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 June 30, 2022

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	**81-4282653**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
3050 Science Park Road San Diego, California	**92121**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (858) 422-4300

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	☐	Accelerated filer	☐
Non-accelerated filer	☑	Smaller reporting company	☑
Emerging growth company	☑		

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 August 8, 2022, the registrant had 40,904,098 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 Balance Sheets
(in thousands, except share and par value amounts)

	June 30, 2022	December 31, 2021
Assets		
Current assets		
Cash and cash equivalents	$ 95,959	$ 257,254
Short term investments	115,823	—
Accounts receivable	1,865	1,079
Prepaid expenses and other current assets	5,703	7,050
Total current assets	219,350	265,383
Property and equipment, net	2,891	1,447
Right-of-use asset	14,377	—
Other assets	971	971
Total assets	$ 237,589	$ 267,801
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 462	$ 1,153
Accrued compensation	2,854	5,378
Accrued expenses and other current liabilities	10,058	6,050
Payable to PLI	110	193
Deferred revenue	1,781	3,668
Lease liabilities, current portion	1,202	—
Total current liabilities	16,467	16,442
Deferred revenue, non-current	15,733	16,204
Lease liabilities, net of current portion	13,558	—
Total liabilities	45,758	32,646
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock—$0.0001 par value; 40,000,000 shares authorized at June 30, 2022 and December 31, 2021; No shares issued and outstanding at June 30, 2022 and December 31, 2021	—	—
Common stock—$0.0001 par value; 400,000,000 shares authorized as of June 30, 2022 and December 31, 2021; 39,699,667 shares and 38,960,716 shares issued at June 30, 2022 and December 31, 2021, respectively; 39,690,686 shares and 38,943,110 shares outstanding at June 30, 2022 and December 31, 2021, respectively;	4	4
Additional paid-in capital	447,191	424,492
Accumulated other comprehensive loss	(310)	—
Accumulated deficit	(255,054)	(189,341)
Total stockholders' equity	191,831	235,155
Total liabilities and stockholders' equity	$ 237,589	$ 267,801

See accompanying notes.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Collaboration revenue	$ 1,269	$ 326	$ 5,188	$ 1,086
Operating expenses:				
Research and development	25,918	13,554	53,848	21,312
General and administrative	9,319	5,618	17,405	10,840
Total operating expense	35,237	19,172	71,253	32,152
Loss from operations	(33,968)	(18,846)	(66,065)	(31,066)
Other income (expense), net:				
Interest income	321	37	352	55
Interest expense	—	(190)	—	(848)
Change in fair value of preferred stock purchase right liability	—	—	—	(980)
Change in fair value of preferred stock warrant liability	—	—	—	(105)
Total other income (expense), net	321	(153)	352	(1,878)
Net loss	(33,647)	(18,999)	(65,713)	(32,944)
Other comprehensive loss:				
Unrealized loss on available-for-sale securities, net	(310)	—	(310)	—
Comprehensive loss	(33,957)	(18,999)	(66,023)	(32,944)
Net loss per share, basic and diluted	$ (0.86)	$ (0.49)	$ (1.68)	$ (1.39)
Weighted average shares outstanding, basic and diluted	39,242,839	38,813,865	39,125,850	23,660,559

See accompanying notes.

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

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2021	38,943,110	$ 4	$ 424,492	$ —	$ (189,341)	$ 235,155
Issuance of common stock upon exercise of stock options	142,391	—	349	—	—	349
Vesting of early exercised stock options	4,311	—	6	—	—	6
Stock-based compensation	—	—	3,279	—	—	3,279
Net loss	—	—	—	—	(32,066)	(32,066)
Balance at March 31, 2022	39,089,812	$ 4	$ 428,126	$ —	$ (221,407)	$ 206,723
Issuance of common stock upon exercise of stock options	21,284	—	98	—	—	98
Issuance of common stock in public offerings, net of issuance costs of $1,184	555,297	—	13,979	—	—	13,979
Issuance of common stock under employee stock purchase plan	19,979	—	346	—	—	346
Vesting of early exercised stock options	4,314	—	6	—	—	6
Stock-based compensation	—	—	4,636	—	—	4,636
Unrealized loss on marketable securities	—	—	—	(310)	—	(310)
Net loss	—	—	—	—	(33,647)	(33,647)
Balance at June 30, 2022	39,690,686	$ 4	$ 447,191	$ (310)	$ (255,054)	$ 191,831

PROMETHEUS BIOSCIENCES, INC.
Unaudited Condensed Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit) (continued)
(in thousands, except share amounts)

	Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Loss	Deficit	(Deficit) Equity
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	—	$ —	38,769,703	$ 4	$ 413,286	$ —	$ (113,091)	$ 300,199
Issuance costs related to initial public offering	—	—	—	—	(46)	—	—	(46)
Issuance of common stock upon exercise of stock options	—	—	54,561	—	62	—	—	62
Vesting of early exercised stock options	—	—	10,803	—	9	—	—	9
Stock-based compensation	—	—	—	—	1,203	—	—	1,203
Net loss	—	—	—	—	—	—	(18,999)	(18,999)
Balance at June 30, 2021	—	$ —	38,835,067	$ 4	$ 414,514	$ —	$ (132,090)	$ 282,428

See accompanying notes.

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

	Six Months Ended June 30,	
	2022	2021
Cash flows from operating activities		
Net loss	$ (65,713)	$ (32,944)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	248	95
Stock-based compensation expenses	7,915	1,995
Amortization of premiums and discounts on marketable securities, net	(158)	—
Noncash lease expense	220	—
Change in fair value of preferred stock purchase right liability	—	980
Change in fair value of preferred stock warrant liability	—	105
Common stock issued in exchange for services	—	3
Noncash interest expense	—	540
Changes in operating assets and liabilities:		
Accounts receivable	(786)	869
Prepaid expenses and other current assets	1,395	(4,815)
Other assets	—	(468)
Accounts payable	(539)	1,143
Accrued compensation	(2,524)	(325)
Accrued expenses and other current liabilities	3,985	114
Payable to PLI	(83)	(897)
Deferred revenue	(2,357)	9,254
Operating lease liabilities	162	—
Net cash used in operating activities	(58,235)	(24,351)
Cash flows from investing activities		
Purchases of property and equipment	(1,843)	(580)
Purchases of marketable securities	(115,975)	—
Net cash used in investing activities	(117,818)	(580)
Cash flows from financing activities		
Proceeds from issuance of convertible preferred stock, net of issuance costs	—	73,749
Proceeds from sale of common stock in initial public offering	—	218,500
Proceeds from sale of common stock in public offerings, gross	15,163	—
Payment of financing costs	(1,172)	(17,256)
Proceeds from issuance of common stock upon stock option exercises	421	126
Proceeds from issuance of common stock under employee stock purchase plan	346	—
Net cash provided by financing activities	14,758	275,119
Net (decrease) increase in cash and cash equivalents	(161,295)	250,188
Cash and cash equivalents at beginning of period	257,254	54,201
Cash and cash equivalents cash at end of period	95,959	304,389
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
Financing costs incurred, but not paid, included in accrued expenses and accounts payable	$ 12	$ —
Vesting of early exercised stock options	$ 12	$ 18
Costs incurred, but not paid, in connection with capital expenditures included in accounts payable	$ 25	$ 208

See accompanying notes.

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 Societé Des Produits Nestlé S.A (together, Nestlé). 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.

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 IPO, 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 June 30, 2022, has an accumulated deficit of $255.1 million. The Company has historically financed its operations primarily through private placements of convertible preferred stock, proceeds from the Company's IPO in March 2021 and proceeds from the sale of its common stock through an "at the market" offering. 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 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 financial statements and accompanying notes. Although these estimates are based on the Company's knowledge of current events and actions it may undertake in the future, actual results may materially differ from these estimates and assumptions.

On an ongoing basis, management evaluates its estimates, primarily related to revenue recognition, stock-based compensation, marketable securities, accrued research and development costs, and the incremental borrowing rate for lease liabilities. 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 June 30, 2022, and for the three and six months ended June 30, 2022 and 2021, 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, 2021, included in the Annual Report on Form 10-K filed with the SEC on March 9, 2022.

Segment Reporting

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by management in making decisions regarding resource allocation and assessing performance. The Company manages its operations as a single operating segment in the United States for the purposes of assessing performance and making operating decisions.

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 June 30, 2022 represents cash in readily available checking and money market accounts, and commercial paper. The cash and cash equivalents balance at December 31, 2021 represents cash in readily available checking and money market accounts.

Marketable Securities

The Company's marketable securities primarily consist of commercial paper and U.S. government and agency securities classified within cash and cash equivalents and short term investments depending on their maturity date at the time of purchase. The Company classifies its marketable securities as available-for-sale and records such assets at estimated fair value in the condensed balance sheets, with unrealized gains and losses, if any, reported as a component of other comprehensive income (loss) within the condensed statements of operations and comprehensive loss and as a separate component of stockholders' equity. The Company classifies marketable securities with remaining maturities greater than one year as current assets because such marketable securities are available to fund the Company's current operations. Realized gains and losses are calculated on the specific identification method and recorded as interest income (loss). There were no realized gains and losses during any of the periods presented.

At each balance sheet date, the Company assesses available-for-sale securities in an unrealized loss position to determine whether the unrealized loss is other-than-temporary. When the Company determines that a decline in the fair value below its cost basis is other-than-temporary, the Company recognizes an impairment loss in the period in which the other-than-temporary decline occurred. There have been no other-than-temporary impairments recognized during any of the periods presented.

Concentration of Credit Risk

Financial instruments, which potentially subject the Company to concentration of credit risk, consist primarily of cash, cash equivalents, short term investments, 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.

Accounts Receivable

Accounts receivable is stated at the original invoice amount and consists of certain research and development and contract manufacturing costs subject to reimbursement under the Company's collaboration agreements. The Company did not record any credit losses as of June 30, 2022 and December 31, 2021.

Property and Equipment, Net

Property and equipment is stated at cost less accumulated depreciation. Depreciation is recorded using the straight-line method over the estimated useful lives of the related assets, which ranges from two to ten years. Repairs and maintenance charges that do not increase the useful life of the assets are charged to operating expenses as incurred.

Long-Lived Assets

The Company's long-lived assets are comprised principally of its property and equipment.

If the Company identifies a change in the circumstances related to its long-lived assets that indicates the carrying value of any such asset may not be recoverable, the Company will perform an impairment analysis. A long-lived asset is not recoverable when the undiscounted cash flows expected to be generated by the asset (or asset group) are less than the asset's carrying amount. Any required impairment loss would be measured as the amount by which the asset's carrying value exceeds its fair value, and would be recorded as a reduction in the carrying value of the related asset and a charge to operating expense.

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 Dr. Falk Pharma GmbH and its collaboration agreement with Millennium Pharmaceuticals, Inc., a subsidiary of Takeda Pharmaceutical Company Limited (collectively, Takeda) 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, information technology, property and 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 related to stock options, restricted stock units, and shares granted under the Company's 2021 Employee Stock Purchase Plan (the ESPP). Stock-based compensation expense represents the cost of the grant date fair value of applicable awards recognized over the requisite service period (usually the vesting period) on a straight-line basis, net of actual forfeitures during the period. The Company estimates the fair value of stock options and shares purchased under the ESPP 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. Stock-based compensation expense related to restricted stock units is determined based upon the fair market value of the Company's stock on the grant date.

Valuation of Common Stock

Prior to the IPO, given the absence of a public trading market for the Company's common stock, the Company's 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 the Nasdaq Global Select Market.

Preferred Stock Purchase Right Liabilities

From time to time, the Company entered into convertible preferred stock financings where, in addition to the initial closing, investors agreed to buy, and the Company agreed 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 evaluated this purchase right and assessed whether it met the definition of a freestanding instrument and, if so, determined the fair value of the purchase right liability and recorded it on the balance sheet with the remainder of the proceeds raised allocated to convertible preferred stock. The preferred stock purchase right liability was 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 six months ended June 30, 2021.

Comprehensive Loss

Comprehensive loss is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources, including unrealized gains and losses on marketable securities. Comprehensive gains (losses) have been reflected in the statements of operations and comprehensive loss for all periods presented

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 11,084 and 13,231 weighted average shares subject to repurchase or forfeiture from the weighted average number of common shares outstanding for the three and six months ended June 30, 2022, respectively, and 35,369 and 41,654 weighted average shares subject to repurchase or forfeiture from the weighted average number of common shares outstanding for the three and six months ended June 30, 2021, respectively. Dilutive common stock equivalents are comprised of options outstanding under the Company's equity incentive plan, warrants to purchase common stock, and 2021 Employee Stock Purchase Plan (ESPP) shares pending issuance.

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 the three and six months ended June 30, 2022 and 2021, 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):

	June 30,	
	2022	2021
Common stock options issued and outstanding	7,544,646	5,190,989
Warrants to purchase common stock	14,884	14,884
ESPP shares pending issuance	9,072	12,536
Total	7,568,602	5,218,409

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.

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 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.

The following tables summarize the Company's financial instruments measured at fair value on a recurring basis (in thousands):

	Total	Fair Value Measurements At Reporting Date Using: Quoted Prices in Active Markets For Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
As of June 30, 2022				
Assets:				
Cash and cash equivalents:				
Money market funds	$ 755	$ 755	$ —	$ —
Commercial paper	33,323	—	33,323	—
Total cash and cash equivalents	34,078	755	33,323	—
Short term investments:				
Commercial paper	$ 99,911	$ —	$ 99,911	$ —
U.S. government and agency securities	15,912	15,912	—	—
	115,823	15,912	99,911	—
Total assets measured at fair value	$ 149,901	$ 16,667	$ 133,234	$ —

The Company had no financial instruments measured at fair value as of December 31, 2021. The Company determines the fair value of its marketable securities based on one or more valuations from its investment accounting and reporting service provider. The investment service provider values the securities using a hierarchical security pricing model that relies primarily on valuations provided by an industry-recognized valuation service. Such valuations may be based on trade prices in active markets for identical assets (Level 1 inputs) or valuation models using inputs that are observable either directly or indirectly (Level 2 inputs), such as quoted prices for similar assets, yield curves, volatility factors, credit spreads, default rates, loss severity, current market and contractual prices for the underlying instruments or debt, and broker and dealer quotes, as well as other relevant economic measures.

There were no transfers within the hierarchy during the three and six months ended June 30, 2022 and 2021. 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 June 30, 2022 and December 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 were as follows:

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

Preferred Stock Purchase Right Liability

Upon the issuance of the shares of Series D-2 convertible preferred stock in January 2021, the liability was remeasured 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, 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 six months ended June 30, 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 June 30, 2021	$ —	$ —

4. Marketable Securities.

The following tables summarize marketable securities (in thousands):

		As of June 30, 2022			
			Unrealized		
	Maturity (in years)	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Cash and cash equivalents:					
Money market funds		$ 755	$ —	$ —	$ 755
Commercial paper	one or less	33,351		(28)	33,323
Total cash and cash equivalents		$ 34,106	$ —	$ (28)	$ 34,078
Short term investments:					
Commercial paper	one or less	$ 100,170	$ —	$ (259)	$ 99,911
U.S. government and agency securities	one or less	15,935	—	(23)	15,912
Total short term investments		$ 116,105	$ —	$ (282)	$ 115,823
Total marketable securities		$ 150,211	$ —	$ (310)	$ 149,901

As of June 30, 2022, none of the marketable securities held have been in an unrealized loss position for greater than 12 months. The Company does not intend to sell these investments and it is not likely that the Company will be required to sell these investments before recovery of their amortized cost basis. Accordingly, no allowance for credit losses was recorded.

There were no marketable securities as of December 31, 2021.

5. Balance Sheet Details

Prepaid Expenses and Other Current Assets

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

	June 30, 2022	December 31, 2021
Prepaid contract manufacturing expenses	$ 930	$ 3,808
Prepaid clinical trial expenses	2,069	1,397
Prepaid research and development expenses	503	627
Other prepaid expenses	2,201	1,218
Total	$ 5,703	$ 7,050

Property and equipment, Net

Property and equipment, net, consist of the following (in thousands):

	June 30, 2022	December 31, 2021
Laboratory equipment	$ 2,579	$ 1,830
Computer equipment	493	24
Office equipment and furniture	474	—
	3,546	1,854
Less accumulated depreciation	(655)	(407)
Total	$ 2,891	$ 1,447

Depreciation expense related to property and equipment was $0.2 million and $0.1 million for the three months ended June 30, 2022 and 2021, respectively, and $0.2 million and $0.1 million for the six months ended June 30, 2022 and 2021, respectively.

Accrued Expenses and Other Current Liabilities

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

	June 30, 2022	December 31, 2021
Accrued research and development	$ 2,841	$ 2,123
Accrued clinical trial expenses	3,635	1,999
Accrued contract manufacturing expenses	2,689	906
Accrued legal expenses	433	531
Unvested early exercise liability	22	35
Accrued other	438	456
Total	$ 10,058	$ 6,050

6. Collaboration and License Agreements

Exclusive License Agreement with Cedars-Sinai Medical Center

In September 2017, the Company entered into an Exclusive License Agreement with Cedars-Sinai Medical Center (Cedars-Sinai), a related party, as amended and restated (the Cedars-Sinai Agreement). Under the terms of the Cedars-Sinai 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 human use. 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, which is an integral part of the Company's Prometheus360 platform. In August 2021, the Company and Cedars-Sinai amended and restated the Cedars-Sinai Agreement to, among other things, add a joint steering committee and cover new intellectual property.

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. The shares of unvested restricted common stock had vesting conditions tied to continuing services required of certain Cedars-Sinai employees pursuant to consulting agreements with the Company. One third of the restricted shares were released from restriction annually on the anniversary of the Cedars-Sinai Agreement over a three-year period. Additionally, the Company is obligated to pay Cedars-Sinai low- to mid-single digit percentage royalties on net sales of products covered under the Cedars-Sinai Agreement. The term of, and the Company's royalty obligations under, the Cedars-Sinai 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.

Co-Development and Manufacturing Agreement with Dr. Falk Pharma GmbH

In July 2020, the Company entered into a Co-Development and Manufacturing Agreement (the Falk 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 PRA052 program. Under the Falk Agreement, the Company is obligated to use commercially reasonable efforts to conduct development activities under an agreed development plan and 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). Falk agreed to fund 25% of the Company's third-party development costs set forth in the development plan.

Under the agreement, Falk paid the Company an upfront payment of $2.5 million and made a second payment of $2.5 million following the parties' mutual agreement on the development plan. In addition, in June 2021, Falk made a milestone payment to the Company of $10 million upon the selection of a clinical candidate for the PRA052 program and, in December 2021, Falk made the final milestone payment of $5 million, based on the Company's development of a companion diagnostic candidate for the PRA052 program. Falk is also obligated to pay the Company a mid-single to low-double digit royalty on net sales of all products incorporating antibodies covered by the agreement in the Falk territory, and the Company agreed to pay Falk a low-single digit royalty on net sales for such products in the Company's territory.

The Company has identified one performance obligation for all the deliverables under the Falk 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 eight-year period over which it expects to satisfy its performance obligation.

The Company included the upfront payment and all 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 Falk Agreement, the Company recognized revenue of $1.3 million and $0.3 million for the three months ended June 30, 2022 and 2021, respectively, and $4.0 million and $0.3 million for the six months ended June 30, 2022 and 2021, respectively. The Company had deferred revenue of $17.5 million and $18.7 million as of June 30, 2022 and December 31, 2021, respectively. This deferred revenue balance is expected to be recognized proportionally as expenses are incurred over the estimated eight-year term.

Companion Diagnostics Development Agreement with Millennium Pharmaceuticals, Inc.

In March 2019, the Company entered into a Companion Diagnostics Development and Collaboration Agreement (the Takeda Agreement) with Millennium Pharmaceuticals, Inc., a wholly-owned subsidiary of Takeda. In March 2022, the Company and Takeda mutually agreed to terminate the agreement, effective April 2022. In connection with the Takeda Agreement, the Company recognized revenue of zero and $0.1 million for the three months ended June 30, 2022 and 2021, respectively, and $1.2 million and $0.3 million for the six months ended June 30, 2022 and 2021, respectively. The Company had deferred revenue of zero and $1.2 million as of June 30, 2022 and December 31, 2021, respectively.

A reconciliation of deferred revenue related to the Falk Agreement and the Takeda Agreement for the six months ended June 30, 2022 is as follows (in thousands):

	Falk Agreement	Takeda Agreement	Total
Balance at December 31, 2021	$ 18,691	$ 1,181	$ 19,872
Amounts received in 2022	2,830	—	$ 2,830
Revenue recognized in 2022	(4,007)	(1,181)	$ (5,188)
Balance at June 30, 2022	$ 17,514	$ —	$ 17,514

7. Long Term Debt

In January 2020, the Company entered into a Loan and Security Agreement (the Loan Agreement) with Oxford Finance LLC and its affiliates (Oxford) (the Oxford Loan) which provided for total borrowings of up to $25.0 million, of which $7.5 million was drawn upon execution of the agreement. Interest accrued 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 was required to make interest only payments. Beginning March 1, 2023, in addition to interest payments, the monthly payments were to include an amount equal to the outstanding principal divided by 24 months. At maturity (or earlier prepayment), the Company was 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 was collateralized by substantially all the Company's assets, excluding intellectual property, which was subject to a negative pledge.

In connection with execution of the Loan Agreement, the Company issued Oxford a warrant to purchase 112,500 shares of the Company's 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 the Company's common stock at an exercise price of $7.558 per share upon the completion of the Company's IPO.

In July 2021, the Company voluntarily prepaid the aggregate outstanding principal balance of $7.5 million plus an additional $0.5 million consisting of the prepayment penalty, accrued interest, and final payment due under the terms of the Oxford Loan, and the Loan Agreement was terminated in accordance with its terms. All liens and security interests securing the Oxford Loan were released upon termination. The Company recognized a $0.6 million loss on extinguishment on the Company's condensed statements of operations for the year ended December 31, 2021.

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.

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 obligated 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 was 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 six months ended June 30, 2021. The liability was then reclassified to stockholders' equity.

Sale Agreement

On April 1, 2022, the Company entered into an Open Market Sale Agreement (the "Sale Agreement") with Jefferies LLC (the "Agent"), pursuant to which the Company may, from time to time, offer and sell shares of the Company's common stock having an aggregate offering price of up to $150.0 million in "at the market" offerings through the Agent. Sales of the shares of common stock, if any, will be made at prevailing market prices at the time of sale, or as otherwise agreed with the Agent. The Agent will receive a commission from the Company of 3.0% of the gross proceeds of any shares of common stock sold under the Sale Agreement.

The Company is not obligated to sell, and the Agent is not obligated to buy or sell, any shares of common stock under the Sale Agreement. No assurance can be given that the Company will sell any shares of common stock under the Sale Agreement, or, if it does, as to the price or amount of shares of common stock that it sells or the dates when such sales will take place. The Company and the Agent may each terminate the Sale Agreement at any time upon specified prior written notice. As of June 30, 2022, the Company has sold 555,297 shares of its common stock under the Sale Agreement at a weighted average price of $27.31 resulting in net proceeds of approximately $14.0 million.

Equity Incentive Plan

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. 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. The number of shares of common stock available for issuance increased by 5% at January 1, 2022, and at June 30, 2022, 2,456,930 shares remain available for issuance under the 2021 Plan, including the automatic increase of 1,948,035 on January 1, 2022.

Grants generally vest at 25% one year from the vesting commencement date and ratably each month thereafter for a period of 36 months, subject to continuous service.

The Company's stock option activity for the six months ended June 30, 2022 is summarized in the following table:

	Number	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2021	6,474,039	$ 12.18	8.5	$ 177,130
Granted	1,325,947	$ 30.34		
Exercised	(163,675)	$ 2.73		
Cancelled/forfeited	(91,665)	$ 20.54		
Outstanding at June 30, 2022	7,544,646	$ 15.47	8.3	$ 108,623
Vested or expected to vest at June 30, 2022	7,544,646	$ 15.47	8.3	$ 108,623
Exercisable at June 30, 2022	2,299,870	$ 4.98	6.6	$ 53,483

The weighted average grant date fair value of options granted during the six months ended June 30, 2022 and 2021 was $20.52 and $5.93, respectively. The total intrinsic value of options exercised during the three months ended June 30, 2022 and 2021 was $0.5 million and $1.2 million, respectively. The total intrinsic value of options exercised during the six months ended June 30, 2022 and 2021 was $6.3 million and $1.3 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 June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Risk-free interest rate	2.7 – 3.0%	1.0 – 1.1%	1.5 – 3.0%	0.6 – 1.1%
Expected volatility	73.8 – 74.4%	73.0 – 74.2%	73.2 – 74.6%	73.0 – 95.2%
Expected term (in years)	5.5 – 6.5	5.8 – 6.1	5.5 – 6.5	5.8 – 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.

Restricted Stock Units

A summary of the Company's restricted stock units activity is as follows (in thousands, except share and per share amounts):

	Number of Outstanding Awards	Weighted Average Grant Date Fair Value	Aggregate Intrinsic Value
Balance at December 31, 2021	—		
Granted	112,886	$ 29.56	
Cancelled	—		
Balance at June 30, 2022	112,886		$ —
Vested or expected to vest at June 30, 2022	112,886		$ —

The Company's current restricted stock units vest 100% three years from the grant date, subject to continued service. The fair-value of each restricted stock unit is determined on the grant date using the closing price of the Company's common stock on the grant date.

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 June 30, 2022 and December 31, 2021, the early exercise liability was $23,000 and $35,000, respectively. For accounting purposes, the early exercise of options is not considered to be a substantive exercise until the underlying awards vest.

The following table summarizes the activity of the unvested common stock issued pursuant to an early exercise of stock option awards for the six months ended June 30, 2022:

Unvested at beginning of period	17,606
Vested or cancelled during the period	(8,625)
Unvested at end of period	8,981

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 were 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 lessor 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. The number of shares of common stock available for issuance under the ESPP increased by 1% at January 1, 2022. Stock-based compensation expense for the three and six months ended June 30, 2022 related to the ESPP was $0.1 million. As of June 30, 2022, the Company has issued 46,129 shares under the ESPP. The Company had an outstanding liability of $0.2 million at June 30, 2022, which is included in accrued compensation on the condensed balance sheet, for employee contributions to the ESPP for shares pending issuance at the end of the offering period. At June 30, 2022, 703,478 shares remain available for issuance under the ESPP, including the automatic increase of 389,607 on January 1, 2022.

The fair value of stock of the stock purchase right under the ESPP was determined using the Black-Scholes option pricing model with the following assumptions:

	Six Months Ended June 30, 2022
Risk-free interest rate	0.03– 2.4%
Expected volatility	69.4 – 83.9%
Expected term (in years)	0.5 – 1.64
Expected dividend yield	—%

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 June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Research and development	$ 1,644	$ 267	$ 2,780	$ 438
General and administrative	2,992	936	5,135	1,557
Total stock-based compensation	$ 4,636	$ 1,203	$ 7,915	$ 1,995

As of June 30, 2022, approximately $70.1 million of total unrecognized compensation expense related to unvested stock options and restricted stock units is expected to be recognized over a weighted average period of 3.0 years.

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance consists of the following:

	June 30, 2022	December 31, 2021
Common stock options issued and outstanding	7,544,646	6,474,039
Warrants to purchase common stock	14,884	14,884
Shares available for issuance under equity incentive plan	2,456,930	1,856,063
Shares available for issuance under the ESPP	703,478	333,850
Total	10,719,938	8,678,836

9. Commitments and Contingencies

Leases

In March 2021, the Company executed a non-cancellable lease agreement for office and laboratory space in San Diego, California ("Second Floor Lease"). The Second Floor Lease and related monthly payments commenced in March 2022, and has an initial term of ten years 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 received $6.3 million of tenant improvements, all of which were deemed to be owned by the landlord. Under the relevant guidance, the Company recognized operating lease right-of-use (ROU) asset and liabilities of $14.6 million each based on the present value of the future minimum lease payments over the lease term at the commencement date, using the Company's assumed incremental borrowing rate, and amortizes the ROU assets and liabilities over the lease term. Lease expense for operating leases is recognized on a straight-line basis over the lease term. The Company's short term lease is not subject to recognition of an ROU asset or liability.

In October 2021, the Company executed an amendment to the lease agreement to expand the leased premises ("First Floor Lease"). The amended lease extends the initial term of the original lease to 127 months following the commencement date of the expansion premises, with an option to extend the lease term for an additional five-year term. At June 30, 2022, the Company had not taken control of the expansion premises and the lease term had not yet commenced. The Company expects the lease for the expansion premises to commence in September 2022 at which point the related ROU asset and lease liabilities will be recorded on the Company's condensed balance sheet. The First Floor Lease provides for initial monthly rental payments for the expansion premises of an additional 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 an additional $6.3 million of tenant improvement allowance for the expansion premises.

In connection with the PLI spinoff on December 31, 2020, the Company entered into a sublease agreement for approximately 40,000 square feet currently occupied in the PLI facility. The sublease agreement was for one year with an option to renew for an additional year. The sublease agreement was extended through June 2022 during the year ended December 31, 2021 and expired on June 30, 2022 in accordance with its terms. No further payment obligations exist at June 30, 2022.

Information related to the Company's operating lease is as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Operating lease expense (including variable costs of $0.1 million and zero during the three and six months ended June 30, 2022 and 2021, respectively)	$ 893	$ 247	$ 1,227	$ 492
Cash paid for amounts included in the measurement of lease liabilities	$ 228	$ —	$ 228	$ —

As of June 30, 2022 the remaining lease term of the Company's operating lease was 129 months and the discount rate on the Company's operating lease was 8.0%.

Future minimum operating lease payments for the Second Floor Lease and information related to the lease liability as of June 30, 2022 are as follows (in thousands):

Remainder of 2022	$	312
2023		1,912
2024		1,970
2025		2,029
2026		2,090
Thereafter		14,552
Total lease payments		22,865
Imputed interest		(8,105)
Lease liability		14,760
Less current portion of lease liability		1,202
Lease liability, net of current portion	$	13,558

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 breech 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 June 30, 2022, no claims exist under indemnification arrangements and accordingly, no amounts have been accrued in its condensed financial statements as of June 30, 2022.

10. Related Party Transactions

As discussed in Note 5, in September 2017, the Company entered into the Cedars-Sinai Agreement. A related-party relationship exists with Cedars-Sinai due to its percentage of common stock ownership and representation on the Company's board of directors. 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 and six months ended June 30, 2022 and 2021, no services were provided under the research agreements.

As disclosed in Note 8, in January 2021, deferred purchase price obligations of $6.1 million due to Nestlé was satisfied with the issuance of 7,219,560 shares of Series D-2 convertible preferred stock in January 2021.

As a result of the PLI spinoff on December 31, 2020, the Company entered into a transition services agreement with PLI, pursuant to which the Company provided PLI certain transitional services, including general and administrative, finance and clinical operations support, and PLI provided 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 transition services agreement was terminated in June 2022. During the three and six months ended June 30, 2022, the Company paid PLI $1.0 million and $1.9 million, respectively, and during the three and six months ended June 30, 2021 the Company paid PLI $0.7 million and $2.2 million, respectively, 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 June 30, 2022 and 2021 were $0.2 million and $0.1 million, respectively. Company contributions made during the six months ended June 30, 2022 and 2021 were $0.6 million and $0.1 million, respectively.

12. COVID-19 Pandemic

The COVID-19 worldwide pandemic has presented substantial public health and economic challenges and has affected, and may continue to affect the Company's employees, patients, physicians and other healthcare providers, communities and business operations, as well as the U.S. and global economies and financial markets. International and U.S. governmental authorities in impacted regions have taken, and are continuing to take, actions in an effort to slow the spread of COVID-19 and variants of the virus. The COVID-19 pandemic continues to rapidly evolve. The extent to which the COVID-19 pandemic may impact the Company's business, including its preclinical studies, planned and ongoing clinical trials, and financial condition will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the continued geographic spread of variants, the duration of the pandemic, the timing and effectiveness of vaccine distribution, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

13. Subsequent Events

From July 1, 2022 through the date of this filing, the Company sold 1,581,583 shares of its common stock under the Sale Agreement at a weighted average price of $33.54 resulting in net proceeds of approximately $51.5 million.

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

The following discussion and analysis and the unaudited interim condensed 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, 2021 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in the Annual Report on Form 10-K for the year ended December 31, 2021 filed with the SEC on March 9, 2022.

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 clinical-stage 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 gastrointestinal (GI) bioinformatics database and sample biobank, to identify novel therapeutic targets and develop therapeutic candidates to engage those targets. In parallel, we are developing genetic-based companion diagnostic tests designed to identify patients more likely to respond to our therapeutic candidates. We have generated a robust pipeline of therapeutic development programs for the treatment of immune-mediated diseases.

Our lead product candidate, PRA023, is a humanized IgG1 monoclonal antibody (mAb) that has been shown to block the tumor necrosis factor (TNF)-like ligand 1A (TL1A), a target associated with both intestinal inflammation and fibrosis that was clinically validated in Pfizer's Phase 2a clinical trial in ulcerative colitis (UC). PRA023 has the potential to substantially improve outcomes for moderate-to-severe IBD patients, especially those predisposed to increased TL1A expression. PRA023's dual mechanism of action, targeting both inflammation and fibrosis, also provides a strong rationale for investigating the potential applicability of TL1A antagonism in areas outside IBD including indications in dermatology, pulmonary or hepatobiliary disease.

In July 2021, we advanced PRA023 into a global Phase 2 randomized placebo-controlled clinical trial in patients with moderate-to-severe UC (ARTEMIS-UC) and an open-label Phase 2a clinical trial in patients with moderate-to-severe Crohn's disease (CD) (APOLLO-CD), each utilizing our genetics-based companion diagnostic candidate designed to identify patients who are predisposed to increased expression of TL1A and therefore potentially more likely to respond to PRA023.

In June 2022, we completed enrollment for APOLLO-CD, which is statistically powered to evaluate the safety and efficacy of PRA023 in approximately 50 patients. In July 2022, we completed enrollment of the initial cohort (Cohort 1) for ARTEMIS-UC, which is statistically powered to evaluate the safety and efficacy of PRA023 in approximately 120 patients, and began enrollment in the expansion cohort (Cohort 2), which is statistically powered to further evaluate the effectiveness of our companion diagnostic candidate in approximately 40 additional patients who are companion diagnostic positive. We currently expect to announce full results from APOLLO-CD and topline results from Cohort 1 of ARTEMIS-UC together in the fourth quarter of 2022 with an update on enrollment of Cohort 2.

We continue to advance our 200 mg/ml subcutaneous formulation of PRA023 for use in potential future registrational studies in UC and CD. We recently completed a subcutaneous bridging study in Caucasian normal healthy volunteers that demonstrated greater than 80% bioavailability of the 200 mg/ml subcutaneous formulation of PRA023. In addition, we have initiated dosing of healthy volunteers of Japanese descent with PRA023 as part of the bridging study to assess safety, tolerability and pharmacokinetics. We believe we are on track to implement an autoinjector in potential future UC and CD registrational studies.

In March 2022, we initiated a Phase 2 clinical trial for PRA023 in Systemic Sclerosis-associated Interstitial Lung Disease (SSc-ILD). The U.S. Food and Drug Administration (FDA) granted fast track designation for PRA023 for the treatment of SSc-ILD in January 2022. Topline results from our Phase 2 trial of PRA023 in Systemic Sclerosis-Associated Interstitial Lung Disease (ATHENA-SSc-ILD) are expected in the first half of 2024.

Our second product candidate, PRA052, is an anti-CD30L mAb. The CD30L-CD30 co-stimulatory pathway has been implicated in IBD by genetic, preclinical, and human translational data. In preclinical studies, CD30L antagonism was observed to improve multiple animal models of colitis. PRA052 is designed to have high affinity and specificity for CD30L and to block both transmembrane and soluble CD30L. We plan to file an investigational new drug application (IND) for PRA052 in the third quarter of 2022 and expect to advance PRA052 into a Phase 1 single ascending dose/multiple ascending dose clinical trial in normal healthy volunteers in the fourth quarter of 2022. We are also developing a proprietary genetics-based companion diagnostic test for PRA052 to identify patients that are more likely to respond to CD30L inhibition.

In 2020, we entered into a co-development and manufacturing agreement (the Falk Agreement) with Dr. Falk Pharma GmbH (Falk) for PRA052, in order to leverage Falk's experience in GI drug development and commercialization in Europe. Under this agreement, we granted to Falk exclusive commercialization rights in Europe, Australia and New Zealand for PRA052 and its companion diagnostic, while we retained commercialization rights in the United States and the rest of the world. In 2021, we earned both pre-clinical milestone payments from Falk related to our selection of the PRA052 clinical candidate and our development of a companion diagnostic candidate for PRA052.

We continue to explore additional potential indications for our development programs and 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 marketed and conducted 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.

We do not expect to generate any revenue from therapeutic product sales until we successfully complete development and obtain regulatory approval for one or more of our therapeutic product candidates and companion diagnostics, which we expect will take a number of years and may never occur.

We have incurred operating losses in each year since inception. Our net losses were $65.7 million and $32.9 million for the six months ended June 30, 2022 and 2021, respectively. As of June 30, 2022, we had an accumulated deficit of $255.1 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 (Loan Agreement) with Oxford Finance LLC and its affiliates (Oxford) ("the Oxford Loan"). 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. In July 2021, we voluntarily prepaid the aggregate outstanding principal balance of the Oxford Loan of $7.5 million plus an additional $0.5 million consisting of the prepayment penalty, accrued interest, and final payment due under the terms of the Loan Agreement and Oxford released all liens against our assets and terminated our other applicable obligations. As of June 30, 2022, we have sold 555,297 shares of common stock under the Open Market Sale Agreement (Sale Agreement) at a weighted average price of $27.31 per share resulting in net proceeds of $14.0 million. As of June 30, 2022, we had cash, cash equivalents, and short term investments of $211.8 million.

Based on our current operating plan, we believe that our existing cash and cash equivalents will be sufficient to fund our operations for at least the next 12 months from the date of issuance of these financial statements. 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, including royalty payments under our license and collaboration agreements. 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 COVID-19 worldwide pandemic has presented substantial public health and economic challenges and has affected, and may continue to affect, our employees, patients, physicians and other healthcare providers, communities and business operations, as well as the U.S. and global economies and financial markets. 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 continue enrolling global clinical trials and advance other product candidates into 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 pandemic 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 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.

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 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 June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
PRA023	$ 17,232	$ 10,462	$ 32,794	$ 15,787
PRA052	5,023	1,433	14,197	3,204
Other preclinical programs	3,663	1,659	6,857	2,321
Total research and development	$ 25,918	$ 13,554	$ 53,848	$ 21,312

We expect our research and development expenses to increase for the foreseeable future as we continue to progress our Phase 2 clinical trials of PRA023 globally, advance PRA052 through IND-enabling studies and initiate a Phase 1 clinical trial, develop companion diagnostics, and continue to advance several preclinical research and development programs. 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, human resources, 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.

Interest and Other Income (Expense)

Interest income

Interest income consists primarily of interest earned on our cash, cash equivalents, and short term investments.

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 recorded to convertible preferred stock, which was then subsequently reclassified to permanent equity in connection with the IPO.

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.

Results of Operations

Comparison of the Three Months Ended June 30, 2022 and 2021

The following table summarizes our results of operations for the three months ended June 30, 2022 and 2021 (in thousands):

	Three Months Ended June 30,		
	2022	2021	Change
Collaboration revenue	$ 1,269	$ 326	$ 943
Operating expenses:			
Research and development	25,918	13,554	12,364
General and administrative	9,319	5,618	3,701
Total operating expenses	35,237	19,172	16,065
Loss from operations	(33,968)	(18,846)	(15,122)
Other income (expense), net:			
Interest income	321	37	284
Interest expense	—	(190)	190
Total other income (expense), net	321	(153)	474
Net loss	$ (33,647)	$ (18,999)	$ (14,648)

Collaboration Revenue

Revenue was $1.3 million for the three months ended June 30, 2022 compared to $0.3 million for the three months ended June 30, 2021 primarily due to an increase in revenue generated under the Falk Agreement.

Research and Development Expenses

Research and development expenses were $25.9 million for the three months ended June 30, 2022 compared to $13.6 million for the three months ended June 30, 2021. The increase of $12.4 million for the three months ended June 30, 2022 compared to the three months ended June 30, 2021 was primarily driven by a $4.2 million increase in clinical trial expenses related to our global Phase 2 clinical trials of PRA023, a $3.6 million increase in expenses related to personnel costs and stock-based compensation due to increased headcount to support increased development activities, and a $2.3 million increase in expenses related to our contract manufacturing activities to support our clinical trials, with the remainder due to increases in expenses related to research and development expenses for our other preclinical development programs.

General and Administrative Expenses

General and administrative expenses were $9.3 million for the three months ended June 30, 2022 compared to $5.6 million for the three months ended June 30, 2021. The increase of $3.7 million for the three months ended June 30, 2022 compared to the three months ended June 30, 2021 was primarily driven by a $2.1 million increase in stock-based compensation expense, a $1.0 million increase in personnel costs, and a $0.4 million increase in facility related expenses, with the remainder primarily due to increases in expenses related to operating as a public company.

Other Income (Expense), Net

Interest income

Interest income was $0.3 million for the three months ended June 30, 2022 and zero for the three months ended June 30, 2021. The increase of $0.3 million for the three months ended June 30, 2022 compared to the three months ended June 30, 2021 was due to higher interest rates and investment in marketable securities.

Interest expense

Interest expense was zero for the three months ended June 30, 2022 and $0.2 million for the three months ended June 30, 2021. The decrease of $0.2 million for the three months ended June 30, 2022 compared to the three months ended June 30, 2021 was primarily due to the payoff of debt under the Loan Agreement in the third quarter of 2021.

Comparison of the Six Months Ended June 30, 2022 and 2021

The following table summarizes our results of operations for the six months ended June 30, 2022 and 2021 (in thousands):

	Six Months Ended June 30,		
	2022	2021	Change
Collaboration revenue	$ 5,188	$ 1,086	$ 4,102
Operating expenses:			
Research and development	53,848	21,312	32,536
General and administrative	17,405	10,840	6,565
Total operating expenses	71,253	32,152	39,101
Loss from operations	(66,065)	(31,066)	(34,999)
Other income (expense), net:			
Interest income	352	55	297
Interest expense	—	(848)	848
Change in fair value of preferred stock purchase right liability	—	(980)	980
Change in fair value of preferred stock warrant liability	—	(105)	105
Total other income (expense), net	352	(1,878)	2,230
Net loss	$ (65,713)	$ (32,944)	$ (32,769)

Collaboration Revenue

Revenue was $5.2 million for the six months ended June 30, 2022 compared to $1.1 million for the six months ended June 30, 2021 primarily due to an increase in revenue generated under the Falk Agreement.

Research and Development Expenses

Research and development expenses were $53.8 million for the six months ended June 30, 2022 compared to $21.3 million for the six months ended June 30, 2021. The increase of $32.5 million for the six months ended June 30, 2022 compared to the six months ended June 30, 2021 was primarily driven by a $12.8 million increase in expenses related to our contract manufacturing activities to support our clinical trials, a $8.0 million increase in clinical trial expenses related to our global Phase 2 clinical trials of PRA023, a $4.3 million increase in expenses related to personnel costs due to increased headcount to support increased development activities, a $2.3 million increase in stock-based compensation expense, and a $1.1 million increase in toxicology study costs related to PRA052, with the remainder due to increases in expenses related to research and development expenses for our other preclinical development programs.

General and Administrative Expenses

General and administrative expenses were $17.4 million for the six months ended June 30, 2022 compared to $10.8 million for the six months ended June 30, 2021. The increase of $6.6 million for the six months ended June 30, 2022 compared to the six months ended June 30, 2021 was primarily driven by a $3.6 million increase in stock-based compensation expense, a $0.9 million increase in personnel costs, and a $0.7 million increase in facility related expenses, with the remainder primarily due to increases in expenses related to operating as a public company.

Other Income (Expense), Net

Interest income

Interest income was $0.4 million for the six months ended June 30, 2022 and zero for the six months ended June 30, 2021. The increase of $0.4 million for the six months ended June 30, 2022 compared to the six months ended June 30, 2021 was primarily due to higher interest rates and investment in marketable securities.

Interest expense

Interest expense was zero for the six months ended June 30, 2022 and $0.8 million for the six months ended June 30, 2021. The decrease of $0.8 million for the six months ended June 30, 2022 compared to the six months ended June 30, 2021 was primarily due to the payoff of debt under the Loan Agreement in the third quarter of 2021.

Change in Fair Value of Convertible Preferred Stock Purchase Right Liability

The change in fair value of convertible preferred stock purchase right liability decreased $1.0 million. 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.

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 Falk and Takeda Agreements. 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 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 June 30, 2022, we had cash, cash equivalents, and short term investments of $211.8 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 accrued 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 preceded the month in which the interest will accrue, and (b) 2.01%, *plus* (II) 5.98%. Notwithstanding the foregoing, the annual rate was at no time to be less than 7.99%. From March 1, 2020 through February 28, 2023, we were required to make interest only payments. Beginning March 1, 2023, in addition to interest payments, the monthly payments were to include an amount equal to the outstanding principal divided by 24 months. At maturity (or earlier prepayment), we were 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 was collateralized by substantially all of our assets, excluding intellectual property, which was subject to a negative pledge.

In July 2021, we voluntarily prepaid the aggregate outstanding principal balance of $7.5 million plus an additional $0.5 million consisting of the prepayment penalty, final payment, and accrued interest due under the terms of the Loan Agreement, and the Loan Agreement was terminated in accordance with its terms. All liens and security interests securing the Oxford Loan were released upon termination.

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.

Open Market Sale Agreement

On April 1, 2022, we entered into the Sale Agreement with Jefferies LLC (the Agent), pursuant to which we may, from time to time, offer and sell shares of our common stock having an aggregate offering price of up to $150.0 million in “at the market” offerings through the Agent. Sales of the shares of common stock, if any, will be made at prevailing market prices at the time of sale, or as otherwise agreed with the Agent. The Agent will receive a commission from us of 3.0% of the gross proceeds of any shares of common stock sold under the Sale Agreement.

We are not obligated to sell, and the Agent is not obligated to buy or sell, any shares of common stock under the Sale Agreement. No assurance can be given that we will sell any shares of common stock under the Sale Agreement, or, if we do, as to the price or amount of shares of common stock that we sell or the dates when such sales will take place. During the six months ended June 30, 2022, we sold 555,297 shares of common stock under the Sale Agreement at a weighted average price of $27.31, resulting in net proceeds of approximately $14.0 million. As of June 30, 2022, we may sell up to an additional $134.8 million of shares of our common stock under the Sale Agreement.

Future Capital Requirements

As of June 30, 2022, we had cash, cash equivalents, and short term investments in the amount of $211.8 million. Based upon our current operating plans, we believe that our existing cash, cash equivalents, and short term investments will be sufficient to fund our operations for at least the next 12 months from date of issuance of these financial statements. 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 payments made to us under 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. 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):

	Six Months Ended June 30,	
	2022	2021
Net cash provided by (used in)		
Operating activities	$ (58,235)	$ (24,351)
Investing activities	(117,818)	(580)
Financing activities	14,758	275,119
Net (decrease) increase in cash and cash equivalents	$ (161,295)	$ 250,188

Operating Activities

Cash used in operating activities was $58.2 million during the six months ended June 30, 2022 as compared to cash used in operating activities of $24.4 million during the six months ended June 30, 2021. The increase of $33.8 million was primarily the result of the increase in net loss between the two periods of $32.8 million and a decrease of $5.6 million from changes in operating assets and liabilities, offset by an increase of $4.5 million in noncash charges.

Investing Activities

Net cash used in investing activities was $117.8 million during the six months ended June 30, 2022 as compared to net cash used in investing activities of $0.6 million during the six months ended June 30, 2021, primarily due to purchases of marketable securities.

Financing Activities

Net cash provided by financing activities was $14.8 million during the six months ended June 30, 2022 as compared to $275.1 million during the six months ended June 30, 2021. During the six months ended June 30, 2022, we received proceeds of $15.2 million from the sale of common stock under the Sale Agreement offset by payment of $1.2 million in financing fees, $0.4 million from stock option exercises, and $0.3 million from issuance of common stock under the ESPP. During the six months ended June 30, 2021, we received proceeds of $201.2 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.

Critical Accounting Polices 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.

There have been no material changes in our critical accounting policies and estimates during the six months ended June 30, 2022 from those disclosed in “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Critical Accounting Policies & Estimates,” included in our Annual Report on Form 10-K for the year ended December 31, 2021 filed with the SEC on March 9, 2022.

Recent Accounting Pronouncements

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

Contractual Obligations and Commitments

During the six months ended June 30, 2022, there have been no material changes outside of the ordinary course of business in the composition to the contractual obligations or commitments discussed in “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Contractual Obligations and Commitments” in the Annual Report on Form 10-K for the year ended December 31, 2021 filed with the SEC on March 9, 2022.

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 December 31, 2022.

Item 3.Quantitative and Qualitative Disclosures About Market Risk

Not applicable.

Item 4.Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our periodic and current reports that we file with the SEC 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 principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. In addition, the design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Our management, with the participation of our principal executive officer and principal financial officer, has evaluated, as of the end of the period covered by this quarterly report on Form 10-Q, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Based on such evaluation, our principal executive officer and principal financial officer have concluded that, as of June 30, 2022, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting identified in connection with the evaluation required by paragraph (d) of Rules 13a-15 or 15d-15 under the Exchange Act that occurred during the three months ended June 30, 2022, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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

There have been no material changes to the risk factors disclosed in Part II, Item 1A, “Risk Factors” of our Annual Report on Form 10-K for the year ended December 31, 2021.

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

Unregistered Sales of Equity Securities

None.

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.

As of June 30, 2022, we estimate that we have used approximately $7.0 million of the proceeds from our IPO for general corporate purposes including to fund research and development of our development programs. There has been no material change in the planned use of proceeds from our initial public offering from that described in the prospectus for the IPO.

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	3/8/2021	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	2/19/2021	4.2	
4.3	Warrant issued to Oxford Finance LLC, dated January 24, 2020	S-1	2/19/2021	4.3	
10.1	Open Market Sale Agreement, dated April 1, 2022, by and between Jefferies LLC and the Registrant	S-3ASR	4/1/2022	1.2	
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)				

* 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: August 11, 2022

By: /s/ Mark C. McKenna
Mark C. McKenna
Chairman of the Board, President and Chief Executive Officer
(Principal Executive Officer)

Date: August 11, 2022

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

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Mark C. McKenna, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q, of Prometheus Biosciences, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant’s other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 11, 2022

By: /s/ Mark C. McKenna
Mark C. McKenna
Chairman of the Board, President and Chief Executive Officer

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Keith W. Marshall, Ph.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q, of Prometheus Biosciences, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant’s other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 11, 2022

By: /s/ Keith W. Marshall, Ph.D.
Keith W. Marshall, Ph.D.
Chief Financial Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Prometheus Biosciences, Inc. (the "Company") on Form 10-Q for the period ending June 30, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: August 11, 2022

By: /s/ Mark C. McKenna
Mark C. McKenna
Chairman of the Board, President and Chief Executive Officer

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Prometheus Biosciences, Inc. (the "Company") on Form 10-Q for the period ending June 30, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: August 11, 2022

By: /s/ Keith W. Marshall, Ph.D.
Keith W. Marshall, Ph.D.
Chief Financial Officer