant Improvements extend the Commencement Date of the Lease.

II. COST OF THE WORK

A. On the Extension Date, Landlord shall provide to Tenant a tenant improvement allowance in the amount of $550,205.00 (the “Landlord Contribution”), with any excess cost to be borne solely by Tenant. The Landlord Contribution shall also be utilized to fund space planning and other architectural costs (including the reasonable cost charged by Landlord’s architect to review Tenant’s drawings and CAD files), construction costs, plan check and permit fees, and fees to Tenant’s construction manager. It is understood that Landlord shall be entitled to a supervision/administrative fee equal to 5% of such costs, which fee shall be paid from the Landlord Contribution; provided, however, if Landlord reasonably determines a permit from the City of San Diego is not required for the Tenant Improvement work, Tenant shall not be liable for such supervision/administrative fee. Notwithstanding the foregoing, Tenant may utilize the Landlord Contribution toward (i) the out-of-pocket expenses incurred by Tenant for furniture, fixtures and equipment (“FF&E Allowance”), or (ii) the next then due Basic Rent (“Basic Rent Credit”), and subsequent months (if applicable) until such amount is exhausted; provided Tenant delivers written notice to Landlord on or prior to March 31, 2013 of its election to apply such Landlord Contribution to the next then due Basic Rent. Should Tenant utilize the Landlord Contribution, or any portion thereof, for the FF&E Allowance, Tenant shall be reimbursed for such expenses by submitting copies of all supporting third-party invoices to Landlord by December 31, 2013. If Tenant elects to utilize any portion of the Landlord Contribution towards FF&E, Landlord shall reimburse Tenant in one installment for the FF&E Allowance within 30 days following receipt of all such invoices. Tenant understands and agrees that any portion of the Landlord Contribution, including the FF&E Allowance and/or the Basic Rent Credit, not utilized by Tenant by December 31, 2013, shall inure to the benefit of Landlord and Tenant shall not be entitled to any credit or payment.

B. Landlord shall fund the Landlord Contribution (less deductions for the above-described supervision fee and charges of Landlord’s architect) in installments as and when costs are incurred and a payment request therefor is submitted by Tenant. Each payment request shall include a copy of all supporting invoices, conditional progress payment lien waivers (in the form prescribed by the California Civil Code) for labor and materials incorporated in such payment request, unconditional lien waivers (in the form prescribed by the California Civil Code) for labor and materials on the basis of which payment has previously been by Landlord, and pertinent back-up (including copies of Tenant’s payment checks to its contractors and suppliers). Landlord shall fund the payment request within 30 days following receipt of the application and supporting materials; provided that a 10% retention shall be held on payments to Tenant until Landlord receives the complete Close-out Package. The remaining balance of the Landlord Contribution shall be funded when Landlord receives the complete Close-out Package. Prior to any payment by Landlord hereunder, Tenant shall provide to Landlord in writing the address to which such payment is to be delivered, together with a complete copy of the construction contract(s) for the Tenant Improvements.
THIRD AMENDMENT

THIS THIRD AMENDMENT (the “Amendment”) is made and entered into as of January 19th 2012, by and between THE IRVINE COMPANY LLC, a Delaware limited liability company (“Landlord”), and PROMETHEUS LABORATORIES INC., a California corporation (“Tenant”).

RECIPIALS

A. Landlord (formerly known as The Irvine Company, a Delaware corporation) and Tenant are parties to that certain lease dated June 22, 2005 (“Original Lease”), which lease has been previously amended by a First Amendment dated January 25, 2010 (“First Amendment”) and a Second Amendment dated October 5, 2011 (“Second Amendment”), (the Original Lease, as amended by the First Amendment and Second Amendment, is hereinafter referred to as the Lease”). Pursuant to the Lease, Landlord has leased to Tenant space currently containing approximately 110,041 rentable square feet (the “Original Premises”) described as the 1st floor and the mezzanine level of the building located at 9410 Carroll Park Drive, San Diego, California (the “9410 Building”).

B. Tenant has requested that additional space containing approximately 41,782 rentable square feet of space, described as the entire building located at 9449 Carroll Park Drive, San Diego, California, (the “9449 Building”) as shown on Exhibit A hereto (the “9449 Expansion Space”), be added to the Original Premises. A portion of the 9449 Expansion Space shall be used by Tenant to conduct its business operations (such portion, “9449 Office Space”), and the balance of the 9449 Expansion Space shall be used as storage space only (such portion, the “9449 Storage Space”).

C. The Lease by its terms is scheduled to expire on December 31, 2017 (“Original Premises Expiration Date”) with respect to the Original Premises, and the parties desire to extend the Term of the Lease as to the 9449 Expansion Space only.

D. Landlord and Tenant have agreed to amend the Lease to reflect the foregoing and other modifications to the Lease, subject and pursuant to the following terms and conditions.

NOW, THEREFORE, in consideration of the above recitals which by this reference are incorporated herein, the mutual covenants and conditions contained herein and other valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Landlord and Tenant agree as follows:

I. 9449 Expansion Effective Date.

A. Effective as of June 1, 2012, subject to adjustment as set forth below (the “9449 Expansion Effective Date”) Landlord shall deliver sole and exclusive possession of the 9449 Expansion Space to Tenant, and upon such delivery: (i) the Original Premises, as defined in the Lease, is increased from 110,041 rentable square feet to 151,823 rentable square feet; and (ii) except as otherwise expressly set forth in this Amendment, the Original Premises and the 9449 Expansion Space, collectively, shall be deemed the “Premises” and the 9410 Building and the 9449 Building, collectively shall be deemed the “Building” (each as defined in and for all purposes under the Lease and this Amendment). With respect to the 9449 Expansion Space only, the Term shall commence on the 9449 Expansion Effective Date and end on the 9449 Expansion Expiration Date (hereinafter defined). During the Term as it so applies, the 9449 Expansion Space is subject to all the terms and conditions of the Lease (as modified hereby) except as expressly stated to the contrary herein and except that any allowances, abatements or other financial concessions granted with respect to the Original Premises shall not apply to the 9449 Expansion Space; provided that the foregoing shall not limit any such concessions which are expressly provided for herein with respect to the 9449 Expansion Space or expressly provided for in the Lease with respect to the Original Premises. For avoidance of doubt, the generality of the immediately previous sentence shall not be limited as a result of any provision of this Amendment which expressly confirms that certain provisions of the Lease shall be applicable to the 9449 Expansion Space.

B. The 9449 Expansion Effective Date shall be delayed to the extent that Landlord fails to deliver possession of the 9449 Expansion Space for any reason, including but not limited to, holding over by prior occupants. Any such delay in the 9449 Expansion Effective Date shall not subject Landlord to any liability for any loss or damage resulting therefrom.

II. Extension. The Term of the Lease, as it applies to the 9449 Expansion Space only, is hereby extended and shall expire on May 31, 2020 ("9449 Extended Expiration Date"), unless sooner terminated in accordance with the terms of the Lease or extended pursuant to the terms of this Amendment. That portion of the Term commencing the day immediately following the Original Premises Expiration Date (as such date may be extended pursuant to Section VII D below) and ending on the 9449 Extended Expiration Date shall be referred to herein as the “9449 Extended Term”. During the 9449 Extended Term, the Original Premises shall no longer be deemed to be a part of the “Premises” and the 9410 Building shall no longer be deemed to be a part of the “Building” (each as used in the Lease or this Amendment), and Tenant shall have no further obligations under the Lease or this Amendment with respect to the Original Premises unless specifically set forth therein.

1
Notwithstanding the foregoing, at all times during the Term, for purposes of Articles XI and XII of the Lease only, the term “Premises” shall be deemed not to be a collective reference to both of the Original Premises and the 9449 Expansion Space, and the term “Building” shall be deemed not to be a collective reference to each of the 9410 Building and the 9449 Building; for avoidance of doubt, in the event any damage, destruction, or taking occurs with respect to any of the 9410 Building or the 9449 Building (or any respective portions thereof, including any portion of the Premises located therein), the provisions of Article XI and/or Article XII, as applicable, shall apply solely to the applicable “Building” or portion of the Premises within such Building.

III. **Basic Rent for 9449 Expansion Space From and After the 9449 Expansion Effective Date.** From and after the 9449 Expansion Effective Date, Tenant shall pay Basic Rent with respect to the 9449 Expansion Space pursuant to the following “Basic Rent Schedules”:

With respect to the 9449 Office Space only:

<table>
<thead>
<tr>
<th>Months of Term or Period</th>
<th>Monthly Rate Per Rentable Square Foot</th>
<th>Minimum Monthly Basic Rent* *(assuming 24,000 rsf, and subject to adjustment as described in this Amendment)</th>
</tr>
</thead>
<tbody>
<tr>
<td>9449 Expansion Effective Date — 5/31/13</td>
<td>$0.80</td>
<td>$19,200.00</td>
</tr>
<tr>
<td>6/1/13-5/31/14</td>
<td>$0.84</td>
<td>$20,160.00</td>
</tr>
<tr>
<td>6/1/14-5/31/15</td>
<td>$0.87</td>
<td>$20,880.00</td>
</tr>
<tr>
<td>6/1/15-5/31/16</td>
<td>$0.91</td>
<td>$21,840.00</td>
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<tr>
<td>6/1/16-5/31/17</td>
<td>$0.95</td>
<td>$22,800.00</td>
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<tr>
<td>6/1/17-5/31/18</td>
<td>$1.00</td>
<td>$24,000.00</td>
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<tr>
<td>6/1/18-5/31/19</td>
<td>$1.04</td>
<td>$24,960.00</td>
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<tr>
<td>6/1/19-5/31/20</td>
<td>$1.09</td>
<td>$26,160.00</td>
</tr>
</tbody>
</table>

With respect to the 9449 Storage Space only:

<table>
<thead>
<tr>
<th>Months of Term or Period</th>
<th>Monthly Rate Per Rentable Square Foot</th>
<th>Maximum Monthly Basic Rent* *(assuming 17,782 rsf, and subject to adjustment as described in this Amendment)</th>
</tr>
</thead>
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<tr>
<td>9449 Expansion Effective Date — 5/31/13</td>
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</tr>
<tr>
<td>6/1/13-5/31/14</td>
<td>$0.42</td>
<td>$7,468.00</td>
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<tr>
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<td>6/1/16-5/31/17</td>
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<td>$8,535.00</td>
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<td>6/1/17-5/31/18</td>
<td>$0.50</td>
<td>$8,891.00</td>
</tr>
<tr>
<td>6/1/18-5/31/19</td>
<td>$0.52</td>
<td>$9,247.00</td>
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<tr>
<td>6/1/19-5/31/20</td>
<td>$0.54</td>
<td>$9,602.00</td>
</tr>
</tbody>
</table>

All such Basic Rent shall be otherwise payable by Tenant in accordance with the terms of the Lease. Notwithstanding anything to the contrary in this Amendment, other than as it may be abated in accordance with this Amendment, Basic Rent for the 9449 Office Space shall not be less than the “Minimum Monthly Basic Rent” set forth in the 9449 Office Space Basic Rent Schedule above, and Basic Rent for the 9449 Storage Space shall not be more than the “Maximum Monthly Basic Rent” set forth in the 9449 Storage Space Basic Rent Schedule above, regardless of whether Tenant elects to configure the 9449 Expansion Space with less than 24,000 rentable square feet of 9449 Office Space or more than 17,782 rentable square feet of 9449 Storage Space. In the event Tenant elects to utilize more than 24,000 rentable square feet of the Premises as office space, the Minimum Monthly Basic Rent shall increase accordingly.
IV. Building Costs and Property Taxes. 9449 Expansion Space From Expansion Effective Date Through 9449 Extended Expiration Date. Tenant shall be obligated to pay Tenant’s Share of Project Costs and Property Taxes accruing in connection with the 9449 Expansion Space in accordance with the terms of the Lease through the 9449 Extended Expiration Date. With respect to the 9449 Expansion Space, Tenant’s Share for the Project is 39.12%.

V. Additional Security Deposit. No security deposit shall be required in connection with this Amendment.

VI. Improvements to 9449 Expansion Space.

A. Condition of 9449 Expansion Space. Tenant has inspected the 9449 Expansion Space and agrees to accept the same “as is” without any agreements, representations, understandings or obligations on the part of Landlord to perform any alterations, repairs or improvements, except as may be expressly provided otherwise in this Amendment.

B. Any construction, alterations or improvements to the 9449 Expansion Space shall be performed by Tenant at its sole cost and expense using contractors selected by Tenant and reasonably approved by Landlord and shall be governed in all other respects by the provisions of Section 7.3 of the Lease, except that Tenant shall not be required to remove or replace any such construction, alterations, or improvements unless same: (i) are Non-Standard Improvements; or (ii) are a skylight, vertical shaft, or an addition to the 9449 Building, and at the time Landlord grants its approval for same, Landlord notifies Tenant that it shall be required to remove same on the 9449 Extended Expiration Date.

C. Landlord warrants to Tenant that the windows and seals, roof and heat pumps serving the 9449 Expansion Space (collectively, the “9449 Systems”) are in good working order as of the 9449 Expansion Effective Date. Provided that, if Tenant shall notify Landlord within 12 months following the 9449 Expansion Effective Date that any of the 9449 Systems are not in good working order and such condition is not caused by the negligence or willful misconduct of Tenant Parties, then such 9449 Systems shall be either replaced or repaired by Landlord such that they are in good operating condition (except that Tenant shall have 24 months following the 9449 Expansion Effective Date to notify Landlord of any such issues related to heat pumps). Any such compliance work required for the above, whether discovered prior to acceptance of the 9449 Expansion Space or during Tenant’s tenant improvement work, may be performed by Landlord concurrently with Tenant’s tenant improvement work (but shall not unreasonably interfere therewith) and such costs shall be at Landlord’s sole expense and shall not be included within Operating Expenses. In addition, Landlord warrants to Tenant that the fire sprinkler system, lighting, heating, ventilation and air conditioning systems and electrical systems serving the 9449 Expansion Space (“Other 9449 Systems”) shall be in good operating condition as of the day the 9449 Expansion Space are delivered to Tenant, and Tenant shall have thirty (30) days following the 9449 Expansion Effective Date to notify Landlord that any of the 9449 Systems are not in good working order; and provided that such condition is not caused by the negligence or willful misconduct of Tenant Parties, Landlord shall promptly repair or replace any such Other 9449 Systems at its sole cost and expense which shall not be included within Operating Expenses (and otherwise subject to the same conditions as set forth above for compliance work related to the 9449 Systems).

VII. Other Pertinent Provisions. Landlord and Tenant agree that, effective as of the date of this Amendment (unless different effective dates are specifically referenced in this Section), the Lease shall be amended in the following additional respects:

A. Parking. Notwithstanding any contrary provision in Section 6.4 (Parking) of the Lease, (i) effective as of the 9449 Expansion Effective Date, Landlord shall lease to Tenant, and Tenant shall lease from Landlord, an additional one hundred-sixty (160) unreserved parking spaces at the 9449 Building, at no additional cost to Tenant through the 9449 Extended Expiration Date.

B. SDN List. Tenant hereby represents and warrants that neither Tenant nor any officer, director, employee, partner, member or other principal of Tenant (collectively, “Tenant Parties”) is listed as a Specially Designated National and Blocked Person (“SDN”) on the list of such persons and entities issued by the U.S. Treasury Office of Foreign Assets Control. In the event Tenant or any Tenant Party is or becomes listed as an SDN, Tenant shall be deemed in breach of this Lease and Landlord shall have the right to terminate the Lease immediately upon written notice to Tenant.
C. **Uses.** Tenant acknowledges and agrees that notwithstanding the terms and conditions of Article I (Basic Lease Provisions)—Item 3 (Use of Premises) and the provisions of Article V (Uses), Tenant shall use only the 9449 Office Space for general office, manufacturing, laboratory, and warehouse purposes consistent with the Permitted Use set forth in Item 3 of the Basic Lease Provisions. Tenant’s architect, at Tenant’s sole cost and expense, shall promptly undertake a comprehensive evaluation of the Tenant’s initial intended use, (which shall be completed no later than December 31, 2011) which shall include, but shall not be limited to, addressing such issues as exiting requirements mandated by the City of San Diego and other code requirements, in determining the exact allocation of the 9449 Expansion Space between the 9449 Office Space and the 9449 Storage Space. The final space measurements of the initial configuration of the 9449 Office Space and 9449 Storage Space shall be reasonably determined by Landlord’s architect. Landlord’s determination of the rentable square footage of the 9449 Expansion Space allocation and applicable Basic Rent shall be conclusive. Landlord and Tenant shall promptly thereafter execute and deliver to each other a confirmation letter or amendment confirming such measurements and the Basic Rent initially due and payable with respect to the 9449 Office Space and the 9449 Storage Space in accordance with Section III.A above.

At any time and from time to time during the Term as it applies to the 9449 Expansion Space, Tenant, upon no less than thirty (30) days prior written notice to Landlord, may expand the portion of the 9449 Expansion Space allocated to the 9449 Storage Space; provided that Landlord shall first review and approve any proposed tenant improvements which may be required for any such reconfiguration (which review and approval shall not be unreasonably withheld, conditioned, or delayed), and which shall be otherwise subject to the terms and conditions of the Lease and completed within one hundred-fifty (150) days following Tenant’s receipt of Landlord’s approval thereto. Promptly following such completion, the final space measurements of the configuration of the 9449 Office Space and 9449 Storage Space shall be re-measured and confirmed in the same manner as the 9449 Expansion Space and 9449 Storage Space, together with a reallocation of Basic Rent due for the 9449 Expansion Space, pursuant to the foregoing paragraph.

Tenant may not convert any 9449 Office Space to 9449 Storage Space.

D. **Right To Extend—9449 Expansion Space.** Tenant shall have a one-time right to extend the 9449 Extended Term to December 31, 2022 (i.e. co-terminus with the Original Premises), pursuant and subject to the terms and conditions of Section 3.3 of the Lease (Right to Extend the Lease), as amended, except that (i) such right shall be exercised, if at all, not less than nine (9) and not more than twelve (12) months prior to the 9449 Extended Expiration Date and (ii) the rental rate during the extended term shall be based on the fair market value for similar age and design “R&D” buildings in the immediate surrounding area, excluding the tenant improvements [in the 9449 Expansion Space or 9449 Building] that Tenant has incurred the cost of installing. Upon such extension, as used herein, the “9449 Extended Expiration Date” shall mean the 9449 Extended Expiration Date as extended.

E. **Emergency Generator.**

1) During the Term as it applies to the 9449 Expansion Space, as extended from time to time, Tenant shall have the right to install a supplemental emergency generator (the “Generator”) to provide emergency additional electrical capacity to the 9449 Building. The Generator shall be placed at a location at the 9449 Building designated by Tenant and reasonably approved by Landlord. Notwithstanding the foregoing, Tenant’s right to install the Generator shall be subject to: (i) Landlord’s reasonable approval of the manner in which the Generator is installed, the manner in which any cables are run to and from the Generator to the Premises and the measures that will be taken to eliminate any vibrations or sound disturbances from the operation of the Generator; and (ii) the covenants, conditions and restrictions of record applicable to the Project, architectural review and any necessary approval by the local municipality and county governments or agencies having authority and jurisdiction over such matters. Landlord shall have the right to require Tenant to provide a reasonably acceptable enclosure (e.g. wood fencing and landscaping) to hide or disguise the existence of the Generator and to minimize any adverse effect that the installation of the Generator may have on the appearance of the 9449 Building and Project. Tenant shall be solely responsible for obtaining all necessary governmental and regulatory permits and approvals and for the cost of installing, operating, maintaining, repairing and removing the Generator. Tenant shall also be responsible for the cost of all utilities consumed and utility connections required in the operation of the Generator.

2) Tenant shall be responsible for assuring that the installation, maintenance, repair, operation and removal of the Generator does not damage the 9449 Building or Project and Tenant shall be responsible for any damages caused thereby. For avoidance of doubt, the installation, maintenance, operation, repair or removal of the Generator shall be subject to the indemnity provisions set forth in Section 10.3 of the Lease.

4
3) Tenant shall be responsible for the installation, operation, repair, cleanliness, maintenance and removal of the Generator and appurtenances, all of which shall remain the personal property of Tenant and shall be removed by Tenant at its own expense as of the 9449 Extended Expiration Date or any earlier expiration or termination of Tenant’s right to possession of the 9449 Expansion Space in accordance with the Lease and this Amendment. Tenant shall repair any damage caused by such removal, including the patching of any holes to match, as closely as possible, the color surrounding the area where the Generator and appurtenances were attached. Such maintenance and operation shall be performed in a manner to avoid any unreasonable interference with any other tenants or Landlord. Tenant agrees to maintain the Generator, including without limitation, any enclosure installed around the Generator, in good condition and repair. Tenant shall be responsible for performing any maintenance and improvements to any enclosure surrounding the Generator so as to keep such enclosure in good condition.

4) Tenant, subject to the reasonable rules and regulations enacted by Landlord, shall have unlimited access to the Generator and its surrounding area for the purpose of installing, operating, repairing, maintaining, using and removing the Generator.

5) Tenant shall only test the Generator before or after normal business hours.

6) Notwithstanding anything in this Amendment or the Lease to the contrary, Tenant may use the Generator for its intended purpose as and when needed (as reasonably determined by Tenant), without any restriction or hindrance from Landlord or any other tenant, subject only to applicable Laws and unreasonable disturbances to other tenants in the Project.

F. **Signs.** The terms and conditions of Section 5.2 of the Lease (“Signs”) shall be applicable to Tenant’s leasing of the 9449 Building and its rights to place any monument, building top and entry door signage in, on or around the 9449 Building during the 9449 Extended Term; such rights, shall be exclusive to Tenant with respect to the top of the 9449 Building and at no additional cost to Tenant; provided, however, that in the case of any sublease or assignment by Tenant (other than a Permitted Transfer), Landlord shall have the right to reasonably approve any signage to be placed on the top of the 9449 Building by any applicable subtenant or assignee.

G. **Hazardous Materials.** The terms and conditions of Section 5.3 of the Lease (“Hazardous Materials”) shall be applicable to Tenant’s leasing of the 9449 Building during the 9449 Extended Term, and in addition to its other obligations under Sections 5.3(f) and 10.3(b), Landlord shall indemnify the Tenant Parties for any losses, damages, judgments, fines, demands, claims, recoveries, and costs sustained or incurred by such Tenant Parties, arising directly or indirectly as a result of any Hazardous Materials conditions described in Section 5.3(f) (and such indemnification obligations shall survive as a part of Section 10.3(b) of the Lease).

H. **Rooftop Rights.** The terms and conditions of Section 7.6 of the Lease (“Communications Equipment”) shall be applicable to Tenant’s leasing of the 9449 Building during the 9449 Extended Term; except that, such License shall be exclusive to Tenant and applicable to the entire rooftop of the 9449 Building; and provided, however, in the case of any sublease or assignment by Tenant (other than a Permitted Transfer), Landlord shall have the right to reasonably approve any Antenna or other equipment to be placed on the top of the 9449 Building by any applicable subtenant or assignee.

I. **Insurance.** Tenant shall be permitted to provide the insurance required under the Lease by obtaining a blanket policy or policies to be maintained by Tenant and/or Nestle S.A. (“Tenant’s Parent Company”). The coverages afforded to Landlord and Landlord’s lenders under this Lease shall in no way be limited, diminished, or reduced under such blanket policy or policies. All or any portion of the coverages Tenant is required to maintain under the Lease may be maintained under policies that include deductibles larger than those otherwise required pursuant to the Lease, including, without limitation, as set forth on Exhibit D thereof, as long as the net worth and net current assets of Tenant’s Parent Company each exceed $75,000,000.00. Further, for so long as such insurance is maintained by a blanket policy or policies as described in this Section, the last sentence of paragraph 4 of Exhibit D of the Lease shall not be applicable or binding upon Tenant.
A. **Effect of Amendments.** The Lease shall remain in full force and effect except to the extent that it is modified by this Amendment. If there is any conflict between the terms and conditions of the Lease and this Amendment, this Amendment shall govern and control.

B. **Entire Agreement.** The Lease, as amended by this Amendment embodies the entire understanding between Landlord and Tenant and can be changed only by a writing signed by Landlord and Tenant.

C. **Counterparts.** If this Amendment is executed in counterparts, each is hereby declared to be an original; all, however, shall constitute but one and the same Amendment. In any action or proceeding, any photographic, photostatic, or other copy of this Amendment may be introduced into evidence without foundation.

D. **Defined Terms.** All words commencing with initial capital letters in this Amendment and defined in the Lease shall have the same meaning in this Amendment as in the Lease, unless they are otherwise defined in this Amendment.

E. **Authority.** If Tenant is a corporation, limited liability company or partnership, or is comprised of any of them, each individual executing this Amendment for the corporation, limited liability company or partnership represents that he or she is duly authorized to execute and deliver this Amendment on behalf of such entity and that this Amendment is binding upon such entity in accordance with its terms.

F. **Attorneys’ Fees.** The provisions of the Lease respecting payment of attorneys’ fees shall also apply to this Amendment.

G. **Execution of Amendment.** Submission of this Amendment by Landlord is not an offer to enter into this Amendment but rather is a solicitation for such an offer by Tenant. Landlord shall not be bound by this Amendment until Landlord has executed and delivered the same to Tenant.

IN WITNESS WHEREOF, Landlord and Tenant have duly executed this Amendment as of the day and year first above written.

**LANDLORD:**

THE IRVINE COMPANY LLC,

a Delaware limited liability company

By: /s/ Steven M. Case

Steven M. Case

Executive President

Office Properties

By: /s/ Michael T. Bennett

Michael T. Bennett

Senior Vice President, Operations

Office Properties

**TENANT:**

PROMETHEUS LABORATORIES INC.,

a California corporation

By: /s/ Joseph M. Limber

Joseph M. Limber

President, CEO

By: /s/ Peter Westlake

Peter Westlake

CFO

6
OUTLINE AND LOCATION OF 9449 EXPANSION SPACE

Exhibit A
FOURTH AMENDMENT

THIS FOURTH AMENDMENT (the “Amendment”) is made and entered into as of May 9, 2016, by and between THE IRVINE COMPANY LLC, a Delaware limited liability company (“Landlord”), and PROMETHEUS LABORATORIES INC., a California corporation (“Tenant”).

RECITALS

A. Landlord (formerly known as The Irvine Company, a Delaware corporation) and Tenant are parties to that certain lease dated June 22, 2005, which lease has been previously amended by a First Amendment dated January 25, 2010, a Second Amendment dated October 5, 2011 (“Second Amendment”) and a Third Amendment dated January 19, 2012 (collectively, the “Lease”). Pursuant to the Lease, Landlord has leased to Tenant space currently containing approximately 151,823 rentable square feet (the “Premises”) described as the 1st floor and the mezzanine level of the building located at 9410 Carroll Park Drive, San Diego, California (the “9410 Building”) comprising approximately 110,041 rentable square feet and the entire building located at 9449 Carroll Park Drive, San Diego, California (the “9449 Building”) comprising approximately 41,782 rentable square feet.

B. The Lease by its terms is scheduled to expire on December 31, 2017 (the “Second 9410 Expiration Date”) with respect to the 9410 Building only and the parties desire to extend the Term of the Lease as to the 9410 Building only.

C. Landlord and Tenant have agreed to amend the Lease to reflect the foregoing and other modifications to the Lease, subject to and pursuant to the following terms and conditions.

NOW, THEREFORE, in consideration of the above recitals which by this reference are incorporated herein, the mutual covenants and conditions contained herein and other valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Landlord and Tenant agree as follows:

I. Extension. The Term of the Lease, as it applies to the 9410 Building only, is hereby extended and shall expire on December 31, 2022 (“Second 9410 Extended Expiration Date”), unless sooner terminated in accordance with the terms of the Lease. That portion of the Term commencing the day immediately following the Second 9410 Expiration Date (“Second 9410 Extension Date”) and ending on the Second 9410 Extended Expiration Date shall be referred to herein as the “Second 9410 Extended Term”.

II. Basic Rent for the 9410 Building. As of the Second 9410 Extension Date, the schedule of Basic Rent payable with respect to the 9410 Building during the Second 9410 Extended Term is the following:

<table>
<thead>
<tr>
<th>Months of Term or Period</th>
<th>Monthly Rate Per Square Foot</th>
<th>Monthly Basic Rent</th>
</tr>
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<tbody>
<tr>
<td>1/1/18 to 12/31/18</td>
<td>$1.40</td>
<td>$154,057.00</td>
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<tr>
<td>1/1/19 to 12/31/19</td>
<td>$1.46</td>
<td>$160,660.00</td>
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<td>1/1/21 to 12/31/21</td>
<td>$1.60</td>
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<tr>
<td>1/1/22 to 12/31/22</td>
<td>$1.67</td>
<td>$183,768.00</td>
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</tbody>
</table>

All such Basic Rent shall be payable by Tenant in accordance with the terms of the Lease.

III. Project Costs and Property Taxes for 9410 Building. During the Second 9410 Extended Term, Tenant shall be obligated to pay Tenant’s Share of Project Costs and Property Taxes accruing in connection with the 9410 Building in accordance with the terms of the Lease.

IV. Additional Security Deposit. No additional security deposit shall be required in connection with this Amendment.

V. Improvements to Premises.

A. Condition of 9410 Building. Tenant is in possession of the 9410 Building and accepts the same “as is” without any agreements, representations, understandings or obligations on the part of Landlord to perform any alterations, repairs or improvements, except as may be expressly provided otherwise in this Amendment.

B. Alterations. Any construction, alterations or improvements to the 9410 Building shall be performed by Tenant at its sole cost and expense using contractors selected by Tenant and approved by Landlord and shall be governed in all respects by the provisions of Section 7.3 of the Lease.

VI. Parking. Notwithstanding any contrary provision in Section 6.4 (Parking) of the Lease, effective as of the Second 9410 Extension Date, Landlord shall lease to Tenant, and Tenant shall lease from Landlord, 278 unreserved parking passes at the 9410 Building at no cost to Tenant through the Second 9410 Extended Term.
VII. **SDN List.** Tenant hereby represents and warrants that neither Tenant nor any officer, director, employee, partner, member or other principal of Tenant (collectively, “Tenant Parties”) is listed as a Specially Designated National and Blocked Person (“SDN”) on the list of such persons and entities issued by the U.S. Treasury Office of Foreign Assets Control (OFAC). In the event Tenant or any Tenant Party is or becomes listed as an SDN, Tenant shall be deemed in breach of this Lease and Landlord shall have the right to terminate the Lease immediately upon written notice to Tenant.

VIII. **Right to Extend.** Tenant shall have an additional one time right to extend the Term of the Lease with respect to the 9410 Building for an additional sixty (60) month period beyond the Second 9410 Extended Expiration Date, pursuant to and subject to the terms and conditions of Section 3.3 (Right to Extend this Lease) of the Lease; except that such right shall be exercised, if at all, not less than nine (9) and not more than twelve (12) months prior to the Second 9410 Extended Expiration Date.

IX. **Deleted Provision.** Section VIII(d) of the Second Amendment (Right of First Offer) shall be deleted in its entirety and of no further force or effect.

X. **GENERAL.**

A. **Effect of Amendments.** The Lease shall remain in full force and effect except to the extent that it is modified by this Amendment.

B. ** Entire Agreement.** This Amendment embodies the entire understanding between Landlord and Tenant and can be changed only by a writing signed by Landlord and Tenant. There have been no additional oral or written representations or agreements. Under no circumstances shall Tenant be entitled to any rent abatement, improvement allowance, leasehold improvements, or any similar economic incentives that may have been provided Tenant in connection with entering into the Lease, unless specifically set forth in this Amendment.

C. **Counterparts; Digital Signatures.** If this Amendment is executed in counterparts, each is hereby declared to be an original; all, however, shall constitute but one and the same amendment. In any action or proceeding, any photographic, photostatic, or other copy of this Amendment may be introduced into evidence without foundation. The parties agree to accept a digital image (including but not limited to an image in the form of a PDF, JPEG, GIF file, or other e-signature) of this Amendment, if applicable, reflecting the execution of one or both of the parties, as a true and correct original.

D. **Defined Terms.** All words commencing with initial capital letters in this Amendment and defined in the Lease shall have the same meaning in this Amendment as in the Lease, unless they are otherwise defined in this Amendment.

E. **Authority.** If Tenant is a corporation, limited liability company or partnership, or is comprised of any of them, each individual executing this Amendment for the corporation, limited liability company or partnership represents that he or she is duly authorized to execute and deliver this Amendment on behalf of such entity and that this Amendment is binding upon such entity in accordance with its terms.

F. **Certified Access Specialist.** As of the date of this Amendment, there has been no inspection of the Building and Project by a Certified Access Specialist as referenced in Section 1938 of the California Civil Code.

G. **Attorneys’ Fees.** The provisions of the Lease respecting payment of attorneys’ fees shall also apply to this Amendment.

H. **Brokers.** Article XVIII of the Lease is amended to provide that the parties recognize the following parties as the brokers who negotiated this Amendment, and agree that Landlord shall be responsible for payment of brokerage commissions to such brokers pursuant to its separate agreements with such brokers: Irvine Realty Company (“Landlord’s Broker”) is the agent of Landlord exclusively and Hughes Marino, Inc. (“Tenant’s Broker”) is the agent of Tenant exclusively. By the execution of this Amendment, each of Landlord and Tenant hereby acknowledge and confirm (a) receipt of a copy of a Disclosure Regarding Real Estate Agency Relationship conforming to the requirements of California Civil Code 2079.16, and (b) the agency relationships specified herein, which acknowledgement and confirmation is expressly made for the benefit of Tenant’s Broker. If there is no Tenant’s Broker so identified herein, then such acknowledgement and confirmation is expressly made for the benefit of Landlord’s Broker. By the execution of this Amendment, Landlord and Tenant are executing the confirmation of the agency relationships set forth herein. The warranty and indemnity provisions of Article XVIII of the Lease, as amended hereby, shall be binding and enforceable in connection with the negotiation of this Amendment.
I. Execution of Amendment. Submission of this Amendment by Landlord is not an offer to enter into this Amendment but rather is a solicitation for such an offer by Tenant. Landlord shall not be bound by this Amendment until Landlord has executed and delivered the same to Tenant.

J. Nondisclosure of Terms. Tenant hereby acknowledges that the provisions of Section 22.1 of the Lease (Nondisclosure of Lease Terms) are hereby restated in full force and effect relative to the terms and conditions of this Amendment and any other subsequent amendment, agreement or other modification of the Lease (as well as the Lease itself).

IN WITNESS WHEREOF, Landlord and Tenant have duly executed this Amendment as of the day and year first above written.

<table>
<thead>
<tr>
<th>LANDLORD:</th>
<th>TENANT:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>THE IRVINE COMPANY LLC,</strong></td>
<td><strong>PROMETHEUS LABORATORIES INC.,</strong></td>
</tr>
<tr>
<td>a Delaware limited liability company</td>
<td>a California corporation</td>
</tr>
<tr>
<td>By /s/ Douglas G. Holte</td>
<td>By /s/ Cathy Kerzner</td>
</tr>
<tr>
<td>Douglas G. Holte</td>
<td>Printed Name: Cathy Kerzner</td>
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<td>Title: President and CEO</td>
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</tr>
<tr>
<td>By /s/ Steven M. Case</td>
<td>By /s/ Peter Westlake</td>
</tr>
<tr>
<td>Steven M. Case,</td>
<td>Printed Name: Peter Westlake</td>
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<tr>
<td>Executive Vice President,</td>
<td>Title: CFO</td>
</tr>
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<tr>
<td>3</td>
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