

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended **March 31, 2021**

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____.

Commission File Number: **001-40187**

PROMETHEUS BIOSCIENCES, INC.

(Exact name of Registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

9410 Carroll Park Drive
San Diego, California
(Address of principal executive offices)

82-4282653
(I.R.S. Employer
Identification No.)

92121
(Zip Code)

Registrant's telephone number, including area code: **(858) 684-1300**

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.0001 par value per share	RXDX	Nasdaq Global Select Market

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days: Yes No

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input checked="" type="checkbox"/>		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of May 10, 2021, the registrant had 38,864,841 shares of common stock (\$0.0001 par value) outstanding.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements (unaudited)

PROMETHEUS BIOSCIENCES, INC.
Unaudited Condensed Consolidated Balance Sheets
(in thousands, except share and par value amounts)

	March 31, 2021	December 31, 2020
Assets		
Current assets		
Cash and cash equivalents	\$ 311,231	\$ 54,201
Accounts receivable	973	1,086
Prepaid expenses and other current assets	6,416	2,169
Total current assets	318,620	57,456
Equipment, net	913	447
Deferred financing costs	—	1,730
Other assets	468	—
Total assets	<u>\$ 320,001</u>	<u>\$ 59,633</u>
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities		
Accounts payable	\$ 2,082	\$ 958
Accrued compensation	1,603	2,722
Accrued expenses and other current liabilities	2,451	2,894
Amounts due to Nestlé, current—related party	—	5,675
Payable to PLI	233	1,130
Deferred revenue	2,418	1,876
Total current liabilities	8,787	15,255
Long-term debt, net	7,365	7,399
Deferred revenue, non-current	3,650	4,597
Preferred stock purchase right liability	—	3,900
Total liabilities	19,802	31,151
Commitments and contingencies (Note 9)		
Convertible preferred stock—\$0.0001 par value; No shares and 254,983,985 shares authorized at March 31, 2021 and December 31, 2020, respectively; No shares and 160,864,434 shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively; liquidation preferences of \$0 and \$130,487 at March 31, 2021 and December 31, 2020, respectively	—	126,023
Stockholders' equity (deficit):		
Preferred stock—\$0.0001 par value; 40,000,000 shares and no shares authorized at March 31, 2021 and December 31, 2020, respectively; No shares issued and outstanding at March 31, 2021 and December 31, 2020	—	—
Common stock—\$0.0001 par value; 400,000,000 shares and 325,000,000 shares authorized as of March 31, 2021 and December 31, 2020, respectively; 38,811,425 shares and 1,768,325 shares issued at March 31, 2021 and December 31, 2020, respectively; 38,769,703 shares and 1,713,622 shares outstanding at March 31, 2021 and December 31, 2020, respectively;	4	—
Additional-paid in capital	413,286	1,605
Accumulated deficit	(113,091)	(99,146)
Total stockholders' equity (deficit)	300,199	(97,541)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	<u>\$ 320,001</u>	<u>\$ 59,633</u>

See accompanying notes.

PROMETHEUS BIOSCIENCES, INC.
Unaudited Condensed Consolidated Statements of Operations
(in thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2021	2020
Collaboration revenue	\$ 760	\$ 228
Operating expenses:		
Research and development	7,758	4,265
General and administrative	5,222	2,387
Total operating expense	12,980	6,652
Loss from operations	(12,220)	(6,424)
Other income (expense), net:		
Interest income	18	2
Interest expense	(658)	(534)
Change in fair value of preferred stock purchase right liability	(980)	—
Change in fair value of preferred stock warrant liability	(105)	2
Total other income (expense), net	(1,725)	(530)
Loss from continuing operations	(13,945)	(6,954)
Loss from discontinued operations	—	(6,174)
Net loss	<u>\$ (13,945)</u>	<u>\$ (13,128)</u>
Net loss per share, basic and diluted:		
Continuing operations	\$ (1.67)	\$ (5.06)
Discontinued operations	—	(4.50)
Net loss per share, basic and diluted	<u>\$ (1.67)</u>	<u>\$ (9.56)</u>
Weighted average shares outstanding, basic and diluted	<u>8,338,892</u>	<u>1,373,050</u>

See accompanying notes.

PROMETHEUS BIOSCIENCES, INC.

Unaudited Condensed Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)
(in thousands, except share amounts)

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
Balance at December 31, 2020	160,864,434	\$ 126,023	1,713,622	\$ —	\$ 1,605	\$ (99,146)	\$ (97,541)
Issuance of Series D-2 convertible preferred stock for cash, net of issuance costs of \$94	86,775,740	73,763	—	—	—	—	—
Issuance of Series D-2 convertible preferred stock for settlement of deferred purchase price	7,219,560	6,144	—	—	—	—	—
Reclassification of convertible preferred stock purchase right liability	—	4,880	—	—	—	—	—
Conversion of convertible preferred stock into common stock at initial public offering	(254,859,734)	(210,810)	25,485,955	3	210,807	—	210,810
Issuance of shares of common stock in initial public offering for cash, net of issuance costs of \$18,662	—	—	11,500,000	1	199,837	—	199,838
Reclassification of convertible preferred stock warrants	—	—	—	—	169	—	169
Issuance of common stock in exchange for services	—	—	500	—	3	—	3
Issuance of common stock upon exercise of stock options	—	—	56,645	—	64	—	64
Vesting of early exercised stock options	—	—	12,981	—	9	—	9
Stock-based compensation	—	—	—	—	792	—	792
Net loss	—	—	—	—	—	(13,945)	(13,945)
Balance at March 31, 2021	<u>—</u>	<u>\$ -</u>	<u>38,769,703</u>	<u>\$ 4</u>	<u>\$ 413,286</u>	<u>\$ (113,091)</u>	<u>\$ 300,199</u>

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
Balance at December 31, 2019	58,145,867	\$ 43,740	1,351,380	\$ —	\$ 483	\$ (37,451)	\$ (36,968)
Issuance of Series C convertible preferred stock for cash, net of issuance costs of \$62	28,063,500	28,001	—	—	—	—	—
Vesting of common shares issued to founders	—	—	18,281	—	—	—	—
Issuance of common stock upon exercise of stock options	—	—	23,750	—	12	—	12
Vesting of early exercised stock options	—	—	8,800	—	3	—	3
Stock-based compensation	—	—	—	—	147	—	147
Net loss	—	—	—	—	—	(13,128)	(13,128)
Balance at March 31, 2020	<u>86,209,367</u>	<u>\$ 71,741</u>	<u>1,402,211</u>	<u>\$ -</u>	<u>\$ 645</u>	<u>\$ (50,579)</u>	<u>\$ (49,934)</u>

See accompanying notes.

PROMETHEUS BIOSCIENCES, INC.
Unaudited Condensed Consolidated Statements of Cash Flows
(in thousands)

	Three Months Ended March 31,	
	2021	2020
Cash flows from operating activities		
Net loss	\$ (13,945)	\$ (13,128)
Loss from continuing operations	(13,945)	(6,954)
Loss from discontinued operations, net of income taxes	—	(6,174)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	39	22
Stock-based compensation expenses	792	115
Change in fair value of preferred stock purchase right liability	980	—
Change in fair value of preferred stock warrant liability	105	(2)
Common stock issued in exchange for services	3	—
Noncash interest expense	508	421
Changes in operating assets and liabilities:		
Accounts receivable	113	(125)
Prepaid expenses and other current assets	(4,258)	(802)
Other assets	(468)	—
Accounts payable	609	189
Accrued compensation	(1,119)	164
Accrued expenses and other current liabilities	(1,051)	127
Payments received from PLI	—	2,393
Payable to PLI	(897)	—
Deferred revenue	(405)	202
Net cash used in operating activities – continuing operations	(18,994)	(4,250)
Net cash used in operating activities – discontinued operations	—	(1,009)
Net cash used in operating activities	(18,994)	(5,259)
Cash flows from investing activities		
Purchase of property and equipment	(298)	(171)
Net cash used in investing activities – continuing operations	(298)	(171)
Net cash used in investing activities – discontinued operations	—	(877)
Net cash used in investing activities	(298)	(1,048)
Cash flows from financing activities		
Proceeds from issuance of convertible preferred stock, net of issuance costs	73,749	27,961
Proceeds from issuance of long-term debt, net of issuance costs	—	7,338
Proceeds from sale of common stock in initial public offering	218,500	—
Payment of financing costs	(16,001)	—
Proceeds from issuance of common stock upon stock option exercises	74	9
Net cash provided by financing activities	276,322	35,308
Net increase in cash and cash equivalents	257,030	29,001
Cash and cash equivalents at beginning of period – continuing operations	54,201	4,450
Cash and cash equivalents at beginning of period – discontinued operations	—	3,921
Cash and cash equivalents cash at end of period	311,231	37,372
Cash and cash equivalents at end of period – discontinued operations	—	2,035
Cash and cash equivalents at end of period – continuing operations	\$ 311,231	\$ 35,337
Supplemental schedule of non-cash investing and financing activities		
Conversion of convertible preferred stock into common stock upon completion of initial public offering	\$ 210,810	\$ —
Reclassification of preferred stock purchase right liability to equity due to issuance of Series D convertible preferred stock	\$ 4,880	\$ —
Reclassification of warrant liability to equity due to conversion from preferred stock warrant to common stock warrant upon completion of initial public offering	\$ 169	\$ —
Issuance of Series D-2 convertible preferred stock for the settlement of deferred purchase price	\$ 6,144	\$ —
Vesting of unvested issued common stock	\$ 9	\$ 3
Financing costs incurred, but not paid, included in accrued expenses and accounts payable	\$ 1,209	\$ —
Costs incurred, but not paid, in connection with capital expenditures included in accounts payable	\$ 237	\$ —
Amounts included in accounts receivable related to Series C convertible preferred stock	\$ —	\$ 100

See accompanying notes.

PROMETHEUS BIOSCIENCES, INC.
Notes to Unaudited Condensed 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 novel therapeutic and companion diagnostic products for the treatment of immune-mediated diseases, starting first with 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 6). PLI markets and conducts several laboratory developed tests useful to gastroenterologists in monitoring their IBD patients' disease state and informing their therapeutic decisions.

On December 31, 2020, the Company completed the spinoff of PLI by making an in-kind distribution of 100% of its interest in PLI to the Company's stockholders of record on December 30, 2020 (see Note 6).

Reverse Stock Split

On March 5, 2021, the Company effected a one-for-ten reverse stock split of the Company's common stock (the Reverse Stock Split). The par value and the authorized shares of the common stock were not adjusted as a result of the Reverse Stock Split. All issued and outstanding common stock and the conversion prices and ratio of the convertible preferred stock have been retroactively adjusted to reflect this Reverse Stock Split for all periods presented.

Initial Public Offering

On March 16, 2021, the Company completed its initial public offering (IPO) with the sale of 11,500,000 shares of common stock, which included the exercise in full by the underwriters of their option to purchase 1,500,000 additional shares, at an initial public offering price of \$19.00 per share and received gross proceeds of \$218.5 million, which resulted in net proceeds to the Company of approximately \$199.8 million, after deducting underwriting discounts and commissions of approximately \$15.3 million and offering-related transaction costs of approximately \$3.4 million.

In addition, in connection with the completion of the Company's initial public offering on March 16, 2021, all outstanding shares of convertible preferred stock were converted into 25,485,955 shares of the Company's common stock; outstanding warrants to purchase 148,848 shares of convertible preferred stock were converted into warrants to purchase 14,884 shares of the Company's common stock; and the Company's certificate of incorporation was amended and restated to authorize 400,000,000 shares of common stock and 40,000,000 shares of undesignated preferred stock.

Liquidity

The Company has incurred net losses since inception, experienced negative cash flows from operations, and as of March 31, 2021, has an accumulated deficit of \$113.1 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 be sufficient for the Company to continue as a going concern for at least one year from the issuance date of these condensed consolidated financial statements.

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.

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 condensed 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 December 31, 2020, the Company completed the spinoff of PLI. The results of operations for the three months ended March 31, 2020 have been presented as discontinued operations in the accompanying condensed consolidated financial statements in accordance with Accounting Standards Codification (ASC) 205-20, *Presentation of Financial Statements—Discontinued Operations*. Unless otherwise noted, discussion within these notes to the condensed consolidated financial statements relates to continuing operations (see Note 6 for additional information on discontinued operations).

On an ongoing basis, management evaluates its estimates, primarily related to revenue recognition, stock-based compensation, accrued research and development costs, and for periods prior to its IPO, the fair value of common stock, the fair value of the convertible preferred stock, and the fair value of the preferred stock purchase right liability. 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.

Unaudited Interim Financial Information

The unaudited financial statements at March 31, 2021, and for the three months ended March 31, 2021 and 2020, have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission (SEC), and with GAAP applicable to interim financial statements. These unaudited financial statements have been prepared on the same basis as the audited financial statements and include all adjustments, consisting of only normal recurring accruals, which in the opinion of management are necessary to present fairly the Company's financial position as of the interim date and results of operations for the interim periods presented. Interim results are not necessarily indicative of results for a full year or future periods. The preparation of financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ materially from those estimates. These unaudited financial statements should be read in conjunction with the Company's audited financial statements for the year ended December 31, 2020, included in the Prospectus dated March 11, 2021 filed pursuant to Rule 424(b) under the Securities Act of 1933, as amended, with the SEC on March 12, 2021.

Principles of Consolidation

The condensed consolidated financial statements include the accounts of the Company and until December 31, 2020, the date at which the spinoff was completed, its wholly-owned subsidiary, PLI, and have been prepared in conformity with GAAP. All intercompany accounts and transactions have been eliminated in consolidation.

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.

Prior to the spinoff of PLI in December 2020, 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, which is recorded as discontinued operations, derives its revenue from diagnostic services in the IBD space generated from the conduct of laboratory developed tests. Subsequent to the spinoff, the Company operates in one segment. The Company operates solely in the United States.

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 March 31, 2021 and December 31, 2020 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.

Deferred Financing Costs

At December 31, 2020, financing costs, consisting of legal, accounting, printer and filing fees related to the Company's IPO, totaled \$1.7 million. Upon the completion of the IPO in March 2021, all of these expenses were offset against the proceeds from the IPO.

Revenue Recognition

The Company recognizes revenue in accordance with ASC Topic 606, *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.

To date, all of the Company's collaboration revenue has been derived from its collaboration agreement with Millennium Pharmaceuticals, Inc., a subsidiary of Takeda Pharmaceutical Company Limited (collectively, Takeda) and its collaboration agreement with Dr. Falk Pharma GmbH as described in Note 5. The terms of these arrangements 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 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.

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 clinical 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.

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.

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.

Valuation of Common Stock

Prior to the IPO, 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 product candidates, the material risks related to its businesses and industry, its results of operations before discontinued 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 fair value of each share of common stock is based on the closing price of the Company's common stock as reported by Nasdaq.

Preferred Stock Purchase Right Liabilities

From time to time, the Company enters into convertible preferred stock financings where, in addition to the initial closing, investors agree to buy, and the Company agrees to sell, additional shares of that convertible preferred stock at a fixed price in the event that certain conditions are met or agreed upon milestones are achieved. The Company evaluates this purchase right and assesses whether it meets the definition of a freestanding instrument and, if so, determines the fair value of the purchase right liability and records it on the balance sheet with the remainder of the proceeds raised allocated to convertible preferred stock. The preferred stock purchase right liability is revalued at each reporting period with changes in the fair value of the liability recorded as change in fair value of preferred stock purchase right liability in the statements of operations. Upon the issuance of the shares of Series D-2 convertible preferred stock in January 2021, the preferred stock purchase right liability no longer required liability accounting and the then fair value of the preferred stock purchase right liability was reclassified into stockholders' equity.

The Company performed the final remeasurement of the preferred stock purchase right liability as of the issuance of the shares of Series D-2 convertible preferred stock and recorded a \$1.0 million change in fair value into other income (expense) for the three months ended March 31, 2021.

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 47,999 and 214,721 weighted-average shares subject to repurchase or forfeiture from the weighted-average number of common shares outstanding for the three months ended March 31, 2021 and 2020, 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 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 three months ended March 31, 2021 and 2020, 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):

	March 31,	
	2021	2020
Convertible preferred stock outstanding	—	8,620,936
Common stock options issued and outstanding	5,023,579	1,719,446
Warrants to purchase common stock	14,884	—
Warrants to purchase convertible preferred stock outstanding	—	11,250
Total	<u>5,038,463</u>	<u>10,351,632</u>

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.

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.

Adoption of New Accounting Standards

In February 2016, the FASB issued Accounting Standards Update (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. The Company early adopted this standard on January 1, 2021 by applying the modified retrospective approach (see Note 9). The Company made accounting policy elections to exclude leases with terms of 12 months or less from the recognition requirements and to not separate lease and non-lease components.

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 Company early adopted this standard on January 1, 2021 by applying the modified retrospective approach and determined there was no cumulative-effect transition adjustment required to the opening balance of accumulated deficit for the

recognition of additional credit losses upon adoption of this standard based on its outstanding accounts receivable, the composition and credit quality of its short-term investments, and current economic conditions as of that date.

In August 2020, the FASB issued ASU No. 2020-06, *Debt – Debt with Conversion and Other options (Subtopic 470-20) and Derivative and Hedging – Contracts in Entity’s Own Equity (Subtopic 815-40)*. The amendments in this ASU reduce the number of accounting models for convertible debt instruments and convertible preferred stock, as well as, amend the guidance for the derivatives scope exception for contracts in an entity’s own equity to reduce form-over-substance-based accounting conclusion. In addition, this ASU improves and amends the related EPS guidance. The amendments in this ASU are effective for the Company on January 1, 2024, including interim periods within those fiscal years. The Company early adopted this standard on January 1, 2021 by applying the modified retrospective approach. The adoption of ASU 2020-06 had no material impact on the Company’s condensed financial statements and accompanying footnotes.

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 carrying amounts of cash and cash equivalents, prepaid and other assets, accounts payable and accrued liabilities are considered to be representative of their respective fair values because of the short-term nature of those instruments. Based on the borrowing rates currently available to the Company for loans with similar terms, which is considered a Level 2 input, the Company believes that the fair value of long-term debt approximates its carrying value.

The Company’s financial instruments that are carried at fair value consist of Level 3 liabilities. There were no transfers within the hierarchy during the three months ended March 31, 2021 and 2020. At December 31, 2020, Level 3 liabilities that were measured at fair value on a recurring basis consisted of warrants to purchase shares of convertible preferred stock and a preferred stock purchase right liability. The Company had no Level 3 liabilities at March 31, 2021 as the liabilities for the warrants to purchase shares of convertible preferred stock and the preferred stock purchase right was remeasured and reclassified to stockholders’ equity upon the closing of the Company’s IPO in March 2021 and the issuance of shares of Series D-2 convertible preferred stock in January 2021, respectively.

Convertible Preferred Stock Warrant Liability

The convertible preferred stock warrant liability was recorded at fair value utilizing the Black-Scholes option pricing model using significant unobservable inputs consistent with the inputs used for the Company’s stock-based compensation expense adjusted for the preferred stock warrants’ expected term and the fair value of the underlying preferred stock.

The assumptions used in the Black-Scholes option pricing model to determine the fair value of the convertible preferred stock warrant liability at the date of the IPO and December 31, 2020 were as follows:

	IPO Date	December 31, 2020
Fair value of underlying preferred stock	\$ 1.90	\$ 0.83
Risk-free interest rate	1.70%	1.70%
Expected volatility	70.00%	70.00%
Expected term (in years)	9.0	9.2
Expected dividend yield	—%	—%

Preferred Stock Purchase Right Liability

At December 31, 2020, the preferred stock purchase right liability was determined using a valuation model that considered: (i) the risk-free rate commensurate with the expected milestone timing of 0.09%; (ii) the probability of the Series D-2 tranche of 80.0%; (iii) volatility of 80.0%; (iv) consideration received for the Series D-1 preferred stock; (v) the number of shares to be issued to satisfy the preferred stock purchase right and at what price; and (vi) certain implied and provided assumptions needed to calibrate the Series D-1 value and the Series D-2 purchase right. Upon the issuance of the shares of Series D-2 convertible preferred stock in January 2021, the liability was remeasured and as a result of closing the sale of shares of Series D-2 convertible preferred stock, a charge of \$1.0 million was recorded in the statement of operations for the three months ended March 31, 2021.

Activity of Liabilities Using Fair Value Level 3 Measurements

The following table summarizes the activity of the financial instruments valued using Level 3 inputs (in thousands):

	Convertible Preferred Stock Warrant Liability	Series D Convertible Preferred Stock Purchase Right Liability
Balance at December 31, 2020	\$ 64	\$ 3,900
Change in fair value	105	980
Conversion/Settlement during 2021	(169)	(4,880)
Balance at March 31, 2021	<u>\$ —</u>	<u>\$ —</u>

4. Balance Sheet Details

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following (in thousands):

	March 31, 2021	December 31, 2020
Prepaid research and development	6,020	1,894
Other prepaid expenses	396	275
Total	<u>\$ 6,416</u>	<u>\$ 2,169</u>

Equipment, Net

Equipment, net, consist of the following (in thousands):

	March 31, 2021	December 31, 2020
Laboratory equipment	\$ 1,077	\$ 572
Office equipment and furniture	24	24
	<u>1,101</u>	<u>596</u>
Less accumulated depreciation	(188)	(149)
Total	<u>\$ 913</u>	<u>\$ 447</u>

Depreciation expense related to property and equipment was \$39,000 and \$22,000 for the three months ended March 31, 2021 and 2020, respectively.

Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following (in thousands):

	March 31, 2021	December 31, 2020
Accrued research and development	\$ 855	\$ 1,940
Accrued legal expenses	666	490
Unvested early exercise liability	57	67
Accrued other	873	397
Total	<u>\$ 2,451</u>	<u>\$ 2,894</u>

5. 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 Prometheus360 platform.

As consideration for the license rights, in September 2017 the Company issued (i) 257,500 shares of fully vested common stock, and (ii) 335,000 shares of unvested restricted common stock, all of which is vested as of December 31, 2020. The fair value of all of the shares were measured at the date of issuance. 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 three months ended March 31, 2021 and 2020, 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). Under the Takeda Agreement, Takeda is responsible for the development and commercialization of any therapeutic clinical candidates that it develops directed against a Collaboration Target for the treatment of IBD (Takeda Drugs), and we are responsible for development and commercialization of the Diagnostic Product(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 March 31, 2021, 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 four-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 \$0.2 million for each of the three months ended March 31, 2021 and 2020, and had deferred revenue of \$1.5 million and \$1.7 million as of March 31, 2021, and December 31, 2020, respectively. The Company expects to recognize \$0.6 million of the deferred revenue balance during the remainder of 2021.

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 is 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).

In consideration of the rights granted to Falk under the Co-Development Agreement, the Company received two upfront payments of \$2.5 million each. The first upfront payment was paid upon execution of the Co-Development Agreement and the second was paid when the underlying development plan was finalized, which occurred in December 2020. All non-internal development costs through both the pre-clinical and clinical phases will be funded 25% by Falk and 75% by the Company. In addition, the Co-Development Agreement includes two pre-clinical milestone payments totaling \$15.0 million and the Company is eligible to receive low-single to low-double digit percentage royalties 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. The term of, and the royalty obligations under, the Falk Agreement expires on a 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 Falk Drug in such country, and (iii) expiration of any applicable regulatory exclusivity for such Falk Drug.

At inception and through March 31, 2021, the Company has identified one performance obligation for all the deliverables under the Co-Development Agreement. Accordingly, the Company is recognizing revenue for the transaction price allocated to the performance obligation in an amount proportional to the collaboration expenses incurred and the total estimated collaboration expenses over the seven year period over which it expects to satisfy its performance obligation. The Company included both milestone payments in the transaction price as it was deemed not probable of significant reversal at the inception of the agreement. In connection with the Co-Development Agreement, the Company recognized revenue of \$0.6 million for the three months ended March 31, 2021 and had deferred revenue of \$4.5 million and \$4.8 million as of March 31, 2021 and December 31, 2020, respectively. This deferred revenue balance is expected to be recognized proportionally as expenses are incurred over the estimated seven-year term. The Company expects to recognize \$0.8 million of the deferred revenue balance during the remainder of 2021.

A reconciliation of deferred revenue related to the Takeda Collaboration Agreement and the Falk Co-Development Agreement for the three months ended March 31, 2021 is as follows (in thousands):

	Takeda Collaboration Agreement	Falk Co-Development Agreement	Total
Balance at December 31, 2020	\$ 1,710	\$ 4,763	\$ 6,473
Amounts received in 2021	—	355	355
Revenue recognized in 2021	(190)	(570)	(760)
Balance at March 31, 2021	<u>\$ 1,520</u>	<u>\$ 4,548</u>	<u>\$ 6,068</u>

6. Discontinued Operations

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 3,500,000 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%. In June 2020, \$5.0 million of deferred cash payments were converted to 5,000,000 shares of Series C convertible preferred stock and in October 2020, \$3.8 million of deferred cash payments were converted to 5,088,851 shares of Series D convertible preferred stock. In addition, in January 2021, \$6.1 million of deferred cash payments were converted to 7,219,560 shares of Series D-2 shares of convertible preferred stock. As of March 31, 2021 and December 31, 2020, a total of \$0 and \$5.7 million, respectively, is recorded as Amounts due to Nestlé, current—related party in the accompanying condensed consolidated balance sheets. 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.

In December 2020, in order to achieve the Company's strategic objectives, the Company's board of directors approved the spinoff of PLI by making an in-kind distribution of 100% of its interest in PLI to the Company's stockholders of record on December 30, 2020.

In connection with the spinoff, which was effected on December 31, 2020, the Company assigned PLI specific intellectual property to PLI; entered into a transition services agreement whereby the Company agreed to provide PLI with certain transition services including general and administrative, finance and clinical operations support; and entered into a sublease agreement under which the Company will continue to occupy approximately 40,000 square feet in the PLI facility for a term of one year.

Post spinoff, the Company retained obligations under the Oxford loan and for the deferred cash payments to Nestlé.

The major line items constituting the loss of PLI for the three months ended March 31, 2020, which are reflected in the accompanying condensed consolidated statements of operations as discontinued operations, are as follows:

Diagnostic services revenue	\$ 10,050
Operating expenses:	
Cost of diagnostic services revenue	3,609
Research and development	1,656
Sales and marketing	4,963
General and administrative	3,410
Restructuring	2,286
Amortization of intangible assets	300
Total operating expenses	<u>16,224</u>
Loss from discontinued operations	<u>\$ (6,174)</u>

Commitments and Contingencies

At the acquisition date, PLI was involved with several legal proceedings and claims against it. All claims against PLI remained obligations of PLI and effective upon the spinoff, the Company has no remaining obligations with respect to these claims.

7. Long Term Debt

As of March 31, 2021, long-term debt consists of the following (in thousands):

Long-term debt	\$	7,500
Final payment		300
		<u>7,800</u>
Less debt discount		(435)
Long-term debt, net	\$	<u>7,365</u>

In January 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. 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 (b) 2.01%, plus 5.98%, with a minimum annual rate of 7.99%. From March 1, 2020 through February 28, 2023, the Company is 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 divided by 24 months. At maturity (or earlier prepayment), the Company is 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. At March 31, 2021, no amounts remain available for borrowing under the Oxford Loan due to the expiration of the provision that allowed for additional borrowings.

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, and contains customary conditions of borrowing, events of default and covenants, including covenants that restrict the Company's ability to dispose of assets, merge with or acquire other entities, incur indebtedness and make distributions to holders of the Company's capital stock. Should an event of default occur, including the occurrence of a material adverse change, the Company could be liable for immediate repayment of all obligations under the Oxford Loan. In December 2020, the Oxford Loan Agreement was amended to allow the PLI spinoff and to release PLI from all obligations pursuant to the Oxford Loan.

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 warrant became exercisable for an aggregate of 14,884 shares of the Company's common stock at an exercise price of \$7.558 per share upon the completion of the IPO. The fair value of the warrant, the debt issuance costs and the final payment totaling approximately \$0.6 million are being amortized to interest expense using the effective interest method over the term of the debt.

As of March 31, 2021, future minimum principal and interest payments under the Oxford Loan, including the final payment, are as follows (in thousands):

Remaining 2021	\$	458
2022		608
2023		3,637
2024		3,966
2025		931
		<u>9,600</u>
Less interest and final payment		(2,100)
Long-term debt	\$	<u>7,500</u>

8. Stockholders' Equity (Deficit)

Amended Certificate of Incorporation

In March 2021, the Company amended its Certificate of Incorporation to authorize 400,000,000 shares of common stock and 40,000,000 shares of preferred stock.

Convertible Preferred Stock

In connection with the completion of the Company's IPO on March 16, 2021, all outstanding shares of convertible preferred stock were converted into 25,485,955 shares of the Company's common stock and outstanding warrants to purchase 148,848 shares of convertible preferred stock were converted into warrants to purchase 14,884 shares of the Company's common stock.

As of December 31, 2020, the Company's convertible preferred stock was classified as temporary equity on the accompanying balance sheet 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.

Series C Convertible Preferred Stock

In March 2020, the Company sold 28,063,500 shares of Series C convertible preferred stock and received net cash proceeds totaling \$28.0 million.

Series D Convertible Preferred Stock

In October 2020, the Company entered into a Series D convertible preferred stock purchase agreement (Series D SPA) under which it issued 61,066,216 shares of Series D-1 convertible preferred stock, for cash, at a price of \$0.7558 per share, for net proceeds of \$46.2 million (the Initial Series D Closing). In addition, 5,088,851 shares of Series D-1 convertible preferred stock were issued to Nestlé in satisfaction of a deferred purchase price obligation of \$3.8 million. The Series D SPA contained provisions that potentially obligates the Company to issue an additional 94,007,051 shares of Series D-2 convertible preferred stock at \$0.8510 per share in an additional closing, 7,231,311 of which is issuable to Nestlé for satisfaction of deferred purchase price obligations of \$6.2 million, upon the approval by the Company's board of directors, or at the option of the investors who participated in the Initial Series D Closing, or upon the achievement of certain milestones as defined in the Series D SPA, which purchase right terminates upon certain specified events, including an initial public offering of the Company, if any.

The Company determined its obligation to issue additional shares of the Company's Series D-2 convertible preferred stock in the Initial Series D Closing represented a freestanding financial instrument that required liability accounting. This freestanding preferred stock purchase right liability for the additional closing was recorded at fair value, with changes in fair value recognized in the statements of operations. As of the Initial Series D Closing, the estimated fair value of the preferred stock purchase right liability was \$3.9 million. In January 2021, 93,995,300 shares of Series D-2 convertible preferred stock were issued, of which, 7,219,560 were issued to Nestlé for the satisfaction of deferred purchase price obligations of \$6.1 million. Upon the closing of the sale of these shares, the preferred stock purchase right liability was remeasured to fair value and the change in fair value of \$1.0 million was recorded in the statement of operations for the three months ended March 31, 2021. The liability was then reclassified to stockholders' equity.

The authorized, issued and outstanding shares of convertible preferred stock as of December 31, 2020 consist of the following (in thousands, except share and per share amounts):

	Shares Authorized	Shares Issued and Outstanding	Per Share Original Issue Price	Liquidation Value	Carrying Value
Series A	14,979,200	14,979,200	\$ 0.50	\$ 7,490	\$ 7,391
Series B	26,666,667	26,666,667	0.75	20,000	19,901
Series C	53,176,000	53,063,500	1.00	53,064	52,937
Series D-1	66,155,067	66,155,067	0.76	49,933	45,794
Series D-2	94,007,051	—	—	—	—
Total	<u>254,983,985</u>	<u>160,864,434</u>		<u>\$ 130,487</u>	<u>\$ 126,023</u>

Equity Incentive Plans

In 2017, the Company adopted the 2017 Equity Incentive Plan (the 2017 Plan), which as amended, had 5,524,354 shares of common stock reserved for issuance. Under the 2017 Plan, the Company could 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 2017 Plan was no more than ten years. Grants generally vested 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 2017 Plan allowed for the early exercise of all stock options granted if authorized by the board of directors at the time of grant.

In February 2021, the board of directors adopted, and the Company's stockholders approved, the 2021 Incentive Award Plan (the 2021 Plan), which became effective in connection with the IPO. Pursuant to the 2021 Plan, the Company ceased granting awards under the 2017 Plan. Under the 2021 Plan, the Company may grant stock options, restricted stock, dividend equivalents, restricted stock units, stock appreciation rights, and other stock or cash-based awards to individuals who are then employees, officers, non-employee directors or consultants of the Company. The number of shares initially available for issuance under awards granted pursuant to the 2021 Plan is the sum of (1) 3,600,000 shares of common stock, plus (2) any shares subject to outstanding awards under the 2017 Plan as of the effective date of the 2021 Plan that become available for issuance under the 2021 Plan thereafter in accordance with its terms. In addition, the number of shares of common stock available for issuance under the 2021 Plan will be increased annually on the first day of each fiscal year during the term of the 2021 Plan, beginning with the 2022 fiscal year, by an amount equal to the lesser of (a) 5% of the shares of common stock outstanding on the final day of the immediately preceding calendar year or (b) such smaller number of shares as determined by the Company's board of directors. At March 31, 2021, 3,548,062 shares remain available for issuance under the 2021 Plan.

The Company's stock option activity for the three months ended March 31, 2021 is summarized in the following table:

	Number	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in Years)	Weighted-Average Grant Date (Fair Value)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2020	2,930,246	\$ 2.10	9.4		\$ 1,104
Granted	2,169,870	\$ 6.74		\$ 5.13	
Exercised	(56,645)	\$ 1.13			
Cancelled/forfeited	(19,892)	\$ 2.98			
Outstanding at March 31, 2021	5,023,579	\$ 4.59	9.4		\$ 68,715
Vested or expected to vest at March 31, 2021	5,023,579	\$ 4.59	9.4		\$ 68,715
Exercisable at March 31, 2021	613,136	\$ 1.69	7.8		\$ 11,664

The total intrinsic value of options exercised during the three months ended March 31, 2021 and 2020 was \$0.2 million and \$0.1 million, respectively. The total intrinsic value of options vested during the three months ended March 31, 2021 and 2020 was \$2.8 million and \$0.1 million, respectively.

The grant date fair value of stock options was determined using the Black-Scholes option pricing model with the following assumptions:

	Three Months Ended March 31,	
	2021	2020
Risk-free interest rate	0.6–1.0%	1.4%
Expected volatility	95.2%	61.5%
Expected term (in years)	5.8–6.1	6.1
Expected dividend yield	—%	—%

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 March 31, 2021 and December 31, 2020, the early exercise liability was approximately \$0.1 million. 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 for the three months ended March 31, 2021:

Unvested at beginning of period	54,703
Vested or cancelled during the period	(12,981)
Unvested at end of period	<u>41,722</u>

Employee Stock Purchase Plan

In February 2021, the Company’s board of directors approved the 2021 Employee Stock Purchase Plan (the ESPP), which became effective upon the pricing of the Company’s IPO on March 16, 2021. The ESPP permits participants to purchase common stock through payroll deductions of up to 20% of their eligible compensation. Initially, a total of 360,000 shares of common stock was reserved for issuance under the ESPP. In addition, the number of shares of common stock available for issuance under the ESPP will be annually increased on the first day of each fiscal year during the term of the ESPP, beginning with the 2022 fiscal year, by an amount equal to the lesser of: (i) 1% of the total number of shares of common stock outstanding on December 31st of the preceding calendar year; or (ii) such other amount as the Company’s board of directors may determine. Stock compensation expense for the three months ended March 31, 2021 related to the ESPP was immaterial.

Stock-Based Compensation Expense

The following table summarizes the components of stock-based compensation expense recognized in the accompanying statements of operations (in thousands):

	Three Months Ended March 31,	
	2021	2020
Research and development	\$ 171	\$ 16
General and administrative	621	99
Discontinued operations	—	32
Total stock-based compensation	<u>\$ 792</u>	<u>\$ 147</u>

The total unrecognized compensation cost related to unvested stock-based awards as of March 31, 2021 was \$14.4 million and is expected to be recognized over a weighted average period of 3.7 years.

9. Commitments and Contingencies

Leases

As a result of the PLI spinoff on December 31, 2020, the Company entered into a sublease agreement with PLI for approximately 40,000 square feet currently occupied in the PLI facility. The sublease agreement is for one year with an option to renew for an additional year. The monthly payment is \$80,000 and total remaining payment obligations at March 31, 2021 and December 31, 2020 are \$0.7 million and \$1.0 million, respectively.

In March 2021, the Company executed a non-cancellable lease agreement for office and laboratory space in San Diego, California. The lease has an initial term of ten years, following the commencement date with an option to extend the lease for an additional five-year term. The lease provides for initial monthly rental payments of approximately \$0.2 million with rent escalation and the Company is also responsible for certain operating expenses and taxes throughout the lease term. In addition, the Company is entitled to up to \$6.3 million of tenant improvement allowance, which the Company has not received as of March 31, 2021. The Company expects the lease to commence by the first quarter of 2022. At March 31, 2021, as the Company had not taken control of the space and the lease term had not yet commenced, no operating lease right-of-use assets or operating lease liabilities for the space has been recorded.

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.

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 March 31, 2021, no claims exist under indemnification arrangements and accordingly, no amounts have been accrued in its condensed consolidated financial statements as of March 31, 2021.

10. Related Party Transactions

As discussed in Note 5, in September 2017, the Company entered into the Agreement with Cedars-Sinai. As consideration for the license rights, the Company issued (i) 257,500 common stock shares at par value of \$0.0001 per share, and (ii) 335,000 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 three months ended March 31, 2021 and 2020, no services were provided under the research agreements.

During the three months ended March 31, 2021, the Company incurred compensation related expenses for one employee who is an immediate family member of a former member of the Company's board of directors. These expenses totaled \$0.1 million for the three months ended March 31, 2021, which is included in research and development expenses in the accompanying condensed consolidated statement of operations. During the three months ended March 31, 2020, the Company incurred compensation related expenses for two employees, each of whom is an immediate family member of a different former member of the Company's board of directors. These expenses totaled \$0.2 million for the three months ended March 31, 2020, of which \$0.1 million is included in general and administrative expenses in the accompanying condensed consolidated statement of operations and \$0.1 million is included in research and development expenses.

As of December 31, 2020, the Company has a \$5.7 million liability recorded within Amounts due to Nestlé, current—related party in the condensed consolidated balance sheet. As disclosed in Note 6, this amount relates to deferred consideration for the acquisition of PLI and was satisfied with the issuance of 7,219,560 shares of Series D-2 convertible preferred stock in January 2021 (see Note 8).

The Company has an ongoing collaboration with Regents of the University of California, where a former member of its board of directors is employed. During each of the three months ended March 31, 2021 and 2020, the Company incurred \$0.2 million and \$0.1 million, respectively, in expense related to this collaboration that was recorded in Loss from discontinued operations in the accompanying condensed consolidated statements of operations for the three months ended March 31, 2020 and research and development expenses in the accompanying condensed consolidated statement of operations for the three months ended March 31, 2021.

As a result of the PLI spinoff on December 31, 2020, the Company entered into a transition services agreement under which it assumed a \$1.1 million liability related to the payout of the PLI bonus for the year ended December 31, 2020. This amount is included in the amount payable to PLI in the accompanying condensed consolidated balance sheets. Additionally, pursuant to this agreement, the Company will be providing PLI certain transitional services, including general and administrative, finance and clinical operations support, and PLI is providing the Company with certain transitional services, including providing for the use of facilities under a sublease, in each case for specified monthly service fees. The initial term of the agreement is for one year, subject to earlier termination and extension thereafter. During the three months ended March 31, 2021, the Company paid PLI \$1.6 million in accordance with the terms of this agreement.

11. 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 three months ended March 31, 2021 and 2020 were \$43,000 and \$46,000, respectively.

12. COVID-19 Pandemic

The current COVID-19 pandemic, which is impacting worldwide economic activity, poses the risk that the Company or its employees, contractors, suppliers, and other partners may be prevented from conducting business activities for an indefinite period of time, including due to shutdowns that may be requested or mandated by governmental authorities. The extent to which the COVID-19 pandemic will impact the Company's business will depend on future developments that are highly uncertain and cannot be predicted at this time.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis and the unaudited interim condensed consolidated financial statements included in this Quarterly Report on Form 10-Q should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 2020 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in the Prospectus dated March 11, 2021 filed pursuant to Rule 424(b) under the Securities Act of 1933, as amended (the Securities Act), with the Securities and Exchange Commission (SEC) on March 12, 2021 (the Prospectus).

Forward-Looking Statements

This Quarterly Report on Form 10-Q (Quarterly Report) contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act). All statements other than statements of historical facts contained in this Quarterly Report, 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 clinical trials for our product candidates, our plans to use our Prometheus360 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 Quarterly Report 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 Quarterly Report and are subject to a number of risks, uncertainties and assumptions, including those described in Part II, Item 1A, "Risk Factors" of this report. 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 do not plan 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.

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 of immune-mediated diseases, starting first with inflammatory bowel disease (IBD). We leverage our proprietary precision medicine platform, Prometheus360™, 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. We have a robust pipeline of therapeutic development programs for the treatment of IBD. Our goal is to revolutionize the treatment of IBD with a precision medicine approach for patients with significant unmet medical needs.

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 ulcerative colitis (UC) and Crohn's disease (CD), and initiated a Phase 1a clinical trial in normal healthy volunteers in December 2020. Assuming favorable safety results in this trial, we expect to commence in parallel in the third quarter of 2021 a Phase 2 randomized placebo-controlled clinical trial in patients with moderate-to-severe UC and an open-label Phase 2a clinical trial in patients with moderate-to-severe CD, with data expected in the second half of 2022 for both indications.

Our PR600 program targets a member of the TNF super family. It has been shown that blocking this target inhibits disease in multiple third-party IBD animal models. We have identified multiple genetic variants linked to patient subpopulations with a

complicated course of disease and intend to leverage Prometheus360 in combination with functional assays to identify patients with these genetic variants. We expect to submit an investigational new drug application (IND) for a therapeutic candidate from the PR600 program in the second half of 2022. Our PR300 program targets an orphan G-protein coupled receptor (GPCR) expressed predominantly in the gastrointestinal (GI) tract that we believe has important functions underlying intestinal epithelial integrity and innate immune cell function.

In addition, we have several additional discovery programs with different mechanisms of action targeting UC and/or CD that are in the discovery stage of development. We also continue to evaluate numerous other drug targets identified through Prometheus360 for therapeutic utility for potential drug discovery development. The research and development of therapeutic product candidates and companion diagnostics comprises our therapeutics business segment.

On June 30, 2019, we acquired from Nestlé Prometheus Laboratories, Inc. (PLI), which markets and conducts several laboratory developed tests useful to gastroenterologists in monitoring their IBD patients' disease state. 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 Prometheus360 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.

On December 31, 2020, we completed the spinoff of PLI by making an in-kind distribution of 100% of our interest in PLI to our stockholders of record on December 30, 2020. Except as specifically indicated, the discussion of our operations excludes the operations of PLI, which are reported as a discontinued operation in the accompanying condensed consolidated financial statements included elsewhere in this Quarterly Report and in the following discussion.

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, including those generated from PLI, were \$29.7 million and \$37.1 million for the years ended December 31, 2019 and 2020, respectively, and \$13.9 million for the three months ended March 31, 2021. As of March 31, 2021, we had an accumulated deficit of \$113.1 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.

From inception and to the date of our initial public offering (IPO) in March 2021, we had raised a total of \$175.6 million to fund our operations from gross proceeds from the sale and issuance of convertible preferred stock and \$7.5 million from proceeds under our loan and security agreement (the Loan Agreement) with Oxford Finance LLC and its affiliates (Oxford). In March 2021, we completed our IPO with the sale of 11,500,000 shares of common stock, which included the exercise in full by the underwriters of their option to purchase 1,500,000 additional shares, at an initial public offering price of \$19.00 per share and received net of approximately \$199.8 million. As of March 31, 2021, we had cash and cash equivalents of \$311.2 million.

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 product candidates, 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 that we would otherwise prefer to develop and market ourselves.

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. While it is not possible at this time to estimate the impact that COVID-19 could have on our 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, impede testing, monitoring, data collection and analysis and other related activities, 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 U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA) or other regulatory authorities, which could result in delays in meetings related to our ongoing and 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 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.

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 Medical Center (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 Prometheus360 platform. As upfront consideration for the license agreement, we issued to Cedars-Sinai 257,500 shares of fully vested common stock and 335,000 shares of restricted common stock, which shares fully vested 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 any related companion diagnostic products, as well any diagnostic products we develop under the Takeda collaboration agreement discussed below, subject to the terms and conditions set forth in the Cedars-Sinai License Agreement.

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 Pharmaceutical Company Limited (Takeda). Pursuant to this agreement, we established a strategic collaboration to 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). Under the Takeda Agreement, Takeda is responsible for the development and commercialization of any therapeutic clinical candidates that it develops directed against a Collaboration Target for the treatment of IBD (Takeda Drugs) and we are responsible for development and commercialization of the Diagnostic Product(s). We received an upfront payment of \$1.5 million in April 2019 and are also eligible to receive certain development, regulatory, commercial and sales milestone payments, and low-single digit royalties on net sales of Takeda Drugs, subject to the terms and conditions set forth in the Takeda Agreement.

Our Collaboration with Dr. Falk Pharma

We entered into a co-development and manufacturing agreement (the Falk Agreement) with Dr. Falk Pharma GmbH (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 are 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 Falk Agreement, Falk agreed to fund 25% of our third party development costs. 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 and we agreed to pay Falk a low-single digit royalty on net sales for such products in our territory, subject to the terms and conditions set forth in the Falk Agreement.

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” in our Prospectus.

Components of Results of Operations

Revenue

Collaboration revenue

We currently derive all of our 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

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 equipment.

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

	Three Months Ended March 31,	
	2021	2020
PRA023	\$ 5,325	\$ 3,483
PR600	1,771	165
Other preclinical programs	662	617
Total research and development	<u>\$ 7,758</u>	<u>\$ 4,265</u>

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;
- 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; and
- the efficacy and safety profile of our product candidates and effectiveness of our companion diagnostics.

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.

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 interest expense incurred in connection with our borrowings under the Loan Agreement and non-cash interest expense associated with the deferred purchase payments for PLI.

Change in fair value of preferred stock purchase liability

In connection with the issuance of our Series D convertible preferred stock in 2020, the investors agreed to buy, and we agreed to sell, additional shares of such preferred convertible stock at the original issue price upon the achievement of pre-defined milestones. These contractual obligations were required to be accounted for as liabilities and remeasured to fair value at each reporting date, with any change in the fair value reported as a component of other income (expense). In January 2021, with the issuance of the Series D-2 convertible preferred stock, this contractual obligation was settled and the preferred stock purchase right liability was remeasured to fair value on the purchase date and reclassified to permanent equity.

Change in fair value of preferred stock warrant liability

Changes in the fair value of preferred stock warrant liabilities relates to warrants for the purchase of convertible preferred stock issued in connection with our Loan Agreement. These warrants were converted into warrants for the purchase of common stock in connection with our IPO and were reclassified into stockholders' equity. Accordingly, no further fair value adjustments for these warrants are expected.

Loss From Discontinued Operations

On December 31, 2020, we completed the spinoff of PLI by making an in-kind distribution of 100% of our interest in PLI to our stockholders of record on December 30, 2020. The results of PLI have been classified as discontinued operations for the three months ended March 31, 2020.

Results of Operations

Comparison of the Three Months Ended March 31, 2021 and 2020

The following table summarizes our results of operations for the three months ended March 31, 2021 and 2020 (in thousands):

	Three Months Ended March 31,		Change
	2021	2020	
Collaboration revenue	\$ 760	\$ 228	\$ 532
Operating expenses:			
Research and development	7,758	4,265	3,493
General and administrative	5,222	2,387	2,835
Total operating expenses	12,980	6,652	6,328
Loss from operations	(12,220)	(6,424)	(5,796)
Other income (expense), net:			
Interest income	18	2	16
Interest expense	(658)	(534)	(124)
Change in fair value of preferred stock purchase right liability	(980)	-	(980)
Change in fair value of preferred stock warrant liability	(105)	2	(107)
Total other income (expense), net	(1,725)	(530)	(1,195)
Loss from continuing operations	(13,945)	(6,954)	(6,991)
Loss from discontinued operations	—	(6,174)	6,174
Net loss	\$ (13,945)	\$ (13,128)	\$ (817)

Revenue

Revenue was \$0.8 million for the three months ended March 31, 2021 compared to \$0.2 million for the three months ended March 31, 2020 due to additional revenue generated from the Falk Agreement.

Research and Development Expenses

Research and development expenses were \$7.8 million for the three months ended March 31, 2021 compared to \$4.3 million for the three months ended March 31, 2020. The increase of \$3.5 million for the three months ended March 31, 2021 compared to the three months ended March 31, 2020 was primarily driven by a \$3.0 million increase in expenses related to research and development expenses for our product candidates and a \$0.5 million increase in expenses related to personnel costs due to increased headcount to support increased development activities.

General and Administrative Expenses

General and administrative expenses were \$5.2 million for the three months ended March 31, 2021 compared to \$2.4 million for the three months ended March 31, 2020. The increase of \$2.8 million for the three months ended March 31, 2021 compared to the three months ended March 31, 2020 was primarily driven by one-time transaction costs indirectly related to our IPO of \$1.8 million with the remainder due to increases in corporate personnel costs due to the expansion of our executive team.

Other Income (Expense), Net

Interest expense

Interest expense was \$0.7 million for the three months ended March 31, 2021 compared to interest expense of \$0.5 million for the three months ended March 31, 2020. The increase of \$0.2 million for the three months ended March 31, 2021 compared to the three months ended March 31, 2020 was primarily related to interest expense associated with our borrowings under our Loan Agreement and non-cash interest expense incurred in connection with the deferred purchase price of PLI.

Change in Fair Value of Convertible Preferred Stock Purchase Right Liability

The change in fair value of convertible preferred stock purchase right liability increased \$1.0 million due to the increase in the fair value of the outstanding Series D-2 preferred stock purchase right liability as a result of closer time proximity to achieving different outcome scenarios and higher probabilities of occurrence. Upon the exercise of the preferred stock purchase right with the issuance of Series D-2 convertible preferred stock in January 2021, we remeasured the Series D-2 preferred stock purchase right liability to fair value and reclassified the resulting value to temporary equity on the balance sheet.

Loss from discontinued operations

For the for the three months ended March 31, 2020, revenue from PLI totaled \$10.0 million and total operating expenses totaled \$16.2 million.

Liquidity and Capital Resources

Sources of Liquidity

From our inception and to the date of our IPO, we received aggregate gross proceeds of \$175.6 million from the sale of convertible preferred stock, \$7.5 million from borrowings under our Loan Agreement with Oxford and \$8.2 million from amounts received under the Takeda and Falk Agreements. In March 2021, we completed our initial public offering (IPO) with the sale of 11,500,000 shares of common stock, which included the exercise in full by the underwriters of their option to purchase 1,500,000 additional shares, at an initial public offering price of \$19.00 per share and received gross proceeds of \$218.5 million, which resulted in net proceeds to us of approximately \$199.8 million, after deducting underwriting discounts and commissions of approximately \$15.3 million and offering-related transaction costs of approximately \$3.4 million. As of March 31, 2021, we had cash and cash equivalents of \$311.2 million.

Oxford Loan and Security Agreement

In January 2020, we entered into the Loan Agreement with Oxford, which provided for total borrowings of up to \$25.0 million, of which \$7.5 million was drawn upon execution of the agreement. No additional amounts remain available for borrowing. 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 annual rate shall at no time be less than 7.99%. From March 1, 2020 through February 28, 2023, 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 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 became exercisable for an aggregate of 14,884 shares of our common stock at an exercise price of \$7.558 per share upon the completion of our IPO.

Future Capital Requirements

As of March 31, 2021, we had cash and cash equivalents in the amount of \$311.2 million. Based upon our current operating plans, we believe that our existing cash and cash equivalents, will be sufficient to fund our operations for at least the next 24 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;
- 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 the Takeda Agreement, the Falk Agreement or any future collaboration agreements;
- the costs of obtaining, maintaining and enforcing our 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 our Prometheus360 platform 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;
- the terms and timing of establishing and maintaining collaborations, licenses and other similar arrangements; and
- costs associated with any products or technologies that we may in-license or acquire.

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 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):

	Three Months Ended March 31,	
	2021	2020
Net cash provided by (used in)		
Operating activities from continuing operations	\$ (18,994)	\$ (4,250)
Operating activities from discontinued operations	—	(1,009)
Investing activities from continuing operations	(298)	(171)
Investing activities from discontinued operations	—	(877)
Financing activities	276,322	35,308
Net increase in cash and cash equivalents	<u>\$ 257,030</u>	<u>\$ 29,001</u>

Operating Activities

Cash used by operating activities from continuing operations was \$19.0 million during the three months ended March 31, 2021 as compared to cash used in operating activities of \$4.3 million during the three months ended March 31, 2020. The increase of \$14.7 million was primarily the result of the increase in net loss between the two periods of \$7.0 million and increased payments in connection with an increase in research and development activities, our expansion of our executive team and us becoming a public company.

Investing Activities

Including the operations of PLI, net cash used by investing activities was \$0.3 million during the three months ended March 31, 2021 as compared to net cash used in investing activities \$1.0 million during the three months ended March 31, 2020, due to cash purchases of property and equipment.

Financing Activities

Net cash provided by financing activities was \$276.3 million during the three months ended March 31, 2021 as compared to \$35.3 million during the three months ended March 31, 2020. During the three months ended March 31, 2021, we received proceeds of \$202.5 million from the sale of our common stock in our IPO, net of issuance costs paid during the period, and proceeds of \$73.7 million from the sale of shares of our Series D-2 convertible preferred stock, net of issuance costs. During the three months ended March 31, 2020, we received \$28.0 million from the issuance of our Series C convertible preferred stock, net of issuance costs, and \$7.3 million from proceeds under the Loan Agreement with Oxford.

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.

Our significant accounting policies are described in more detail in Note 2 to our consolidated financial statements included in the Prospectus dated March 11, 2021 filed pursuant to Rule 424(b) under the Securities Act of 1933, as amended, with the SEC on March 12, 2021 and in Note 2 to our condensed consolidated financial statements included elsewhere in this Quarterly Report. We believe that the accounting policies related to revenue recognition, stock-based compensation and accrued research and development costs are the most critical to understanding and evaluating our historical and future performance.

Recent Accounting Pronouncements

See Note 2 to our condensed consolidated financial statements included elsewhere in this Quarterly Report for a description of recent accounting pronouncements.

Contractual Obligations and Commitments

During the three months ended March 31, 2021, other than the one item discussed below, there have been no material changes outside of the ordinary course of business in the composition of these contractual obligations or commitments as discussed in “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Contractual Obligations and Commitments” in the Prospectus.

In March 2021, the Company executed a non-cancellable lease agreement for office and laboratory space in San Diego, California. The lease has an initial term of ten years, following the commencement date with an option to extend the lease for an additional five-year term. The lease provides for initial monthly rental payments of approximately \$0.2 million with rent escalation and the Company is also responsible for certain operating expenses and taxes throughout the lease term. The Company expects the lease to commence by the first quarter of 2022 (see Note 9 to our condensed consolidated financial statements included elsewhere in this Quarterly Report). The table included in the Prospectus as of December 31, 2020 does not include amounts for the payment obligations entered into in connection with this lease agreement.

Off-Balance Sheet Arrangements

During the periods presented we did not have, nor do we currently have, any off-balance sheet arrangements as defined under the rules and regulations of the SEC.

JOBS Act

As an emerging growth company under the Jumpstart Our Business Startups Act of 2012 (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, will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. We 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. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

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 our IPO, (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 non-convertible debt securities during the prior three-year period.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Not required.

Item 4. Controls and Procedures

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed by us in our reports that we file or submit pursuant to the Securities Exchange Act of 1934, as amended (the Exchange Act), is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Under the supervision and with participation of our management, including our Chief Executive Officer and our Chief Financial Officer, we carried out an evaluation of the effectiveness of our disclosure controls and procedures (as such term is defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of the end of the period covered by this report. Based on this evaluation and the material weakness previously identified and further discussed below, our Company's Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were not effective at the reasonable level of assurance.

Material Weakness in Internal Control over Financial Reporting

We identified deficiencies in our internal controls over financial reporting related 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. In March 2021, we reported these deficiencies to the Audit Committee of our Board of Directors and a material weakness related to these deficiencies existed at December 31, 2020.

Remediation Efforts related to the Material Weakness During 2020 and 2021

The material weakness in our internal controls over financial reporting relates 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 that existed as a result of our limited number of accounting personnel. This resulted in a reasonable possibility that a material misstatement of our annual or interim financial statements may not be prevented or detected on a timely basis. To remediate the deficiencies described above and prevent similar deficiencies in the future, 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.

Although we have begun the implementation of these remediation efforts, the deficiencies will not be considered fully remediated until the applicable remedial controls operate for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively. Any actions we have taken or may take to remediate these deficiencies are subject to continued management review supported by testing, as well as oversight by the Audit Committee of our Board of Directors.

We cannot provide complete assurance that other material weaknesses or significant deficiencies will not occur in the future or that we will be able to remediate such weaknesses or deficiencies in a timely manner. The occurrence of such material weaknesses or our inability to remediate these deficiencies could impair our ability to accurately and timely report our financial position, results of operations or cash flows.

Changes in Internal Control over Financial Reporting

The Company is implementing remedial procedures to address the material weakness in our internal controls over financial reporting. These remedial procedures will continue throughout the remainder of fiscal 2021 and had no impact on our internal control over financial reporting during the period covered by this report.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

We are not currently subject to any material legal proceedings. From time to time, we may be involved in legal proceedings or subject to claims incident to the ordinary course of business. Regardless of the outcome, such proceedings or claims can have an adverse impact on us because of defense and settlement costs, diversion of resources and other factors, and there can be no assurances that favorable outcomes will be obtained.

Item 1A. 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 included in this Quarterly Report on Form 10-Q and in the Prospectus dated March 11, 2021 filed pursuant to Rule 424(b) under the Securities Act with the SEC on March 12, 2021, including our financial statements and related notes and “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” before making an investment decision to purchase or sell shares of our common stock. 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. The risks described below are not the only ones that we may face, and additional risks or uncertainties not known to us or that we currently deem immaterial may also impair our business and future prospects.

Summary of Risks Related to Our Business

The principal risks and uncertainties affecting our business include the following:

- 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 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 Prometheus360 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 Prometheus360 obsolete.
- We are early in our development efforts and all of our development programs are in the clinical, 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 ongoing or 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 into, 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.

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. We are in the early stages of our development efforts and have only one product candidate, PRA023, in early clinical development. We commenced operations in 2016, and to date, we have focused primarily on organizing and staffing our company, business planning, raising capital, developing Prometheus360, discovering and identifying product candidates, establishing our intellectual property portfolio and conducting research and preclinical studies. Our approach to the discovery and development of product candidates based on Prometheus360 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, Prometheus Laboratories, Inc. (PLI), which we acquired from Nestlé on June 30, 2019 and spun-off in December 2020, 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, including those generated from PLI, were \$29.7 million and \$37.1 million for the years ended December 31, 2019 and December 31, 2020, respectively, and \$13.9 million for the three months ended March 31, 2021. As of March 31, 2021, we had an accumulated deficit of \$113.1 million. 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.

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.

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, 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 our existing cash and cash equivalents, will enable us to fund our operations for at least the next 24 months. In particular, we expect that these funds will allow us to complete our planned Phase 2 clinical trial in patients with moderate-to-severe UC and Phase 2a clinical trial in patients with moderate-to-severe CD for PRA023, and complete IND-enabling preclinical studies and complete a Phase 1 clinical trial for our PR600 program. 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 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 Prometheus360 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;
- the terms and timing of establishing and maintaining collaborations, licenses and other similar arrangements; and
- costs associated with any products or technologies that we may in-license or acquire.

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, 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 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, selling or licensing our assets, making capital expenditures, declaring dividends or encumbering 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, Prometheus360 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.

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 Prometheus360 is unproven, and we do not know whether we will be able to develop any therapeutics or companion 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 Prometheus360 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 Prometheus360 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 Prometheus360, 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. While we have had favorable preclinical study results utilizing Prometheus360, 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, entered Phase 1a clinical development in December 2020 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 Prometheus360 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 Prometheus360, 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 Prometheus360, 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 Prometheus360 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 have only one product candidate in early clinical development. All of our other 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 have only one product candidate in early clinical development. All of our other development programs are in the preclinical or drug discovery stage. We have not yet completed any clinical trials for any product candidate. We have invested substantially all of our efforts in developing Prometheus360, identifying potential therapeutic product candidates and conducting preclinical studies. Although PRA023 entered a Phase 1a clinical trial in December 2020, we will need to progress all of our other development programs 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 our 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 ongoing and 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. 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 any of our ongoing and planned preclinical studies or clinical trials will be successful.

Any difficulties or delays in the commencement or completion, or termination or suspension, of our ongoing or 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 ongoing or 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 ongoing or 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 completed 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 commenced our first Phase 1 clinical trial in December 2020. However, we have not previously conducted any clinical trials, have limited experience as a company in preparing, submitting and prosecuting regulatory filings and have not submitted 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 ongoing or 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. 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, if any, 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 or a collaborator will need to obtain approval of PMA applications from the FDA in order to legally market such companion diagnostics in the United States. As a company, 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 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.

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. On April 14, 2021, the FDA announced the publication of guidance describing how the FDA will request and conduct remote interactive evaluations for the duration of the COVID-19 public health emergency at certain facilities where pharmaceutical products, including biological products, are manufactured, processed, packed or held. 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 Prometheus360.

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 the Takeda Agreement with Millennium Pharmaceuticals, Inc., pursuant to which we established a strategic collaboration to develop a companion diagnostic product for one selected drug target, with the option for Takeda to select an additional drug target, in support of development and potential commercialization by Takeda of any therapeutic clinical candidates that it develops in connection with the agreement for the treatment of IBD. In addition, we have entered into a co-development and

manufacturing agreement with 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. 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 uncurbed 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 Prometheus360, 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 and clinical 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 current and future clinical trials, including our ongoing 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.

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.

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;
- 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 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.

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 product. 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, Rinvoq, 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.

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 Prometheus360, 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 and companion diagnostics, which may change from time to time;
- coverage and reimbursement policies with respect to our therapeutic product candidates 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 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 have taken and may continue to take actions in an effort to slow the spread of COVID-19, including issuing varying forms of “stay-at-home” orders, and restricting business functions. While it is not possible at this time to estimate the impact that COVID-19 could have on our business in the future, particularly as we advance our product candidates through 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 ongoing or 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 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 33 full-time employees and 3 part-time employees as of March 31, 2021. 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 March 31, 2021, 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 laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our 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 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 constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- the federal Health Insurance Portability and Accountability Act of 1996, 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 during the previous year to other health care providers, including physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiology assistants 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 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 prescribe our 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, 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 inseparable 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. The U.S. Supreme Court is currently reviewing the 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 March 31, 2021, 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. 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. The likelihood of implementation of any of these reform initiatives is uncertain, particularly in light of the new presidential administration. 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.

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 hold approximately \$10 million in product liability insurance coverage in the aggregate. 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, 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 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 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, 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 spinoffs, 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.

Our ability to use net operating loss carryforwards and other tax attributes may be limited.

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, 2020, we had federal and state net operating loss (NOL) carryforwards of approximately \$50.1 million and \$9.8 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 Coronavirus Aid, Relief and Economic Security Act (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 Internal Revenue Code of 1986, as amended (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 our initial public offering (IPO) 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 our IPO. 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. While we co-own with Dr. Falk Pharma GmbH one U.S. provisional patent application related to the composition of our PR600 product candidate, we do not currently own or license any issued composition of matter patents covering our PR600 product candidate, and we cannot be certain that any non-provisional patent applications we or our licensors may file will result in issued patent claims covering the composition of matter of our PR600 product candidate. Provisional patent applications are not eligible to become issued patents until, among other things, a non-provisional patent application is filed claiming priority to one or more of our related provisional applications within 12 months of filing the first-filed provisional patent application. 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 we 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. 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 Prometheus360 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 Prometheus360, 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 impeding 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 Prometheus360, 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 CCPA 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

Prior to our IPO, there was no public market for our common stock, and an active, liquid and orderly market for our common stock may not develop or be maintained.

Prior to our IPO, there was no public market for our common stock. Our common stock only recently began trading on the Nasdaq Global Market (Nasdaq), and we can provide no assurance that we will be able to develop an active trading market for our common stock. Even if an active trading market is developed, it may not be maintained. 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 price at which they paid. 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;
- innovations, clinical trial results, product approvals and other developments regarding our competitors;
- 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.

Our executive officers, directors and principal stockholders, if they choose to act together, have the ability to control or significantly influence all matters submitted to stockholders for approval.

As of March 31, 2021, our executive officers, directors and greater than 5% stockholders, in the aggregate, own approximately 67.4% of our outstanding common stock. As a result, such persons, acting together, have the ability to control or 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.

In connection with our IPO, our directors and executive officers and holders of substantially all of our outstanding securities 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 the prospectus for our IPO, 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. 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, these shares of common stock will be eligible for sale in the public market, except that shares held by our directors, executive officers and other affiliates will be subject to volume limitations under Rule 144 under the Securities Act.

In addition, as of March 31, 2021, 5,023,579 shares of common stock are subject to outstanding options under our employee benefit plans and 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.

The holders of 26,853,508 shares of our outstanding common stock, or approximately 69.2% of our total outstanding common stock based on shares outstanding as of March 31, 2021, 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. 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 our IPO. 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 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 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 our IPO, we had been a private company with limited accounting personnel and other resources to address our internal control over financial reporting. In connection with the audits of our 2019 and 2020 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.

Provisions in our governing 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 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 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 provides 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 provides that the Court of Chancery of the State of Delaware will be 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 also provides that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States will 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.

General Risk Factors

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

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. We are subject to the reporting requirements of the Exchange Act, which requires, 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.

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 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.

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. For further discussion on the potential liability related to the violation of these laws, see “Risk Factors—We, our collaborators and our service providers may be subject to a variety of privacy and data security laws and contractual obligations, which could increase compliance costs and our failure to comply with them could subject us to potentially significant fines or penalties and otherwise harm our business.”

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.

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.

Changes in laws and policy relating to taxes may have an adverse effect on our financial condition, results of operations and cash flows. For example, the Tax Act significantly changed the U.S. federal income taxation of U.S. corporations. The Tax Act remains unclear in various 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) NOL rules (as discussed above), (ii) the alternative minimum tax refund and (iii) business interest deduction limitations under Section 163(j) of 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 any changes in tax law and the potential tax consequences of investing in our common stock.

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. 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.

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 begins 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.

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.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Unregistered Sales of Equity Securities

During the quarter ended March 31, 2021, pursuant to our 2017 Equity Incentive Plan, certain of our employees and consultants were granted options to purchase an aggregate of 2,116,870 shares of common stock at an exercise prices ranging from \$3.70 to \$6.70 per share. During the quarter ended March 31, 2021, options to purchase 56,645 shares of our common stock issued under our 2017 Equity Incentive Plan were exercised for aggregate consideration of \$64,117, at a weighted average exercise price of \$1.13. The stock options and the common stock issuable upon the exercise of such options as described 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 Rule 506 promulgated thereunder as a transaction not involving any public offering.

In January 2021, in a subsequent closing pursuant to a Series D preferred stock purchase agreement, dated October 30, 2020, we sold to investors 93,995,300 shares of Series D-2 convertible preferred stock, in a private placement, including shares issued to Nestlé Health Science US Holdings, Inc. (NHS) as part of our acquisition of Prometheus Laboratories, Inc., at a per share purchase price of \$0.8510. We received gross proceeds of approximately \$73.8 million from the sale of Series D-2 convertible preferred stock to investors, excluding NHS, during the quarter ended March 31, 2021.

Use of Proceeds

On March 11, 2021, our registration statement on Form S-1 (File No. 333-253323) was declared effective by the SEC for our IPO. At the closing of the offering on March 16, 2021, we sold 11,500,000 shares of common stock, which included the exercise in full by the underwriters of their option to purchase 1,500,000 additional shares, at an initial public offering price of \$19.00 per share and received gross proceeds of \$218.5 million, which resulted in net proceeds to us of approximately \$199.8 million, after deducting underwriting discounts and commissions of approximately \$15.3 million and offering-related transaction costs of approximately \$3.4 million. None of the expenses associated with the initial public offering were paid to directors, officers, persons owning ten percent or more of any class of equity securities, or to their associates, or to our affiliates. SVB Leerink LLC and Credit Suisse Securities (USA) LLC acted as joint book-running managers for the offering.

There has been no material change in the planned use of proceeds from our initial public offering from that described in the Prospectus.

Issuer Repurchases of Equity Securities

None.

Item 3. Defaults Upon Senior Securities

Not Applicable.

Item 4. Mine Safety Disclosures

Not Applicable.

Item 5. Other Information

None.

Item 6.Exhibits

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
3.1	Amended and Restated Certificate of Incorporation	8-K	3/17/2021	3.1	
3.2	Amended and Restated Bylaws	8-K	3/17/2021	3.2	
4.1	Specimen stock certificate evidencing the shares of common stock	S-1/A	3/8/21	4.1	
4.2	Amended and Restated Investors' Rights Agreement, dated October 30, 2020, by and among the Registrant and certain of its stockholders	S-1	2/19/21	4.2	
4.3	Warrant issued to Oxford Finance LLC, dated January 24, 2020	S-1	2/19/21	4.3	
10.1#	Prometheus Biosciences, Inc. 2021 Incentive Award Plan and form of stock option grant notice and stock option agreement thereunder	S-1/A	3/8/21	10.2	
10.2#	Prometheus Biosciences, Inc. 2021 Employee Stock Purchase Plan	S-1/A	3/8/21	10.3	
10.3#	Non-Employee Director Compensation Program	S-1/A	3/8/21	10.4	
10.4#	Amended and Restated Employment Letter Agreement, dated February 17, 2021, by and between Mark C. McKenna and the Registrant	S-1	2/19/21	10.5	
10.5#	Amended and Restated Employment Letter Agreement, dated February 17, 2021, by and between Keith W. Marshall, Ph.D. and the Registrant	S-1	2/19/21	10.6	
10.6#	Amended and Restated Employment Letter Agreement, dated February 17, 2021, by and between Allison Luo, M.D. and the Registrant	S-1	2/19/21	10.7	
10.7#	Amended and Restated Employment Letter Agreement, dated February 17, 2021, by and between Timothy K. Andrews and the Registrant	S-1	2/19/21	10.8	
10.8#	Employment Letter Agreement, dated February 7, 2021, by and between Mark Stenhouse and the Registrant	S-1/A	3/8/21	10.9	
10.9#	Form of Indemnification Agreement for Directors and Officers	S-1	2/19/21	10.9	
10.10	Lease Agreement, by and between SNH Medical Office Properties Trust and the Registrant, dated March 24, 2021				X
31.1	Certification of Chief Executive Officer of Prometheus Biosciences, Inc., as required by Rule 13a-14(a) or Rule 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
31.2	Certification of Chief Financial Officer of Prometheus Biosciences, Inc., as required by Rule 13a-14(a) or Rule 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
32.1*	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
32.2*	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X

101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.	X
101.SCH	Inline XBRL Taxonomy Extension Schema Document	X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	X
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)	

Indicates management contract or compensatory plan.

* This certification is deemed not filed for purpose of section 18 of the Exchange Act or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

PROMETHEUS BIOSCIENCES, INC.

Date: May 13, 2021

By: /s/ Mark C. McKenna
Mark C. McKenna
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 13, 2021

By: /s/ Keith W. Marshall, Ph.D.
Keith W. Marshall, Ph.D.
Chief Financial Officer
(Principal Financial and Accounting Officer)

LEASE

BY AND BETWEEN

SNH MEDICAL OFFICE PROPERTIES TRUST
LANDLORD

AND

PROMETHEUS BIOSCIENCES, INC.
TENANT

3050 SCIENCE PARK ROAD
SAN DIEGO, CALIFORNIA

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LEASE

3050 Science Park Road San Diego, CA 92121

ARTICLE 1

Reference Data

1.1 Introduction and Subjects Referred To.

This is a lease (this "Lease") entered into by and between SNH Medical Office Properties Trust, a Maryland real estate investment trust ("Landlord") and Prometheus Biosciences, Inc., a Delaware corporation ("Tenant").

Each reference in this Lease to any of the following terms or phrases shall be construed to incorporate the corresponding definition stated in this Section 1.1.

Date of this Lease: March 24, 2021

Building and Property: That building in the City of San Diego located at 3050 Science Park Road (the "Building"). The Building and the land parcels on which it is located and the sidewalks adjacent thereto are hereinafter collectively referred to as the "Property". The Property and the buildings located at 3030 and 3040 Science Park Road are collectively referred to as the "Complex" and are depicted on the Site Plan attached as Exhibit A hereto

Premises: The entire rentable area of the second (2nd) floor of the Building, substantially as shown on Exhibit A hereto.

Premises Rentable Area: 27,834 square feet.

Original Term: Ten (10) years, expiring on the day preceding the tenth (10th) anniversary of the Commencement Date, except that if the Commencement Date shall occur on a day other than the first day of a month, the Original Term shall expire on the last day of the month in which such anniversary shall occur.

Annual Fixed Rent:

<u>Months</u>		<u>Annual Fixed Rent per rentable square foot per annum</u>	<u>Annual Fixed Rent</u>	<u>Monthly Installments</u>
1-12	\$	67.20	\$ 1,870,444.80	\$ 155,870.40
13-24	\$	69.22	\$ 1,926,558.14	\$ 160,546.51
25-36	\$	71.29	\$ 1,984,354.89	\$ 165,362.91
37-48	\$	73.43	\$ 2,043,885.53	\$ 170,323.79
49-60	\$	75.63	\$ 2,105,202.10	\$ 175,433.51
61-72	\$	77.90	\$ 2,168,358.16	\$ 180,696.51
73-84	\$	80.24	\$ 2,233,408.92	\$ 186,117.41
85-96	\$	82.65	\$ 2,300,411.16	\$ 191,700.93
97-108	\$	85.13	\$ 2,369,423.52	\$ 197,451.96
109-120	\$	87.68	\$ 2,440,506.24	\$ 203,375.52

For purposes of the schedule above, if the Commencement Date is not the first day of a month, the first calendar month shall be the month following the partial month in which the Commencement Date shall occur (such that there shall be twelve (12) full calendar months before Month 13). So long as there shall not be a Default of Tenant (as defined in Section 8.1) hereunder, Annual Fixed Rent shall be abated in full for months two (2) through seven (7) (the "Abatement Period") as set forth in the schedule above. Should there be a Default of Tenant at any time prior to the expiration of the Abatement Period (such expiration of the Abatement Period being the "Full Rent Date"), Tenant shall no longer be entitled to such abatement of Annual Fixed Rent from and after the date of such Default of Tenant.

Tenant's Percentage: The percentage equivalent (calculated to the second decimal place) of the number obtained by dividing the Premises Rentable Area by the rentable area of the Building (deemed to be 55,102 square feet). Tenant's Percentage shall be fifty and fifty-one hundredths percent (50.51%).

Permitted Uses: General office and laboratory uses, subject to the provisions of Subsection 6.1.2.

Security Deposit: \$467,611.20.

Commercial General
Liability Insurance

Limits: \$5,000,000 per occurrence.

Original Address of

Landlord: SNH Medical Office Properties Trust
c/o The RMR Group LLC
8631 West Third Street Suite 301E
Los Angeles, California 90048 Attn: Vice President West Region

Landlord's Agent: The RMR Group LLC or such other entity as shall be designated by Landlord from time to time.

Original Address of

Tenant: Prometheus Biosciences, Inc.
12670 High Bluff Drive
San Diego, California 92130 Attention: CFO and General Counsel

Address for

Payment

of Rent: SNH Medical Office Properties Trust PNC Bank, NA
c/o The RMR Group LLC Dept #300
P.O. Box 31001-2144
Pasadena, California 91110-2144

1.2 Exhibits.

The Exhibits listed below in this section are incorporated in this Lease by reference and are to be construed as a part of this Lease.

- EXHIBIT A. Plans showing the Premises and Complex.
- EXHIBIT A-1. Base Building Work.
- EXHIBIT A-2. Space Plan.
- EXHIBIT B. Rules and Regulations.
- EXHIBIT C. Alterations Requirements.
- EXHIBIT D. Contractor's Insurance Requirements.
- EXHIBIT E. Intentionally Omitted.
- EXHIBIT F. Declaration By Landlord and Tenant.
- EXHIBIT G. LEED Requirements.
- EXHIBIT H. Confidentiality Agreement.

ARTICLE 2

Premises and Term

2.1 Premises. Landlord hereby leases the Premises to Tenant and Tenant hereby leases the Premises from Landlord, subject to and with the benefit of the terms, covenants, conditions and provisions of this Lease, excluding exterior faces of exterior walls. Tenant shall have, as appurtenant to the Premises, rights to use, in common with others, subject to reasonable rules of general applicability to tenants of the Building from time to time made by Landlord of which Tenant is given notice, the common lobbies, hallways, stairways, stairwells, elevators, elevator shafts, common walkways and

driveways (if any) necessary for access to the Building, parking facilities and other common areas and those portions of the Complex that are provided or operated for use in common by Landlord (the "Common Areas"). Landlord reserves control of the pipes, ducts, conduits, wires and appurtenant fixtures and other common facilities serving the Common Areas (provided that, subject to Landlord's reasonable approval, Tenant shall have the right to use its pro rata share of such areas to provide services or utilities to the Premises) and the premises of other tenants in the Building.

2.2 Term. The term of this Lease shall be for a period beginning on the Commencement Date (as defined in Section 3.1) and continuing for the Original Term and any extension of the term hereof in accordance with the provision of this Lease, unless sooner terminated as hereinafter provided. When the dates of the beginning and end of the Original Term have been determined such dates shall be evidenced by a confirmatory document executed by Landlord and Tenant in the form substantially as shown on Exhibit F hereto and delivered each to the other, but the failure of Landlord and Tenant to execute or deliver such document shall have no effect upon such dates. The Original Term and any extension of the term hereof in accordance with the provisions of this Lease is hereinafter referred to as the "term" of this Lease.

2.3 Early Access. Commencing approximately thirty (30) days prior to the projected Substantial Completion Date, Tenant and its contractors shall have access to the Premises for the purposes of installing furniture, fixtures and telecommunications equipment and cabling, but only to the extent that such work shall not interfere with or delay the performance of Landlord's Work and provided that Tenant and its contractors, employees and agents shall comply with all directions given by Landlord and its contractors to prevent any such interference or delay and for the protection of Landlord's Work. Any such work performed by Tenant shall be subject to the provisions of Subsection 6.2.5 of this Lease.

2.4 Early Termination Option. Tenant shall have an option (the "Early Termination Option") to terminate the term of this Lease without cause effective as of the seventh (7th) anniversary of the Full Rent Date (the "Early Termination Date") by giving Landlord written notice of Tenant's election to exercise the Early Termination Option not less than twelve (12) months prior to the Early Termination Date. As a condition to the effectiveness of Tenant's notice exercising the Early Termination Option Tenant shall pay Landlord, concurrently with such notice, a termination fee equal to \$2,750,000.00 plus any portion of Landlord's Moving Contribution, as defined in Section 3.3(d), that has not yet been repaid to Landlord as of the Early Termination Date.

2.5 Right of First Refusal. So long as this Lease is still in full force and effect, if within one hundred twenty (120) days following the Date of this Lease Landlord shall receive a bona fide written offer from a third party (a "Prospect") to lease any available space on the first (1st) floor of the Building which Landlord intends to accept, or if Landlord shall make a bona fide written offer to a Prospect to lease any available space on any such floor of the Building which is acceptable to such Prospect, Landlord shall so notify Tenant (the "ROFR Notice") identifying the space (the "ROFR Space") Landlord proposes to lease to the Prospect and Tenant may, by giving notice to Landlord (the "ROFR Acceptance") within five (5) Business Days after receipt of the ROFR Notice, irrevocably elect to lease the ROFR Space. If Tenant shall have so elected to lease the ROFR Space, it shall, within ten (10) days after submission by Landlord, enter into an amendment to this Lease, which shall be in a commercially reasonable form prepared by Landlord, confirming the lease of such ROFR Space to Tenant on the terms and conditions then and thereafter applicable to the Premises initially demised hereunder. If (a) Tenant shall not elect to lease the ROFR Space within the aforesaid five (5) Business Day period, or (b) if Landlord shall not, within one hundred twenty (120) days following the Date of this Lease, receive a bona fide written offer from a Prospect to lease any available space on the first (1st) floor of the Building

which Landlord intends to accept, or (c) if Landlord shall not, within one hundred twenty (120) days following the Date of this Lease, make a bona fide written offer to a Prospect to lease any available space on any such floor of the Building which is acceptable to such Prospect, then Tenant shall have no further rights under this Section 2.5 and Landlord shall thereafter be free to lease any or all of the ROFR Space to the Prospect or to any other third party on such terms as Landlord shall determine, it being agreed that time is of the essence with respect to the exercise of Tenant's rights under this Section 2.5.

2.6 Extension Option. So long as this Lease is still in full force and effect, and subject to the Conditions (as hereinafter defined), which Landlord may waive, in its discretion, at any time, but only by notice to Tenant, Tenant shall have the right to extend the term of this Lease for one (1) additional period (the "Extended Term") of five (5) years, commencing on the day succeeding the expiration of the Original Term and ending on the day immediately preceding the fifth (5th) anniversary of the commencement of the Extended Term. All of the terms, covenants and provisions of this Lease applicable immediately prior to the commencement of the Extended Term shall apply to the Extended Term except that (i) the Annual Fixed Rent for the Extended Term shall be the Market Rate (as hereinafter defined) for the Premises determined as of the commencement of such Extended Term, as designated by Landlord by notice to Tenant ("Landlord's Notice"), but subject to Tenant's right to dispute as hereinafter provided; and (ii) Tenant shall have no further right to extend the term of this Lease beyond the Extended Term. If Tenant shall elect to exercise the aforesaid option, it shall do so by giving Landlord notice (an "Election Notice") of its election not later than twelve (12) months nor sooner than fifteen (15) months prior to the expiration of the Original Term. If Tenant fails to give such notice to Landlord, the term of this Lease shall automatically terminate no later than the end of the Original Term, and Tenant shall have no further option to extend the term of this Lease, it being agreed that time is of the essence with respect to the giving of such notice. If Tenant shall extend the term hereof pursuant to the provisions of this Section 2.6, such extension shall (subject to satisfaction of the Conditions, unless waived by Landlord) be automatically effected without the execution of any additional documents, but the parties shall, at the request of either, execute an agreement confirming the Annual Fixed Rent for the Extended Term. Following a request by Tenant made not earlier than eighteen (18) months prior to the expiration of the Original Term, for Landlord's determination of the fair market rental value for the Extended Term, Landlord shall give Tenant notice of such determination not later than thirty (30) days after receipt of such request. The "Conditions" are that, as of the date of the Election Notice there shall exist no Default of Tenant and Prometheus Biosciences, Inc. (or any successor by Merger, or any Affiliate) shall actually occupy the entire Premises.

"Market Rate" shall mean the then fair market annual rent for the Premises for the Extended Term (determined as set forth below). If Tenant disagrees with Landlord's designation of the Market Rate, then Tenant shall give notice thereof to Landlord within twenty (20) days after Landlord's Notice (failure to provide such notice of disagreement within such 20-day period constituting acceptance by Tenant of Market Rate as set forth in Landlord's Notice); and if the parties cannot agree upon the Market Rate by the date that is thirty (30) days following Landlord's Notice, then the Market Rate shall be submitted to appraisal as follows: Within fifteen (15) days after the expiration of such thirty (30) day period, Landlord and Tenant shall each give notice to the other specifying the name and address of the appraiser each has chosen. The two appraisers so chosen shall meet within ten (10) days after the second appraiser is appointed and if, within twenty (20) days after the second appraiser is appointed, the two appraisers shall not agree upon a determination of the Market Rate in accordance with the following provisions of this Section 2.6 they shall together appoint a third appraiser. If only one appraiser shall be chosen whose name and address shall have been given to the other party within such fifteen (15) day period and who shall have the qualifications hereinafter set forth, that sole appraiser shall render the decision which would otherwise have been made as hereinabove provided.

If said two appraisers cannot agree upon the appointment of a third appraiser within ten (10) days after the expiration of such twenty (20) day period, then either party, on behalf of both and on notice to the other, may request such appointment by the then President of the Real Estate Board (or any similar or successor organization) for the Torrey Pines submarket of San Diego in accordance with its then prevailing rules. If said President shall fail to appoint said third appraiser within ten (10) days after such request is made, then either party, on behalf of both and on notice to the other, may request such appointment by the American Arbitration Association (or any successor organization) in accordance with its then prevailing rules. In the event all three appraisers cannot agree upon the Market Rate within fifteen (15) days after the third appraiser shall have been appointed, the appraisers selected by Landlord and Tenant shall each simultaneously submit to the third appraiser in a sealed envelope his or her determination of the Market Rate, and the third appraiser shall then determine the Market Rate by selecting either the Market Rate determination of the appraiser selected by Landlord or the Market Rate determination of the appraiser selected by Tenant. The third appraiser's decision as to which of the other two appraisers' Market Rate determination shall be the Market Rate for the applicable Extended Term shall be rendered in writing to both Landlord and Tenant and shall be final and binding upon them.

Each of the appraisers selected as herein provided shall have at least ten (10) years' experience as a commercial real estate broker in the Torrey Pines submarket of San Diego dealing with properties of the same type and quality as the Building. Each party shall pay the fees and expenses of the appraiser it has selected and the fees of its own counsel. Each party shall pay one half (1/2) of the fees and expenses of the third appraiser (or the sole appraiser, if applicable) and all other expenses of the appraisal. The decision and award of the appraiser(s) shall be in writing and shall be final and conclusive on all parties, and counterpart copies thereof shall be delivered to both Landlord and Tenant. Judgment upon the award of the appraiser(s) may be entered in any court of competent jurisdiction.

The appraiser(s) shall determine the Market Rate of the Premises for the Extended Term and render a decision and award as to their determination to both Landlord and Tenant (a) within twenty (20) days after the appointment of the second appraiser, (b) within twenty (20) days after the appointment of the third appraiser or (c) within fifteen (15) days after the appointment of the sole appraiser, as the case may be. In rendering such decision and award, the appraiser(s) shall assume (i) that neither Landlord nor the prospective tenant is under a compulsion to rent, and that Landlord and Tenant are typically motivated, well-informed and well-advised, and each is acting in what it considers its own best interest, (ii) the Premises are fit for immediate occupancy and use "as is", (iii) that in the event the Premises have been damaged by fire or other casualty prior to the commencement of the Extended Term, they have been fully restored. The appraisers shall also take into consideration the rents contained in leases for comparable space in the Building, or in comparable buildings in the Torrey Pines submarket of San Diego, for comparable periods of time.

If the dispute between the parties as to the Market Rate has not been resolved before the commencement of Tenant's obligation to pay the Annual Fixed Rent based upon determination of such Market Rate, then Tenant shall pay the Annual Fixed Rent under the Lease based upon the Market Rate designated by Landlord in Landlord's Notice until either the agreement of the parties as to the Market Rate, or the decision of the appraiser(s), as the case may be, at which time Tenant shall pay any underpayment of the Annual Fixed Rent to Landlord, or Landlord shall refund any overpayment of the Annual Fixed Rent to Tenant.

Landlord and Tenant hereby waive the right to an evidentiary hearing before the appraiser(s) and agree that the appraisal shall not be an arbitration nor be subject to state or federal law relating to arbitrations.

2.7 Measurement of the Premises. Landlord and Tenant agree that the Premises Rentable Area identified in Section 1.1 is recited for administrative purposes only and that, although the Annual Fixed Rent has been determined by reference to such square footage (regardless of the possibility that the actual measurement of the Premises may be more or less than the number identified, irrespective of measurement method used), Annual Fixed Rent and Tenant's Percentage shall not be changed except as expressly provided in this Lease. Notwithstanding the foregoing, if Landlord makes alterations, additions or improvements to the Building lobby that result in an increase or decrease in the rentable area of the Building and the Premises Rentable Area, Annual Fixed Rent and Tenant's Percentage shall be adjusted to take into account any such increase or decrease.

2.8 CASp Disclosures. For purposes of Section 1938(a) of the California Civil Code, Landlord hereby discloses to Tenant, and Tenant hereby acknowledges, that the Premises have not undergone inspection by a Certified Access Specialist (CASp). As required by Section 1938(e) of the California Civil Code, Landlord hereby states as follows: "A Certified Access Specialist (CASp) can inspect the subject premises and determine whether the subject premises comply with all of the applicable construction-related accessibility standards under state law. Although state law does not require a CASp inspection of the subject premises, the commercial property owner or lessor may not prohibit the lessee or tenant from obtaining a CASp inspection of the subject premises for the occupancy or potential occupancy of the lessee or tenant, if requested by the lessee or tenant. The parties shall mutually agree on the arrangements for the time and manner of the CASp inspection, the payment of the fee for the CASp inspection, and the cost of making any repairs necessary to correct violations of construction-related accessibility standards within the premises." In furtherance of the foregoing, Landlord and Tenant hereby agree as follows: (a) any CASp inspection requested by Tenant shall be conducted, at Tenant's sole cost and expense, by a CASp designated by Landlord, subject to Landlord's reasonable rules and requirements; (b) Tenant, at its sole cost and expense, shall be responsible for making any improvements or repairs within the Premises to correct violations of construction-related accessibility standards; and (c) if a CASp inspection done by or for Tenant in its use or occupancy of the Premises shall require any improvements or repairs to the Building or Property (outside the Premises) to correct violations of construction-related accessibility standards, then Tenant shall reimburse Landlord upon demand, as Additional Rent, for the cost to Landlord of performing such improvements or repairs.

ARTICLE 3

Commencement and Condition

3.1 Commencement Date. The Commencement Date shall be the Substantial Completion Date, as defined in Section 3.3(e). Notwithstanding the foregoing, if Tenant's personnel shall occupy all or any part of the Premises for the conduct of its business prior to the Commencement Date as determined pursuant to the preceding sentence, such date of conduct of business shall, for all purposes of this Lease, be the Commencement Date. For clarity, Tenant's personnel may perform tasks designed to prepare the Premises for occupancy, such as IT functions, which will not be deemed conduct of business for purposes of this Section 3.1.

3.2 Condition of Premises. Landlord shall deliver possession of the Premises to Tenant and Tenant agrees to accept the Premises with the work set forth on Exhibit A-1 in the column titled "Provided by Landlord at Landlord Cost" and the areas labelled as "Base Building Work" on Exhibit A-2 (such work being the "Base Building Work") and with Landlord's Work, as defined below, substantially complete. Other than with respect to the Base Building Work and Landlord's Work, the Premises shall be delivered in its current condition as of the Date of this Lease, Landlord's sole obligation to make changes to such current condition prior to the Commencement Date being the Base Building Work and Landlord's Work. Tenant acknowledges that except as set forth in this Section 3.2, it is not relying on any representations of Landlord or Landlord's agents or employees as to the current condition or the condition of the Base Building Work, and Landlord shall have no obligation with respect thereto except as may be expressly set forth in this Lease. The Base Building Work will be completed in accordance with all applicable laws and building codes and in compliance with plans and permits for the Base Building Work as submitted to the City of San Diego, and no costs associated with the Base Building Work will be charged against the Landlord Contribution or otherwise charged to Tenant, including any costs associated with changes required to cause the Base Building Work to comply with applicable laws. As of the Commencement Date, the base Building systems and facilities serving the Premises shall be in good working order and in material compliance with applicable laws and building codes.

3.3 Preparation of the Premises.

(a) Landlord shall construct certain improvements to the Premises as shown generally in the "Space Plan" attached hereto as Exhibit A-2, using Building standard materials and installations except as agreed otherwise and specified in the Space Plan. Landlord shall cause its architect to prepare construction drawings and specifications ("Landlord's Plans") for said improvements and shall deliver Landlord's Plans to Tenant for its approval. Tenant shall give Landlord a notice approving or disapproving Landlord's Plans not later than ten (10) Business Days (as defined in the Rules and Regulations) after Landlord's Plans are delivered to Tenant. Any notice of disapproval shall identify with reasonable specificity any items that Tenant disapproves, provided that any such items that represent a requested change from the Space Plan shall be subject to Landlord's reasonable approval, which may be withheld if the requested change is reasonably anticipated to (i) require changes that would affect (a) the Base Building Work serving or located in areas outside the Premises or (b) the condition of the Building outside of the Premises, and in all events any costs associated with any approved changes to the Base Building Work and/or the Building as set forth in this clause (i) shall be deducted from Landlord's Contribution or (ii) result in more than a de minimus delay in the completion of Landlord's Work (unless Tenant agrees that any such delay will be a Tenant Delay, without the requirement of further notice). In the event Tenant gives Landlord a timely notice of disapproval, to the extent that the requested changes are reasonably acceptable to Landlord (subject to the conditions set forth in the immediately preceding sentence), Landlord shall make the necessary corrections to Landlord's Plans and shall resubmit Landlord's Plans to Tenant for Tenant's approval (in which case Tenant shall have three (3) Business Days to review the corrected Landlord's Plans and to notify Landlord of any errors or omissions as aforesaid, and to the extent Tenant fails to so notify Landlord, such resubmission shall be deemed approved) and this process shall continue until final Landlord's Plans are approved by Tenant.

(b) Promptly after approval of Landlord's Plans, Landlord shall exercise all reasonable efforts to complete the work specified therein (collectively, "Landlord's Work") by February 1, 2022, but Tenant shall have no claim against Landlord for failure so to complete Landlord's Work by any such date except the right to terminate this Lease in accordance with Section 3.3(e). Landlord shall perform

Landlord's Work in compliance with all applicable laws, codes and regulations and in a good and workmanlike manner. Tenant agrees that Landlord may make any changes in Landlord's Work from that shown on Landlord's Plans to the extent necessary to accommodate field conditions, permitting requirements, unavailability of materials and other circumstances or conditions which first become apparent following approval of Landlord's Plans, with the approval of Tenant, not to be unreasonably withheld or delayed. As soon as reasonably practicable, Landlord shall provide Tenant with a schedule for the completion of Landlord's Work and will keep Tenant reasonably informed of any changes to such schedule.

(c) Landlord shall provide Tenant with an allowance ("Landlord's Contribution") of \$6,262,650.00 for the performance of Landlord's Work (which may include those portions of Landlord's Work set forth on Exhibit A-1 in the column titled "Provided at Tenant's Cost, subject to payment from Landlord's Contribution and/or the Moving Allowance, subject to cap on FF&E Costs & the Moving Allowance"), and Tenant shall not be liable for any cost of Landlord's Work to the extent that such cost thereof is less than or equal to Landlord's Contribution, nor shall Tenant be entitled to any refund, credit or rent abatement except as set forth herein. To the extent that the cost of Landlord's Work, as shown on the Approved Budget (defined below) exceeds Landlord's Contribution (such excess being the "Excess Cost"), Tenant shall pay the entire Excess Cost within ten (10) days after delivery to Tenant of a final accounting of the cost of Landlord's Work. For purposes of this Section 3.3(c), the "cost" of Landlord's Work shall be the actual cost to Landlord of performing Landlord's Work including, without limitation, all architectural and engineering fees and expenses and all contractor charges for the cost of work and materials, the general contractor's profit, general conditions and overhead and all filing fees and other permitting costs, Tenant's project manager's fee (not to exceed two percent (2%) of Landlord's Contribution) and a construction management fee to be retained by Landlord for managing the design and construction of Landlord's Work equal to three percent (3%) of the cost of Landlord's Work exclusive of such fee (which shall be Landlord's only fee in connection with Landlord's Work). At Landlord's request, Tenant shall execute an agreement (the "Excess Cost Agreement") confirming only (i) Landlord's estimate of any Excess Cost, and (ii) Tenant's obligation to pay such Excess Cost in accordance with the terms of this Lease, within five (5) Business Days after Landlord's request, and Landlord shall have no obligation to commence Landlord's Work until Tenant shall have executed such Excess Cost Agreement.

Prior to the commencement of Landlord's Work, Landlord will provide Tenant with a breakdown of all costs and expenses anticipated to be incurred in connection with Landlord's Work, which budget will be prepared by Landlord based on bids, where applicable, and the general contractor's reasonable estimate, and which will be a good faith estimate of the costs of Landlord's Work. Tenant will approve or reasonably disapprove of such bids and budget (together, the "Bid Package") within five (5) Business Days after its receipt of the Bid Package and in the event Tenant disapproves of any item in the Bid Package, Tenant will state with reasonable specificity which items it disapproves. Landlord and Tenant will work together to resolve any disputes relating to the Bid Package, including making changes to Landlord's Work as needed. The Bid Package will thereafter be revised and resubmitted to Tenant for approval and such process will be repeated until the Bid Package is approved by Tenant (as so approved, the "Approved Budget"). Any time required to revise Landlord's Plans in order to reduce the budget as set forth above in excess of fifteen (15) Business Days will be considered a Tenant Delay (as defined below). Landlord shall not commence Landlord's Work until Tenant shall have approved the Approved Budget. Throughout the construction of Landlord's Work, Landlord will notify Tenant promptly upon its discovery of any material changes to the Approved Budget. If the cost of Landlord's Work is less than \$6,262,650.00, then up to \$278,340.00 of such difference (such lesser amount being the "Balance") may be used by Tenant as reimbursement for (i) the purchase of furniture, trade fixtures and equipment for the

Premises, (ii) costs incurred by Tenant in connection with its move into the Premises or otherwise preparing the Premises for occupancy, and (iii) the purchase and installation of cabling for the Premises (collectively, the “FF&E Costs”). Landlord shall reimburse Tenant for the FF&E Costs (in an amount equal to the lesser of the invoices submitted by Landlord or the Balance) within thirty (30) days after Tenant submits to Landlord paid invoices, provided that Landlord shall have no obligation to make any payment to Tenant hereunder prior to the time that the cost of Landlord’s Work shall have been determined or at any time that there exists a Default of Tenant (as defined in Section 8.1) or with respect to any request for payment received later than ninety (90) days following the Substantial Completion Date, time being of the essence. In addition to the foregoing, if once the cost of Landlord’s Work shall have been finally determined the cost is less than \$6,262,650.00, then one-half of any such difference, in an amount not to exceed \$347,925.00, shall be made available to Tenant (in addition to the Balance) to be applied to the FF&E Costs.

(d) Further, if requested by Tenant in writing, Landlord will provide Tenant with a moving allowance (the “Landlord’s Moving Contribution”) in an amount not to exceed \$139,170.00 to be used as reimbursement for costs incurred by Tenant in connection with (i) moving expenses incurred in connection with Tenant’s move into the Premises, (ii) the purchase of furniture, trade fixtures and equipment for the Premises, (iii) the purchase and installation of cabling for the Premises, (iv) Tenant’s costs to install signage as set forth in Subsection 6.2.7 and (v) any Excess Costs, provided that Landlord’s Moving Contribution shall be repaid to Landlord as hereinafter provided. Landlord’s Moving Contribution shall be paid to Tenant within thirty (30) days after Tenant submits to Landlord a written request for payment accompanied by invoices from Tenant’s contractors and vendors for such costs; provided that, notwithstanding the foregoing, Landlord shall have no obligation to make Landlord’s Moving Contribution available at any time that there exists a Default of Tenant or with respect to any request for payment received later than six (6) months after the Commencement Date. Tenant shall repay any portion of Landlord’s Moving Contribution disbursed pursuant to this Section 3.3(d) to Landlord by increasing the Annual Fixed Rent for the portion of the Original Term commencing on the first day of the first month after which Landlord’s Moving Contribution is paid to Tenant, by an amount equal to the level monthly payments of principal and interest, payable monthly, in advance, which would be necessary to repay the portion of Landlord’s Moving Contribution disbursed pursuant to this Section 3.3(d), together with interest thereon at a rate of eight percent (8%) per annum, over the period from the day Landlord’s Moving Contribution is paid to Tenant through the last day of the Original Term. Tenant shall execute an amendment to this Lease confirming the increase in the Annual Fixed Rent on account of Landlord’s Moving Contribution within five (5) Business Days after Landlord’s request.

(e) The “Substantial Completion Date” shall be the first day as of which (a) the Base Building Work is substantially complete, (b) Landlord’s Work has been completed except for minor items of work, correction or adjustment which can be completed without causing undue interference with Tenant’s use of the Premises (i.e. so called “punch list” items), (c) a Certificate of Substantial Completion in the form of the American Institute of Architects document G704, or its equivalent, executed by the project architect and the project general contractor shall have been certified to Landlord and a copy thereof delivered to Tenant and (d) Landlord shall have obtained a certificate of occupancy or its equivalent for the Premises (which may be conditional or temporary) if required by law for Tenant to occupy and use the Premises for the Permitted Uses. Landlord shall complete as soon as reasonably possible using good faith and continuous efforts all “punch list” items and Tenant shall afford Landlord access to the Premises for such purpose. Landlord shall notify Tenant in writing when Landlord in good faith believes that Landlord’s Work is substantially completed. Within three (3) Business Days after the giving of such notice to Tenant, Landlord, Landlord’s architect, Tenant (and Tenant’s architect or project manager, if any) shall jointly inspect the Premises at a time reasonably agreed to by the parties and

develop the list of punch list items, provided that in the event of any dispute between Landlord and Tenant regarding whether or not Landlord's Work is substantially complete, or if Tenant or Tenant's architect or project manager (if any) shall fail to attend such inspection, the determination of Landlord's architect as to whether Landlord's Work is substantially complete and any list of punch list items developed by Landlord and/or Landlord's architect shall be final and binding on Landlord and Tenant.

If the Substantial Completion Date is delayed due to any change requested by Tenant to the Space Plan, or due to any change requested by Tenant to Landlord's Plans or Landlord's Work after Tenant shall have approved Landlord's Plans, or due to any negligence, breach of this Lease or other wrongful conduct of Tenant or anyone acting under Tenant, or any interference with the performance of Landlord's Work due to Tenant's occupancy of portions of the Premises as provided in Section 3.1 above, such delay in the Substantial Completion Date shall be a "Tenant Delay", and in such event Landlord may, at its option, require Tenant to commence payment of Annual Fixed Rent as of the date that the Commencement Date would have occurred in the absence of such Tenant Delay(s), provided that such election by Landlord shall not accelerate the actual Commencement Date and any amount payable by Tenant pursuant to such election shall be payable as Additional Rent in addition to all Annual Fixed Rent and Additional Rent payable by Tenant during the term. Notwithstanding the foregoing, no Tenant Delay shall be deemed to have occurred unless and until Landlord has provided notice to Tenant's Construction Representative pursuant to Section 3.5 below specifying the action or inaction that constitutes a Tenant Delay. If such action or inaction is not cured within one (1) Business Day after the giving of such notice, then a Tenant Delay, as set forth in such notice, shall be deemed to have occurred commencing as of the date such notice was given and continuing for the number of days that the Substantial Completion Date is in fact delayed as a result of such Tenant Delay.

If the Substantial Completion Date has not occurred by May 1, 2022 (as such date may be extended for Tenant Delay and/or Force Majeure) and the Commencement Date shall not have occurred pursuant to the provisions of the second sentence of Section 3.1, then Tenant may give Landlord notice thereof at any time thereafter detailing in what respects Landlord's Work is not substantially complete and if Landlord shall not substantially complete all of Landlord's Work within seven (7) days after delivery of such notice (other than due to Tenant Delay and/or Force Majeure), Tenant shall be entitled to receive a credit against the Annual Fixed Rent next coming due under the Lease in the amount of \$5,124.51 for each day during the period commencing upon the expiration of such seven (7) day period and ending on the Substantial Completion Date. If the Substantial Completion Date has not occurred by July 1, 2022 (as such date may be extended for Tenant Delay and/or Force Majeure) and the Commencement Date shall not have occurred pursuant to the provisions of the second sentence of Section 3.1, Tenant may by giving notice to Landlord at any time prior to the Substantial Completion Date, elect to terminate this Lease; and if Tenant shall make such election this Lease shall cease and come to an end without further liability or obligation on the part of either party thirty (30) days after the giving of such notice it being agreed that time is of the essence with respect to the giving of such notice, unless, within such thirty (30) day period after Tenant's notice, Landlord substantially completes Landlord's Work (in which event such termination election shall be null and void). Tenant's right to a rent credit and Tenant's termination right, as set forth in this paragraph, shall be Tenant's sole and exclusive remedy at law or in equity for Landlord's failure to complete Landlord's Work. If Tenant exercises the termination option in accordance with this paragraph and this Lease terminates as set forth herein, then as of the date of any such termination this Lease shall thereafter be of no further force or effect, and Tenant will not be obligated to pay any amounts to Landlord on account of Excess Costs and Landlord will refund to Tenant any Security Deposit, pre-paid rent or other amounts paid hereunder. As used herein, "Force Majeure" shall be defined as any strike or other labor trouble, fire, flood or other casualty, breakage, accident, repairs, unusually severe weather, governmental preemption of priorities or

other controls in connection with a national or other public emergency, governmental moratoria, or inaction of governmental authority (or shortages of fuel, supplies or labor resulting therefrom), war, civil commotion, labor or transportation difficulties, inability to obtain supplies, or any other cause, whether similar or dissimilar, beyond Landlord's reasonable control.

3.4 Conclusiveness of Landlord's Performance. Tenant shall be conclusively deemed to have accepted Landlord's Work except for aspects of Landlord's Work that are not in good working order and that are specified by Tenant in a notice to Landlord given within sixty (60) days after any such deficient aspect of Landlord's Work becomes apparent to Tenant and not later than eleven (11) months after the Substantial Completion Date, time being of the essence. Landlord will obtain industry-standard warranties (which, to the extent available, shall be one (1) year warranties) from all contractors performing Landlord's Work and Base Building Work (whether new equipment is installed or existing equipment is refurbished) and will enforce such warranties in the event Tenant delivers notice of a deficiency within the time periods set forth in this Section 3.4.

3.5 Construction Representatives. Both Landlord and Tenant shall appoint one individual as its "Construction Representative" who is authorized to act on its behalf in connection with any matters arising pursuant to this Article 3. The Construction Representative may be changed from time to time by notice hereunder from the then current Construction Representative to the other party's Construction Representative or by notice from Landlord or Tenant pursuant to Section 10.1. Notwithstanding Section 10.1, any notices or other communication under this Article 3 may be made by letter or other writing sent by U.S. mail, facsimile or email, provided the communication is made by one party's Construction Representative to the other party's Construction Representative.

ARTICLE 4

Rent, Additional Rent, Insurance and Other Charges

4.1 The Annual Fixed Rent. Tenant shall pay Annual Fixed Rent to Landlord, or as otherwise directed by Landlord, without offset, abatement (except as provided in Article 7), deduction or demand. Annual Fixed Rent shall be payable in equal monthly installments, in advance, on the first day of each and every calendar month during the term of this Lease, at the Address for Payment of Rent, or at such other place as Landlord shall from time to time designate by notice, by check drawn on a domestic bank.

Annual Fixed Rent for any partial month shall be prorated on a daily basis (based on a 365 day year), and if Annual Fixed Rent commences on a day other than the first day of a calendar month, the first payment which Tenant shall make to Landlord shall be payable on the date Annual Fixed Rent commences and shall be equal to such pro-rated amount plus the installment of Annual Fixed Rent for the succeeding calendar month.

4.2 Additional Rent. Tenant shall pay to Landlord, as Additional Rent, Tenant's Percentage of Taxes and Operating Costs as provided in Subsections 4.2.1 and 4.2.2 and all other charges and amounts payable by or due from Tenant to Landlord (all such amounts referred to in this sentence being "Additional Rent").

4.2.1 Real Estate Taxes. Tenant shall reimburse Landlord for Tenant's Percentage of all Taxes ("Tenant's Tax Payment") attributable to any portion of the term of this Lease, as Additional Rent. Except as otherwise provided in the immediately following paragraph, Tenant shall pay Tenant's Tax Payment to Landlord at least ten (10) days prior to the date or dates within any year during the term

hereof that Taxes, or any fractional share thereof, shall be due and payable to any governmental authority responsible for collection of same (as stated in a notice to Tenant given at least thirty (30) days prior to the date or dates any such payment shall be due, which notice shall set forth the manner of computation of Tenant's Tax Payment due from Tenant, except that such payment shall be made to Landlord not later than thirty (30) days after such notice to Tenant if such notice is given subsequent to the date thirty (30) days prior to the date such portion of Taxes is due and payable as aforesaid).

At Landlord's election, Tenant shall pay to Landlord, as Additional Rent on the first day of each calendar month during the term but otherwise in the manner provided for the payment of Annual Fixed Rent, estimated payments on account of Tenant's Tax Payment, such monthly amounts to be sufficient to provide Landlord by the time Tax payments are due or are to be made by Landlord a sum equal to Tenant's Percentage thereof, as reasonably estimated by Landlord from time to time on account of Taxes for the then current Tax year. If the total of such monthly remittances is greater than Tenant's Percentage of Taxes for such Tax year, Landlord shall credit such overpayment against Tenant's subsequent obligations on account of Taxes (or promptly refund such overpayment if the term of this Lease has ended and Tenant has no further obligations to Landlord); if the total of such remittances is less than Tenant's Percentage of Taxes for such Tax year, Tenant shall pay the difference to Landlord within thirty (30) days after being so notified by Landlord.

If, after Tenant shall have made all payments due to Landlord pursuant to this Subsection 4.2.1, Landlord shall receive a refund of any portion of Taxes as a result of an abatement of such Taxes by legal proceedings, settlement or otherwise (without either party having any obligation to undertake any such proceedings), Landlord shall pay or credit to Tenant Tenant's Percentage of that percentage of the refund (after first deducting any expenses, including attorneys', consultants' and appraisers' fees, incurred in connection with obtaining any such refund) which equals the percentage of the applicable Tax year.

In the event that the Commencement Date shall occur or the term of this Lease shall expire or be terminated during any calendar year for which Taxes are being computed or Tenant's Percentage shall be modified during the term due to a change in the rentable area of the Building and/or the Premises or otherwise, as the case may be, then the amount of Taxes which may be payable by Tenant as provided in this Subsection 4.2.1 shall be pro-rated on a daily basis based on a 365 day year.

"Taxes" shall mean all taxes, assessments, excises and other charges and impositions which are general or special, ordinary or extraordinary, foreseen or unforeseen, of any kind or nature which are levied, assessed or imposed by any governmental authority upon or against or with respect to the Property, Landlord or the owner or lessee of personal property used by or on behalf of Landlord in connection with the Property, or taxes in lieu thereof, and additional types of taxes to supplement real estate taxes due to legal limits imposed thereon as well as an allocation reasonably and equitably determined by Landlord of any Taxes assessed to Common Areas or attributable to portions of the 3040 Science Park Road building (the "3040 Building") (or any other building in the Complex) containing a gym or conference center and any food service facility or other amenity for the Complex. Taxes shall include any assessment, tax, fee, levy or charge in addition to, or in substitution, partially or totally, of any assessment, tax, fee, levy or charge previously included within the definition of real property tax, it being acknowledged by Tenant and Landlord that Proposition 13 was adopted by the voters of the State of California in the June 1978 election ("Proposition 13") and that assessments, taxes, fees, levies and charges may be imposed by governmental agencies for such services as fire protection, street, sidewalk and road maintenance, refuse removal and for other governmental services formerly provided without charge to property owners or occupants, and, in further recognition of the decrease in the level and quality of governmental services and amenities as a result of Proposition 13, Taxes shall also include any

governmental or private assessments or the Property's contribution towards a governmental or private cost-sharing agreement for the purpose of augmenting or improving the quality of services and amenities normally provided by governmental agencies. Taxes shall not include franchise, estate, inheritance, income (except to the extent that a tax on income or revenue is levied solely on rental revenues and not on other types of income and then only from rental revenue generated by the Property and is of a type customarily passed through to tenants in the Torrey Pines submarket of San Diego) or capital levy taxes assessed on Landlord. Taxes also shall include all court costs, attorneys', consultants' and accountants' fees, and other expenses incurred by Landlord in analyzing and contesting Taxes through and including all appeals (provided any such costs will not exceed the reasonably anticipated savings in Taxes). Taxes shall include any estimated payment made by Landlord on account of a fiscal tax period for which the actual and final amount of taxes for such period has not been determined by the governmental authority as of the date of any such estimated payment. If any Taxes may be paid in installments without incurring a penalty or interest, then Landlord shall be deemed to have paid said Taxes over the longest period so allowed (whether or not actually paid in that manner), and only the installments allocable to periods included within the term shall be considered within the meaning of Taxes.

4.2.2 Operating Costs. Tenant shall reimburse Landlord for Tenant's Percentage of Operating Costs. Except as otherwise provided in the immediately following paragraph Tenant shall pay Tenant's Percentage of Operating Costs to Landlord within thirty (30) days from the date Landlord shall furnish to Tenant an itemized statement thereof, prepared, allocated and computed in accordance with customs and practices of the real estate industry in the greater San Diego area, consistently applied. Any year-end statement by Landlord relating to Operating Costs (other than an invoice for a monthly estimate) shall be final and binding upon Tenant unless Tenant shall contest any items therein by giving Landlord a Dispute Notice timely as hereinafter provided.

At the election of Landlord, Tenant shall pay to Landlord, as Additional Rent on the first day of each calendar month during the term but otherwise in the manner provided for the payment of Annual Fixed Rent, estimated payments on account of Operating Costs, such monthly amounts to be sufficient to provide to Landlord, by the end of each calendar year, a sum equal to Operating Costs for such year, as estimated by Landlord from time to time. If, at the expiration of each year in respect of which monthly installments of Operating Costs shall have been made as aforesaid, the total of such monthly remittances is greater than Operating Costs for such year, Landlord shall credit such overpayment against Tenant's subsequent obligations on account of Operating Costs (or promptly refund such overpayment if the term of this Lease has ended and Tenant has no further obligation to Landlord); if the total of such remittances is less than Operating Costs for such year, Tenant shall pay the difference to Landlord within thirty (30) days after being so notified by Landlord.

In the event that the Commencement Date shall occur or the term of this Lease shall expire or be terminated during any calendar year for which Operating Costs are being computed or Tenant's Percentage shall be modified during the term due to a change in the rentable area of the Building and/or the Premises or otherwise, as the case may be, then the amount of Operating Costs which may be payable by Tenant as provided in this Subsection 4.2.2 shall be pro-rated on a daily basis based on a 365 day year.

“Operating Costs” shall include, without limitation, all costs and expenses paid or incurred for the operation, cleaning, management, maintenance, repair, insurance, upkeep and security of the Property, including an allocation as reasonably determined by Landlord of those costs attributable to Common Areas, including, without limitation:

(a) all salaries, wages, fringe benefits, payroll taxes and workmen’s compensation insurance premiums related thereto and all other costs paid or incurred with respect to employment of personnel engaged in operation, administration, cleaning, maintenance, repair, upkeep and security of the Property including, without limitation, supervisors, property managers, accountants, bookkeepers, janitors, carpenters, engineers, mechanics, electricians and plumbers, provided that if any employee whose compensation is included in Operating Expenses is not employed solely in connection with the operation of the Complex, then only the portion of such employee’s compensation allocable to such employee’s services in connection with the Complex (as allocated to the Property) shall be included in Operating Expenses.

(b) all utilities and other costs related to provision of heat (including oil, steam and/or gas), electricity, air conditioning, and water (including sewer charges) and other utilities to the Common Areas;

(c) all costs, including supplies, material and equipment costs, for cleaning and janitorial services to the Property, the Building and, if applicable, adjacent walks and ways (including, without limitation, trash removal and interior and exterior window cleaning), and interior and exterior landscaping and pest control;

(d) the cost of replacements for tools and other similar equipment used in the repair, maintenance, cleaning and protection of the Property, provided that, in the case of any such equipment used jointly on other property of Landlord, such costs shall be suitably prorated among the Property and such other properties;

(e) all costs and premiums for fire, casualty, rental income, liability and such other insurance as may be maintained from time to time by Landlord relating to the Property and premiums for fidelity bonds covering persons having custody or control over funds or other property of Landlord relating to the Property;

(f) all costs of maintaining, repairing, operating, inspecting and protecting the Property (including, without limitation, lighting, installation, maintenance, repair and alteration of signs (but not signs for a specific tenant), snow removal on the Property and adjacent walks and ways, paving, patching and restriping of parking areas and operation, maintenance, replacement and repair of heating, ventilating and air conditioning equipment, fire protection and security systems, elevators, roofs, parking areas and any other common Building equipment, systems or facilities), and all costs of structural and other repairs and, to the extent subject to the limits on capital expenditures as set forth herein, replacements (other than repairs for which Landlord has received full reimbursement from contractors, other tenants of the Building or from others) necessary to keep the Property in good working order, repair, appearance and condition;

(g) costs of compliance with any laws, rules, regulations, ordinances, agreements or standards applicable to the Building or the Property, which conformance is not the responsibility of any tenant of the Building, and which Landlord elects or is required to perform;

(h) Landlord's office overhead costs provided that, if any such administrative or supervisory personnel are also employed on other property of Landlord, such cost of compensation shall be suitably prorated among the Property and such other properties;

(i) payments under all service contracts relating to matters referred to in Items (a) through (h) hereof;

(j) a management fee of three (3%) percent of gross rents payable by tenants of the Property; and

(k) attorney's fees and disbursements (exclusive of any such fees and disbursements incurred in tax abatement proceedings or in the preparation of leases) and auditing and other professional fees and expenses.

Notwithstanding the foregoing, for purposes of this Lease, Operating Costs shall not include the following:

(i) the cost of investigating, removing or remediating any Hazardous Materials on or under the Property that are determined to be in violation of Environmental Laws (as such terms are defined in Subsection 6.2.8 below) as of the Date of this Lease or that migrate onto the Property through no fault of Tenant;

(ii) all items and services for which Tenant or any other tenant in the Property separately reimburses Landlord or which Landlord provides selectively to one or more tenants (but not to Tenant) without reimbursement;

(iii) costs for which Landlord is separately reimbursed by any tenant or occupant of the Property (other than pursuant to an operating cost clause) or by insurance by its carrier or any tenant's carrier (or if Landlord fails to carry insurance required to be carried by Landlord under this Lease, costs which would have been covered by insurance had Landlord obtained the coverage required to be carried under this Lease) or by anyone else, and electric power costs for which any tenant directly contracts with the local utility;

(iv) Costs, including marketing costs, legal fees, space planner's fees, and brokerage fees incurred in connection with the original construction and development of the Property or the original or future leasing of the Property, and costs, including permit, license and inspection costs and allowances and other costs incurred with respect to the installation of tenant improvements made for new tenants in the Property or incurred in renovating or otherwise improving, decorating, painting or redecorating vacant leasable space for tenants or other occupants (or prospective tenants or occupants) of the Property;

(v) depreciation, interest and principal payments on mortgages or ground lease payments, and other debt costs except for the interest factor included in the annual charge off of those capital expenditures that are included in Operating Costs as hereinafter provided;

(vi) any cost or expense, fines, penalties or interest incurred as a result of violation by Landlord of any applicable laws;

- (vii) Landlord's or Landlord's property manager's corporate general overhead or corporate general administrative expenses;
- (viii) any compensation paid to clerks, attendants or other persons in commercial concessions operated by the Landlord;
- (ix) any bad debt loss, rent loss, or reserves for bad debts or rent loss;
- (x) costs, including marketing costs, legal fees, space planner's fees, and brokerage fees incurred in connection with the original construction and development of the Property or the original or future leasing of the Property, and costs, including permit, license and inspection costs and allowances and other costs incurred with respect to the installation of tenant improvements made for new tenants in the Property or incurred in renovating or otherwise improving, decorating, painting or redecorating vacant leasable space for tenants or other occupants (or prospective tenants or occupants) of the Property;
- (xi) all items and services for which Tenant reimburses Landlord outside of Operating Costs, by insurance proceeds or otherwise, or pays third persons, or which Landlord provides selectively to one or more tenants or occupants of the Building (other than Tenant) without reimbursement;
- (xii) attorney's fees and other legal expenses incurred in connection with negotiations with or disputes of tenants or occupants of the Building;
- (xiii) costs, other than those incurred in ordinary maintenance and repair for sculptures, paintings, fountains or other objects of art;
- (xiv) costs incurred to remove, study, test, remediate or otherwise related to the presence of Hazardous Materials (as defined below) in or about the Building, the Property or the Complex that are not brought upon, kept used, stored, handled, treated, generated in, or disposed of from, the Premises by Tenant or any of its agents, employees or invitees other than routine air and water testing or filtering;
- (xv) wages and/or benefits attributable to personnel above the level of senior property manager;
- (xvi) costs of work or replacements covered by warranties;
- (xvii) any costs associated with the Base Building Work or Landlord's Work or any refurbishment work or capital replacements which occurred prior to the Commencement Date;
- (xviii) cost to provide electricity, gas or water and sewer to any tenants' premises; and
- (xix) except for a property management fee to the extent allowed above, overhead and profit increment paid to the Landlord or to subsidiaries or affiliates of the Landlord for services in the Project to the extent the same exceeds the costs of such services rendered by qualified, first-class unaffiliated third parties on a competitive basis.

If, during the term of this Lease, Landlord shall make any capital expenditure, the total cost thereof shall not be included in Operating Costs for the Operating Year in which it was made, but Landlord may include in Operating Costs for such Operating Year in which such expenditure was made and in Operating Costs for each succeeding Operating Year an annual charge-off of such capital expenditure, provided such expenditure is (i) made to comply with any law, rule, regulation, order or ordinance, or any amendment thereto or interpretation thereof, first enacted after the Commencement Date, or (ii) made to protect the health, safety of the occupants of the Property, or (iii) made to replace worn out or obsolete items or to keep the Property in first-class condition, or (iv) designed to reduce Operating Costs. Any capital expenditure not included in the foregoing list will not be included in Operating Costs. Annual charge-offs shall be determined by dividing the original capital expenditure plus an interest factor, reasonably determined by Landlord as being the interest rate then being charged for long-term mortgages by institutional lenders on like properties, by the number of years of useful life of the improvement, repair, alteration or replacement made with the capital expenditure; and the useful life shall be determined reasonably by Landlord in accordance with then prevailing customs and practices of the real estate industry, consistently applied. Notwithstanding the foregoing, any capital expenditures required as a result of (i) any installations, alterations or additions to the Premises made by Tenant after the Commencement Date, or (ii) any particular use of the Premises by Tenant (i.e., a use other than typical general office and laboratory use) shall be borne by Tenant alone and shall be paid by Tenant to Landlord as Additional Rent in the Operating Year in which such expenditures are incurred.

Operating Costs attributable to the Common Areas or to all the properties in the Complex (for example, landscaping and insurance) may be allocated by Landlord among the Property and such other properties as Landlord may reasonably and equitably determine, whether by rentable square foot, acreage, value or other metric. Notwithstanding the foregoing, Operating Costs shall not include any costs incurred with respect to a building in the Complex other than the Building if such costs do not benefit the Complex as a whole or are not incurred with respect to any common areas or common facilities located in such other building.

In addition, if during any portion of any year for which Operating Costs are being computed, less than one hundred percent (100%) of the rentable area of the Building was leased to tenants or if Landlord is supplying less than one hundred percent (100%) of the rentable area of the Building with the services and utilities being supplied hereunder, Landlord may, at its option, reasonably project, on an item-by-item basis, the Operating Costs that would have been incurred if one hundred percent (100%) of the Building were occupied for such year and such services and utilities were being supplied to one hundred percent (100%) of the rentable area of the Building, and such projected amount shall, for the purposes hereof, be deemed to be the Operating Costs for such year.

Notwithstanding any provision of this Subsection 4.2.2 to the contrary, for purposes of computing Tenant's Percentage of Operating Costs under this Lease, in no event shall the amount of Controllable Operating Costs, as hereinafter defined, included in Operating Costs for any calendar year exceed the Controllable Cost Cap, as hereinafter defined, for such calendar year. For the purposes of this paragraph the following definitions shall apply:

(a) "Controllable Operating Costs" shall mean all Operating Costs, except for the following, which shall not be subject to the limitations on increases described above: (i) real estate and other taxes included within Operating Costs, (ii) utility charges (including sewer), (iii) insurance premiums, (iv) management fees, (v) the costs to comply with any law, rule, regulation, order or ordinance with which the Property complied, or was not required to comply, prior to the Commencement Date, or to comply with any amendment or change in interpretation of any such legal requirements after

the Commencement Date, (vi) the cost of health insurance provided by Landlord as a benefit to employees whose compensation is an Operating Cost, (vii) the cost of repairs to the Property required by casualty damage or other causes beyond Landlord's reasonable control, except to the extent Landlord is reimbursed by insurance or third parties and not in excess of commercially reasonable deductible amounts, (viii) the costs of snow and ice treatment and removal (if any); (ix) any Operating Costs, or portions thereof, which are governed or established by collective bargaining agreements; and (x) the Building's share of Operating Costs allocable to all buildings in the Complex.

(b) "Controllable Cost Cap" shall mean (i) for the first twelve (12) month period following the Commencement Date, one hundred percent (100%) of the Controllable Operating Costs (i.e. the amount thereof shall not be limited for such year), and (ii) for each succeeding twelve (12) month period, one hundred five percent (105%) of the amount of the Controllable Cost Cap for the immediately preceding twelve (12) month period.

Provided Tenant shall have paid all amounts invoiced by Landlord on account of Operating Costs for the applicable Operating Year, Landlord shall permit Tenant, at Tenant's sole cost and expense except as hereinafter provided, to review any of Landlord's invoices and statements relating to Operating Costs for such Operating Year at the place where such invoices and statements are customarily maintained by Landlord, provided such review is commenced within one hundred and twenty (120) days of Tenant's receipt of Landlord's final statement of Operating Costs for the applicable Operating Year (the "Final Statement") and thereafter undertaken by Tenant or its accountants (provided such accountants are compensated at usual hourly rate and not on a contingency fee basis) with due diligence. If any of Landlord's invoices or statements (or copies thereof) are not customarily maintained at Landlord's office in the San Diego area, then, at Tenant's expense, Landlord shall have copies of such documents made and sent to Landlord's San Diego area office so that Tenant may conduct its examination at such office. If Tenant objects to Landlord's accounting of any Operating Costs, Tenant shall, on or before the date one hundred and eighty (180) days following receipt of the Final Statement, notify Landlord that Tenant disputes the correctness of such accounting ("the "Dispute Notice"), specifying the particular line items which Tenant claims are incorrect otherwise, Tenant shall be deemed to have waived any and all objections to such Final Statement. If such dispute has not been settled by agreement within two (2) months thereafter, either party may submit the dispute to arbitration in accordance with the commercial arbitration rules of the American Arbitration Association. The decision of the arbitrators shall be final and binding on Landlord and Tenant and judgment thereon may be entered in any court of competent jurisdiction.

If it should be agreed or decided that Operating Costs were overstated by five percent (5%) or more, then Landlord shall promptly reimburse Tenant for the reasonable costs incurred by Tenant in reviewing Landlord's invoices and statements, Tenant's reasonable arbitration costs, plus any excess amount paid by Tenant on account of overstated Operating Costs with interest at the Default Rate. If it should be decided that Operating Costs were not overstated at all, then Tenant shall, as Additional Rent, promptly reimburse Landlord for its costs incurred in the arbitration and in preparing for Tenant's review of invoices and statements, and if Operating Costs shall have been understated or Tenant shall not have paid the Operating Costs Obligation in full, Tenant shall, as additional Rent, promptly pay any deficiency. In the event of an overstatement which is less than five percent (5%), each party shall be responsible for its own costs incurred in connection with such dispute. Tenant shall keep confidential all agreements involving the rights provided in this section and the results of any audits or arbitration conducted hereunder. Notwithstanding the foregoing, Tenant shall be permitted to furnish the foregoing information to its attorneys and accountants to the extent necessary to perform their respective service for Tenant

4.3 Personal Property and Sales Taxes. Tenant shall pay all taxes charged, assessed or imposed upon the personal property of Tenant and all taxes on the sales of services or inventory, merchandise and any other goods by Tenant in or upon the Premises.

4.4 Insurance.

4.4.1 Insurance Policies. Tenant shall, at its expense, take out and maintain, throughout the term of this Lease, the following insurance:

4.4.1.1 Commercial general liability insurance (on an occurrence basis, including without limitation, contractual liability, bodily injury, property damage, fire legal liability, and products and completed operations coverage) under which Tenant is named as an insured and Landlord and Landlord's Agent (and the holder of any mortgage on the Premises or Property, as set out in a notice from time to time) are named as additional insureds as their interests may appear, in an amount which shall, at the beginning of the term, be at least equal to the Commercial General Liability Insurance Limits, and, which, from time to time following the Original Term, shall be for such higher limits, if any, as Landlord shall determine to be customarily carried in the area in which the Premises are located at property comparable to the Premises and used for similar purposes;

4.4.1.2 Worker's compensation insurance with statutory limits covering all of Tenant's employees working on the Premises; and

4.4.1.3 Property insurance on a "replacement cost" basis with an agreed value endorsement covering all furniture, furnishings, fixtures and equipment and other personal property brought to the Premises by Tenant and anyone acting under Tenant and all improvements and betterments to the Premises performed at Tenant's expense; and

4.4.1.4 Business income and extra expense insurance covering twelve months loss of income.

4.4.2 Requirements. All policies of insurance maintained by Tenant shall contain deductibles and self-insured retentions not in excess of that reasonably approved by Landlord, shall contain a clause confirming that such policy and the coverage evidenced thereby shall be primary with respect to any insurance policies carried by Landlord and shall be obtained from insurers qualified to do business and in good standing in the State of California having a rating by A.M. Best Company of at least A- VIII or otherwise be acceptable to Landlord. Tenant shall, prior to the Commencement Date and thereafter, not less than thirty (30) days prior to any policy expiration, deliver to Landlord a certificate of the insurer, certifying that such policy has been issued and paid in full, providing the coverage required by this Section and containing provisions specified herein. Each such policy shall not be materially changed with respect to the interest of Landlord and such mortgagees of the Property (and others that are in privity of estate with Landlord of which Landlord provides notice to Tenant from time to time) without at least ten (10) days' prior written notice thereto. Any insurance required of Tenant under this Lease may be furnished by Tenant under a blanket policy carried by it provided that such blanket policy shall reference the Premises, and shall guarantee a minimum limit available for the Premises equal to the insurance amounts required in this Lease.

4.4.3 Waiver of Subrogation. Landlord and Tenant shall each endeavor to secure an appropriate clause in, or an endorsement upon, each property damage insurance policy obtained by it and covering the Building, the Premises or the personal property, fixtures and equipment located therein or thereon, pursuant to which the respective insurance companies waive subrogation and permit the insured, prior to any loss, to agree with a third party to waive any claim it might have against said third party. The waiver of subrogation or permission for waiver of any claim hereinbefore referred to shall extend to the agents of each party and its employees and, in the case of Tenant, shall also extend to all other persons and entities occupying or using the Premises by, through or under Tenant. If and to the extent that such waiver or permission can be obtained only upon payment of an additional charge then the party benefiting from the waiver or permission shall pay such charge upon demand, or shall be deemed to have agreed that the party obtaining the insurance coverage in question shall be free of any further obligations under the provisions hereof relating to such waiver or permission from such insurance companies.

Subject to the foregoing provisions of this Subsection 4.4.3, each party hereby releases the other with respect to any claim which it might otherwise have against the other party for any loss or damage to its property to the extent such damage is actually covered or would have been covered by policies of property insurance required by this Lease to be carried by the respective parties hereunder. In addition, Tenant agrees to exhaust any and all claims against its insurer(s) prior to commencing an action against Landlord for any loss covered by insurance required to be carried by Tenant hereunder.

4.5 Utilities. Tenant shall during the term pay all electricity charges allocable to the Premises and all charges for telephone and other utilities or services not supplied by Landlord pursuant to Subsections 5.1.1 and 5.1.2, whether designated as a charge, tax, assessment, fee or otherwise, all such charges to be paid as the same from time to time become due. Except as otherwise provided in this Section 4.5 or in Article 5, it is understood and agreed that Tenant shall make its own arrangements for the installation or provision of all utilities and services and that Landlord shall be under no obligation to furnish any utilities to the Premises.

Tenant acknowledges that Annual Fixed Rent and Additional Rent for Operating Costs do not include the cost of supplying electricity, gas, emergency power, chilled water or domestic water and sewer to the Premises. Landlord shall arrange for a supply of such utilities to the Premises as provided in Subsections 5.1.2 and 5.1.3. Chilled water, domestic water and electricity supplied to the Premises may be submetered and, if Tenant's Plans provide for such submetering Landlord, at Landlord's cost, will install such submeters as part of the Base Building Work. Tenant shall pay as Additional Rent upon invoicing by Landlord, the cost to Landlord of all such utilities that are submetered and supplied to the Premises as reasonably determined by Landlord on the basis of such submetering, without mark-up for profit to Landlord, and the cost maintaining and repairing the submeters used to measure Tenant's electrical consumption. Alternatively, if such submetering is not available with respect to the Premises (which shall include gas and emergency power), or if Tenant's Plans do not provide for submetering, Tenant shall pay Tenant's Percentage of the charges for such utilities allocable to those portions of the Building leased or intended to be leased to tenants within thirty (30) days of invoice therefor or, at Landlord's discretion and notwithstanding the first sentence of this paragraph, such costs shall be included in Operating Costs; provided, however, that if some or all of the areas leased or intended to be leased to tenants are submetered for any such utility, such Tenant's Percentage for purposes of this Section 4.5 only shall be determined by dividing the rentable area of the Premises by the rentable area of the portions of the Building not separately metered for consumption of the applicable utility.

If permitted by law, Landlord shall have the right at any time, and from time to time during the term of this Lease, to contract for electric services from the company of Landlord's choice, whether the company is the provider currently providing electric service to the Property ("Current Provider") or a different company or companies ("Alternate Provider"). Tenant shall cooperate with Landlord and Current Provider or Alternate Provider at all times, and, as reasonably necessary, shall allow Landlord and Current Provider or Alternate Provider reasonable access to the electric lines, feeders, risers, wiring, and any other equipment within the Premises. Landlord shall in no way be liable or responsible for any loss, damage or expense that Tenant may sustain or incur by reason of any change, failure, interference, disruption, or defect in the supply or character of the electric energy furnished to the Premises, or if the quantity or character of the electric energy supplied by the Current Provider or any Alternate Provider is no longer available or suitable for Tenant's requirements, and no such change, failure, defect, unavailability, or unsuitability shall constitute an actual or constructive eviction, in whole or in part, or entitle Tenant to any abatement or diminution of rent, or relieve Tenant from any of its obligations under the Lease. Notwithstanding the foregoing, Landlord will use commercially reasonable efforts not to disrupt Tenant's business operations in the Premises or to allow any Current Provider or any Alternate Provider to disrupt Tenant's business operations in the Premises.

4.6 Late Payment of Rent. If any installment of Annual Fixed Rent or any Additional Rent is not paid on or before the date the same is due, it shall bear interest (as Additional Rent) from the date due until the date paid at the Default Rate (as defined in Section 8.4). In addition, if any installment of Annual Fixed Rent or Additional Rent is unpaid for more than five (5) days after the date due, Tenant shall pay to Landlord a late charge equal to the greater of One Hundred Dollars (\$100) or ten percent (10%) of the delinquent amount. Notwithstanding the foregoing, as to the first such late payment in any calendar year, Tenant shall not be required to pay such late charge unless Tenant fails to pay the amount due within five (5) days after Landlord gives Tenant notice of such late payment, except that once Landlord shall have given Tenant such a notice, no such notice shall be required as a condition to Tenant's obligation to pay the late charge with respect to any subsequent late payments in the same calendar year. The parties agree that the amount of such late charge represents a reasonable estimate of the cost and expense that would be incurred by Landlord in processing and administration of each delinquent payment by Tenant, but the payment of such late charges shall not excuse or cure any default by Tenant under this Lease. Absent specific provision to the contrary, all Additional Rent shall be due and payable in full thirty (30) days after demand by Landlord.

4.7 Security Deposit. Upon execution of this Lease, Tenant shall deposit with Landlord the Security Deposit. The Security Deposit shall be held by Landlord as security for the faithful performance of all the terms of this Lease to be observed and performed by Tenant. The Security Deposit shall not be mortgaged, assigned, transferred or encumbered by Tenant and any such act on the part of Tenant shall be without force and effect and shall not be binding upon Landlord. Tenant shall cause the Security Deposit to be maintained throughout the term in the amount set forth in Section 1.1.

If the Annual Fixed Rent or Additional Rent payable hereunder shall be overdue and unpaid or should Landlord make any payment on behalf of the Tenant, or Tenant shall fail to perform any of the terms of this Lease, then Landlord may, at its option and without notice or prejudice to any other remedy which Landlord may have on account thereof, appropriate and apply the entire Security Deposit or so much thereof as may be necessary to compensate Landlord toward the payment of Annual Fixed Rent, Additional Rent or other sums or loss or damage sustained by Landlord due to such breach by Tenant; and Tenant shall forthwith upon demand restore the Security Deposit to the amount stated in Section 1.1. Notwithstanding the foregoing, upon the application by Landlord of all or any portion of the Security Deposit (with or without notice thereof to Tenant) to compensate Landlord for a failure by Tenant to pay

any Annual Fixed Rent or Additional Rent when due or to perform any other obligation hereunder, and until Tenant shall have restored the Security Deposit to the amount required by Section 1.1, Tenant shall be deemed to be in default in the payment of Additional Rent for purposes of Section 8.1(a)(I) hereof. So long as Tenant shall not be in default of its obligations under this Lease, Landlord shall return the Security Deposit, or so much thereof as shall have not theretofore been applied in accordance with the terms of this Section 4.7 (and less any amounts Landlord shall estimate shall be due from Tenant following year-end reconciliation of Operating Costs and Taxes) to Tenant promptly following the expiration or earlier termination of the term of this Lease and the surrender of possession of the Premises by Tenant to Landlord in accordance with the terms of this Lease. While Landlord holds the Security Deposit, Landlord shall have no obligation to pay interest on the same and shall have the right to commingle the same with Landlord's other funds. If Landlord conveys Landlord's interest under this Lease, the Security Deposit, or any part thereof not previously applied, shall be turned over by Landlord to Landlord's grantee, and Tenant shall look solely to such grantee for proper application of the Security Deposit in accordance with the terms of this Section 4.7 and the return thereof in accordance herewith. The holder of a mortgage on the Property shall not be responsible to Tenant for the return or application of the Security Deposit, whether or not it succeeds to the position of Landlord hereunder, unless such holder actually receives the Security Deposit.

Tenant shall have the right to post the Security Deposit in the form of a letter of credit (the "Letter of Credit"), which shall (a) be unconditional and irrevocable and otherwise in form and substance reasonably satisfactory to Landlord; (b) permit multiple draws; (c) be issued by a commercial bank reasonably acceptable to Landlord from time to time; (d) be made payable to, and expressly transferable in its entirety only by, Landlord (at no cost to Landlord); (e) be payable at sight upon presentment of a sight draft accompanied by a certificate of Landlord stating either that Tenant is in default under this Lease or that Landlord is otherwise permitted to draw upon such Letter of Credit under the express terms of this Lease, and the amount that Landlord is owed (or is permitted to draw) in connection therewith; and (f) expire not earlier than the ninety (90) days following the expiration of the term of this Lease, provided however such Letter of Credit may expire one (1) year following date of issuance but in such case Tenant shall deliver a replacement Letter of Credit or extension of the existing Letter of Credit and subsequent replacement Letters of Credit or extensions prior to the expiration of any existing Letter of Credit so that the original Letter of Credit or a replacement thereof (each of whose expiration date shall be not earlier than one year from issuance) shall be in full force and effect throughout the term of this Lease and for a period of at least ninety (90) days thereafter. Tenant shall maintain the Letter of Credit in the amount of the Security Deposit and shall deliver to Landlord any replacement Letter of Credit or confirmation of the extension of the expiration date of the existing Letter of Credit prior to the expiration of the then current Letter of Credit. Notwithstanding anything in this Lease to the contrary, any grace period or cure periods which are otherwise applicable under Section 8.1 hereof, shall not apply to any of the foregoing, and, specifically, if Tenant fails to comply with the requirements of subsection (f) above or if Tenant shall fail to maintain the Letter of Credit in the full amount of the Security Deposit after any draw thereon by Landlord, Landlord shall have the immediate right to draw upon the Letter of Credit in full and hold the proceeds thereof as a cash security deposit. Each Letter of Credit shall be issued by a commercial bank that has a credit rating with respect to certificates of deposit, short term deposits or commercial paper of at least P-2 (or equivalent) by Moody's Investor Service, Inc., or at least A-2 (or equivalent) by Standard & Poor's Corporation. If the issuer's credit rating is reduced below P-2 (or equivalent) by Moody's Investor Service, Inc., or at least A-2 (or equivalent) by Standard & Poor's Corporation, or if the financial condition of the issuer changes in any other materially adverse way, then Landlord shall have the right to require that Tenant obtain from a different issuer a substitute Letter of Credit that complies in all respects with the requirements of this Section, and Tenant's failure to obtain such substitute Letter of Credit within ten (10) days after Landlord's demand therefor (with no other

notice, or grace or cure period being applicable thereto) shall entitle Landlord immediately to draw upon the existing Letter of Credit in full, without any further notice to Tenant. Landlord may use, apply or retain the proceeds of the Letter of Credit to the same extent that Landlord may use, apply or retain any cash security deposit, as set forth herein. If Landlord is entitled to use, apply or retain the proceeds of the Letter of Credit, Landlord may draw on the Letter of Credit, in whole or in part, at Landlord's election. If Landlord draws against the Letter of Credit, Tenant shall, within five (5) Business Days after notice from Landlord, provide Landlord with either an additional Letter of Credit in the amount so drawn or an amendment to the existing Letter of Credit restoring the amount thereof to the amount initially provided. Tenant hereby agrees to cooperate promptly, at its expense with Landlord to execute and deliver to Landlord any modifications, amendments and replacements of the Letter of Credit, as Landlord may reasonably request to carry out the terms and conditions hereof.

Tenant hereby irrevocably waives and relinquishes any and all rights, benefits, or protections, if any, Tenant now has, or in the future may have, under Section 1950.7 of the California Civil Code, any successor statute, and all other provisions of law, now or hereafter in effect, including, but not limited to, any provision of law which (i) establishes the time frame by which a landlord must refund a security deposit under a lease, or (ii) provides that a landlord may claim from a security deposit only those sums reasonably necessary to remedy defaults in the payment of rent, to repair damage caused by a tenant, or to clean the subject premises. Tenant acknowledges and agrees that (A) any statutory time frames for the return of a security deposit are superseded by the express period identified in this Section 4.7, above, and (B) rather than be so limited, Landlord may claim from the Security Deposit (i) any and all sums expressly identified in this Section 4.7, above, and (ii) any additional sums reasonably necessary to compensate Landlord for any and all losses or damages caused by Tenant's default of this Lease, including, but not limited to, all damages or rent due upon termination of this Lease pursuant to Section 1951.2 of the California Civil Code.

ARTICLE 5

Landlord's Covenants

5.1 Affirmative Covenants. Landlord shall, during the term of this Lease provide the following:

5.1.1 Heat and Air-Conditioning. Landlord shall provide and maintain heat, ventilation and air-conditioning ("HVAC") equipment in accordance with the specifications set forth in the Base Building Work. If the temperature otherwise maintained in any portion of the Premises by the HVAC system is adversely affected as a result of (i) the type or quantity of any lights, machines or equipment used by Tenant in the Premises, (ii) the occupancy of any portion of the Premises by more than one person per two hundred (200) square feet of rentable area, (iii) an electrical load for lighting or power in excess of the limits specified in Subsection 6.2.4, or (iv) any partitioning or other improvements installed by Tenant, then at Tenant's sole cost, Landlord may install any equipment, or modify any existing equipment Landlord deems reasonably necessary to restore the temperature balance. Tenant agrees to keep closed, when necessary, blinds or other window treatments which, because of the sun's position, must be closed to provide for the efficient operation of the air conditioning system, and Tenant agrees to cooperate with Landlord and to abide by the reasonable regulations and requirements which Landlord may prescribe for the proper functioning and protection of the HVAC system. Landlord shall have no responsibility for providing any service from Separate HVAC Equipment, as defined in Subsection 6.1.3.

5.1.2 Cleaning; Water. Landlord shall provide cleaning, maintenance and landscaping to the Common Areas in accordance with standards generally prevailing throughout the term hereof in comparable office buildings in the greater San Diego area and furnish water to the Premises for the Permitted Use.

Notwithstanding anything contained herein to the contrary, in no event shall Landlord's cleaning or janitorial obligations relate to or refer to any of the following:

- (a) Any waste that is generated in the diagnosis, treatment, or immunization of human beings or animals, in research pertaining thereto, or in the production or testing of biologicals,
- (b) Any waste, device, instrument or item that comes in contact with bodily fluids, including, but not limited to, bandages, swabs, gauze, sponges, wraps, pads, paper, plastic, sutures, needles, scalpels, blades, or syringes,
- (c) Any medical device or paraphernalia that is utilized to treat any patient or other person for any medicinal, medical, diagnostic or therapeutic reason or purpose,
- (d) Any material of any type or nature whatsoever that is radioactive to any degree, whether as the result of its manufacture, use or application or any device, instrument or item that emits radiation,
- (e) Any waste that is considered a regulated medical waste, including, but not limited to, bio-hazardous waste or infectious waste, under any applicable laws, or
- (f) Any device, instrument or item that has become infected, contaminated, diseased, or otherwise exposed to harmful, contagious, or communicable organisms, bacteria, or other life form.

Tenant and Landlord agree that the removal, disposal, or destruction of all items listed in the preceding paragraphs of this Subsection 5.1.2 (hereinafter "Excepted Waste") shall be exclusively the responsibility of Tenant under all circumstances, and their disposal shall not become the obligation of Landlord for any reason. All such disposals of Excepted Waste shall comply with all applicable laws and shall be accomplished at times, in a manner and in a path prepared by Tenant and approved in writing and in advance by Landlord. Tenant agrees that Excepted Waste will be disposed of separately from the trash that is removed by Landlord. Tenant also agrees that Tenant will not mix or place Excepted Waste in regular trash containers. The parties further agree that Tenant shall be liable for Tenant's or its agents, employees, guests, visitors, invitees or licensees (collectively, "Tenant Parties") failure to timely, thoroughly and completely dispose of Excepted Waste, the manner in which handling or disposal of such Excepted Waste is accomplished, or due to exposure of any third party with such Excepted Waste. Tenant shall be liable to and shall pay any injured party for all damages, costs or expenses, including attorney fees, arising out of any exposure, harm, injury, disease, contamination, or affliction suffered as the result of any Excepted Waste stored, generated, or disposed of by Tenant or in the Premises. Tenant shall provide to Landlord any written plan of Excepted Waste management Tenant prepares, from which plan Tenant may redact any proprietary information before providing same to Landlord. Tenant shall contract with a reputable medical waste disposal company that shall be reasonably approved by Landlord and shall maintain all records regarding the disposal of Excepted Waste required by federal, state and local law or regulation and make such records available for Landlord review upon request.

5.1.3 Elevator, Lighting and Electricity. Landlord shall furnish non-exclusive passenger elevator service from the lobby to the Premises; purchase and install, at Tenant's expense, all building standard lamps, tubes, bulbs, starters and ballasts for lighting fixtures in the Premises; provide lighting to public and common areas of the Property; and arrange for the supply of electrical power to the Premises to accommodate a load not exceeding the limitations contained in Subsection 6.2.4.

5.1.4 Repairs. Except as otherwise expressly provided herein, Landlord shall, as part of Operating Costs as set forth in Subsection 4.2.2 above, make such repairs and replacements to the roof, exterior walls, floor slabs and other structural components of the Building, and to the Common Areas and facilities of the Building (including any common plumbing, electrical and HVAC equipment, life safety systems, roof membrane, elevators and any other common equipment or systems in the Building and all utility lines providing utilities to the Building) as may be necessary to keep them in good repair and condition (exclusive of equipment installed by Tenant and except for those repairs required to be made by Tenant pursuant to Subsection 6.1.3 hereof and repairs or replacements occasioned by any act or negligence of Tenant, its servants, agents, customers, contractors, employees, invitees, or licensees). Tenant hereby waives any and all rights under and benefits of subsection 1 of Section 1932 and Tenant hereby waives and releases its right to make repairs at Landlord's expense under Sections 1941 and 1942 of the California Civil Code or under any similar law, statute, or ordinance now or hereafter in effect.

5.1.5 Data Obligations. Tenant shall submit to Landlord, within thirty (30) days of request, but not more frequently than semi-annually, any waste management, recycling, energy and water consumption data in Tenant's possession, including usage and charges as they may appear on any utility bills received by Tenant. Landlord shall provide such non-proprietary, current information relating to Property energy and water consumption, waste management and recycling as Landlord has readily available, within thirty (30) days of request by Tenant, not more frequently than semi-annually.

5.2 Interruption. Landlord shall have no responsibility or liability to Tenant for failure, interruption, inadequacy, defect or unavailability of any services, facilities, utilities, repairs or replacements or for any failure or inability to provide access or to perform any other obligation under this Lease caused by breakage, accident, fire, flood or other casualty, strikes or other labor trouble, order or regulation of or by any governmental authority, inclement weather, repairs, inability to obtain or shortages of utilities, supplies, labor or materials, war, civil commotion or other emergency, transportation difficulties or due to any act or neglect of Tenant or Tenant's servants, agents, employees or licensees or for any other cause beyond the reasonable control of Landlord, and in no event shall Landlord be liable to Tenant for any indirect or consequential damages suffered by Tenant due to any such failure, interruption, inadequacy, defect or unavailability; and failure or omission on the part of Landlord to furnish any of same for any of the reasons set forth in this paragraph shall not be construed as an eviction of Tenant, actual or constructive, nor entitle Tenant to an abatement of rent, nor render the Landlord liable in damages, nor release Tenant from prompt fulfillment of any of its covenants under this Lease. Landlord will use commercially reasonable efforts to avoid any unreasonable disturbance of Tenant's access to and use of the Premises and, except in the event of an emergency, to consult with Tenant in advance of any such work which is reasonably expected to be disruptive as to the scheduling of any such planned repair work.

Landlord reserves the right to deny access to the Building and to interrupt the services of the HVAC, plumbing, electrical or other mechanical systems or facilities in the Building when necessary from time to time by reason of accident or emergency, or for repairs, alterations, replacements or improvements which in the reasonable judgment of Landlord are reasonably necessary, until such repairs, alterations, replacements or improvements shall have been completed. Landlord shall use

reasonable efforts to minimize the duration of any such interruption and to give to Tenant at least three (3) days' notice if service is to be interrupted, except in cases of emergency.

If due to Landlord's default, (i) the Premises or any portion thereof are unusable by Tenant for a period of more than ten (10) consecutive Business Days following notice, complying with the last sentence of this paragraph, from Tenant due to (I) a lack of any of HVAC services (other than HVAC services provided by any Separate HVAC), water, sewer, elevator service, access or electricity or (II) the failure by Landlord to perform repairs which Landlord is obligated to perform pursuant to Subsection 5.1.4, and (ii) Tenant shall, concurrently with the giving of such notice, discontinue use of the Premises or the portion thereof which is unusable as a result (other than for sporadic purposes such as salvage, security or retrieval of property), then as Tenant's sole remedy the Annual Fixed Rent and Additional Rent on account of Taxes and Operating Costs shall be equitably abated for such portion of the Premises rendered unusable for the period commencing on the expiration of such ten (10) Business Day period and ending on the date that the Premises (or such portion) is rendered usable. If more than fifty percent (50%) of the Premises is rendered unusable and if Tenant shall vacate the entire Premises, then the aforesaid abatement shall be a full abatement. In addition, if Tenant is entitled to a full abatement of Annual Fixed Rent hereunder for a period in excess of one hundred and eighty (180) consecutive days, and if Tenant shall have discontinued use of the entire Premises during all of such abatement period, then Tenant thereafter shall have the right to terminate the term of this Lease by giving notice of such election to Landlord at any time before Landlord shall have remedied the condition giving rise to such abatement, time being of the essence. Any notice from Tenant pursuant to the first sentence of this paragraph shall expressly state that the failure of Landlord to cure any claimed default timely shall give rise to Tenant's rights of rent abatement and termination hereunder.

5.3 Outside Services. In the event Tenant wishes to obtain services or to hire vendors relating to the repair, maintenance or security of the Premises, Tenant shall first obtain the prior approval of Landlord, not to be unreasonably withheld, for the installation and/or utilization of such services or vendors. Such services shall include, but shall not be limited to, utility providers, security services, moving services, equipment installers and the like. Notwithstanding any Landlord approval of the installation and/or utilization of such services or vendors, such installation and utilization shall be at Tenant's sole cost, risk and expense. Landlord will reasonably cooperate with Tenant's request for such vendor access.

Landlord shall, promptly following a request from Tenant, enter into commercially reasonable access or right-of-entry agreements (collectively, "Access Agreements") required by any telecommunications service provider reasonably approved by Landlord. In connection with the installation and operation of any telecommunications services, Landlord agrees that it shall not require any such approved carrier to pay any rent, fee, or similar charge in order to permit such carrier to retransmit its signal and/or have access to the Building; provided that the foregoing shall not restrict Landlord from collecting from any such carrier Landlord's legal fees reasonably incurred in connection with entering into any Access Agreements.

5.4 Access to Building. Subject to Section 5.2 and force majeure events, Tenant shall have access to the Building twenty-four (24) hours per day, seven (7) days per week. During Normal Building Operating Hours, the Building shall, subject to the provisions of Section 5.2, be open and access to the Premises shall be freely available, subject to the Rules and Regulations. During periods other than Normal Building Operating Hours, Tenant shall have access to the Premises, but such access shall also be subject to the Rules and Regulations. Tenant acknowledges that Tenant is responsible for providing security to the Premises following Tenant's entry onto the Premises for any reason and for its own

personnel whenever located therein. Subject to the foregoing, Landlord shall, at all times, retain the right to control and prevent such access by all persons whose presence, in the sole discretion of Landlord, may jeopardize the safety, protection, character, reputation and interests of the Building and its tenants or occupants. Landlord shall in no case be liable for damages resulting from any error with regard to the admission or exclusion of any person from the Building.

With Landlord's approval, which approval shall not be unreasonably withheld, conditioned or delayed, Tenant shall be permitted to install an electronic access control system for the Premises. Tenant shall provide Landlord with the proper access codes or keys necessary for Landlord to obtain access to the Premises, subject to Subsection 6.1.6 below. Such access control system may be installed as an Alteration (and may be funded by Landlord's Moving Contribution or as part of the FF&E Costs as provided in Section 3.3(c) or 3.3(d) above, or if not included in Landlord's Work, installed at any time during the term in accordance with Subsection 6.2.5 and at Tenant's sole cost and expense.

5.5 Parking. During the term hereof, Landlord shall make available to Tenant, its employees and invitees, at no additional charge, sixty-seven (67) unreserved parking spaces in the surface parking lot appurtenant to the Building and the building located at 3040 Science Park Road (collectively, the "Parking Facility"), all of which shall be available on a first-come, first-served basis. Tenant, its employees and invitees shall use the Parking Facility for the parking of passenger vehicles only and shall not allow any of its vehicles, or any vehicles on the Parking Facility through Tenant, to be left in the Parking Facility overnight (except for vehicles belonging to employees or invitees of Tenant who are either present at the Premises or whose vehicles shall remain in the Parking Facility for periods of not more than two (2) consecutive days while such persons are traveling for Tenant). Landlord reserves the right to (a) implement and modify systems to regulate access to and use of the Parking Facility, (b) designate and redesignate reserved and unreserved parking areas within the Parking Facility (for some or all tenants), (c) change entrances or exits and alter traffic flow within the Parking Facility, and (d) modify the Parking Facility to any extent, provided that no such changes in (a) – (d) will decrease the number of parking spaces available for Tenant's use. Landlord further reserves the right to close the Parking Facility or portions thereof temporarily to the extent necessary for maintenance and repairs. Landlord will use commercially reasonable efforts to schedule any work over a weekend. Tenant acknowledges that Landlord is not required to provide any security or security services for any of the Parking Facility. Tenant shall use reasonable efforts to cause its employees to comply with all reasonable rules and regulations pertaining to the Parking Facility, as the same may be established, amended, revised or supplemented by Landlord.

5.6 Legal Compliance. Landlord shall keep the structure and the Common Areas and systems of the Building in material compliance with all laws, building codes and regulations applicable thereto (including the Americans With Disabilities Act) after giving effect to any so-called legacy exceptions (provided Tenant shall have complied with its obligations under Subsection 6.1.3 and 6.1.4).

5.7 Indemnification. Subject to all limitations, waivers, exclusions and conditions contained in this Lease (each of which shall control in the event of any conflict or inconsistency with this Section 5.7), Landlord shall defend and indemnify Tenant and its directors, officers, agents and employees against and from any and all demands, claims, causes of action, fines, penalties, damage, liabilities, judgments and expenses (including, without limitation, reasonable attorneys' fees) asserted by or on behalf of any third party on account of bodily injury or damage to the property of such third party (excluding damage to the property of any subtenant or assignee of Tenant) arising out of the negligence or other wrongful conduct of Landlord or its agents, contractors or employees during the term of this Lease. In case of any action or proceeding brought against Tenant by reason of any such claim,

Landlord, upon notice from Tenant, shall resist or defend such action or proceeding and employ counsel therefor reasonably satisfactory to Tenant.

5.8 Landlord's Insurance. At all times during the term, Landlord, as part of the Operating Costs, shall keep in full force and effect the following insurance:

- (i) standard form property insurance on the Building, in an amount not less than the full replacement value thereof (subject to the deductibles and excluding footings and foundations and any leasehold improvements performed by tenants) the proceeds thereof shall be used in accordance with Article 7 below to the extent that the term of this Lease shall not be terminated; and
- (ii) any combination of Commercial General Liability (or an equivalent), Excess Liability and/or Umbrella Liability in the amount of at least Five Million Dollars (\$5,000,000).

5.9 Landlord's Hazardous Waste Representation. Landlord represents that to Landlord's knowledge, Landlord has not used, generated, manufactured, produced, stored, released, discharged or disposed of on, under, or about the Premises (or off-site of the Premises that might affect the Premises) or transferred to or from the Premises, any Hazardous Materials (as defined in Subsection 6.2.8) or allowed any other person or entity to do so, except in material compliance with Environmental Laws (as defined in Subsection 6.2.8). Landlord agrees that Operating Costs shall not include the cost of investigating, removing or remediating any Hazardous Materials on or under the Property that are determined to be in violation of Environmental Laws as of the Date of this Lease. To Landlord's knowledge as of the Date of this Lease, there are no Hazardous Materials at the Complex in violation of Environmental Laws or that require ongoing remediation or abatement.

ARTICLE 6

Tenant's Additional Covenants

6.1 Affirmative Covenants. Tenant shall do the following:

6.1.1 Perform Obligations. Tenant shall perform promptly all of the obligations of Tenant set forth in this Lease; and pay when due the Annual Fixed Rent and Additional Rent and all other amounts which by the terms of this Lease are to be paid by Tenant.

6.1.2 Use. Tenant shall, during the term of this Lease, use the Premises only for the Permitted Uses and from time to time, procure and maintain all licenses and permits necessary therefor and for any other use or activity conducted at the Premises, at Tenant's sole expense. Tenant shall comply with the requirements recited in Exhibit G; provided, however, that in the event of an inconsistency between the requirements of Exhibit G and Tenant's required safety procedures related to the Permitted Use, Tenant's compliance with Exhibit G shall be excused to the extent required for Tenant to comply with any such required safety procedures; and provided further that the foregoing provisions of this sentence shall not be deemed to require Tenant to obtain an independent LEED certification for Tenant's use of the Premises or any alterations or improvements performed by or for Tenant in the Premises. Landlord and Tenant shall, from time to time, provide to the other the name and contact information for a representative of such party with whom issues relating to sustainability and energy use may be communicated. Such issues may include, but not be limited to, retrofitting projects, building issues, energy efficiency upgrades and data access.

6.1.3 Repair and Maintenance. Tenant shall, during the term of this Lease, maintain the Premises in neat and clean order and condition and perform all repairs to the Premises and all fixtures, systems, and equipment exclusively serving the Premises (including Tenant's equipment and other personal property and any HVAC Equipment serving all or any portion of the Premises to the exclusion of any other space in the Building ("Separate HVAC Equipment")) as are necessary to keep them in good and clean working order, appearance and condition, reasonable use and wear thereof and damage by fire or by unavoidable casualty only excepted and shall replace any damaged or broken glass in interior windows and doors of the Premises (except glass in the exterior walls or doors of the Building) with glass of the same quality as that damaged or broken. Tenant shall contract separately for janitorial services for the Premises with Landlord's janitorial services provider, provided Landlord's preferred provider has competitive rates or, at Tenant's option another janitorial services provider reasonably acceptable to Landlord and Tenant shall cause the Premises to be cleaned in accordance with standards at least equal to Landlord's janitorial standards for comparable space in the buildings in the vicinity of the Building. Tenant shall dispose of all trash and rubbish in such manner as Landlord reasonably directs and shall comply with any reasonable recycling programs established by Landlord for the Building.

6.1.4 Compliance with Law. Tenant shall, during the term of this Lease, make all repairs, alterations, additions or replacements to the Premises required by any law or ordinance or any order or regulation of any public authority; keep the Premises safe and equipped with all safety appliances so required by applicable law or governmental authority; and comply with, and perform all repairs, alterations, additions or replacements required by, the orders and regulations of all governmental authorities with respect to zoning, building, fire, health and other codes, regulations, ordinances or laws applicable to the Premises or other portions of the Property and arising out of any particular use or manner of use of the Premises by Tenant (i.e. other than mere occupancy for general office or laboratory purposes) or arising out of any work performed by Tenant, except that Tenant may (but only so long as (i) Landlord shall not be subject to any fine or charge, (ii) neither the Property nor any portion thereof shall be subject to being condemned or vacated and (iii) neither the Property nor any portion thereof shall be subject to any lien or encumbrance) defer compliance so long as the validity of any such law, ordinance, order or regulation shall be contested by Tenant in good faith and by appropriate legal proceedings, if Tenant first gives Landlord assurance or security against any loss, cost or expense on account thereof in form and amount acceptable to Landlord.

6.1.5 Indemnification. Tenant shall neither hold, nor attempt to hold, Landlord or its employees or Landlord's agents or their employees liable for, and Tenant shall indemnify and hold harmless Landlord, its employees and Landlord's agents and their employees from and against, any and all demands, claims, causes of action, fines, penalties, damage, liabilities, judgments and expenses (including, without limitation, attorneys' fees) incurred in connection with or arising from: (i) any matter occurring on the Premises during the term; (ii) any negligence or willful misconduct of Tenant or any person claiming under Tenant, or the contractors, agents, employees, invitees or visitors of Tenant or any such person; (iii) any breach, violation or nonperformance by Tenant of any term, covenant or provision of this Lease or any law, ordinance or governmental requirement of any kind; and (iv) any injury or damage to the person, property or business of Tenant, its employees, agents, contractors, invitees, visitors or any other person entering upon the Property under the express or implied invitation of Tenant. If any action or proceeding is brought against Landlord or its employees or Landlord's agents or their employees by reason of any such claim, Tenant, upon notice from Landlord, shall defend the same, at Tenant's expense, with counsel reasonably satisfactory to Landlord. Notwithstanding the foregoing in no event shall this Subsection 6.1.5 require Tenant to hold harmless, indemnify or defend Landlord or its employees or Landlord's agents or their employees against any loss, cost, damage, liability, claim, or

expense to the extent arising out of the negligence or willful misconduct of Landlord or its employees or Landlord's agents or their employees.

6.1.6 Landlord's Right to Enter. Tenant shall, during the term of this Lease, permit Landlord and its agents and invitees to enter into and examine the Premises at reasonable times and to show the Premises to prospective lessees (during the last twelve (12) months of the term only), lenders, partners and purchasers and others having a bonafide interest in the Premises, and to make such repairs, alterations and improvements and to perform such testing and investigation as Landlord shall reasonably determine to make or perform and, during the last six (6) months prior to the expiration of this Lease, to keep affixed in suitable places notices of availability of the Premises. In exercising its rights hereunder, Landlord shall use reasonable efforts to minimize, to the extent practicable, any interference with the conduct of Tenant's business, but this shall not obligate Landlord to perform any work or to schedule any entry upon the Premises outside of Normal Building Operating Hours. Except in instances posing an imminent threat to life or property or to perform Landlord's routine obligations under Article 5, so long as this Lease is in full force and effect, Landlord shall give Tenant reasonable notice prior to making any entry into the Premises and use reasonable efforts to follow Tenant's reasonable safety and security protocols, provided, however, notwithstanding Section 10.1 to the contrary, such notice or request for entry by Landlord hereunder may be made orally, and Landlord's personnel, agents and contractors shall not seek entry into the Premises unless accompanied by an employee of Tenant. Notwithstanding any provision of this Lease or the Rules and Regulations to the contrary, Tenant may place separate locks on particular rooms, closets or storage spaces within the Premises and need not give Landlord copies of such keys (such rooms or other areas, "Secured Areas") and in such event Landlord agrees that it shall not, absent an emergency, seek entry into such Secured Areas so long as this Lease is in full force and effect, except to the extent necessary to make repairs or perform maintenance to the Building or to perform its other obligations or exercise its rights under this Lease, and Tenant agrees to give Landlord access to such Secured Areas promptly upon receiving a request from Landlord therefor (and Tenant's personnel may accompany Landlord during such access). Tenant shall provide Landlord with the name and telephone number of a representative of Tenant (the "Tenant Contact") whom Landlord can contact twenty four (24) hours per day, seven (7) days per week, to obtain access to the Premises (including any Secured Areas), and Tenant agrees to give Landlord and its agents and contractors access to the Premises as set forth in this Subsection

6.1.6 within twenty-four (24) hours after receiving a request from Landlord therefor (except in cases of emergency, when access shall be provided immediately upon request). If Tenant fails to give Landlord reasonably prompt access to the Premises to perform its obligations or to exercise its rights under this Lease after Landlord shall have given (or shall have attempted to give) the Tenant Contact a request for access, then Landlord may enter the Premises without further notice to Tenant and without being accompanied by a representative of Tenant and by force if necessary, and Landlord shall have no liability whatsoever to Tenant as a result of such entry and Tenant shall pay all reasonable costs and expenses incurred by Landlord to repair or reconstruct any damage to the Premises resulting from any such forcible entry by Landlord.

6.1.7 Personal Property at Tenant's Risk. Tenant shall, during the term of this Lease keep, at the sole risk and hazard of Tenant, all of the furnishings, fixtures, equipment, effects and property of every kind, nature and description of Tenant and of all persons claiming by, through or under Tenant which may be on the Property.

6.1.8 Payment of Landlord's Cost of Enforcement. Tenant shall pay on demand Landlord's expenses, including reasonable attorneys' fees, incurred in enforcing any obligation of Tenant under this Lease or in curing any default by Tenant under this Lease as provided in Section 8.4.

6.1.9 Yield Up. Tenant shall, at the expiration or earlier termination of the term of this Lease, or upon any earlier reentry or retaking of possession of the Premises by Landlord and/or termination of Tenant's right of possession and/or occupancy of the Premises, as applicable, surrender all keys to the Premises; remove all of its trade fixtures and personal property in the Premises; remove such installations (including wiring and cabling installed by or for Tenant wherever located), alterations (provided that, upon Tenant's request, Landlord shall have notified Tenant at the time of Landlord's consent to such Alterations that removal of such Alterations would be required upon the expiration or earlier termination of this Lease), signs and improvements made (or if applicable, restore any items removed) by or on behalf of Tenant as Landlord may request, wherever located; repair all damage caused by such removal; and vacate and yield up the Premises (including all installations, alterations, signs and improvements made by or on behalf of Tenant except as Landlord shall request Tenant to remove at the time of its consent, as set forth above), broom clean and in the good order and repair in which Tenant is obliged to keep and maintain the Premises by the provisions of this Lease. If Landlord so requests, Tenant, at its sole cost and expense, shall properly cap or seal its wiring and cabling (wherever located) at each end, properly label such wiring and cabling for future use, and surrender such wiring and cabling in a good and safe condition on or before the earlier of (i) the expiration or earlier termination of the term of this Lease, or (ii) the date on which Tenant discontinues the use of such wiring and cabling. Any property not so removed shall be deemed abandoned and may be removed and disposed of by Landlord in such manner as Landlord shall determine and Tenant shall pay Landlord the entire cost and expense incurred by it in effecting such removal and disposition and in making any incidental repairs and replacements to the Premises and for use and occupancy during the period after the expiration or earlier termination of the term of this Lease and prior to the performance by Tenant of its obligations under this Subsection 6.1.9.

Notwithstanding the preceding provisions of this Subsection 6.1.9, Tenant shall not be required to remove or restore any of the initial Landlord's Work installed in the Premises upon the expiration or earlier termination of the Lease.

6.1.10 Rules and Regulations. Tenant shall, during the term of this Lease, observe and abide by the Rules and Regulations of the Building set forth as Exhibit B, as the same may from time to time be amended, revised or supplemented (the "Rules and Regulations"), provided that such amendments, revisions or supplements shall not materially change the obligations of Landlord or Tenant as set forth in this Lease as of the Date of this Lease. Tenant shall further be responsible for compliance with the Rules and Regulations by the employees, servants, agents and visitors of Tenant. Landlord agrees that it shall apply the Rules and Regulations in a nondiscriminatory manner, but Landlord may waive Rules and Regulations with respect to particular tenants when Landlord shall have a good faith basis to do so. The failure of Landlord to enforce any of the Rules and Regulations against Tenant, or against any other tenant or occupant of the Building, shall not be deemed to be a waiver of such Rules and Regulations. In the event of a conflict between the express terms of this Lease and any requirement of the Rules and Regulations, the terms of this Lease shall control.

6.1.11 Estoppel Certificate. Tenant shall, within ten (10) Business Days' following written request by Landlord, execute, acknowledge and deliver to Landlord a statement in commercially reasonable form in writing certifying that this Lease is unmodified and in full force and effect and that to the best of Tenant's knowledge Tenant has no defenses, offsets or counterclaims against its obligations

to pay the Annual Fixed Rent and Additional Rent and any other charges and to perform its other covenants under this Lease (or, if there have been any modifications, that this Lease is in full force and effect as modified and stating the modifications and, if there are any defenses, offsets or counterclaims, setting them forth in reasonable detail), the dates to which the Annual Fixed Rent and Additional Rent and other charges have been paid, and any other matter pertaining to this Lease. Any such statement delivered pursuant to this subsection 6.1.11 may be relied upon by any prospective purchaser or mortgagee of the Property, or any prospective assignee of such mortgage.

6.1.12 Landlord's Expenses For Consents. Tenant shall reimburse Landlord, as Additional Rent, promptly on demand for all out-of-pocket legal, engineering and other professional services expenses incurred by Landlord in connection with all requests by Tenant for consent or approval hereunder.

6.1.13 Financial Information. Except to the extent such information is generally available to the public at no charge via the internet (or by other medium not requiring a special request to Tenant), Tenant shall, from and after the Date of this Lease and thereafter throughout the term of this Lease (but not more often than once per calendar year), provide Landlord with such information as to Tenant's financial condition and/or organizational structure as Landlord or the holder of any mortgage of the Property requires, within fifteen (15) days of request. Tenant may condition delivery of financial information hereunder upon Landlord's execution and delivery to Tenant of a Confidentiality Agreement in the form attached to this Lease as Exhibit H.

6.2 Negative Covenants. Tenant shall not do the following.

6.2.1 Assignment and Subletting. Tenant shall not assign, mortgage, pledge, hypothecate, encumber or otherwise transfer this Lease or any interest herein or sublease (which term shall be deemed to include the granting of concessions and licenses and the like) all or any part of the Premises or suffer or permit this Lease or the leasehold estate hereby created or any other rights arising under this Lease to be assigned, transferred, mortgaged, pledged, hypothecated or encumbered, in whole or in part, whether voluntarily, involuntarily or by operation of law, or permit the use or occupancy of the Premises by anyone other than Tenant except as hereinafter provided, without Landlord's prior written consent, which, subject to the terms and conditions of this Subsection 6.2.1, shall not be unreasonably withheld, conditioned or delayed. Unless Tenant's stock shall be traded or offered for trade (including in connection with an initial public offering) on a domestic national securities exchange, any transfer of the stock or partnership or beneficial interests or other evidences of ownership of Tenant or the issuance of additional stock or partnership or beneficial interests or other indicia of ownership in Tenant or any transaction pursuant to which Tenant is merged or consolidated with another entity or pursuant to which all or substantially all of Tenant's assets are transferred to any other entity shall be deemed to be an assignment of this Lease.

Notwithstanding the foregoing, Tenant may, without the need for Landlord's consent, but only upon not less than ten (10) days prior notice to Landlord (and Landlord agrees to hold in confidence and not to directly or indirectly reveal, publish, disclose or transfer any confidential information furnished or made available in connection with such notice, to any person or entity without the advance written permission of Tenant and, if required to comply with the terms of such transaction, Landlord will sign its standard form of confidentiality agreement as set forth in Exhibit H), assign its interest in this Lease (a "Permitted Assignment") to (i) any entity which shall be a successor to Tenant either by merger or consolidation (a "Merger") or to a purchaser of all or substantially all of Tenant's assets or stock in either case provided the successor or purchaser shall have a tangible net worth, after giving effect to the

transaction, of not less than \$200,000,000.00 (the “Required Net Worth”) or (ii) any entity (an “Affiliate”) which is a direct or indirect subsidiary or parent (or a direct or indirect subsidiary of a parent) of the named Tenant set forth in Section 1.1, in either case of (i) or (ii) only so long as (I) the principal purpose of such assignment is not the acquisition of Tenant’s interest in this Lease (except if such assignment is made for a valid intracorporate business purpose to an Affiliate) and is not made to circumvent the provisions of this Subsection 6.2.1, (II) except if pursuant to a Merger permitted by clause (i) above, Tenant shall, contemporaneously with such assignment, provide Landlord with a fully executed counterpart of any such assignment, which assignment shall comply with the provisions of this Subsection 6.2.1 and shall include an agreement by the assignee in form reasonably satisfactory to Landlord, to assume all of Tenant’s obligations under this Lease and be bound by all of the terms of this Lease, (III) in the case of an actual or deemed assignment pursuant to clause (i), Tenant shall provide Landlord, not less than ten (10) days in advance of any such assignment, evidence reasonably satisfactory to Landlord of the Required Net Worth of the successor or purchaser, and (IV) there shall not be a Default of Tenant at the effective date of such assignment. Tenant shall also be permitted, without the need for Landlord’s consent, but only upon not less than ten (10) days prior notice to Landlord, to enter into any sublease (a “Permitted Sublease”) with any Affiliate provided that such sublease shall expire upon any event pursuant to which the sublessee thereunder shall cease to be an Affiliate. Any assignment to an Affiliate shall provide that it may, at Landlord’s election, be terminated and deemed void if during the term of this Lease such assignee or any successor to the interest of Tenant hereunder shall cease to be an Affiliate; provided, however, that Landlord shall not make such election with respect to an assignment to an Affiliate if such Affiliate (i) satisfies the Required Net Worth requirements at the time of the assignment to such Affiliate and (ii) satisfies the Required Net Worth requirements at the time that such assignee or successor to the interest of Tenant hereunder shall cease to be an Affiliate.

In the event that Tenant shall enter into any sublease or assignment other than a Permitted Sublease or Permitted Assignment (which shall include any event pursuant to which an Affiliate to which the Lease has been assigned as set forth in the immediately preceding paragraph shall cease to be an Affiliate and shall not satisfy the Required Net Worth requirements at the time of the assignment to such Affiliate and at the time that such assignee or successor to the interest of Tenant hereunder shall cease to be an Affiliate), Tenant shall, not later than thirty (30) days prior to the proposed commencement of such sublease or assignment, give Landlord notice thereof, identifying the proposed subtenant or assignee, all of the material terms and conditions of the proposed sublease or assignment and such other information as the Landlord may reasonably request.

Landlord shall not unreasonably delay, condition or withhold its consent to the applicable assignment or sublease, provided that, in addition to any other reasonable grounds for withholding of consent, Landlord may withhold its consent if in Landlord’s good faith and reasonable judgment: (i) the proposed assignee or subtenant does not have a financial condition reasonably acceptable to Landlord; (ii) the business and operations of the proposed assignee or subtenant are not of comparable quality to the business and operations being conducted by the majority of other tenants in the Building; (iii) the proposed assignee or subtenant is a business competitor of Landlord or is an affiliate of a business competitor of Landlord; (iv) the identity of the proposed assignee or subtenant is, or the intended use of any part of the Premises, would be, in Landlord’s determination, inconsistent with first-class office space or Landlord’s commitments to other tenants in the Building or any covenants, conditions or restrictions binding on Landlord or applicable to the Property; (v) at the time of the proposed assignment or subleasing Landlord is able to meet the space requirements of Tenant’s proposed assignee or subtenant by leasing available space in the Building to such person or entity and either (a) the proposed assignee or subtenant is a tenant or other occupant of the Building or any building in the Complex, or (b) the proposed assignee or subtenant is an entity, or is affiliated with any entity, which shall have entered into negotiation with Landlord for space in the Building or Complex within the preceding twelve (12)

months; or (vi) any such sublease shall result in the Premises being occupied by more than two (2) parties (including Tenant) at any one time.

If this Lease is assigned or if the Premises or any part thereof are sublet (or occupied by any party other than Tenant and its employees) after a Default of Tenant Landlord may collect the rents from such assignee, subtenant or occupant, as the case may be, and apply the net amount collected to the Annual Fixed Rent and Additional Rent herein reserved, but no such collection shall be deemed a waiver of the provisions set forth in the first paragraph of this Subsection 6.2.1, the acceptance by Landlord of such assignee, subtenant or occupant, as the case may be, as a tenant, or a release of Tenant from the future performance by Tenant of its covenants, agreements or obligations contained in this Lease.

Any sublease of all or any portion of the Premises shall provide that it is subject and subordinate to this Lease and to the matters to which this Lease is or shall be subject or subordinate, that other than the payment of Annual Fixed Rent and Additional Rent due pursuant to Sections 4.1, 4.2.1 and 4.2.2 or any obligation relating solely to those portions of the Premises which are not part of the subleased premises, the subtenant shall comply with and be bound by all of the obligations of Tenant hereunder, that unless Landlord waives such prohibition, the subtenant may not enter into any sub-sublease, sublease assignment, license or any other agreement granting any right of occupancy of any portion of the subleased premises; and that Landlord shall be an express beneficiary of any such obligations, and that in the event of termination of this Lease or reentry or dispossession of Tenant by Landlord under this Lease, Landlord may, at its option, take over all of the right, title and interest of Tenant, as lessor under such sublease, and such subtenant shall, at Landlord's option, attorn to Landlord pursuant to the then executory provisions of such sublease, except that neither Landlord nor any mortgagee of the Property, as holder of a mortgage or as Landlord under this Lease if such mortgagee succeeds to that position, shall (a) be liable for any act or omission of Tenant under such sublease, (b) be subject to any credit, counterclaim, offset or defense which theretofore accrued to such subtenant against Tenant, or (c) be bound by any previous modification of such sublease unless consented to by Landlord and such mortgagee or by any previous prepayment of more than one (1) month's rent, (d) be bound by any covenant of Tenant to undertake or complete any construction of the Premises or any portion thereof, (e) be required to account for any security deposit of the subtenant other than any security deposit actually received by Landlord, (f) be bound by any obligation to make any payment to such subtenant or grant any credits unless specifically agreed to by Landlord and such mortgagee, (g) be responsible for any monies owing by Tenant to the credit of subtenant or (h) be required to remove any person occupying the Premises or any part thereof; and such sublease shall provide that the subtenant thereunder shall, at the request of Landlord, execute a suitable instrument in confirmation of such agreement to attorn. To enable Landlord to confirm that any sublease which Tenant shall desire to enter into shall comply with the provisions of this Subsection 6.2.1 and/or otherwise be acceptable to Landlord, Tenant shall submit the final form of sublease to Landlord not less than thirty (30) days prior to its execution. The provisions of this paragraph shall not be deemed a waiver of the provisions set forth in the first paragraph of this Subsection 6.2.1; and any breach of any obligation of any subtenant of Tenant shall be attributable to Tenant and constitute a breach of this Lease by Tenant.

Tenant shall not enter into, nor shall it permit any person having an interest in the possession, use, occupancy or utilization of any part of the Premises to enter into, any sublease, license, concession, assignment or other agreement for use, occupancy or utilization of the Premises (i) which provides for rental or other compensation based on the income or profits derived by any person or on any other formula such that any portion of such sublease rental, or other consideration for a license, concession, assignment or other occupancy agreement, would fail to qualify as "rents from real property" within the meaning of Section 856(d) of the Internal Revenue Code or any similar or successor provision thereto, or

(ii) under which fifteen percent (15%) or more of the total rent or other compensation received by Tenant is attributable to personal property and any such purported lease, sublease, license, concession or other agreement shall be absolutely void and ineffectual as a conveyance of any right or interest in the possession, use, occupancy or utilization of such part of the Premises.

No subletting or assignment shall in any way impair the continuing primary liability of the Tenant named in Section 1.1, and any immediate or remote successor in interest, and no consent to any subletting or assignment in a particular instance shall be deemed to be a waiver of the obligation to obtain the Landlord's written approval in the case of any other subletting or assignment. The joint and several liability of Tenant named herein and any immediate and remote successor in interest (by assignment or otherwise) for the payment of Annual Fixed Rent and Additional Rent, and the timely performance of all non-monetary obligations on Tenant's part to be performed or observed, shall not in any way be discharged, released or impaired by any (a) agreement which modifies any of the rights or obligations of the parties under this Lease, (b) stipulation which extends the time within which an obligation under this Lease is to be performed, (c) waiver of the performance of an obligation required under this Lease, or (d) failure to enforce any of the obligations set forth in this Lease. No assignment, subletting or occupancy shall affect the Permitted Uses. Any subletting, assignment or other transfer of Tenant's interest in this Lease in contravention of this Subsection 6.2.1 shall be voidable at Landlord's option. Tenant shall not occupy any space in the Building (by assignment, sublease or otherwise) other than the Premises, without Landlord's prior consent, not to be unreasonably withheld.

If the rent and other sums (including, without limitation, all monetary payments plus their reasonable value given by any assignee or subtenant in consideration of such assignment or sublease), either initially or over the term of any assignment or sublease (other than a Permitted Assignment or a Permitted Sublease), payable by such assignee or subtenant exceed the Annual Fixed Rent plus Additional Rent called for hereunder with respect to the space assigned or sublet, Tenant shall pay fifty percent (50%) of such excess to Landlord, as Additional Rent, payable monthly at the time for payment of Annual Fixed Rent, provided that in computing the amount of any such excess the amortized portion of the following "Transfer Expenses" paid by Tenant in connection with such assignment or sublease may first be deducted from the monthly amount of any such excess: (i) the cost of alterations or improvements made by Tenant to the Premises in order to consummate an assignment or to the portion of Premises that is subleased in order to consummate a sublease, (ii) any free rent granted to such transferee, (iii) reasonable brokerage commissions or fees, and (iv) reasonable attorney's fees. Any such Transfer Expenses shall be amortized in equal monthly installments over the term of the assignment or sublease and shall be verified by Tenant by written documentation reasonably satisfactory to Landlord within sixty (60) days after the date of delivery of possession to the assignee or sublessee. Nothing in this paragraph shall be deemed to abrogate the provisions of this Subsection 6.2.1 and Landlord's acceptance of any sums pursuant to this paragraph shall not be deemed a granting of consent to any assignment of the Lease or sublease of all or any portion of the Premises.

6.2.2 Nuisance. Tenant shall not injure, deface or otherwise harm the Premises; nor commit any nuisance; nor permit in the Premises any vending machine (except such as is used for the sale of merchandise to employees of Tenant) or inflammable fluids or chemicals (except such as are customarily used in connection with standard office equipment or the Permitted Use); nor permit any cooking to such extent as requires special exhaust venting; nor permit the emission of any objectionable noise or odor; nor make, allow or suffer any waste; nor make any use of the Premises which is improper, offensive or contrary to any law or ordinance or which will invalidate or increase the premiums for any of Landlord's insurance or which is liable to render necessary any alteration or addition to the Building; nor conduct any auction, fire, "going out of business" or bankruptcy sales.

6.2.3 Floor Load; Heavy Equipment. Tenant shall not place a load upon any floor of the Premises exceeding the lesser of the floor load capacity which such floor was designed to carry or which is allowed by law. Landlord reserves the right to prescribe the weight and position of all heavy business machines and equipment, including safes, which shall be placed so as to distribute the weight. Business machines and mechanical equipment which cause vibration or noise shall be placed and maintained by Tenant at Tenant's expense in settings sufficient to absorb and prevent vibration, noise and annoyance. Tenant shall not move any safe, heavy machinery, heavy equipment, freight, construction materials or fixtures into or out of the Premises without Landlord's prior consent which consent may include a requirement to provide insurance naming Landlord, and the holder of any mortgage affecting the Property, as additional insureds, with such coverage and in such amount as Landlord reasonably requires. If any such safe, machinery, heavy equipment, freight, or fixtures requires special handling, Tenant agrees to employ only persons holding a master rigger's license to do said work, and that all work in connection therewith shall comply with applicable laws and regulations. Any such moving shall be at the sole risk and hazard of Tenant and Tenant hereby agrees to exonerate, indemnify and save Landlord harmless against and from any liability, loss, injury, claim or suit resulting directly or indirectly from such moving. Tenant shall schedule such moving at such times as Landlord shall reasonably designate.

6.2.4 Electricity; Utilities. Tenant shall not connect to the electrical distribution system or any other utility serving the Premises a total load exceeding the lesser of the capacity of such system or the maximum load permitted from time to time under applicable governmental regulations. The capacity of the electrical distribution system and other utilities serving the Premises shall be the lesser of (a) the capacity of the branch of the system or utility serving the Premises exclusively or (b) Tenant's Percentage of the capacity of the system or utility serving the entire Building, less any capacity required for the Common Areas.

6.2.5 Installation, Alterations or Additions. Tenant shall not make any installations, alterations, additions or improvements (collectively and individually referred to in this paragraph as "work") in, to or on the Premises nor permit the making of any holes in the walls, partitions, ceilings or floors without on each occasion obtaining the prior consent of Landlord, and then only pursuant to plans and specifications approved by Landlord in advance in each instance. Landlord's approval shall not be unreasonably withheld or delayed with respect to alterations, additions or improvements which (i) do not affect the structural elements of the Building, (ii) equal or exceed Building standards in quality, (iii) do not adversely affect the plumbing, HVAC, mechanical, electrical or life-safety systems of the Building or require any modifications to the plumbing, HVAC, mechanical, electrical or life-safety systems of the Building (or if any such modifications are required, Landlord's consent shall not be unreasonably withheld or delayed provided that Tenant shall agree to reimburse Landlord for such modifications), (iv) will not increase Taxes or Operating Costs unless Tenant agrees to reimburse Landlord for all such increases, and (v) will not require Landlord to perform any work to the Property (collectively, the "Approval Standards"). Notwithstanding the foregoing, Tenant need not obtain Landlord's consent to perform work that meets the Approval Standards and which (a) does not require a building permit, and (b) costs not more than \$150,000.00 with respect to any single project or series of related projects, provided Tenant shall give Landlord at least thirty (30) days prior notice thereof (which shall reasonably describe the work) and any such work shall be scheduled at a time reasonably acceptable to Landlord so as not to disturb other tenants or Building operations. All work to be performed to the Premises by Tenant shall (i) be performed in a good and workmanlike manner by contractors approved in advance by Landlord, such approval not to be unreasonably withheld, conditioned or delayed (provided that Landlord may require Tenant to use subcontractors designated by Landlord for any work affecting the electrical, mechanical, plumbing, HVAC, fire protection, life-safety or other base building systems or

equipment provided the rates of such subcontractors are commercially reasonable) and in compliance with the provisions of Exhibit C and Exhibit G and all applicable zoning, building, fire, health and other codes, regulations, ordinances and laws, (ii) be made at Tenant's sole cost and expense and at such times and in such a manner as Landlord may from time to time reasonably designate, and (iii) be free of liens and encumbrances and become part of the Premises and the property of Landlord without being deemed additional rent for tax purposes, Landlord and Tenant agreeing that Tenant shall be treated as the owner of the work for tax purposes until the expiration or earlier termination of the term hereof, subject to Landlord's rights pursuant to Section 6.1.9 to require Tenant to remove such work at or prior to the expiration or earlier termination of the term of this Lease and, to the extent Landlord shall make such election, title thereto shall remain vested in Tenant at all times. Tenant shall pay promptly when due the entire cost of any work to the Premises so that the Premises, Building and Property shall at all times be free of liens, and, at Landlord's request, Tenant shall furnish to Landlord a bond or other security acceptable to Landlord assuring that any such work will be completed in accordance with the plans and specifications theretofore approved by Landlord and assuring that the Premises will remain free of any mechanics' lien or other encumbrances that may arise out of such work. Prior to the commencement of any such work, Tenant shall cause its general contractor to execute and deliver an agreement in the form attached hereto as Exhibit D, and Tenant shall, throughout any such work, maintain, or cause to be maintained, the insurance required by Exhibit D. In addition, Tenant shall save Landlord harmless and indemnified from all injury, loss, claims or damage to any person or property occasioned by or arising out of such work. Whenever and as often as any mechanic's or materialmen's lien shall have been filed against the Property based upon any act of Tenant or of anyone claiming through Tenant, Tenant shall within fifteen (15) days of notice from Landlord to Tenant take such action by bonding, deposit or payment as will remove or satisfy the lien. Tenant shall, upon request of Landlord (which may be made only if the cost of work, together with any related project, shall exceed \$1,000,000.00), execute and deliver to Landlord a bill of sale covering any work Tenant shall be required to surrender hereunder. Without limiting the terms in this Section 6.2.5, upon Landlord's obtaining knowledge of the commencement of any work in or to the Premises, Landlord shall be permitted to post a timely Notice of Non-Responsibility at the Premises, which shall also be recorded in the office of the Recorder of the County in which the Property is located, all in accordance with the terms of Sections 8444 and 8060 of the California Civil Code. Upon the completion of any work in or to the Premises, Tenant shall cause a timely Notice of Completion to be recorded in the office of the Recorder of the County in which the Property is located in accordance with the terms of Section 8182 of the California Civil Code, and Tenant shall deliver to Landlord a conformed copy of such Notice of Completion.

Tenant shall not, at any time, directly or indirectly, employ or permit the employment of any contractor, mechanic or laborer in the Premises, if such employment will interfere or cause any conflict with other contractors, mechanics or laborers engaged in the construction, maintenance or operation of the Building by Landlord, Tenant or others. In the event of any such interference or conflict, Tenant, upon demand of Landlord, shall cause all contractors, mechanics or laborers causing such interference or conflict to leave the Building immediately.

6.2.6 Abandonment. Tenant shall not abandon the Premises during the term.

6.2.7 Signs. Tenant shall not paint or place any signs or place any curtains, blinds, shades, awnings, aeriels, or the like, visible from outside the Premises without Landlord's prior consent, which shall not be unreasonably withheld. Landlord shall not unreasonably withhold consent for signs or lettering on or adjacent to the entry doors to the Premises provided such signs conform to building standards adopted by Landlord and Tenant has submitted to Landlord a plan or sketch of the sign to be placed on such entry doors. Landlord agrees, however, to maintain a tenant directory in the lobby of the

Building in which will be placed Tenant's name and the location of the Premises in the Building.

So long as this Lease is still in full force and effect (the "Sign Condition"), Tenant shall have the nonexclusive right, subject to applicable legal requirements and the terms of this Lease, at Tenant's sole cost and expense, to install and maintain a single building-mounted sign (hereinafter, "Tenant's Sign") on the top of the Building. The size, construction, location and design of Tenant's Sign shall be subject to Landlord's approval, not to be unreasonably withheld. Without limiting the foregoing, Landlord may refuse to approve any sign that is not consistent with Landlord's sign criteria for the Complex, the architecture and general appearance of the Building and Property, will cause undue damage to the Building. The content of Tenant's Sign shall be limited to Tenant's name or trade name and/or business logo. Tenant, at its expense, shall obtain all permits and approvals required for the installation of Tenant's Sign prior to the installation thereof (but shall not be permitted to seek any zoning or similar relief for Tenant's Sign without Landlord's consent, which may be withheld in Landlord's sole discretion), and shall keep all such permits and approvals in full force and effect throughout the term. Tenant acknowledges that Tenant's Sign shall be at Tenant's risk and Tenant shall maintain Tenant's Sign in good condition. The installation, repair, maintenance and removal of Tenant's Sign shall be subject to the provisions of Subsection 6.2.5 of this Lease and Landlord's other reasonable requirements. Landlord reserves the right, upon reasonable notice to Tenant, at Landlord's cost, to require Tenant to remove Tenant's Sign temporarily if necessary in connection with any repairs, renovations, improvements or additions to the Building, provided that Landlord shall minimize, to the extent practical, the duration of any period during which Tenant's Sign shall need to be removed. Prior to the expiration or earlier termination of the term of this Lease, and if at any time any of the Sign Condition shall no longer prevail, Tenant shall remove Tenant's Sign (and all associated hardware) from the Building and shall restore the affected area to the condition existing prior to the installation of Tenant's Sign (or as close to such condition as is commercially reasonable).

6.2.8 Oil and Hazardous Materials. Except as hereinafter provided and as provided in Subsection 6.2.9 below, Tenant shall not introduce on or transfer to the Premises or Property, any Hazardous Materials (as hereinafter defined); nor dump, flush or otherwise dispose of any Hazardous Materials into the drainage, sewage or waste disposal systems serving the Premises or Property; nor generate, store, use, release, spill or dispose of any Hazardous Materials in or on the Premises or the Property, or transfer any Hazardous Materials from the Premises to any other location; and Tenant shall not commit or suffer to be committed in or on the Premises or Property any act which would require any reporting or filing of any notice with any governmental agency pursuant to any statutes, laws, codes, ordinances, rules or regulations, present or future, applicable to the Property or to Hazardous Materials.

Tenant agrees that if it shall generate, store, release, spill, dispose of or transfer to the Premises or Property any Hazardous Materials (other than as permitted by and in strict accordance with Subsection 6.2.9), it shall forthwith remove the same, at its sole cost and expense, in the manner provided by all applicable Environmental Laws (as hereinafter defined), regardless of when such Hazardous Materials shall be discovered. Furthermore, Tenant shall pay any fines, penalties or other assessments imposed by any governmental agency with respect to any such Hazardous Materials and shall forthwith repair and restore any portion of the Premises or Property which it shall disturb in so removing any such Hazardous Materials to the condition which existed prior to Tenant's disturbance thereof.

Tenant shall indemnify, defend (by counsel satisfactory to Landlord), protect, and hold Landlord free and harmless from and against any and all claims, or threatened claims, including without limitation, claims for death of or injury to any person or damage to any property, actions, administrative proceedings, whether formal or informal, judgments, damages, punitive damages, liabilities, penalties,

finances, costs, taxes, assessments, forfeitures, losses, expenses, attorneys' fees and expenses, consultant fees, and expert fees that arise from or are caused in whole or in part, directly or indirectly, by (i) the presence or suspected presence in, on, under or about the Premises or discharge in or from the Premises of any Hazardous Materials, or Tenant's use, analysis, storage, transportation, disposal, release, threatened release, discharge or generation of Hazardous Materials to, in, on, under, about or from the Premises, or (ii) Tenant's failure to comply with any Environmental Laws. Tenant's obligations hereunder shall include, without limitation, and whether foreseeable or unforeseeable, all costs (including, without limitation, capital, operating and maintenance costs) incurred in connection with any investigation or monitoring of site conditions, repair, cleanup, containment, remedial, removal or restoration work, or detoxification or decontamination of the Premises, and the preparation and implementation of any closure, remedial action or other required plans in connection therewith. For purposes of this Subsection 6.2.8, any acts or omissions of Tenant, or its subtenants or assignees or its or their employees, agents, or contractors (whether or not they are negligent, intentional, willful or unlawful) shall be attributable to Tenant. Notwithstanding anything to the contrary contained in this Lease, Tenant shall not have any obligations or liabilities, including any obligations to indemnify, defend, protect, and hold Landlord free and harmless from, with respect to either (i) any Hazardous Materials existing in, on, under, about or from the Premises, the Property or the Complex prior to the Commencement Date which Tenant does not negligently release into the environment or occupiable space in the Building, or (ii) any Hazardous Materials brought in, on, under, about, from or to the Premises, the Property or the Complex by any parties other than Tenant, its assignees or subtenants, or their respective employees, contractors or invitees.

The term "Hazardous Materials" shall mean and include any oils, petroleum products, asbestos, radioactive, biological, medical or infectious wastes or materials, and any other toxic or hazardous wastes, materials and substances which are defined, determined or identified as such in any Environmental Laws, or in any judicial or administrative interpretation of Environmental Laws.

The term "Environmental Laws" shall mean any and all federal, state and municipal statutes, laws, regulations, ordinances, rules, judgments, orders, decrees, codes, plans, injunctions, permits, concessions, grants, franchises, licenses, agreements or other governmental restrictions relating to the environment or to emissions, discharges or releases of pollutants, contaminants, petroleum or petroleum products, medical, biological, infectious, toxic or hazardous substances or wastes into the environment including, without limitation, ambient air, surface water, ground water or land, or otherwise relating to the manufacture, processing, distribution, use, treatment, storage, disposal, transport or handling of pollutants, contaminants, petroleum or petroleum products, medical, biological, infectious, toxic or hazardous substances or wastes or the cleanup or other remediation thereof.

6.2.9 Hazardous Materials Documents. Landlord acknowledges that it is not the intent of this Subsection 6.2.8 above or this Subsection 6.2.9 to prohibit Tenant from operating its business for the Permitted Uses. Tenant may operate its business according to the custom of Tenant's industry so long as the use or presence of Hazardous Materials is strictly and properly monitored in accordance with applicable laws. As a material inducement to Landlord to allow Tenant to use Hazardous Materials in connection with its business, Tenant agrees to deliver to Landlord (a) a list identifying each type of Hazardous Material to be present at the Premises that is subject to regulation under any environmental applicable laws, (b) a list of any and all approvals or permits from governmental authorities required in connection with the presence of such Hazardous Material at the Premises and (c) correct and complete copies of (i) notices, orders or similar documents concerning any violations of applicable laws related to Hazardous Materials or with respect to any Hazardous Materials affecting the Premises or Property and (ii) plans relating to the installation of any storage tanks to be installed in, on, under or about the Property

(provided that installation of storage tanks shall only be permitted after Landlord has given Tenant its written consent to do so, which consent Landlord may withhold in its sole and absolute discretion) and closure plans or any other documents required by any and all governmental authorities for any storage tanks installed in, on, under or about the Property by a Tenant Party for the closure of any such storage tanks (collectively, "Hazardous Materials Documents"). Tenant shall deliver to Landlord updated Hazardous Materials Documents (l) no later than thirty (30) days prior to the initial occupancy of any portion of the Premises or the initial placement of equipment using Hazardous Materials anywhere at the Property, (m) annually thereafter, but only if there are any changes to the Hazardous Materials Documents from the prior submitted documents or if otherwise required by applicable law, and (n) thirty (30) days prior to the initiation by Tenant of any Alterations or changes in Tenant's business that involve any material increase in the types or amounts of Hazardous Materials. For each type of Hazardous Material listed, the Hazardous Materials Documents shall include (t) the chemical name, (u) the material state (e.g., solid, liquid, gas or cryogen), (v) the concentration, (w) the storage amount and storage condition (e.g., in cabinets or not in cabinets), (x) the use amount and use condition (e.g., open use or closed use), (y) the location (e.g., room number or other identification) and (z) if known, the chemical abstract service number. Notwithstanding anything in this Section to the contrary, Tenant shall not be required to provide Landlord with any Hazardous Materials Documents containing information of a proprietary nature. Landlord may, at Landlord's expense, cause the Hazardous Materials Documents to be reviewed by a person or firm qualified to analyze Hazardous Materials to confirm compliance with the provisions of this Lease and with applicable laws. In the event that a review of the Hazardous Materials Documents indicates non-compliance with this Lease or applicable laws, Tenant shall, at its expense, diligently take steps to bring its storage and use of Hazardous Materials into compliance.

6.2.10 Exit Survey. At least five (5) Business Days (and not more than sixty (60) days) prior to the expiration or earlier termination of the term of this Lease, Tenant shall provide Landlord with a facility decommissioning and Hazardous Materials closure plan for the Premises ("Exit Survey") prepared by an independent third party reasonably acceptable to Landlord. The Exit Survey shall comply with the American National Standards Institute's Laboratory Decommissioning guidelines (ANSI/AIHA Z9.11-2008) or any successor standards published by ANSI or any successor organization (or, if ANSI and its successors no longer exist, a similar entity publishing similar standards). In addition, at least ten (10) days (and not more than sixty (60) days) prior to the expiration or earlier termination of the term of this Lease, Tenant shall provide Landlord with written evidence of all appropriate governmental releases obtained by Tenant in accordance with applicable laws, including laws pertaining to the surrender of the Premises. Tenant's obligations under this Section shall survive the expiration or earlier termination of the Lease.

6.2.11 Odors and Exhaust. Tenant acknowledges that Landlord would not enter into this Lease with Tenant unless Tenant assured Landlord that under no circumstances will any other occupants of the Building or the Property (including persons legally present in any outdoor areas of the Property) be subjected to odors or fumes (whether or not noxious), and that the Building and the Property will not be damaged by any exhaust, in each case from Tenant's operations. Landlord and Tenant therefore agree as follows:

(a) Tenant shall not cause or permit (or conduct any activities that would cause) any release of any odors or fumes of any kind from the Premises due to Tenant's operations

(b) Tenant shall, at Tenant's sole cost and expense, provide odor eliminators and other devices (such as filters, air cleaners, scrubbers and whatever other equipment may in Landlord's reasonable judgment be necessary or appropriate from time to time) to completely remove,

eliminate and abate any odors, fumes or other substances in Tenant's exhaust stream that, in Landlord's reasonable judgment, emanate from the Premises. Any work Tenant performs under this Section shall constitute Alterations (as that term is defined in Exhibit C attached hereto).

(c) Tenant's responsibility to remove, eliminate and abate odors, fumes and exhaust shall continue throughout the Term. Landlord's approval of any Alterations or other tenant improvements or construction of any work to be performed by Landlord in the Premises shall not preclude Landlord from reasonably requiring additional measures to eliminate odors, fumes and other adverse impacts of Tenant's exhaust stream (as Landlord may designate in Landlord's reasonable discretion). Tenant shall install additional equipment as Landlord reasonably requires from time to time under the preceding sentence. Such installations shall constitute Alterations.

(d) If Tenant fails to install satisfactory odor control equipment within thirty (30) days after Landlord's demand made at any time, then Landlord may, without limiting Landlord's other rights and remedies, require Tenant to cease and suspend any operations in the Premises that, in Landlord's reasonable determination, cause odors or fumes. For example, if Landlord determines that Tenant's production of a certain type of product causes odors or fumes, and Tenant does not install satisfactory odor control equipment within thirty (30) days after Landlord's request, then Landlord may require Tenant to stop producing such type of product in the Premises unless and until Tenant has installed odor control equipment satisfactory to Landlord.

ARTICLE 7

Casualty or Taking

7.1 Termination. In the event that the Premises or the Property, or any material part thereof shall be destroyed or damaged by fire or casualty, shall be taken by any public authority or for any public use or shall be condemned by the action of any public authority, then the term of this Lease may be terminated at the election of Landlord. Such election, which may be made notwithstanding the fact that Landlord's entire interest may have been divested, shall be made by the giving of notice by Landlord to Tenant not later than one hundred twenty (120) days after the date of the taking or casualty.

In the event that any material portion of the Premises is made unusable for the conduct of Tenant's business due to a taking or condemnation by any public authority (other than temporarily for a period of less than one hundred eighty (180) days), then the term of this Lease may be terminated at the election of Tenant by the giving of notice by Tenant to Landlord within sixty (60) days after the date of the taking or condemnation. In the event any material part of the Premises shall be destroyed or damaged or shall be made inaccessible or untenable by fire or other casualty (and Landlord has not elected to terminate the term of this Lease pursuant to the preceding paragraph), then within a reasonable time after the occurrence of such casualty damage, Landlord shall give Tenant a notice (the "Restoration Notice") advising Tenant whether or not Landlord intends to restore the Premises and access thereto to a condition substantially the same as existed immediately prior to such damage (subject to any modification required by then current laws, rules, regulations and ordinances and excluding any improvements to the Premises made by or on behalf of Tenant) and if Landlord intends to so restore, of the time required to substantially complete such work, as reasonably estimated by an architect or general contractor selected by Landlord. If the Restoration Notice indicates either that (a) Landlord shall not restore the Premises as provided above, or (b) the estimated time required for Landlord to substantially complete such restoration work shall exceed one hundred and eighty (180) days from the occurrence of such casualty damage or the number of days which as of the date of the casualty constitutes more than half of the then

remainder of the term, whichever period is shorter, Tenant may elect to terminate the term of this Lease by giving notice to Landlord not later than thirty (30) days after the date on which Landlord gives Tenant the Restoration Notice. Tenant may also elect to terminate the term of this Lease by notice to Landlord if Landlord shall not have caused the restoration work to have been substantially completed on or before the date thirty (30) days after the date identified therefor in the Restoration Notice, subject to extension for Force Majeure (as defined in Section 10.10) events, whereupon the term of this Lease shall terminate thirty (30) days following the date of such notice, unless Landlord substantially completes such restoration work with such thirty-day period, in which case such notice of termination shall be a nullity. Notwithstanding the foregoing, Tenant shall have no right to terminate the term of this Lease due to a fire or other casualty if the cause thereof was due to the gross negligence or intentional misconduct of Tenant or any subtenant of Tenant or any agent or employee of Tenant or its subtenant(s).

7.2 Restoration. If neither party so elects to terminate, this Lease shall continue in force and (so long as the damage is not caused by the negligence or other wrongful act of Tenant or its employees, agents, contractors or invitees) a just proportion of the Annual Fixed Rent reserved, according to the nature and extent of the damages sustained by the Premises, shall be suspended or abated until the Premises (excluding any improvements to the Premises made at Tenant's expense), or what may remain thereof, shall be put by Landlord in proper condition for use, which Landlord covenants to do with reasonable diligence to the extent permitted by the net proceeds of insurance recovered or damages awarded for such destruction, taking, or condemnation and subject to zoning and building laws or ordinances then in existence. "Net proceeds of insurance recovered or damages awarded" refers to the gross amount of such insurance or damages actually made available to Landlord (and not retained by any Superior Lessor or Superior Mortgagee) less the reasonable expenses of Landlord incurred in connection with the collection of the same, including without limitation, fees and expenses for legal and appraisal services.

7.3 Award. Irrespective of the form in which recovery may be had by law, all rights to seek reimbursement for damages or compensation arising from fire or other casualty or any taking by eminent domain or condemnation shall belong to Landlord in all cases. Tenant hereby grants to Landlord all of Tenant's rights to such claims for damages and compensation and covenants to deliver such further assignments thereof as Landlord may from time to time request. Nothing contained herein shall be construed to prevent Tenant from prosecuting in any condemnation proceedings a claim for relocation expenses, damages to Tenant's inventory, fixtures and/or leasehold improvements, or any other award Tenant exclusively may be entitled to recover from the taking authority, or from seeking recovery for Tenant's personal property or personal injuries or other damages suffered by Tenant, provided that any such action shall not affect the amount of compensation otherwise recoverable by Landlord from the taking authority.

7.4 Waiver of Statutory Provisions. The provisions of this Lease, including this Article 7, constitute an express agreement between Landlord and Tenant with respect to any and all damage to, or destruction of, all or any part of the Premises, the Building or the Property, and any statute or regulation of the State of California including, without limitation, Sections 1932(2) and 1933(4) of the California Civil Code, with respect to any rights or obligations concerning damage or destruction in the absence of an express agreement between the parties, and any other statute or regulation, now or hereafter in effect, shall have no application to this Lease or any damage or destruction to all or any part of the Premises, the Building or the Property.

ARTICLE 8

Defaults

8.1 Default of Tenant. The occurrence of any of the following shall constitute a default of this Lease by Tenant (collectively and individually, a “Default of Tenant”): (a) (I) If Tenant shall default in its obligations to pay the Annual Fixed Rent or Additional Rent or any other charges or amounts under this Lease when due and if any such default shall continue for three (3) days after notice from Landlord designating such default or shall default in complying with its obligations under Sections 4.4 or 6.1.11 of this Lease and if any such default shall continue for five (5) days after notice from Landlord designating such default, or (II) if as promptly as possible but in any event within thirty (30) days after notice from Landlord to Tenant specifying any default or defaults other than those set forth in clause (I) Tenant has not cured the default or defaults so specified, or if such default is of such a nature that it cannot be cured within thirty (30) days using best efforts, if Tenant does not commence the curing of such default within such thirty-day period and thereafter diligently and continuously prosecute such cure to completion within such additional time as may be necessary, but in no event to exceed forty-five (45) days from the date of Landlord’s notice to Tenant specifying the default; or (b) if any assignment shall be made by Tenant for the benefit of creditors; or (c) if Tenant’s leasehold interest shall be taken on execution; or (d) if a lien or other involuntary encumbrance shall be filed against Tenant’s leasehold interest or Tenant’s other property, including said leasehold interest, and shall not be discharged within sixty (60) days thereafter; or (e) if a petition shall be filed by Tenant for liquidation, or for reorganization or an arrangement under any provision of any bankruptcy law or code as then in force and effect; or (f) if an involuntary petition under any of the provisions of any bankruptcy law or code shall be filed against Tenant and such involuntary petition shall not be dismissed within thirty (30) days thereafter; or (g) if a custodian or similar agent shall be authorized or appointed to take charge of all or substantially all of the assets of Tenant; or (h) if Tenant dissolves or shall be dissolved or shall liquidate or shall adopt any plan or commence any proceeding, the result of which is intended to include dissolution or liquidation; or (i) if any order shall be entered in any proceeding by or against Tenant decreeing or permitting the dissolution of Tenant or the winding up of its affairs. The notice periods provided herein are in lieu of, and not in addition to, any notice periods provided by law.

8.2 Remedies. Upon the occurrence of any event of default by Tenant, Landlord shall have, in addition to any other remedies available to Landlord at law or in equity (all of which remedies shall be distinct, separate and cumulative), the option to pursue any one or more of the following remedies, each and all of which shall be cumulative and nonexclusive, without any notice or demand whatsoever.

8.2.1 Terminate this Lease, in which event Tenant shall immediately surrender the Premises to Landlord, and if Tenant fails to do so, Landlord may, without prejudice to any other remedy which it may have for possession or arrearages in rent, enter upon and take possession of the Premises and expel or remove Tenant and any other person who may be occupying the Premises or any part thereof, without being liable for prosecution or any claim for damages therefor; and Landlord may recover from Tenant the following:

- (a) The worth at the time of award of any unpaid rent which has been earned at the time of such termination; plus
- (b) The worth at the time of award of the amount by which the unpaid rent which would have been earned after termination until the time of award exceeds the amount of such rental loss that Tenant proves could have been reasonably avoided; plus

(c) The worth at the time of award of the amount by which the unpaid rent for the balance of the Lease Term after the time of award exceeds the amount of such rental loss that Tenant proves could have been reasonably avoided; plus

(d) 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 therefrom, specifically including but not limited to, brokerage commissions and advertising expenses incurred, expenses of remodeling the Premises or any portion thereof for a new tenant, whether for the same or a different use, and any special concessions made to obtain a new tenant; and

(e) At Landlord's election, such other amounts in addition to or in lieu of the foregoing as may be permitted from time to time by applicable law.

The term "rent" as used in this Subsection 8.2.1 shall be deemed to be and to mean all sums of every nature required to be paid by Tenant pursuant to the terms of this Lease, whether to Landlord or to others. As used in Sections 8.2.1(a) and (b), above, the "worth at the time of award" shall be computed by allowing interest at the Interest Rate. As used in Subsection 8.2.1(c), above, the "worth at the time of award" shall be computed by discounting such amount at the discount rate of the Federal Reserve Bank of San Francisco at the time of award plus one percent (1%).

8.2.2 Landlord shall have the remedy described in California Civil Code Section 1951.4 (lessor may continue lease in effect after lessee's breach and abandonment and recover rent as it becomes due, if lessee has the right to sublet or assign, subject only to reasonable limitations). Accordingly, if Landlord does not elect to terminate this Lease on account of any default by Tenant, Landlord may, from time to time, without terminating this Lease, enforce all of its rights and remedies under this Lease, including the right to recover all rent as it becomes due.

8.2.3 Landlord shall at all times have the rights and remedies (which shall be cumulative with each other and cumulative and in addition to those rights and remedies available under Subsections 8.2.1 and 8.2.2, above, or any law or other provision of this Lease), without prior demand or notice except as required by applicable law, to seek any declaratory, injunctive or other equitable relief, and specifically enforce this Lease, or restrain or enjoin a violation or breach of any provision hereof.

8.2.4 Whether or not Landlord elects to terminate this Lease on account of any default by Tenant, as set forth in this Section 8.2, Landlord shall have the right to terminate any and all subleases, licenses, concessions or other consensual arrangements for possession entered into by Tenant and affecting the Premises or may, in Landlord's sole discretion, succeed to Tenant's interest in such subleases, licenses, concessions or arrangements. In the event of Landlord's election to succeed to Tenant's interest in any such subleases, licenses, concessions or arrangements, Tenant shall, as of the date of notice by Landlord of such election, have no further right to or interest in the rent or other consideration receivable thereunder.

Nothing contained in this Lease shall, however, limit or prejudice the right of Landlord to prove for and obtain in proceedings for bankruptcy or insolvency by reason of the termination of this Lease, an amount equal to the maximum allowed by any statute or rule of law in effect at the time when, and governing the proceedings in which, the damages are to be proved, whether or not the amount be greater than, equal to, or less than the amount of the loss or damages referred to above.

No re-entry or repossession, repairs, maintenance, changes, alterations and additions, reletting, appointment of a receiver to protect Landlord's interests hereunder, or any other action or omission by Landlord shall be construed as an election by Landlord to terminate this Lease or Tenant's right to possession, or to accept a surrender of the Premises, nor shall same operate to release Tenant in whole or in part from any of Tenant's obligations hereunder, unless express written notice of such intention is sent by Landlord to Tenant. If Landlord is required by applicable laws to mitigate its damages under this Lease: (i) Landlord shall be required only to use reasonable efforts to mitigate, which shall not exceed such efforts as Landlord generally uses to lease other space at the Property; (ii) Landlord will not be deemed to have failed to mitigate if Landlord leases any other portions of the Property before reletting all or any portion of the Premises; (iii) Landlord shall not be obligated to lease the Premises to a replacement tenant who does not, in Landlord's good faith opinion, have sufficient financial resources to operate the Premises in a first-class manner and to fulfill all of the obligations in connection with the lease as and when the same become due; and (iv) any failure to mitigate as required herein with respect to any period of time shall only reduce the Rent and other amounts to which Landlord is entitled hereunder. Tenant hereby acknowledges and agrees that the value of the Property depends on the rental rates and terms of the Property leases, and Tenant further acknowledges and agrees that Landlord's rejection of a prospective replacement tenant based on an offer of rentals below Landlord's published rates for new leases of comparable space at the Property at the time in question, or at Landlord's option, below the rates provided in this Lease, or containing terms less favorable than those contained herein, shall not give rise to a claim by Tenant that Landlord failed to mitigate its damages. To the fullest extent permitted by law, Tenant hereby expressly waives any and all rights of redemption granted under any present or future laws in the event of Tenant being evicted or dispossessed, or in the event of Landlord obtaining possession of the Premises, by reason of the violation by Tenant of any of the covenants and conditions of this Lease.

8.3 Remedies Cumulative. Except as expressly provided otherwise in Section 8.2, any and all rights and remedies which Landlord may have under this Lease, and at law and equity (including without limitation actions at law for direct, indirect, special and consequential (foreseeable and unforeseeable) damages), for Tenant's failure to comply with its obligations under this Lease shall be cumulative and shall not be deemed inconsistent with each other, and any two or more of all such rights and remedies may be exercised at the same time insofar as permitted by law.

Notwithstanding anything to the contrary contained in this Lease, in no event shall Tenant ever be liable to Landlord for any punitive damages or for any loss of business or any other indirect, special or consequential damages suffered by Landlord (excluding, for purposes of clarity, damages specified in Section 8.2) arising out of any breach of this Lease by Tenant, except for any damages to which Landlord may be entitled arising from violation of any Environmental Laws as provided in Subsection 6.2.8 or arising under Section 8.5 and provided that the foregoing waiver shall also not apply to claims asserted by a third party for which Landlord may be liable as a result, in whole or part, of a breach of this Lease by Tenant or Tenant's other wrongful conduct.

8.4 Landlord's Right to Cure Defaults. At any time with or without notice, Landlord shall have the right, but shall not be required, to pay such sums or do any act which requires the expenditure of monies which may be necessary or appropriate by reason of the failure or neglect of Tenant to comply with any of its obligations under this Lease (provided Landlord shall not exercise such right until there is a Default of Tenant unless earlier action by Landlord is necessary to prevent injury or damage to persons or property, as determined by Landlord in good faith), and in the event of the exercise of such right by Landlord, Tenant agrees to pay to Landlord forthwith upon demand, as Additional Rent, all such sums

including reasonable attorneys' fees, together with interest thereon at a rate (the "Default Rate") equal to the lesser of six hundred basis points above the Prime Rate or the maximum rate allowed by law. "Prime Rate" shall mean the annual floating rate of interest, determined daily and expressed as a percentage from time to time announced by Bank of America as its "prime" or "base" rate, so-called, or if at any time Bank of America ceases to announce such a rate, as announced by the largest national or state-chartered banking institution then having an office in the City of Boston and announcing such a rate. If at any time neither Bank of America nor the largest national or state-chartered banking institution having an office in the City of Boston is announcing such a floating rate, "Prime Rate" shall mean a rate of interest, determined daily, which is two hundred basis points above the yield of 90-day U.S. Treasury Bills.

8.5 Holding Over. Any failure by Tenant to comply timely with its obligations under Section 6.1.9, as to all or any portion of the Premises, shall constitute a holding over of the entire Premises and be treated as a daily tenancy at sufferance at a rental rate for the first thirty (30) days of such holding over equal to one and one-quarter (1.25) times the sum of Annual Fixed Rent plus Additional Rent on account of Operating Costs and Taxes in effect immediately prior to the expiration or earlier termination of the term (prorated on a daily basis) and thereafter at a rental rate equal to one and one-half (1.5) times the sum of Annual Fixed Rent plus Additional Rent on account of Operating Costs and Taxes in effect immediately prior to the expiration or earlier termination of the term (prorated on a daily basis). Tenant shall also pay to Landlord all damages, direct and/or consequential (foreseeable and unforeseeable), sustained by reason of any such holding over. Otherwise, all of the covenants, agreements and obligations of Tenant applicable during the term of this Lease shall apply and be performed by Tenant during such period of holding over as if such period were part of the term of this Lease.

8.6 Effect of Waivers of Default. Any consent or permission by Landlord to any act or omission by Tenant shall not be deemed to be consent or permission by Landlord to any other similar or dissimilar act or omission and any such consent or permission in one instance shall not be deemed to be consent or permission in any other instance.

8.7 No Waiver, etc. The failure of Landlord or Tenant to seek redress for violation of, or to insist upon the strict performance of, any covenant or condition of this Lease shall not be deemed a waiver of such violation nor prevent a subsequent act, which would have originally constituted a violation, from having all the force and effect of an original violation. The receipt by Landlord of rent with knowledge of the breach of any covenant of this Lease shall not be deemed to have been a waiver of such breach by Landlord, or by Tenant, unless such waiver be in writing signed by the party to be charged. No consent or waiver, express or implied, by Landlord or Tenant to or of any breach of any agreement or duty shall be construed as a waiver or consent to or of any other breach of the same or any other agreement or duty.

8.8 No Accord and Satisfaction. No acceptance by Landlord of a lesser sum than the Annual Fixed Rent, Additional Rent or any other charge then due shall be deemed to be other than on account of the earliest installment of such rent or charge due, nor shall any endorsement or statement on any check or any letter accompanying any check or payment as rent or other charge be deemed an accord and satisfaction, and Landlord may accept such check or payment without prejudice to Landlord's right to recover the balance of such installment or pursue any other remedy in this Lease provided.

ARTICLE 9

Rights of Holders

9.1 Rights of Mortgagees or Ground Lessor. On the condition Landlord shall perform its obligations under Section 9.3, this Lease, and all rights of Tenant hereunder, are and shall be subject and subordinate to any ground or master lease, and all renewals, extensions, modifications and replacements thereof, and to all mortgages, which may now or hereafter affect the Building or the Property and/or any such lease, whether or not such mortgages shall also cover other lands and/or buildings and/or leases, to each and every advance made or hereafter to be made under such mortgages, and to all renewals, modifications, replacements and extensions of such leases and such mortgages and all consolidations of such mortgages. This Section shall be self-operative and no further instrument of subordination shall be required. In confirmation of such subordination, Tenant shall promptly execute, acknowledge and deliver any instrument that Landlord, the lessor under any such lease or the holder of any such mortgage or any of their respective successors in interest may reasonably request to evidence such subordination. Any lease to which this Lease is subject and subordinate is herein called "Superior Lease" and the lessor of a Superior Lease or its successor in interest, at the time referred to, is herein called "Superior Lessor"; and any mortgage to which this Lease is subject and subordinate, is herein called "Superior Mortgage" and the holder of a Superior Mortgage is herein called "Superior Mortgagee".

If any Superior Lessor or Superior Mortgagee or the nominee or designee of any Superior Lessor or Superior Mortgagee shall succeed to the rights of Landlord under this Lease, whether through possession or foreclosure action or delivery of a new lease or deed, or otherwise, then at the request of such party so succeeding to Landlord's rights (herein called "Successor Landlord") and upon such Successor Landlord's written agreement to accept Tenant's attornment, Tenant shall attorn to and recognize such Successor Landlord as Tenant's landlord under this Lease and shall promptly execute and deliver any instrument that such Successor Landlord may reasonably request to evidence such attornment. Upon such attornment, this Lease shall continue in full force and effect as a direct lease between the Successor Landlord and Tenant upon all of the terms, conditions and covenants as are set forth in this Lease, except that the Successor Landlord (unless formerly the landlord under this Lease) shall not be (a) liable in any way to Tenant for any act or omission, neglect or default on the part of Landlord under this Lease (but nothing herein shall relieve a Successor Landlord from the obligation to remedy defaults in the performance of Landlord's maintenance, repair or service obligations which continue after such Successor Landlord shall have succeeded to the rights of Landlord under this Lease), (b) responsible for any monies owing by or on deposit with Landlord to the credit of Tenant except for any security deposit of Tenant delivered to Successor Landlord, (c) subject to any counterclaim or setoff which theretofore accrued to Tenant against Landlord, (d) bound by any modification of this Lease subsequent to such Superior Lease or Superior Mortgage, or by any previous prepayment of Annual Fixed Rent or Additional Rent for more than one (1) month, which was not approved in writing by the Successor Landlord, (e) liable to the Tenant beyond the Successor Landlord's interest in the Property, (f) responsible for the performance of any work to be done by Landlord under this Lease to render the Premises ready for occupancy by the Tenant, or (g) required to remove any person occupying the Premises or any part thereof, except if such person claims by, through or under the Successor Landlord. Tenant agrees at any time and from time to time to execute a suitable instrument in confirmation of Tenant's agreement to attorn, as aforesaid.

9.2 Modifications. If any Superior Lessor or Superior Mortgagee shall require any modification(s) of this Lease, Tenant shall, at Landlord's request, promptly execute and deliver to Landlord such instruments effecting such modification(s) as Landlord shall require, provided that such

modification(s) do not adversely affect in any material respect any of Tenant's rights under this Lease. In addition, and notwithstanding Section 9.1 to the contrary, any Superior Lessor or Superior Mortgagee may, at its option, subordinate the Superior Lease or Superior Mortgage of which it is the lessor or holder to this Lease by giving Tenant ten (10) days prior written notice of such election, whereupon this Lease shall, irrespective of dates of execution, delivery and recording, be superior to such Superior Lease or Superior Mortgage and no other documentation shall be necessary to effect such change.

9.3 Subordination, Non-Disturbance and Attornment. Landlord represents that the Property is not subject to any Superior Lease or Superior Mortgage as of the Date of this Lease. Landlord shall request a so-called non-disturbance agreement ("SNDA") from any future Superior Mortgagee in the form customarily used by such Superior Mortgagee, but Landlord shall have no obligation to incur any expense or liability in connection with such request (or to become involved in any request by Tenant for changes to the form of SNDA) and, if such Superior Mortgagee shall fail or refuse to provide or to execute such SNDA (or to consider or agree to any changes to the form of SNDA requested by Tenant), such failure or refusal shall not constitute a default or breach of this Lease by Landlord; provided that Tenant will not be required to subordinate or attorn to any future Superior Mortgagee who refuses to provide an SNDA. If any future Superior Mortgagee shall agree to provide an SNDA, then at Landlord's request, Tenant shall first execute and deliver such SNDA to Landlord

ARTICLE 10

Miscellaneous Provisions

10.1 Notices. Except as may be expressly provided herein otherwise, all notices, requests, demands, consents, approval or other communications to or upon the respective parties hereto shall be in writing, shall be delivered by hand or mailed by certified or registered mail, return receipt requested, or by a nationally recognized courier service that provides a receipt for delivery such as Federal Express, United Parcel Service or U.S. Postal Service Express Mail and shall be addressed as follows: If intended for Landlord, to the Original Address of Landlord set forth in Section 1.1 of this Lease with a copy to Landlord c/o The RMR Group LLC, 255 Washington Street, Suite 300, Newton, Massachusetts 02458, Attn: Jennifer B. Clark (or to such other address or addresses as may from time to time hereafter be designated by Landlord by notice to Tenant); and if intended for Tenant, addressed to Tenant at the Original Address of Tenant set forth in Section 1.1 of this Lease (or to such other address or addresses as may from time to time hereafter be designated by Tenant by notice to Landlord). Notices shall be effective on the date delivered to (or the first date such delivery is attempted and refused by) the party to which such notice is required or permitted to be given or made under this Lease. Notices from Landlord may be given by Landlord's Agent, if any, or Landlord's attorney; and any bills or invoices for Annual Fixed Rent or Additional Rent may be given by mail (which need not be registered or certified) and, if so given, shall be deemed given on the third Business Day following the date of posting.

10.2 Quiet Enjoyment; Landlord's Right to Make Alterations, Etc. Landlord agrees that upon Tenant's paying the rent and performing and observing the agreements, conditions and other provisions on its part to be performed and observed, Tenant shall and may peaceably and quietly have, hold and enjoy the Premises during the term hereof without any manner of hindrance or molestation from Landlord or anyone claiming under Landlord, subject, however, to the terms of this Lease; provided, however, Landlord reserves the right at any time and from time to time, without the same constituting breach of Landlord's covenant of quiet enjoyment or an actual or constructive eviction, and without Landlord incurring any liability to Tenant or otherwise affecting Tenant's obligations under this Lease, to make such changes, alterations, improvements, repairs or replacements in or to the interior and

exterior of the Building (including the Premises to the extent required to comply with applicable laws or Landlord's obligations pursuant to a lease, including this Lease, at the Building) and the fixtures and equipment thereof, and in or to the Property, or properties adjacent thereto, as Landlord may deem necessary or desirable, and to change (provided that there be no unreasonable obstruction of the right of access to the Premises by Tenant and that Landlord use commercially reasonable efforts to minimize, to the extent practical, any interference with the conduct of business at the Premises) the arrangement and/or location of entrances or passageways, doors and doorways, corridors, elevators, or other common areas of the Building and Property. During any such work performed by Landlord, Landlord will use reasonable efforts to minimize interference with Tenant's operations in the Premises, which may include scheduling any work which generates unreasonable fumes, noise, vibrations or dust outside of Normal Building Operating Hours.

Without incurring any liability to Tenant, Landlord may permit access to the Premises and open the same, whether or not Tenant shall be present, upon any demand of any receiver, trustee, assignee for the benefit of creditors, sheriff, marshal or court officer Landlord reasonably believes is entitled to such access for the purpose of taking possession of, or removing, Tenant's property or for any other lawful purpose (but this provision and any action by Landlord hereunder shall not be deemed a recognition by Landlord that the person or official making such demand has any right or interest in or to this Lease, or in or to the Premises), or upon demand of any representative of the fire, police, building, sanitation or other department of the city, state or federal governments.

10.3 Lease not to be Recorded; Confidentiality of Lease Terms. Tenant agrees that it will not record this Lease. Both parties shall, upon the request of either (and at the expense of the requesting party), execute and deliver a notice or short form of this Lease in such form, if any, as may be acceptable for recording with the land records of the governmental entity responsible for keeping such records for the City of San Diego. In no event shall such documents set forth the rent or other charges payable by Tenant pursuant to this Lease; and any such document shall expressly state that it is executed pursuant to the provisions contained in this Lease and is not intended to vary the terms and conditions of this Lease.

Tenant acknowledges that the terms under which the Landlord has leased the Premises to Tenant (including, without limitation, the rental rate(s), term and other financial and business terms), constitute confidential information of Landlord ("Confidential Information"). Tenant covenants and agrees to keep the Confidential Information confidential and not to disclose the same to third parties; provided, however, that such Confidential Information may be disclosed by Tenant to those of its officers, employees, investors, attorneys, accountants, lenders and financial advisors (collectively, "Representatives") who need to know such information in connection with Tenant's use and occupancy of the Premises and for financial reporting and credit related activities or to prospective subtenants or assignees. In addition, Tenant may disclose this Lease, including any amendments hereto, to the extent necessary in order to comply with any legal requirements or SEC filing requirement. Neither Landlord nor Tenant shall make or permit to be made any press release regarding this Lease without the prior approval of the other party, which approval shall not be unreasonably withheld. Tenant furthermore agrees to inform its Representatives of the confidential nature of such Confidential Information and to use all reasonable efforts to cause each Representative to treat such Confidential Information confidentially and in accordance with the terms of this paragraph.

Landlord shall not use Tenant's trademarks, service marks, trade name, logo or copyrights (herein individually or collectively called "Intellectual Property") (including to express or imply any endorsement by Tenant) without Tenant's prior written consent in each instance, which may be withheld by Tenant in the exercise of its sole and absolute discretion, notwithstanding the fact that prior written permission to use such Intellectual Property in any previous endeavor had been granted by Tenant.

10.4 Assignment of Rents and Transfer of Title; Limitation of Landlord's Liability. Tenant agrees that the assignment by Landlord of Landlord's interest in this Lease, or the rents payable hereunder, whether absolute or conditional in nature or otherwise, which assignment is made to the holder of a mortgage on property which includes the Premises, shall never be treated as an assumption by such holder of any of the obligations of Landlord hereunder unless such holder shall, by notice sent to Tenant, specifically otherwise elect and that, except as aforesaid, such holder shall be treated as having assumed Landlord's obligations hereunder (subject to the limitations and other terms set forth in Section 9.1) only upon foreclosure of such holder's mortgage and the taking of possession of the Premises.

The term "Landlord", so far as covenants or obligations to be performed by Landlord are concerned, shall be limited to mean and include only the owner or owners at the time in question of Landlord's interest in the Property, and in the event of any transfer or transfers of such title to said property, Landlord (and in case of any subsequent transfers or conveyances, the then grantor) shall be concurrently freed and relieved from and after the date of such transfer or conveyance, without any further instrument or agreement, of all liability with respect to the performance of any covenants or obligations on the part of Landlord contained in this Lease thereafter to be performed, it being intended hereby that the covenants and obligations contained in this Lease on the part of Landlord, shall, subject as aforesaid, be binding on Landlord, its successors and assigns, only during and in respect of their respective period of ownership of such interest in the Property.

Notwithstanding the foregoing, in no event shall the acquisition of Landlord's interest in the Property by a purchaser which, simultaneously therewith, leases Landlord's entire interest in the Property back to Landlord or the seller thereof be treated as an assumption by operation of law or otherwise, of Landlord's obligations hereunder. Tenant shall look solely to such seller-lessee, and its successors from time to time in title, for performance of Landlord's obligations hereunder. The seller-lessee, and its successors in title, shall be the Landlord hereunder unless and until such purchaser expressly assumes in writing the Landlord's obligations hereunder.

Tenant shall not assert nor seek to enforce any claim for breach of this Lease against any of Landlord's assets other than Landlord's interest in the Property, including Landlord's interest in the rents payable by Tenant and Landlord's interest in the proceeds of any insurance maintained by Landlord or Tenant with respect to the Premises, and Tenant agrees to look solely to such interest for the satisfaction of any liability or claim against Landlord under this Lease, it being specifically agreed that in no event whatsoever shall Landlord ever be personally liable for any such liability. Tenant furthermore agrees that no trustee, officer, director, general or limited partner, member, shareholder, beneficiary, employee or agent of Landlord (including any person or entity from time to time engaged to supervise and/or manage the operation of Landlord) shall be held to any liability, jointly or severally, for any debt, claim, demand, judgment, decree, liability or obligation of any kind (in tort, contract or otherwise) of, against or with respect to Landlord or arising out of any action taken or omitted for or on behalf of Landlord.

10.5 Landlord's Default. Landlord shall not be deemed to be in breach of, or in default in the performance of, any of its obligations under this Lease unless it shall fail to perform such obligation(s) and such failure shall continue for a period of thirty (30) days, or such additional time as is reasonably

required to correct any such breach or default, after written notice has been given by Tenant to Landlord specifying the nature of Landlord's alleged breach or default. Tenant shall have no right to terminate this Lease for any breach or default by Landlord hereunder and no right, for any such breach or default, to offset or counterclaim against any rent due hereunder. In no event shall Landlord ever be liable to Tenant, and Tenant hereby waives any claim against Landlord, for any punitive damages or for any loss of business or any other indirect, special or consequential damages suffered by Tenant from whatever cause. Tenant further agrees that if Landlord shall have failed to cure any such breach or default within thirty (30) days of such notice to Landlord (or if such breach or default cannot be cured within said time, then within such additional time as may be necessary if within said thirty days Landlord has commenced and is diligently pursuing the remedies necessary to cure such breach or default), then the holder(s) of any mortgage(s) or the lessor under any ground lease entitled to notice pursuant to Section 10.6 shall have an additional thirty (30) days within which to cure such breach or default if such breach or default cannot be cured within that time, then such additional time as may be necessary, if within such thirty (30) days any such holder or lessor has commenced and is diligently pursuing the remedies necessary to cure such breach or default (including but not limited to commencement of foreclosure proceedings, if necessary to effect such cure).

10.6 Notice to Mortgagee and Ground Lessor. After receiving notice from any party that it holds a mortgage which includes the Premises as part of the mortgaged premises, or that it is the ground lessor under a lease with Landlord, as ground lessee, which includes the Premises as part of the demised premises, which notice contains the address of such party for receipt of notices from Tenant, no notice from Tenant to Landlord shall be effective unless and until a copy of the same is given to such holder or ground lessor, and the curing of any of Landlord's defaults by such holder or ground lessor shall be treated as performance by Landlord.

10.7 Brokerage. Tenant and Landlord warrant and represent that they have dealt with no broker in connection with the consummation of this Lease, other than Cushman & Wakefield and Jones Lang LaSalle, and in the event of any brokerage claims or liens, other than by Cushman & Wakefield and/or Jones Lang LaSalle, against Landlord, Tenant or the Property predicated upon or arising out of prior dealings with Tenant or Landlord, the party with whom the broker claims to have dealt agrees to defend the same and indemnify and hold the other party harmless against any such claim, and to discharge any such lien.

10.8 Waiver of Jury Trial. LANDLORD AND TENANT HEREBY WAIVE TRIAL BY JURY IN ANY ACTION, PROCEEDING OR COUNTERCLAIM BROUGHT BY EITHER OF THEM AGAINST THE OTHER IN CONNECTION WITH THIS LEASE.

10.9 Applicable Law and Construction. This Lease shall be governed by and construed in accordance with the laws of the State of California and if any provisions of this Lease shall to any extent be invalid, the remainder of this Lease shall not be affected thereby. Tenant expressly acknowledges and agrees that Landlord has not made and is not making, and Tenant, in executing and delivering this Lease, is not relying upon, any warranties, representations, promises or statements, except to the extent that the same are expressly set forth in this Lease or in any other written agreement which may be made between the parties concurrently with the execution and delivery of this Lease and which shall expressly refer to this Lease. All understandings and agreements heretofore made between the parties are merged in this Lease and any other such written agreement(s) made concurrently herewith, which alone fully and completely express the agreement of the parties and which are entered into after full investigation, neither party relying upon any statement or representation not embodied in this Lease or any other such written agreement(s) made concurrently herewith. This Lease may be amended, and the provisions

hereof may be waived or modified, only by instruments in writing executed by Landlord and Tenant. The titles of the several Articles and Sections contained herein are for convenience only and shall not be considered in construing this Lease. The submission of this document for examination and negotiation does not constitute an offer to lease, or a reservation of, or option for, the Premises, and Tenant shall have no right to the Premises hereunder until the execution and delivery hereof by both Landlord and Tenant. Except as herein otherwise provided, the terms hereof shall be binding upon and shall inure to the benefit of the successors and assigns, respectively, of Landlord and Tenant and, if Tenant shall be an individual, upon and to his heirs, executors, administrators, successors and assigns. Time is of the essence with respect to the exercise of any of Tenant's rights, and the performance of any and all of Tenant's obligations, under this Lease. The reference contained to successors and assigns of Tenant is not intended to constitute a consent to assignment by Tenant. Except as otherwise set forth in this Lease, any obligations of Tenant which arise during the term of this Lease and by their nature would survive the expiration of this Lease (including, without limitation, obligations to pay rental and other monetary obligations for periods during the term of this Lease or Tenant's occupancy of the Premises, repair and maintenance obligations attributable to the term or Tenant's occupancy of the Premises and obligations to indemnify Landlord), shall survive the expiration or earlier termination of this Lease, and Tenant shall immediately reimburse Landlord for any expense incurred by Landlord in curing Tenant's failure to satisfy any such obligation (notwithstanding the fact that such cure might be effected by Landlord following the expiration or earlier termination of this Lease.

10.10 Force Majeure. Except as otherwise expressly provided in this Lease and except for the payment of Annual Fixed Rent, Additional Rent or other sums due under this Lease (as to which this Section 10.10 shall not apply), where a period of time is prescribed in this Lease for any action to be taken by Landlord or Tenant, neither Landlord nor Tenant shall be liable or responsible for, and there shall be excluded from the computation for any such period of time, any delays due to strikes, riots, Acts of God, scarcity of labor or materials (including energy), war, regulations or restrictions of governmental authorities or any other causes of any kind which are beyond the control of Landlord or Tenant, as the case may be. A party's financial inability to perform its obligations shall in no event constitute Force Majeure. Nothing in this Section shall excuse or delay Tenant's obligation to pay any rent or other charges due under this Lease.

10.11 Counterparts. This Lease may be executed in any number of counterparts, which may be delivered electronically, via facsimile or by other means. Each party may rely upon signatures delivered electronically or via facsimile as if such signatures were originals. Each counterpart of this Lease shall be deemed to be an original, and all such counterparts (including those delivered electronically or via facsimile), when taken together, shall be deemed to constitute one and the same instrument.

WITNESS the execution hereof under seal on the day and year first above written.

Landlord:

SNH Medical Office Properties Trust

By: The RMR Group LLC, its agent

By /s/ Jennifer F. Francis
Jennifer F. Francis
Executive Vice President

Tenant:

Prometheus Biosciences, Inc.

By /s/ Mark McKenna
Name: Mark McKenna
Title: President and Chief Executive Officer

