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

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2022

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

Commission File Number: 001-39049

EXAGEN INC.

(Exact name of registrant as specified in its charter)

Delaware	**20-0434866**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
1261 Liberty Way Vista, California	**92081**
(Address of Principal Executive Offices)	**(Zip Code)**

(760) 560-1501

(Registrant's Telephone Number, Including Area Code)

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, par value $0.001 per share	**XGN**	**The Nasdaq Global 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 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 during the preceding 12 months (or for such shorter period that the registrant was required to submit and post 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 Securities Exchange Act of 1934.

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 Securities Act ☐

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

Total shares of common stock outstanding as of the close of business on July 29, 2022 was 16,260,445.

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Unaudited Condensed Balance Sheets
(in thousands, except share and per share data)

	June 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 76,387	$ 99,442
Accounts receivable, net	9,590	9,654
Prepaid expenses and other current assets	3,062	3,638
Total current assets	89,039	112,734
Property and equipment, net	7,216	4,772
Operating lease right-of-use assets	5,338	—
Goodwill	5,506	5,506
Other assets	625	433
Total assets	$ 107,724	$ 123,445
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,105	$ 2,492
Operating lease liabilities	979	—
Accrued and other current liabilities	5,489	6,826
Total current liabilities	9,573	9,318
Borrowings-non-current portion, net of discounts and debt issuance costs	27,828	27,478
Non-current operating lease liabilities	5,027	—
Deferred tax liabilities	306	306
Other non-current liabilities	810	1,407
Total liabilities	43,544	38,509
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized, no shares issued or outstanding as of June 30, 2022 and December 31, 2021	—	—
Common stock, $0.001 par value; 200,000,000 shares authorized as of June 30, 2022 and December 31, 2021; 16,258,807 and 16,164,994 shares issued and outstanding as of June 30, 2022 and December 31, 2021, respectively	16	16
Additional paid-in capital	295,885	293,060
Accumulated deficit	(231,721)	(208,140)
Total stockholders' equity	64,180	84,936
Total liabilities and stockholders' equity	$ 107,724	$ 123,445

The accompanying notes are an integral part of these condensed financial statements

Exagen Inc.

Unaudited Condensed Statements of Operations
(in thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Revenue	$ 8,962	$ 12,772	$ 19,356	$ 23,359
Operating expenses:				
Costs of revenue	6,078	5,451	11,895	10,162
Selling, general and administrative expenses	12,903	11,171	25,055	21,211
Research and development expenses	2,689	1,892	4,793	3,295
Total operating expenses	21,670	18,514	41,743	34,668
Loss from operations	(12,708)	(5,742)	(22,387)	(11,309)
Interest expense	(606)	(663)	(1,204)	(1,308)
Other income (expense), net	5	(5)	10	(2)
Net loss	$ (13,309)	$ (6,410)	$ (23,581)	$ (12,619)
Net loss per share, basic and diluted	$ (0.78)	$ (0.38)	$ (1.39)	$ (0.84)
Weighted-average number of shares used to compute net loss per share, basic and diluted	17,058,516	16,928,613	17,025,636	14,946,935

The accompanying notes are an integral part of these condensed financial statements

Exagen Inc.

Unaudited Condensed Statements of Stockholders' Equity
(in thousands, except share data)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balances as of December 31, 2021	16,164,994	$ 16	$ 293,060	$ (208,140)	$ 84,936
Issuance of stock from vested restricted stock units and payment of employees' taxes	30,523	—	(115)	—	(115)
Issuance of stock under Employee Stock Purchase Plan	35,681	—	231	—	231
Stock-based compensation	—	—	1,376	—	1,376
Net loss	—	—	—	(10,272)	(10,272)
Balances as of March 31, 2022	16,231,198	16	294,552	(218,412)	76,156
Issuance of stock from vested restricted stock units and payment of employees' taxes	27,609	—	(107)	—	(107)
Stock-based compensation	—	—	1,440	—	1,440
Net loss	—	—	—	(13,309)	(13,309)
Balances as of June 30, 2022	16,258,807	$ 16	$ 295,885	$ (231,721)	$ 64,180

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balances as of December 31, 2020	12,652,308	$ 13	$ 223,115	$ (181,289)	$ 41,839
Issuance of stock in public offering, net of issuance costs of $4,435	4,255,000	4	64,705	—	64,709
Exercise of stock options	3,381	—	44	—	44
Issuance of stock under Employee Stock Purchase Plan	14,991	—	175	—	175
Stock-based compensation	—	—	912	—	912
Net loss	—	—	—	(6,209)	(6,209)
Balances as of March 31, 2021	16,925,680	17	288,951	(187,498)	101,470
Retirement of common stock in exchange for common stock warrant	(804,951)	(1)	(12,774)	—	(12,775)
Issuance of common stock warrant in exchange for retirement of common stock	—	—	12,775	—	12,775
Exercise of stock options	6,055	—	35	—	35
Stock-based compensation	—	—	1,285	—	1,285
Net loss	—	—	—	(6,410)	(6,410)
Balances as of June 30, 2021	16,126,784	$ 16	$ 290,272	$ (193,908)	$ 96,380

The accompanying notes are an integral part of these condensed financial statements

Exagen Inc.

Unaudited Condensed Statements of Cash Flows
(in thousands)

	Six Months Ended June 30,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$ (23,581)	$ (12,619)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	597	407
Amortization of debt discount and debt issuance costs	78	148
Non-cash interest expense	272	266
Non-cash lease expense	514	—
Stock-based compensation	2,816	2,197
Changes in assets and liabilities:		
Accounts receivable, net	64	130
Prepaid expenses and other current assets	576	987
Other assets	(201)	(13)
Operating lease liabilities	(382)	—
Accounts payable	751	(102)
Accrued and other current liabilities	(1,232)	(163)
Net cash used in operating activities	(19,728)	(8,762)
Cash flows from investing activities:		
Purchases of property and equipment	(3,033)	(881)
Net cash used in investing activities	(3,033)	(881)
Cash flows from financing activities:		
Proceeds from exercise of stock options	—	79
Payments of taxes withheld on vested restricted stock units	(222)	—
Proceeds from common stock issued under Employee Stock Purchase Plan	231	175
Principal payments on finance lease obligations	(303)	(220)
Proceeds from the issuance of common stock in public offering, gross	—	69,144
Payment of issuance costs related to public offering	—	(4,407)
Net cash (used in) provided by financing activities	(294)	64,771
Net change in cash, cash equivalents and restricted cash	(23,055)	55,128
Cash, cash equivalents and restricted cash, beginning of period	99,542	57,548
Cash, cash equivalents and restricted cash, end of period	$ 76,487	$ 112,676
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 860	$ 892
Supplemental disclosure of non-cash items:		
Equipment purchased under finance lease obligations	$ 293	$ 940
Costs incurred, but not paid, in connection with capital expenditures	$ 391	$ 91
Deferred offering costs reclassified to equity	$ —	$ 28

The accompanying notes are an integral part of these condensed financial statements

Exagen Inc.

Notes to Unaudited Interim Condensed Financial Statements

Note 1. Organization

Description of Business

Exagen Inc. (the Company) is dedicated to transforming the care continuum for patients suffering from debilitating and chronic autoimmune diseases by enabling timely differential diagnosis and optimizing therapeutic intervention.

Liquidity

The Company has incurred recurring losses and negative cash flows from operating activities since inception. The Company anticipates that it will continue to incur net losses into the foreseeable future. As of June 30, 2022, the Company had cash and cash equivalents of $76.4 million and had an accumulated deficit of $231.7 million. Since inception, the Company has financed its operations primarily through a combination of equity financings of common stock and private placements of preferred securities, debt financing arrangements, and revenue from sales of the Company's products. Based on the Company's current business plan, management believes that its existing capital resources will be sufficient to fund the Company's obligations for at least twelve months following the issuance of these condensed financial statements.

To execute its business plans, the Company may need additional funding to support its continuing operations and pursue its growth strategy. Until such time as the Company can achieve significant cash flows from operations, if ever, it expects to finance its operations through the sale of its stock, debt financings or other strategic transactions. Although the Company has been successful in raising capital in the past, there is no assurance that it will be successful in obtaining such additional financing on terms acceptable to the Company, if at all. The terms of any financing may adversely affect the holdings or the rights of the Company's stockholders. If the Company is unable to obtain funding, the Company could be forced to delay, reduce or eliminate some or all of its programs, product portfolio expansion plans or commercialization efforts, which could have a material adverse effect on the Company's business, operating results and financial condition and the Company's ability to achieve its intended business objectives.

Impact of COVID-19 Pandemic

In 2020, due to the worldwide COVID-19 pandemic, the Company began to experience a reduction in patient test volumes, delays in patient enrollment in ongoing and planned clinical studies, and delays in the procurement of its testing supplies. The full extent to which the COVID-19 pandemic will directly or indirectly continue to impact the Company's business, results of operations and financial condition, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain or treat COVID-19, including, the success of ongoing vaccination efforts, the emergence and prevalence of variant strains of COVID-19, the institution or reinstitution of shutdowns, "stay-at-home-orders" and other public health measures as well as the related economic impact of these matters on local, regional and international markets.

Note 2. Summary of Significant Accounting Policies

Basis of Presentation and Use of Estimates

The accompanying interim condensed balance sheet as of June 30, 2022, the condensed statements of operations and the condensed statements of stockholders' equity for the three and six months ended June 30, 2022 and 2021, cash flows for the six months ended June 30, 2022 and 2021 and the related footnote disclosures are unaudited and have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission (SEC), and with accounting principles generally accepted in the United States (GAAP) applicable to interim financial statements. In management's opinion, the unaudited interim condensed financial statements have been prepared on the same basis as the audited financial statements and include all normal adjustments, necessary for the fair

presentation of the Company's financial position as of June 30, 2022 and its results of operations for the three and six month periods presented. The results for the six months ended June 30, 2022 are not necessarily indicative of the results expected for the full fiscal year or any other interim period. The year-end condensed balance sheet data was derived from audited financial statements, but does not include all disclosures required by GAAP. These unaudited condensed financial statements should be read in conjunction with the Company's audited financial statements for the year ended December 31, 2021, included in its Annual Report on Form 10-K filed with the SEC on March 22, 2022.

The preparation of the accompanying condensed financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities as of the date of the condensed financial statements, and the reported amounts of revenue and expenses during the reporting period. Actual results could materially differ from those estimates.

Significant estimates and assumptions made in the accompanying condensed financial statements include, but are not limited to revenue recognition, estimated incremental borrowing rate for the determination of the Company's operating lease right-of-use (ROU) assets, the recoverability of its long-lived assets (including goodwill) and net deferred tax assets (and related valuation allowance). The Company evaluates its estimates and assumptions on an ongoing basis using historical experience and other factors and adjusts those estimates and assumptions when facts and circumstances dictate. Actual results could materially differ from those estimates.

Concentration of Credit Risk and Other Risk and Uncertainties

Financial instruments that potentially subject the Company to credit risk consist principally of cash, cash equivalents, and accounts receivable. Substantially all the Company's cash and cash equivalents are held at one financial institution that management believes is of high credit quality. Such deposits may, at times, exceed federally insured limits.

Significant payors and customers are those which represent more than 10% of the Company's total revenue or accounts receivable balance at each respective balance sheet date. For each significant payor and customer, revenue as a percentage of total revenue and accounts receivable as a percentage of total accounts receivable are as follows:

	Revenue			
	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Medicare Advantage	23 %	13 %	19 %	12 %
Medicare	19 %	19 %	20 %	19 %
Aetna	11 %	*	*	*
Blue Shield	*	11 %	*	11 %

* Less than 10%.

	Accounts Receivable, Net	
	June 30, 2022	December 31, 2021
United Healthcare	13 %	18 %
Medicare	13 %	*
Medicare Advantage	11 %	*
Aetna	10 %	*
Blue Shield	*	19 %

* Less than 10%.

For each of the three months ended June 30, 2022 and 2021, approximately 81% of the Company's revenue was related to the AVISE® CTD test. For the six months ended June 30, 2022 and 2021, approximately 82% and 81%, respectively, of the Company's revenue was related to the AVISE® CTD test.

The Company is dependent on key suppliers for certain laboratory materials. For each of the three months ended June 30, 2022 and 2021, approximately 97% of the Company's diagnostic testing supplies were purchased from two suppliers. For the six months ended June 30, 2022 and 2021, approximately 96% and 97%, respectively, of the Company's diagnostic testing supplies were purchased from two suppliers. An interruption in the supply of these materials would impact the Company's ability to perform testing services.

Disaggregation of Revenue

The following table includes the Company's revenues as disaggregated by payor and customer category (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Revenue:				
Healthcare insurers	$ 5,286	$ 7,381	$ 11,709	$ 13,408
Government	1,689	2,394	3,809	4,403
Client(1)	1,785	2,427	3,376	4,392
Other(2)	202	270	462	556
Janssen (SIMPONI®)	—	300	—	600
Total revenue	$ 8,962	$ 12,772	$ 19,356	$ 23,359

(1) Includes hospitals, other laboratories, etc.
(2) Includes patient self-pay.

Fair Value Measurements

The carrying value of the Company's cash and cash equivalents approximate fair value due to the short-term nature of these items. The estimated fair value of the Company's long-term borrowings are determined by Level 2 inputs and is based primarily on quoted market prices for the same or similar issues. The recorded value of the Company's long-term borrowings approximates the current fair value as the interest rate and other terms are that which are currently available to the Company.

Fair value is defined as the exchange price that would be received for an asset or an exit price paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs.

The fair value hierarchy defines a three-level valuation hierarchy for disclosure of fair value measurements as follows:

Level 1 - Unadjusted quoted prices in active markets for identical assets or liabilities;

Level 2 - Inputs other than quoted prices included within Level I that are observable, unadjusted 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 related assets or liabilities; and

Level 3 - Unobservable inputs that are supported by little or no market activity for the related assets or liabilities.

The categorization of a financial instrument within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement.

Cash, Cash Equivalents and Restricted Cash

The Company considers all highly-liquid investments purchased with a remaining maturity date upon acquisition of three months or less to be cash equivalents and are stated at cost, which approximates fair value.

The Company has an arrangement with a financial institution with which it has an existing banking relationship whereby, in exchange for the issuance of corporate credit cards, the Company agreed to obtain a $0.1 million certificate of deposit with this financial institution as collateral for the balances borrowed on these credit cards. The Company has classified the value of this certificate of deposit (including all interest earned thereon) within other assets in the accompanying balance sheets. The Company has the right to terminate the credit card program at any time. Upon termination of the credit card program and repayment of all outstanding balances owed, the Company may redeem the certificate of deposit (and all interest earned thereon).

Cash, cash equivalents and restricted cash presented in the accompanying condensed statements of cash flows consist of the following (in thousands):

	June 30, 2022	December 31, 2021
Cash and cash equivalents	$ 76,387	$ 99,442
Restricted cash	100	100
	$ 76,487	$ 99,542

Revenue Recognition

Substantially all of the Company's revenue has been derived from sales of its testing products and is primarily comprised of a high volume of relatively low-dollar transactions. The Company primarily markets its testing products to rheumatologists and their physician assistants in the United States. The healthcare professionals who order the Company's testing products and to whom test results are reported are generally not responsible for payment for these products. The parties that pay for these services (each, payors) consist of healthcare insurers, government payors (primarily Medicare and Medicaid), client payors (i.e., hospitals, other laboratories, etc.), and patient self-pay. The Company's service is a single performance obligation that is completed upon the delivery of test results to the prescribing physician which triggers revenue recognition.

Payors are billed at the Company's list price. Net revenues recognized consist of amounts billed net of allowances for differences between amounts billed and the estimated consideration the Company expects to receive from such payors. The process for estimating revenues and the ultimate collection of accounts receivable involves significant judgment and estimation. The Company follows a standard process, which considers historical denial and collection experience, insurance reimbursement policies and other factors, to estimate allowances and implicit price concessions, recording adjustments in the current period as changes in estimates occur. Further adjustments to the allowances, based on actual receipts, are recorded upon settlement. Included in revenues for the three months ended June 30, 2022 and 2021 was a $1.8 million net revenue decrease and a $0.1 million net revenue increase, respectively, associated with changes in estimated variable consideration related to performance obligations satisfied in previous periods. Such amounts of variable consideration for the six months ended June 30, 2022 and 2021 were $2.2 million and $0.1 million, respectively, of net revenue decreases. The transaction price is estimated using an expected value method on a portfolio basis. The Company's portfolios are grouped per payor (i.e. each individual third-party insurance, Medicare, client payors, patient self-pay, etc.) and per test basis. Consideration may be constrained and excluded from the transaction price in situations where there is no contractually agreed upon reimbursement coverage or in absence of a predictable pattern and history of collectability with a payor. Accordingly, in such situations revenues are recognized on the basis of actual cash collections.

Collection of the Company's net revenues from payors is normally a function of providing complete and correct billing information to the healthcare insurers and generally occurs within 30 to 90 days of billing. Contracts do not contain significant financing components based on the typical period of time between performance of services and collection of consideration.

Janssen Promotion Agreement

In December 2018, the Company entered into a co-promotion agreement (as amended from time to time, the Janssen Agreement) with Janssen Biotech, Inc. (Janssen) to co-promote SIMPONI® in the United States. In August 2021, the Company and Janssen mutually agreed to terminate the Janssen Agreement effective on August 31, 2021.

Pursuant to the Janssen Agreement, as amended, the Company was responsible for the costs associated with its sales force over the course of such co-promotion. Janssen was responsible for all other aspects of the commercialization of SIMPONI® under the Janssen Agreement. In exchange for the Company's sales and co-promotional services, the Company was entitled to a quarterly tiered promotion fee based on the incremental increase in total prescribed units of SIMPONI® for that quarter over a predetermined baseline. The Company's obligations relating to sales and co-promotion services for SIMPONI® were a series of single performance obligations since Janssen simultaneously received and consumed benefits provided by the Company's sales and co-promotional services. The method for measuring progress towards satisfying the performance obligations was based on prescribed units in excess of the contractual baseline at the contractual rate earned per unit since the Janssen Agreement, as amended, was cancelable. The Company recognized no co-promotion revenue and $0.3 million during the three months ended June 30, 2022 and 2021, respectively. The Company recognized no co-promotion revenue and $0.6 million during the six months ended June 30, 2022 and 2021, respectively. The related expenses for marketing SIMPONI® are included in selling, general and administrative expenses and are expensed as incurred.

Upon the termination of the Janssen Agreement on August 31, 2021, the Company became entitled to receive an aggregate of $0.6 million in consideration, which was earned in the year ended December 31, 2021. Pursuant to the terms of the termination, we were restricted until May 31, 2022 from promoting any other biologic or Janus kinase inhibitor used for the treatment of indications covered by the Janssen Agreement without first obtaining Janssen's written consent. The restriction no longer applies.

Leases

The Company categorizes leases at their commencement as either operating or finance leases. Effective January 1, 2022 upon the adoption of ASC 842, the Company recognizes operating lease ROU assets and operating lease liabilities for each lease arrangement identified. Lease liabilities are recorded at the present value of future lease payments discounted using the Company's incremental borrowing rate for the lease established at the commencement date and ROU assets are measured at the amount of the lease liability plus any initial direct costs, less any lease incentives received before commencement. Lease expense is recognized as a single lease cost over the lease term on a straight-line basis. The Company has elected not to apply the recognition requirements to short-term leases and not to separate non-lease components from lease components for its leases. See Note 5 for details on the Company's leases.

Research and Development

Costs associated with research and development activities are expensed as incurred and include, but are not limited to, personnel-related expenses, including stock-based compensation expense, materials, laboratory supplies, consulting costs, costs associated with setting up and conducting clinical studies and allocated overhead including rent and utilities.

Advertising and Marketing Costs

Costs associated with advertising and marketing activities are expensed as incurred. Total advertising and marketing costs were approximately $0.6 million and $0.4 million for the three months ended June 30, 2022 and 2021, respectively, and $0.9 million and $0.6 million for the six months ended June 30, 2022 and 2021, respectively, and are included in selling, general and administrative expenses in the accompanying condensed statements of operations.

Shipping and Handling Costs

Costs incurred for shipping and handling are included in costs of revenue in the accompanying condensed statements of operations and totaled approximately $0.7 million and $0.6 million for the three months ended June 30, 2022 and 2021, respectively, and $1.3 million and $1.0 million for the six months ended June 30, 2022 and 2021, respectively.

Stock-Based Compensation

The Company recognizes compensation expense for all stock-based awards to employees and directors based on the grant-date estimated fair values over the requisite service period of the awards (usually the vesting period) on a straight-line basis. The fair value of stock options and purchases under the Company's 2019 Employee Stock Purchase Plan (ESPP) rights are determined using the Black-Scholes-Merton (BSM) option pricing model, which requires management to make certain assumptions regarding a number of complex and subjective variables. Equity award forfeitures are recorded as they occur.

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 and generally vest from the grant date in four equal annual installments subject to the holder's continued service with the Company. The Company issues new shares to satisfy restricted stock units upon vesting.

Comprehensive Loss

Comprehensive loss is defined as a change in equity of a business enterprise during a period, resulting from transactions from nonowner sources. There have been no items qualifying as other comprehensive loss and, therefore, for all periods presented, the Company's comprehensive loss was the same as its reported net loss.

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 and if-converted methods. The weighted-average number of shares in 2022 and 2021 used to compute basic and diluted shares includes shares issuable upon the exercise of pre-funded warrants at a nominal price. Potentially dilutive common stock equivalents are comprised of warrants for the purchase of common stock, options, restricted stock units outstanding under the Company's 2019 Incentive Award Plan (the 2019 Plan) and shares of the Company's common stock pursuant to the ESPP. 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 as the inclusion of the potentially dilutive securities would be antidilutive.

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**
Warrants to purchase common stock	409,108	426,827
Common stock options	1,949,374	2,123,617
Restricted stock units	784,940	375,525
Employee stock purchase plan	30,303	12,525
Total	3,173,725	2,938,494

Segment Reporting

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker in making decisions regarding resource allocation and assessing performance. The Company views its operations as, and manages its business in, one operating segment.

Recent Accounting Pronouncements Not Yet Adopted

From time to time, new accounting pronouncements 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. Under the Jumpstart Our Business Startups Act of 2012 (JOBS Act), the Company meets the definition of an emerging growth company (EGC). The Company has elected to use the extended transition period for complying with new or revised

accounting standards pursuant to Section 107(b) of the JOBS Act. 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 June 2016, the FASB issued Accounting Standards Update (ASU) 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, which requires the measurement of expected credit losses for financial instruments carried at amortized cost, such as accounts receivable, held at the reporting date based on historical experience, current conditions and reasonable forecasts. The main objective of this ASU is to provide financial statement users with more decision-useful information about the expected credit losses on financial instruments and other commitments to extend credit held by a reporting entity at each reporting date. In November 2018, the FASB issued ASU 2018-19, *Codification Improvements to Topic 326, Financing Instruments-Credit Losses*, which included an amendment of the effective date for nonpublic entities. For non-EGCs, ASU 2016-13 is effective for fiscal years beginning after December 15, 2019. For EGCs, the standard was to be effective for fiscal years beginning after December 15, 2021. However, in November 2019, the FASB issued ASU 2019-10, which included a one-year deferral of the effective date of ASU 2016-13 for certain entities. As a result, the ASU 2016-13 is now effective for EGCs for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. The Company is currently evaluating the impact of Topic 326 on its condensed financial statements.

Recently Adopted Accounting Standards

In February 2016, the FASB issued ASU 2016-02, *Leases* (Topic 842). The new topic supersedes Topic 840, *Leases*, and increases transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and requires disclosures of key information about leasing arrangements. In July 2018, the FASB issued ASU 2018-10, *Codification Improvements to Topic 842*, which provides narrow amendments to clarify how to apply certain aspects of the new lease standard, and ASU 2018-11, *Leases: Targeted Improvements*, which was issued to provide relief to companies from restating comparative periods. Pursuant to this ASU, in the period of adoption the Company will not restate comparative periods presented in its condensed financial statements. On January 1, 2022, the Company adopted ASU 2016-12 using the modified retrospective transition method. Periods prior to January 1, 2022 have not been restated for the adoption of ASC 842 and continue to reflect the accounting treatment of leases in accordance with the prior lease accounting guidance, ASC 840, *Leases*. The Company adopted the new lease standard using a cumulative effect to accumulated deficit and there was no impact to accumulated deficit upon adoption. The Company elected the package of practical expedients, which among other things allowed the Company to carry forward its historical lease classification. As part of the adoption, the Company recorded operating lease liabilities of $6.4 million, operating lease ROU assets of $5.9 million, adjusted for deferred rent and lease incentive obligations of $0.5 million previously included in other non-current liabilities and accrued and other current liabilities, pertaining to its office and laboratory space operating leases. See Note 5 for details on the Company's leases.

Note 3. Other Financial Information

Prepaid Expenses and Other Current Assets

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

	June 30, 2022	December 31, 2021
Diagnostic testing supplies	$ 1,077	$ 1,091
Prepaid product royalties	44	49
Prepaid maintenance and insurance contracts	1,511	2,008
Other prepaid expenses and other current assets	430	490
Prepaid expenses and other current assets	$ 3,062	$ 3,638

Property and Equipment, Net

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

	June 30, 2022	December 31, 2021
Furniture and fixtures	$ 98	$ 83
Laboratory equipment	4,846	4,361
Computer equipment and software	1,274	1,206
Leasehold improvements	1,367	1,151
Construction in progress	4,103	1,855
Total property and equipment	11,688	8,656
Less: accumulated depreciation and amortization	(4,472)	(3,884)
Property and equipment, net	$ 7,216	$ 4,772

Depreciation and amortization expense for the three months ended June 30, 2022 and 2021 was approximately $0.3 million and $0.2 million, respectively, and for the six months ended June 30, 2022 and 2021, was approximately $0.6 million and $0.4 million, respectively.

Accrued and Other Current Liabilities

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

	June 30, 2022	December 31, 2021
Accrued payroll and related expenses	$ 2,900	$ 4,048
Accrued interest	136	139
Accrued purchases of goods and services	1,040	510
Accrued royalties	124	180
Accrued clinical study activity	158	254
Finance lease obligations, current portion	679	587
Other accrued liabilities	452	1,108
Accrued and other current liabilities	$ 5,489	$ 6,826

Note 4. Borrowings

2017 Term Loan

In September 2017, the Company executed a term loan agreement (the 2017 Term Loan) with Innovatus Life Sciences Lending Fund I, LP (Innovatus) and borrowed $20.0 million, $17.8 million of which was immediately used to repay the Company's existing loan with Capital Royalty Partners II L.P. and its affiliates. On December 7, 2018, the Company borrowed an additional $5.0 million under the 2017 Term Loan. The 2017 Term Loan was subsequently amended in November 2019 and November 2021. As of June 30, 2022, no additional amounts remain available to borrow under the 2017 Term Loan.

In November 2021, the Company executed the Second Amendment to the Loan and Security Agreement (the 2017 Loan Amendment). The interest rate on all borrowings under the 2017 Loan Amendment is 8.0%, of which 2.0% is paid in-kind in the form of additional term loans (PIK Loans) until December of 2024, after which interest accrues at an annual rate of 8.0%. The Company has estimated the effective interest rate of this loan to be approximately 8.5%. Accrued interest is due and payable monthly, unless the Company elects to pay paid-in-kind interest. The outstanding principal and accrued interest on the 2017 Loan Amendment will be repaid in twenty-four equal monthly installments commencing in December 2024. Upon repayment of the final installment under the 2017 Loan Amendment, the Company is required to pay an additional fee of $1.0 million. This obligation is being accreted into interest expense over the term of the 2017 Loan Amendment using the effective interest method. For each of the three months ended June 30, 2022 and 2021, the Company issued PIK Loans totaling $0.1 million. For each of the six months ended June 30, 2022 and 2021, the Company issued PIK Loans totaling $0.3 million.

The 2017 Loan Amendment requires a prepayment premium of 3% of the aggregate outstanding principal. The prepayment premium decreases by 1% on November 1, 2022, 2023 and 2024.

The 2017 Loan Amendment is collateralized by a first priority security interest in substantially all of the Company's assets, including intellectual property. The affirmative covenants of the 2017 Loan Amendment require that the Company timely file taxes, maintain good standing and government compliance, maintain liability and other insurance, provide prompt notification of significant corporate events, and furnish audited financial statements within 150 days of fiscal year end without qualification as to the scope of the audit or as to going concern and without any other similar qualification.

The affirmative covenants require that the Company achieve a specified level of revenue, as measured quarterly on a rolling twelve-month basis, and commencing with the quarter ending December 31, 2022. The consequences of failing to achieve the performance covenant may be cured if, within sixty days of failing to achieve the performance covenant, the Company issues additional equity securities or subordinated debt with net proceeds sufficient to fund any cash flow deficiency generated from operations, as defined. The 2017 Loan Amendment requires that the Company maintain certain levels of minimum liquidity and maintains an unrestricted cash balance of $2.0 million.

The negative covenants provide, among other things, that without the prior consent of Innovatus subject to certain exceptions, the Company may not dispose of certain assets, engage in certain business combinations or acquisitions, incur additional indebtedness or encumber any of the Company's property, pay dividends on the Company's capital stock or make prohibited investments. The 2017 Loan Amendment provides that an event of default will occur if, among other triggers, (i) the Company defaults in the payment of any amount payable under the agreement when due, (ii) there occurs any circumstance(s) that could reasonably be expected to result in a material adverse effect on the Company's business, operations or condition, or on the Company's ability to perform its obligations under the agreement, (iii) the Company becomes insolvent, (iv) the Company undergoes a change in control or (v) the Company breaches any negative covenants or certain affirmative covenants in the agreement or, subject to a cure period, otherwise neglects to perform or observe any material item in the agreement.

As of June 30, 2022, the Company was in compliance with all covenants of the 2017 Loan Amendment.

Upon an event of default in any of the 2017 Loan Amendment covenants, the repayment of the 2017 Loan Amendment may be accelerated, and the applicable interest rate will be increased by 4.0% until the default is cured. Although repayment of the 2017 Loan Amendment can be accelerated under certain circumstances, the Company believes acceleration of this loan is not probable as of the date of these condensed financial statements. Accordingly, the Company has reflected the amounts of the 2017 Loan Amendment due beyond twelve months of the balance sheet date as non-current.

Future Minimum Payments on the Outstanding Borrowings

As of June 30, 2022, future minimum aggregate payments, including interest, for outstanding borrowings under the 2017 Loan Amendment are as follows (in thousands):

2022 (remaining)	$	837
2023		1,686
2024		2,980
2025		16,152
2026		14,786
Total		36,441
Less:		
Unamortized debt discount and issuance costs		(182)
Interest		(8,431)
Total borrowings, net of discounts and debt issuance costs	$	27,828

Note 5. Leases

The Company adopted ASC 842, *Leases*, as of January 1, 2022. Prior period amounts have not been adjusted and continue to be reported in accordance with the Company's historic accounting under ASC 840, *Leases*.

Operating Leases

The Company leases office and laboratory spaces in Vista, California, under leases that expire in April 2027, with an option to extend portions of the leases for additional 5-year periods. The Company has not included the optional renewal periods in the measurement of the lease liabilities because it is not reasonably certain that the Company will exercise these renewal options. The Company's lease payments under each of these leases are subject to escalation clauses.

Effective on August 23, 2021, the Company entered into a sub-lease agreement for an additional office space in Carlsbad, California. The sub-lease commenced in October 2021 and expires in April 2027. The sub-lease agreement provides for monthly base rent of $66,021 which began on October 1, 2021, and such amount shall increase by approximately 3% annually beginning October 1, 2022. The Company is entitled to base rent abatement for a specified period of time which began on November 1, 2021.

The Company determines if a contract contains a lease at inception or modification of a contract. The Company discounts their lease obligations using its incremental borrowing rate at the commencement date. The incremental borrowing rate is the rate of interest the Company would have to pay to borrow on a collateralized basis over a similar term and amount equal to the lease payments in a similar economic environment. The Company primarily considers industry data, its credit rating and the lease term to determine its incremental borrowing rate.

Finance Leases

The Company has entered into various finance lease agreements to obtain laboratory equipment. The terms of the Company's finance leases generally range from three to five years and are typically secured by the underlying equipment. The portion of the future payments designated as principal repayments were classified as finance lease liabilities on the Company's balance sheet.

Operating and Finance Leases Balances and Costs

Operating and finance leases consist of the following (in thousands):

Lease Balance	Classification	June 30, 2022
Lease Assets		
Operating	Operating lease right-of-use assets	$ 5,338
Finance	Property and equipment, net	$ 1,579
Lease Liabilities		
Current		
Operating	Operating lease liabilities	$ 979
Finance	Accrued and other current liabilities	$ 679
Non-current		
Operating	Non-current operating lease liabilities	$ 5,027
Finance	Other non-current liabilities	$ 781

Costs associated with the Company's leases were included in the statements of operations as follows (in thousands):

Lease Cost	Three months ended June 30, 2022	Six months ended June 30, 2022
Operating leases		
Operating lease cost[1]	$ 384	$ 773
Finance lease cost		
Amortization of lease assets	158	315
Interest on finance lease liabilities	21	40
Total lease cost	$ 563	$ 1,128

(1) Includes variable lease cost of $42,000 and $84,000 for the three and six months ended June 30, 2022, respectively.

Supplemental cash flow information on leases is as follows (in thousands):

Cash paid for amounts included in the measurement of lease liabilities	Six months ended June 30, 2022
Operating cash out flows from operating leases	$ 557
Operating cash out flows from interest paid on finance leases	$ 40
Financing cash out flows from finance leases	$ 303

Information regarding the weighted-average lease term and weighted average discount rate are as follows:

	June 30, 2022
Weighted-average remaining lease term (years)	
Operating leases	4.8
Finance leases	2.4
Weighted-average discount rate	
Operating leases	8.0 %
Finance leases	5.5 %

Future payments under operating and finance leases as of June 30, 2022 are as follows (in thousands):

	Operating Leases	Finance Leases
2022 (remaining)	$ 705	$ 378
2023	1,446	672
2024	1,489	418
2025	1,533	92
2026	1,584	—
Thereafter	539	—
Total minimum lease payments	7,296	1,560
Less: imputed interest	(1,290)	(100)
Total lease liabilities	6,006	1,460
Less: current portion	(979)	(679)
Lease obligations, net of current portion	$ 5,027	$ 781

Disclosures Under ASC 840

Minimum annual lease payments under non-cancelable operating lease arrangements as of December 31, 2021 are as follows (in thousands):

Years Ending December 31,	Operating Leases
2022	$ 1,337
2023	1,445
2024	1,489
2025	1,533
2026	1,584
Thereafter	539
Total minimum lease payments	$ 7,927

For the three and six months ended June 30, 2021, rent expense was $0.2 million and $0.3 million, respectively.

Note 6. Commitments and Contingencies

Acquisition-related liabilities

In connection with the acquisition of the medical diagnostics division of Royalty Pharma Collection Trust (Royalty Pharma) (formerly known as Cypress Bioscience, Inc.) in 2010, the Company was required to pay certain amounts in the event that certain revenue milestones were achieved and upon the first commercial sale of a product associated with this acquisition, for which the obligations no longer exist.

In addition, the Company has ongoing royalty payment obligations with Royalty Pharma of 2.5% on net sales of products which incorporate certain acquired technologies. Future royalties payable under these arrangements are limited to the lesser of (i) an aggregate of $1.2 million (including an upfront payment of $0.1 million) and (ii) the total royalties earned through January 1, 2024.

Licensing Agreements

The Company has licensed technology for use in its diagnostic tests. In addition to the milestone payments required by these agreements as described above, individual license agreements generally provide for ongoing royalty payments ranging from 1.5% to 7.0% on net sales of products which incorporate licensed technology, as defined in such agreements. Royalties are accrued when earned and recorded in costs of revenue in the accompanying condensed statements of operations.

In May 2021, the Company entered into an exclusive license agreement with Allegheny Health Network Research Institute (AHN), to obtain an exclusive license to AHN's patent rights in certain inventions, pursuant to which the Company paid AHN an initial license fee of $0.4 million. In addition, under the terms of the exclusive license agreement, the Company is required to pay the greater of royalties in the low single digits on net sales of diagnostic tests using the assigned patents or a flat annual minimum royalty amount, pending approvals and commercialization.

In November 2021, the Company entered into an exclusive license agreement with Queen Mary University of London (QMUL), to obtain an exclusive license to QMUL's patent rights in certain inventions, pursuant to which the Company paid QMUL an initial license fee of $0.4 million. The Company is obligated to make a one-time payment of $0.1 million relating to the first commercial sale of the licensed products. In addition, after the first 18 months of commercial sales under the terms of the exclusive license agreement, the Company is required to pay royalties in the high single-digits on net sales of testing products using the assigned patents, pending approvals and commercialization.

Supply Agreement

In December 2021, the Company entered into an amended supply agreement with one supplier for reagents which includes minimum annual purchase commitments of $6.0 million and $6.9 million for the years ending December 31, 2022 and 2023, respectively, with a 15% annual increase thereafter for unconditional minimum purchase commitments through the year ending December 31, 2025.

Collaboration Obligations

In May 2021, the Company entered into a master research collaboration agreement with AHN, pursuant to which the Company is required to pay AHN a collaboration fee of $0.4 million for each year during the initial term of the agreement. Collaboration expenses under the master research collaboration agreement were $0.1 million for each of the three months ended June 30, 2022 and 2021. Collaboration expenses under the master research collaboration agreement were $0.2 million and $0.1 million, for the six months ended June 30, 2022 and 2021, respectively. Collaboration expenses under the AHN collaboration are included in research and development expenses.

Equipment Purchase Obligations

In May 2022, the Company ordered laboratory equipment costing approximately $1.2 million, which is expected to be received in the third quarter of 2022. Upon receipt of the equipment, monthly payments of approximately $25,000 will commence and continue for 48 months.

Contingencies

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications; including for subpoenas and other civil investigative demands, from governmental agencies, Medicare or Medicaid payors and managed care organizations reviewing billing practices or requesting comment on allegations of billing irregularities that are brought to their attention through billing audits or third parties. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future, but have not yet been made or that the Company believes to be immaterial. The Company accrues a liability for such matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated.

Litigation

From time to time, the Company may be subject to various legal proceedings that arise in the ordinary course of business activities. The Company does not believe the outcome of any such matters will have a material effect on its financial position or results of operations.

Note 7. Fair Value Measurements

The following table sets forth the Company's financial instruments that were measured at fair value on a recurring basis within the fair value hierarchy (in thousands):

	June 30, 2022			
	Total	Level 1	Level 2	Level 3
Assets:				
Money market funds, included in cash and cash equivalents	$ 72,078	$ 72,078	$ —	$ —

	December 31, 2021			
	Total	Level 1	Level 2	Level 3
Assets:				
Money market funds, included in cash and cash equivalents	$ 95,761	$ 95,761	$ —	$ —

The fair value of the Company's money market funds is based on quoted market prices.

Note 8. Stockholders' Equity

Common Stock

On November 10, 2020, the Company filed a registration statement on Form S-3 (the Shelf Registration Statement), covering the offering, from time to time, of up to $150.0 million of common stock, preferred stock, debt securities, warrants and units, which Shelf Registration Statement became effective on November 19, 2020.

On March 25, 2021, the Company completed a public offering of 4,255,000 shares of its common stock at a public offering price of $16.25 per share. Net proceeds from the offering were approximately $64.7 million, after deducting underwriting discounts, commissions and other offering expenses of $4.4 million. The shares were registered pursuant to the Company's Shelf Registration Statement discussed above.

Exchange Agreement

On June 22, 2021, the Company entered into an exchange agreement (the Exchange Agreement) with an Investor and its affiliates (the Exchanging Stockholders), pursuant to which the Company exchanged an aggregate of 804,951 shares of the Company's common stock owned by the Exchanging Stockholders for pre-funded warrants (the Exchange Warrants) to purchase an aggregate of 804,951 shares of common stock (subject to adjustment in the event of any stock dividends and splits, reverse stock split, recapitalization, reorganization or similar transaction, as described in the Exchange Warrants), with an exercise price of $0.001 per share. The Exchange Warrants do not expire and are exercisable at any time except that the Exchange Warrants cannot be exercised by the Exchanging Stockholders if, after giving effect thereto, the Exchanging Stockholders would beneficially own more than 4.99% of the Company's common stock, which percentage may change at the Exchanging Stockholder's election to any other percentage upon 61 days' notice to the Company. The Company recorded the retirement of common stock exchanged as a reduction of common shares outstanding and additional paid-in-capital at the fair value of the Exchange Warrants on the issuance date. The Exchange Warrants are classified as equity and the fair value of the Exchange Warrants was recorded as an increase to additional paid-in-capital and is not subject to remeasurement. The Company determined that the fair value of the Exchange Warrants is substantially similar to the fair value of the retired shares on the issuance date due to the negligible exercise price for the Exchange Warrants. As of June 30, 2022, none of the Exchange Warrants have been exercised.

Outstanding Warrants

The following equity classified warrants to purchase common stock were outstanding as of June 30, 2022:

	Shares	Exercise Price	Issuance date	Expiration date
Common stock warrants	237,169	$ 1.84	January 19, 2016	January 19, 2026
Common stock warrants	67,086	$ 1.84	March 31, 2016	March 31, 2026
Common stock warrants	131	$ 1.84	April 1, 2016	April 1, 2026
Common stock warrants	83,778	$ 14.32	September 7, 2017	September 7, 2024
Common stock warrants	20,944	$ 14.32	December 7, 2018	December 7, 2025
Common stock warrants (Exchange Warrants)	804,951	$ 0.001	June 22, 2021	None
	1,214,059			

During the three and six months ended June 30, 2022, no warrants to purchase common stock was exercised.

Note 9. Stock Option Plan

2019 Incentive Award Plan

In September 2019, the Company's Board of Directors adopted, and the Company's stockholders approved, the 2019 Plan. Under the 2019 Plan, which expires in September 2029, the Company may grant stock options, stock appreciation rights, restricted stock, restricted stock units and other awards to individuals who are then employees, officers, non-employee directors or consultants of the Company or its subsidiaries. The options generally expire ten years after the date of grant and are exercisable to the extent vested. Vesting is established by the Board of Directors and is generally four years from the date of grant. As of June 30, 2022, 1,430,690 shares of common stock remained available for future awards.

2019 Employee Stock Purchase Plan

In September 2019, the Board of Directors adopted, and the Company's stockholders approved, the ESPP. The ESPP became effective on the day the ESPP was adopted by the Company's Board of Directors. The ESPP permits participants to purchase common stock through payroll deductions of up to 20% of their eligible compensation. As of June 30, 2022, 453,484 shares of common stock remained available for issuance under the ESPP.

Stock Options

Stock option activity under the Company's 2019 Plan is set forth below:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding, December 31, 2021	2,014,330	$ 12.10	7.87	$ 5,428
Granted	63,000	$ 5.25		
Forfeited	(102,110)	$ 13.79		
Expired	(25,846)	$ 14.39		
Outstanding, June 30, 2022	1,949,374	$ 11.76	7.00	$ 2,611
Vested and expected to vest, June 30, 2022	1,949,374	$ 11.76	7.00	$ 2,611
Options exercisable, June 30, 2022	1,334,116	$ 10.76	6.55	$ 2,365

The intrinsic value is calculated as the difference between the fair value of the Company's common stock and the exercise price of the stock options. As of June 30, 2022, total unrecognized compensation cost related to option awards was $4.2 million, which is expected to be recognized over a remaining weighted-average vesting period of 1.6 years.

Restricted Stock Units

Restricted stock unit activity under the Company's 2019 Plan is set forth below:

	Number of Shares	Weighted-Average Grant Date Fair Value	Aggregate Intrinsic Value (in thousands)
Outstanding, December 31, 2021	415,325	$ 16.54	$ 4,830
Awards granted	540,225	$ 8.66	
Awards released	(90,821)	$ 17.05	
Awards canceled	(79,789)	$ 11.96	
Outstanding, June 30, 2022	784,940	$ 11.53	$ 4,506

As of June 30, 2022, total unrecognized compensation cost related to restricted stock units was $8.2 million, which is expected to be recognized over a remaining weighted-average vesting period of 3.3 years.

Stock-Based Compensation Expense

Stock Options

The fair value of employee stock options was estimated using the following assumptions to determine the fair value of stock options granted:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Expected volatility	54%	83%	54%	83%-84%
Risk-free interest rate	3.4%	1.1%	3.4%	0.8%-1.1%
Dividend yield	—	—	—	—
Expected term (in years)	5.50	5.50-6.08	5.50	5.50-6.08

Employee Stock Purchase Plan

The following assumptions were used to calculate the stock-based compensation for each stock purchase right granted under the ESPP:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Expected volatility	45%	60%	45%	60%
Risk-free interest rate	0.6%	0.1%	0.6%	0.1%
Dividend yield	—	—	—	—
Expected term (in years)	0.50	0.50	0.50	0.50

Stock-based compensation expense for the ESPP was less than $0.1 million for the three and six months ended June 30, 2022 and 2021. As of June 30, 2022, total unrecognized compensation cost related to stock purchase rights granted under the ESPP was less than $0.1 million, which is expected to be recognized over a remaining weighted-average vesting period of 0.2 years.

Total non-cash stock-based compensation expense recorded related to options granted, restricted stock units granted and stock purchase rights granted under the ESPP in the condensed statements of operations is as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Costs of revenue	$ 59	$ 61	$ 103	$ 72
Selling, general and administrative	1,203	1,049	2,321	1,840
Research and development	178	175	392	285
Total	$ 1,440	$ 1,285	$ 2,816	$ 2,197

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

You should read the following discussion of our financial condition and results of operations in conjunction with the unaudited condensed financial statements and the notes thereto included elsewhere in this Quarterly Report on Form 10-Q and with our audited financial statements and notes thereto for the year ended December 31, 2021 included in our Annual Report on Form 10-K for the year ended December 31, 2021.

Forward Looking Statements

The following discussion and other parts of this quarterly report contain forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or 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, the impact of the COVID-19 pandemic, current and future product offerings, reimbursement and coverage, the expected benefits from our partnerships or promotion arrangements with third-parties, evaluations and interpretation of study results, research and development costs, timing and likelihood of success and plans and objectives of management for future operations, are forward-looking statements. These statements are often identified by the use of words such as "may," "will," "expect," "believe," "anticipate," "intend," "could," "should," "estimate," or "continue," and similar expressions or variations. 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 financial condition, operating results, business strategy, and short-term and long-term business operations and objectives. 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." 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. 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 dedicated to transforming the care continuum for patients suffering from debilitating and chronic autoimmune diseases by enabling timely differential diagnosis and optimizing therapeutic intervention. We have developed and are commercializing a portfolio of innovative testing products under our AVISE® brand, several of which are based on our proprietary Cell-Bound Complement Activation Products (CB-CAPs) technology. Our goal is to enable healthcare providers to improve care for patients through the differential diagnosis, prognosis and monitoring of complex autoimmune and autoimmune-related diseases, including systemic lupus erythematosus (SLE), and rheumatoid arthritis (RA). Our business model of integrating testing products and therapeutics positions us to offer targeted solutions to rheumatologists and, ultimately, better serve patients.

We currently market 10 testing products under our AVISE® brand that allow for the differential diagnosis, prognosis and monitoring of complex autoimmune and autoimmune-related diseases. Our lead testing product, AVISE® CTD, enables differential diagnosis for patients presenting with symptoms indicative of a wide variety of connective tissue diseases (CTDs), and other related diseases with overlapping symptoms. We commercially launched AVISE® CTD in 2012 and revenue from this product comprised 82% and 81% of our revenue for the six months ended June 30, 2022 and 2021, respectively. There is an unmet need for rheumatologists to add clarity in their CTD clinical evaluation, and we believe there is a significant opportunity for our tests that enable the differential diagnosis of these diseases, particularly for potentially life-threatening diseases such as SLE.

We are leveraging our portfolio of testing products to establish partnerships with leading pharmaceutical companies, academic research centers and patient advocacy organizations. We also have agreements with GlaxoSmithKline plc. (GSK), Labcorp Drug Development and Parexel, among others, that leverage our testing products and/or the information generated from such tests. We provide GSK, a leader in lupus therapeutics, our test result data to provide market insight into and help increase awareness of the benefits of early and accurate diagnosis of SLE and lupus nephritis, and monitoring disease activity. We partner with academic research centers and patient advocacy organizations, such as Brigham and Women's Hospital, Hospital for Special Surgery, Duke University and Emory University as well as the Lupus Foundation of America, to help improve the quality of life for people affected by

autoimmune diseases through programs of research, education, support and advocacy. We plan to pursue additional strategic partnerships that are synergistic with our evolving portfolio of testing products.

We perform all of our AVISE® tests in our approximately 10,000 square foot clinical laboratory, which is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), by the Centers for Medicare and Medicaid Services (CMS), and accredited by the College of American Pathologists (CAP), and located in Vista, California. Our laboratory is certified for performance of high-complexity testing by CMS in accordance with CLIA and is licensed by all states requiring out-of-state licensure. Our clinical laboratory reports all AVISE® testing product results within five business days. In the second half of 2021, we began the conversion of approximately 8,000 square feet of warehouse space into additional clinical laboratory space and approximately 6,000 square feet of warehouse space into additional research and development facility space. In the second quarter of 2022, we completed the clinical laboratory space conversion, which is currently being utilized for both clinical laboratory and research and development purposes. We expect to complete the conversion of the research and development facility space by the second half of 2022. The expansion of our clinical laboratory and research and development facility is expected to allow us to enhance our testing capacity and improve efficiencies as well as allow us to develop molecular and multiomic capabilities and advance our product pipeline, including support of development of tests for fibromyalgia, RA, thrombosis and lupus nephritis.

We market our AVISE® testing products using our specialized sales force. As of June 30, 2022, we have a sales force of 57 representatives covering a total of 63 territories. Unlike many diagnostic sales forces that are trained only to understand the comparative benefits of their tests, the specialized backgrounds of our sales force coupled with our comprehensive training enable our sales representatives to interpret results from our de-identified patient test reports and provide unique insights in a highly tailored discussion with rheumatologists. Our integrated testing and therapeutics strategy results in a unique opportunity to promote and sell targeted therapies in patient focused sales calls with rheumatologists, including those with whom we have a longstanding relationship and history using our portfolio of testing products.

Reimbursement for our testing services comes from several sources, including commercial third-party payors, such as insurance companies and health maintenance organizations, government payors, such as Medicare, and patients. Reimbursement rates vary by product and payor. We continue to focus on expanding coverage among existing contracted rheumatologists and to achieve coverage with commercial payors, laboratory benefit managers and evidence review organizations.

Since inception we have devoted substantially all of our efforts to developing and marketing products for the diagnosis, prognosis and monitoring of autoimmune diseases. Although our revenue has historically increased sequentially year over year, with the exception of the six months ended June 30, 2022 compared to 2021, we have never been profitable and, as of June 30, 2022, we had an accumulated deficit of $231.7 million. We incurred net losses of $23.6 million and $12.6 million for the six months ended June 30, 2022 and 2021, respectively. We expect to continue to incur operating losses in the near term as our operating expenses will increase to support the growth of our business, as well as additional costs associated with being a public company. We have funded our operations primarily through equity and debt financings and revenue from sales of our products. We completed our initial public offering (IPO), in September 2019, raising net proceeds from the offering of approximately $50.4 million, net of underwriting discounts, commissions and other offering expenses, for aggregate expenses of approximately $7.5 million. In March 2021, we completed a public offering of 4,255,000 shares of our common stock at a public offering price of $16.25 per share. Net proceeds from the offering were approximately $64.7 million, net of underwriting discounts and commissions and offering costs of $4.4 million. As of June 30, 2022, we had $76.4 million of cash and cash equivalents.

Recent Developments

In March 2022, we entered into an agreement with Centene Corporation, pursuant to which, effective June 1, 2022, AVISE® test offerings became an in-network, covered benefit with Centene Corporation, including its subsidiary WellCare Health Plans, providing enhanced care to over 22.7 million members.

In June 2022, we entered into an agreement with MediNcrease Health Plans, LLC's national provider network, pursuant to which, effective July 1, 2022, AVISE® test offerings became an in-network, covered benefit to its approximately 7.5 million commercial lives. As a result, AVISE® tests will surpass 99 million lives as an in-network benefit for patients.

Last quarter we disclosed that the Centers for Medicare & Medicaid Services (CMS) agreed, effective April 1, 2022, to recognize a new Proprietary Laboratory Analyses (PLA) code for our protein-based test, AVISE® Lupus, and that Noridian, our Medicare Administrative Contractor, priced this PLA code at $1,085 per test. The process for obtaining and maintaining consistent reimbursement for new tests (particularly for protein-based tests) can be uncertain, lengthy and time consuming. A pricing determination is not synonymous with a coverage determination. Having a price associated with the PLA code for any particular test does not secure coverage or reimbursement for that PLA code from Medicare or any other third-party payor.

During the quarter, we submitted to Noridian 3,749 claims for Medicare Part B reimbursement under our PLA code for AVISE® Lupus. As of August 1, 2022, 76 of these claims have been paid, 335 claims have been denied, 2,778 claims are subject to requests from Noridian for additional information (such as medical records), and the balance of those claims remain pending with no responses received as of this date.

While we are still gathering information from Noridian, we believe these denials and requests for additional information may be due in part to confusion regarding appropriate American Medical Association (AMA) Common Procedural Terminology (CPT) coding for the AVISE® CTD test, which includes the AVISE® Lupus test plus conventional antibody tests. We interpret AMA coding guidelines to support that we submit claims for AVISE® CTD using the individual codes that describe the other conventional antibody tests included in AVISE® CTD, in addition to the PLA code for AVISE® Lupus. Although we routinely include explanatory notes in our reimbursement requests, this practice can create confusion. We are actively working with Noridian on the issue.

In order to confirm coverage and payment of claims and in addition to ongoing discussions with Noridian regarding our coding approach, we submitted a formal request to Noridian for coverage of our AVISE® Lupus test under the new PLA Code. We have not yet received a response. In the meantime, we will continue to submit Medicare claims for AVISE® Lupus, appeal denials and respond to requests for additional information.

However, until this reimbursement issue is resolved, we anticipate a significant interruption to our revenue from AVISE® Lupus with respect to Medicare claims. The aggregate amount of reimbursement we are seeking for our unpaid AVISE® Lupus Medicare claims in the second quarter of 2022 is approximately $4.0 million, and, as previously noted, all of the unpaid AVISE® Lupus Medicare claims are either under review, being appealed or subject to requests for additional information, which we are in the process of addressing. Variable consideration for these claims is deemed to be fully constrained due to the uncertainty of the outcome of these claims. For fully constrained claims, we generally recognize revenue in the period the uncertainty is definitively resolved and we can provide no assurance that such resolution will be achieved on a timely basis, or at all.

Recent Publications

In July 2022, we announced new, real-world evidence illustrating that AVISE® testing enables decisive clinical action in the differential diagnosis of lupus. The "Complement Activation Products vs Standard ANA Testing: Treatment Outcomes, Diagnosis, and Economic Impact in Systemic Lupus Erythematosus," (CAPSTONE) study was the largest comparative utility study in lupus diagnostics and was published in the Journal of Managed Care & Specialty Pharmacy. The study leveraged multiple databases encompassing electronic health records and linked insurance claims data on nearly 50,000 patients tested with AVISE® or standard of care labs from hundreds of rheumatologists across the United States, comparing diagnosis, treatment, and cost of care outcomes for new patients tested with AVISE® Lupus and those tested with a traditional ANA (tANA) approach, including specific autoantibodies. The CAPSTONE study supports that the AVISE® Lupus test is more clinically effective, both for patients who test positive and those who test negative, as compared to the current standard of care. Important key findings of the CAPSTONE study included, among other things, a: (i) 2x decrease in diagnostic testing costs in the first six-month follow-up period for AVISE® Lupus [-] vs tANA[-]; (ii) 3.5x less frequent repeat testing overall when using AVISE® Lupus vs. tANA; (iii) 6x increased odds of establishing a new SLE diagnosis with AVISE® Lupus [+] vs tANA[+]; and (iv) 3x increased odds of initiating one or more SLE treatments with AVISE® Lupus [+] vs tANA[+]. The CAPSTONE study exemplifies the advantages of the AVISE® Lupus test for patients, providers, and payors. Delayed diagnosis leads to increased disease burden and diminished quality of life for the patient relative to the current standard of care. By receiving conclusive results, providers are able to initiate treatment early, reducing the need for more aggressive approaches down the road that can lead to irreversible consequences for the patient. Additionally, a conclusive negative test allows providers to lower the number of repeat tests and follow-up visits which is a critical step for achieving diagnostic clarity for the patient.

Impact of COVID-19

The full extent of which the COVID-19 pandemic will directly or indirectly continue to impact our business, results of operations and financial condition and will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain it or treat COVID-19, including the success of ongoing vaccination efforts, the emergence and prevalence of variant strains of COVID-19, the institution or reinstitution of shutdowns, "stay-at-home-orders" and other public health measures, as well as the related economic impact of these matters on local, regional and international markets.

We have implemented business continuity plans designed to address the COVID-19 pandemic and minimize disruptions to ongoing operations. While for the three months ended June 30, 2022 as compared to the same period in 2021, we experienced an AVISE® CTD test volume increase of approximately 5%, and for the six months ended June 30, 2022 as compared to the same period in 2021, we experienced an AVISE® CTD test volume increase of approximately 6%, the patient flow and our related test volumes have in the past been, and may continue to be, impacted by the COVID-19 pandemic. We have experienced, and may again, experience significant impacts on our test volume, delays in patient enrollment for ongoing and planned clinical trials, and delays in procurement of our testing supplies as a result of the COVID-19 pandemic.

In addition, COVID-19 travel limitations and government-mandated work-from-home or shelter-in-place orders have, and may again, cause supply chain delays or reduce the number of in-person meetings between our sales force and healthcare providers and limit the ability of our sales force to engage in various types of healthcare provider education activities, which may lead to a decline in orders of our testing products. To mitigate the impact of COVID-19 on our business, we put in place certain safety measures for our employees, patients, healthcare providers, and suppliers to limit exposure and a portion of our workforce was required to work remotely in an effort to reduce that spread of COVID-19.

We are facing and may continue to face increased competition for laboratory and scientific employees due to the increased demand in the industry for such personnel. As the circumstances surrounding the COVID-19 pandemic remain uncertain, we may inaccurately estimate the duration or severity of the COVID-19 pandemic, which could, among other things, cause us to misalign our staffing, spending, activities and precautionary measures with market current or future market conditions.

Factors Affecting Our Performance

In addition to the impact of COVID-19, we believe there are several important factors that have impacted, and that we expect will impact, our operating performance and results of operations, including:

- ***Continued Adoption of Our Testing Products.*** Since the launch of AVISE® CTD in 2012 and through June 30, 2022, we have delivered over 680,000 of these tests. Through the second quarter of 2022, 65,822 AVISE® CTD tests were delivered, representing approximately 6% growth over the same period in 2021. The number of ordering healthcare providers in the second quarter of 2022 was a record 2,273, representing an approximate 18% increase over the same period in 2021, and we had a record 797 adopting healthcare providers (defined as those who previously prescribed at least 11 diagnostic tests in the corresponding period) compared to 703 in the same period in 2021. A high percentage of adopting healthcare providers continue to order tests in subsequent quarters, as approximately 99% of adopting healthcare providers from the first quarter of 2022 ordered at least one diagnostic test in the second quarter of 2022. Revenue growth for our testing products will depend on our ability to continue to expand our base of ordering healthcare providers and increase our penetration with existing healthcare providers.
- ***Reimbursement for Our Testing Products***. Our revenue depends on achieving broad coverage and reimbursement for our tests from third-party payors, including both commercial and government payors such as Medicare. Payment from third-party payors differs depending on whether we have entered into a contract with the payors as a "participating provider" or do not have a contract and are considered a "non-participating provider." Payors will often reimburse non-participating providers, if at all, at a lower amount than participating providers. We have received a substantial portion of our revenue from a limited number of third-party commercial payors, most of which have not contracted with us to be a participating provider. In addition to the challenges described under the heading "Overview - Recent Developments" above, historically, we have experienced situations where commercial payors proactively reduced the amounts they were willing to reimburse for our tests, and in other situations, commercial payors have determined that the amounts they previously paid were too high and have sought to recover those perceived excess payments by deducting such amounts from payments otherwise being made. When we contract to serve as a

participating provider, reimbursements are made pursuant to a negotiated fee schedule and are limited to only covered indications. If we are not able to obtain or maintain coverage and adequate reimbursement from third-party payors, we may not be able to effectively increase our testing volume and revenue as expected. Additionally, retrospective reimbursement adjustments can negatively impact our revenue and cause our financial results to fluctuate.

- ***Synergistic Partnerships***. In August 2021, we mutually agreed to terminate the Janssen Agreement regarding our promotion efforts with SIMPONI®, effective August 31, 2021. Our SIMPONI® promotion efforts contributed no co-promotion revenue and approximately $0.6 million in revenue during the six months ended June 30, 2022 and 2021, respectively. We will continue to rely on our existing testing products to drive revenue growth.
- ***Development of Additional Testing Products.*** We rely on sales of our AVISE® CTD test to generate the significant majority of our revenue. We expect to continue to invest in research and development in order to develop additional testing products and expect these costs to increase. Our success in developing new testing products will be important in our efforts to grow our business by expanding the potential market for our testing products and diversifying our sources of revenue.
- ***Maintain Meaningful Margin***. We believe we are well positioned to maintain meaningful margin through a continued focus on increasing operating leverage through the implementation of certain internal initiatives, such as conducting additional validation and reimbursement oriented clinical studies to facilitate payor coverage of our testing products, capitalizing on our growing reagent purchasing to negotiate improved volume-based pricing and automation in our clinical laboratory to reduce material and labor costs.
- ***Timing of Our Research and Development Expenses***. Our spending on experiments and clinical studies may vary substantially from quarter to quarter. We also expend funds to secure clinical samples that can be used in discovery, product development, clinical validation, utility and outcome studies. The timing of these research and development activities is difficult to predict. If a substantial number of clinical samples are obtained in a given quarter or if a high-cost experiment is conducted in one quarter versus the next, the timing of these expenses will affect our financial results. We conduct clinical studies to validate our new testing products, as well as ongoing clinical and outcome studies to further expand the published evidence to support our commercialized AVISE® testing products. Spending on research and development for both experiments and studies may vary significantly by quarter depending on the timing of these various expenses.
- ***How We Recognize Revenue***. We record revenue on an accrual basis based on our estimate of the amount that will be ultimately realized for each test upon delivery based on a historical analysis of amounts collected by test and by a payor and other factors. Variable consideration for the open AVISE® Lupus Medicare claims is deemed to be fully constrained due to the uncertainty of the outcome of these claims. For fully constrained claims, we generally recognize revenue in the period the uncertainty is definitively resolved and we can provide no assurance that such resolution will be achieved on a timely basis, or at all. Changes to such estimates may increase or decrease revenue recognized in future periods.

While each of these areas presents significant opportunities for us, they also pose significant risks and challenges that we must address. We discuss many of these risks, uncertainties and other factors in the section entitled "*Risk Factors*."

Janssen Promotion Agreement

In December 2018, we entered into the Janssen Agreement, under which we were responsible for the costs associated with our sales force in promoting SIMPONI® in the United States. In August 2021, we and Janssen mutually agreed to terminate the Janssen Agreement effective August 31, 2021. Pursuant to the Janssen Agreement, as amended, Janssen was responsible for all other costs associated with our promotion of SIMPONI® under the Janssen Agreement. In exchange for our sales and co-promotional services, we were entitled to a quarterly tiered promotion fee based on the incremental increase in total prescribed units of SIMPONI® for that quarter over a predetermined baseline. Upon termination of the Janssen Agreement on August 31, 2021, we became entitled to receive an aggregate of $0.6 million in consideration, which was earned in the year ended December 31, 2021. Pursuant to the terms of the termination, we were restricted until May 31, 2022 from promoting any other biologic or Janus kinase inhibitor used for the treatment of indications covered by the Janssen Agreement without first obtaining Janssen's written consent. The restriction no longer applies.

We recognized no revenue and approximately $0.6 million in revenue during the six months ended June 30, 2022 and 2021, respectively, for our promotional efforts under the Janssen Agreement.

Seasonality

Based on our experience to date, we expect some seasonal variations in our financial results due to a variety of factors, such as the year-end holiday period and other major holidays, vacation patterns of both patients and healthcare providers, including medical conferences, climate and weather conditions in our markets (for example excess sun exposure can cause flares in SLE), seasonal conditions that may affect medical practices and provider activity, including for example influenza outbreaks that may reduce the percentage of patients that can be seen, and other factors relating to the timing of patient benefit changes, as well as patient deductibles and co-insurance limits.

Financial Overview

Revenue

To date, we have derived nearly all of our revenue from the sale of our testing products, most of which is attributable to our AVISE® CTD test. We primarily market our testing products to rheumatologists in the United States. The rheumatologists who order our testing products and to whom results are reported are generally not responsible for payment for these products. The parties that pay for these services, or payors, consist of healthcare insurers, government payors (primarily Medicare and Medicaid), client payors (e.g. hospitals, other laboratories, etc.), and patient self-pay. Our service is completed upon the delivery of test results to the prescribing rheumatologists which triggers billing for the service.

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

As more fully described under the heading "Overview - Recent Developments" above, we experienced a disruption in our revenue recognition and cash collection during the quarter ended June 30, 2022 in relation to Medicare Part B reimbursements for our AVISE® Lupus test. Variable consideration for the open AVISE® Lupus Medicare claims is deemed to be fully constrained due to the uncertainty of the outcome of these claims. For fully constrained claims, we generally recognize revenue in the period the uncertainty is definitively resolved and we can provide no assurance that such resolution will be achieved on a timely basis, or at all.

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

As discussed above, our volume of AVISE® CTD tests delivered substantially recovered to pre-COVID-19 levels in the fourth quarter of 2020. However, the continued spread of COVID-19, including any of its viral variants, may adversely affect testing volumes in future periods, and the extent of any such adverse effects is highly uncertain.

Operating Expenses

Costs of Revenue

Costs of revenue represents the expenses associated with obtaining and testing patient specimens. The components of our costs of revenue include materials costs, direct labor, equipment and infrastructure expenses associated with testing specimens, shipping charges to transport specimens, blood specimen collections fees, royalties, depreciation and allocated overhead, including rent and utilities.

Each payor, whether a commercial third-party, government, or individual, reimburses us at different amounts. These differences can be significant. As a result, our costs of revenue as a percentage of revenue may vary significantly from period to period due to the composition of payors for each period's billings.

Assuming future testing volumes are not negatively impacted by the continued spread of COVID-19, we expect that our costs of revenue will increase in absolute dollars as the number of tests we perform increases. However, we expect that the cost per test will decrease over time due to volume discounts on materials and other volume efficiencies we may gain as the number of tests we perform increases. The decrease in cost per test may be partially offset due to increased depreciation and allocated overhead associated with our clinical laboratory expansion as well as increased labor, material and shipping costs (including as a result of inflation) associated with the commercialization of our portfolio products. As discussed above, the continued spread of COVID-19 may adversely affect testing volumes which may result in an increase in cost per test due to our inability to realize volume efficiencies.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist of personnel costs, including stock-based compensation expense, direct marketing expenses, accounting and legal expenses, consulting costs, and allocated overhead including rent, information technology, depreciation and utilities.

We expect that our selling, general and administrative expenses will increase in absolute dollars in 2022 as compared to 2021, due to expected additions to headcount and associated increases for personnel costs, including stock-based compensation.

Research and Development Expenses

Research and development expenses include costs incurred to develop our technology, test products and product candidates, collect clinical specimens and conduct clinical studies to develop and support our testing products and product candidates. These costs consist of personnel costs, including stock-based compensation expense, materials, laboratory supplies, consulting costs, costs associated with setting up and conducting clinical studies and allocated overhead including rent and utilities. We expense all research and development costs in the periods in which they are incurred.

We expect that our research and development expenses will increase in absolute dollars in 2022 as compared to 2021, as we continue to invest in research and development activities related to our existing testing products and product candidates, including the expansion of our clinical research and development facility, expected additions to headcount and associated increases for personnel costs, including stock-based compensation.

Interest Expense

Interest expense consists of cash and non-cash interest expense associated with our financing arrangements, including the borrowings under our amended loan and security agreement with Innovatus Life Sciences Lending Fund I, LP (Innovatus).

We expect interest expense to remain substantially consistent in the near term.

Other Income (Expense), Net

Other income (expense), net, consists primarily of interest income earned on our cash and cash equivalents.

Results of Operations

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

	Three Months Ended June 30,		
	2022	2021	Change
	(in thousands)		
Revenue	$ 8,962	$ 12,772	$ (3,810)
Operating expenses:			
Costs of revenue	6,078	5,451	627
Selling, general and administrative expenses	12,903	11,171	1,732
Research and development expenses	2,689	1,892	797
Total operating expenses	21,670	18,514	3,156
Loss from operations	(12,708)	(5,742)	(6,966)
Interest expense	(606)	(663)	57
Other income (expense), net	5	(5)	10
Net loss	$ (13,309)	$ (6,410)	$ (6,899)

Revenue

Revenue decreased $3.8 million, or 29.8%, for the three months ended June 30, 2022 compared to the three months ended June 30, 2021, primarily due a decrease in AVISE® CTD revenue of $3.2 million. The decrease in AVISE® CTD revenue was primarily due to (i) a decrease in average reimbursement per AVISE® CTD test, (ii) a net negative adjustment associated with changes in estimated variable consideration related to performance obligations satisfied in previous periods and (iii) uncertainty of the outcome of certain claims, which have been deemed fully constrained. The number of AVISE® CTD tests delivered, which accounted for 81% of revenue in each of the three months ended June 30, 2022 and 2021, increased to 34,919 tests delivered in the three months ended June 30, 2022 compared to 33,328 tests delivered in the same 2021 period. The adoption of the AVISE® CTD test by healthcare providers for the three months ended June 30, 2022 increased to 2,273 ordering healthcare providers as compared to 1,934 ordering healthcare providers in the same 2021 period. Revenue resulting from the Janssen Agreement contributed no revenue for the three months ended June 30, 2022 compared to $0.3 million for the three months ended June 30, 2021.

Costs of Revenue

Costs of revenue increased $0.6 million, or 11.5%, for the three months ended June 30, 2022 compared to the three months ended June 30, 2021. This increase was primarily due to increased direct costs such as labor, materials and supplies, shipping and handling and allocated overhead associated with the increase in test volume in 2022 compared to 2021. Gross margin as a percentage of revenue decreased to 32.2% for the three months ended June 30, 2022, compared to 57.3% for the three months ended June 30, 2021. This was primarily attributable to a decrease in average reimbursement per AVISE® CTD test and a decrease in revenue resulting from the Janssen Agreement.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased $1.7 million, or 15.5%, for the three months ended June 30, 2022 compared to the three months ended June 30, 2021. This increase was primarily due to an increase of $0.8 million of employee related expenses, including stock-based compensation and recruitment expenses, increases related to audit and professional services of $0.2 million, legal fees of $0.2 million, marketing expenses of $0.2 million, allocated overhead of $0.2 million and insurance expenses of $0.1 million.

Research and Development Expenses

Research and development expenses increased $0.8 million for the three months ended June 30, 2022 compared to the three months ended June 30, 2021. This increase was primarily due to increases in expenses related to current, former and potential future employees, including severance, stock-based compensation and recruitment expenses of $0.7 million, collaboration expenses of $0.4 million, laboratory supplies expense of $0.2 million,

consulting costs of $0.1 million and allocated overhead of $0.1 million, partially offset by decreases in license fees of $0.4 million and clinical trial expenses of $0.3 million.

Interest Expense

Interest expense remained substantially consistent for the three months ended June 30, 2022 compared to the three months ended June 30, 2021.

Other Income (Expense), Net

Other income (expense), net, remained substantially consistent for the three months ended June 30, 2022 compared to the three months ended June 30, 2021.

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

	Six Months Ended June 30,		
	2022	2021	Change
	(in thousands)		
Revenue	$ 19,356	$ 23,359	$ (4,003)
Operating expenses:			
Costs of revenue	11,895	10,162	1,733
Selling, general and administrative expenses	25,055	21,211	3,844
Research and development expenses	4,793	3,295	1,498
Total operating expenses	41,743	34,668	7,075
Loss from operations	(22,387)	(11,309)	(11,078)
Interest expense	(1,204)	(1,308)	104
Other income (expense), net	10	(2)	12
Net loss	$ (23,581)	$ (12,619)	$ (10,962)

Revenue

Revenue decreased $4.0 million, or 17.1%, for the six months ended June 30, 2022 compared to the six months ended June 30, 2021, primarily due a decrease in AVISE® CTD revenue of $3.0 million. The decrease in AVISE® CTD revenue was primarily due to (i) a decrease in average reimbursement per AVISE® CTD test, (ii) a net negative adjustment associated with changes in estimated variable consideration related to performance obligations satisfied in previous periods and (iii) uncertainty of the outcome of certain claims, which have been deemed fully constrained. The number of AVISE® CTD tests delivered, which accounted for 82% and 81% of revenue in the six months ended June 30, 2022 and 2021, respectively, increased to 65,822 tests delivered in the six months ended June 30, 2022 compared to 62,357 tests delivered in the same 2021 period. The number of ordering healthcare providers increased to 2,273 for the three months ended June 30, 2022 compared to 1,934 in the same 2021 period. Revenue resulting from the Janssen Agreement contributed no revenue for the six months ended June 30, 2022 compared to $0.6 million during the six months ended June 30, 2021.

Costs of Revenue

Costs of revenue increased $1.7 million, or 17.1%, for the six months ended June 30, 2022 compared to the six months ended June 30, 2021. This increase was primarily due to increased direct costs such as materials and supplies, labor, shipping and handling and allocated overhead associated with the increase in test volume and increase in cost per test in 2022 compared to 2021. Gross margin as a percentage of revenue decreased to 38.5% for the six months ended June 30, 2022, compared to 56.5% for the six months ended June 30, 2021. This was primarily attributable to a decrease in average reimbursement per AVISE® CTD test, an increase in cost per test, and a decrease in revenue resulting from the Janssen Agreement.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased $3.8 million, or 18.1%, for the six months ended June 30, 2022 compared to the six months ended June 30, 2021. This increase was primarily due to an increase of $2.4 million of employee related expenses, including stock-based compensation and recruitment expenses, increases related to allocated overhead of $0.4 million, legal fees of $0.4 million, audit and professional services of $0.2 million, marketing expenses of $0.2 million and insurance expenses of $0.1 million.

Research and Development Expenses

Research and development expenses increased $1.5 million, or 45.5%, for the six months ended June 30, 2022 compared to the six months ended June 30, 2021. This increase was primarily due to increases in expenses related to current, former and potential employees, including severance, stock-based compensation and recruitment expenses of $1.2 million, collaboration expenses of $0.5 million, allocated overhead of $0.3 million, laboratory supplies expense of $0.3 million and consulting fees of $0.1 million, partially offset by decreases in clinical trial expenses of $0.4 million and license fees of $0.4 million.

Interest Expense

Interest expense remained substantially consistent for the six months ended June 30, 2022 compared to the six months ended June 30, 2021.

Other Income (Expense), Net

Other income (expense), net, remained substantially consistent for the six months ended June 30, 2022 compared to the six months ended June 30, 2021.

Liquidity and Capital Resources

We have incurred net losses since our inception. For the six months ended June 30, 2022 and 2021, we incurred a net loss of $23.6 million and $12.6 million, respectively, and we expect to incur additional losses and increased operating expenses in future periods. As of June 30, 2022, we had an accumulated deficit of $231.7 million. To date, we have generated only limited revenue, and we may never achieve revenue sufficient to offset our expenses.

Our primary sources of capital have been sales of our common stock and redeemable convertible preferred stock, the sale of our common stock in our IPO, and, to a lesser extent, borrowings under various debt financings. On November 10, 2020, we filed a registration statement on Form S-3 (Shelf Registration Statement), which was declared effective by the SEC on November 19, 2020, covering the offering, from time to time, of up to $150.0 million of common stock, preferred stock, debt securities, warrants and units. In March 2021, we completed a public offering of 4,255,000 shares of our common stock at a public offering price of $16.25 per share, which shares were sold under the Shelf Registration Statement. Net proceeds from the offering were approximately $64.7 million, net of underwriting discounts and commissions and other offering expenses of $4.4 million. As of June 30, 2022, we had $76.4 million of cash and cash equivalents. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. Currently, our funds are held in cash and money market funds.

In September 2017, we entered into the loan and security agreement with Innovatus under which we immediately drew down $20.0 million. In December 2018, we borrowed an additional $5.0 million under the loan agreement. In each of November 2019 and November 2021, we amended the loan and security agreement with Innovatus, which we collectively refer to as the Amended Loan Agreement. Pursuant to the Amended Loan Agreement, the loan term is for nine years with a final maturity date of November 2026. The Amended Loan Agreement accrues interest at an annual rate of 8.0%, of which 2.0% will be payable in-kind. Paid in-kind interest is added to the principal balance each period. After December 1, 2024, the entire 8.0% will be paid in cash at the end of each period. On or after November 1, 2022, we may, at our option, prepay the term loan borrowings by paying the lender a prepayment premium. The prepayment premium was 3% as of November 2021 and decreases by 1% on each of November 1, 2022, November 1, 2023 and November 1, 2024.

Our obligations under the Amended Loan Agreement are secured by a security interest in substantially all of our assets, including our intellectual property. The Amended Loan Agreement contains customary conditions to borrowing, events of default, and covenants, including covenants requiring us to maintain certain levels of minimum

liquidity of $2.0 million, performance covenants to achieve certain minimum amounts of revenue, and covenants limiting our ability to dispose of assets, undergo a change in control, merge with or acquire other entities, incur debt, incur liens, pay dividends or other distributions to holders of our capital stock, repurchase stock and make investments, in each case subject to certain exceptions. The consequences of failing to achieve the performance covenant will be cured if, within sixty days of failing to achieve the performance covenant, we issue additional equity securities or subordinated debt with net proceeds sufficient to fund any cash flow deficiency generated from operations, as defined in the Amended Loan Agreement. As of June 30, 2022, we were in compliance with all covenants of the Amended Loan Agreement. In addition, upon the occurrence of an event of default, Innovatus, among other things, can declare all indebtedness due and payable immediately, which would adversely impact our liquidity and reduce the availability of our cash flows to fund working capital needs, capital expenditures and other general corporate purposes.

Funding Requirements

Our primary uses of cash are to fund our operations as we continue to grow our business. We expect to continue to incur operating losses in the near term as our operating expenses will be increased to support the growth of our business. We expect that our costs of revenue, selling, general and administrative expenses, and research and development expenses will continue to increase as we increase our test volume, expand our marketing efforts and increase our internal sales force to drive increased adoption of and reimbursement for our AVISE® testing products, prepare to commercialize new testing products, continue our research and development efforts and further develop our product pipeline. We believe we have sufficient laboratory capacity to support increased test volume. We expect to make significant investments for laboratory equipment and capital expenditures in the near term related to our laboratory facilities and expansion of research capabilities, including an investment to convert approximately 8,000 square feet of warehouse space into additional clinical laboratory space and approximately 6,000 square feet of warehouse space into additional research and development facility space. We began such conversion in the second half of 2021 and completed the conversion for the clinical laboratory space in the second quarter of 2022 and expect to complete the conversion for the additional research and development facility in the second half of 2022. The converted clinical laboratory space is currently being utilized for both clinical laboratory and research and development purposes. The expansion of our clinical laboratory and research and development facility are expected to allow us to enhance our testing capacity and improve efficiencies as well as allow us to develop molecular and multiomic capabilities and advance our product pipeline, including support of the development of tests for fibromyalgia, RA, thrombosis and lupus nephritis. Cash used to fund operating expenses is impacted by the timing of when we pay expenses, as reflected in the change in our outstanding accounts payable and accrued expenses.

We expect that our near- and longer-term liquidity requirements will continue to consist of working capital and general corporate expenses associated with the growth of our business, including payments we may be required to make upon the achievement of previously negotiated milestones associated with intellectual property we have licensed, payments related to non-cancelable purchase obligations with one supplier for reagents, payments related to our principal and interest under our long term borrowing arrangements, payments for operating leases related to our office and laboratory space in Vista, California and our office space in Carlsbad, California, and payments for finance leases related to our laboratory equipment. Based on our current business plan, we believe that our existing cash and cash equivalents and our anticipated future revenue, will be sufficient to meet our anticipated cash requirements for at least the next 12 months from the date of this filing.

Our estimate of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including:

- the impact of the COVID-19 pandemic on our business;
- our ability to maintain and grow sales of our AVISE® testing products, as well as the costs associated with conducting clinical studies to demonstrate the utility of our products and support reimbursement efforts;
- our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third-party payors and adequate market share and revenue for our testing products;
- fluctuations in working capital;
- the costs of developing our product pipeline, including the costs associated with conducting our ongoing and future validation, utility and outcome studies as well as the success of our development efforts;
- the additional costs we may incur as a result of operating as a public company;

- the extent to which we establish additional partnerships or in-license, acquire or invest in complementary businesses or products as well as the success of our existing partnerships and/or in-licenses; and
- the costs associated with our promotion of other therapeutics, if any, including the expansion of our sales capabilities, and the extent and timing of generating revenue from each such promotion, if any.

Until such time, if ever, as we can generate revenue to support our costs structure, we expect to finance our operations through equity offerings, debt financings or other capital sources, including potentially collaborations, licenses and other similar arrangements. Debt 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. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders may be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. If additional funding is required or desired, there can be no assurance that additional funds will be available to us on acceptable terms on a timely basis, if at all, or that we will generate sufficient cash from operations to adequately fund our operating needs or achieve or sustain profitability. If we are unable to raise additional capital or generate sufficient cash from operations to adequately fund our operations, we will need to delay, reduce or eliminate some or all of our research and development programs, product portfolio expansion plans or commercialization efforts. Doing so will likely have an unfavorable effect on our ability to execute on our business plan and could have a negative impact on our commercial and strategic relationships. If we cannot expand our operations or otherwise capitalize on our business opportunities because we lack sufficient capital, our business, financial condition, and results of operations could be adversely affected.

Cash Flows

The following table summarizes our cash flows for the periods indicated:

	Six Months Ended June 30,	
	2022	2021
(in thousands)		
Net cash (used in) provided by:		
Operating activities	$ (19,728)	$ (8,762)
Investing activities	(3,033)	(881)
Financing activities	(294)	64,771
Net change in cash, cash equivalents and restricted cash	$ (23,055)	$ 55,128

Cash Flows from Operating Activities

Net cash used in operating activities for the six months ended June 30, 2022 was $19.7 million and primarily resulted from (i) our net loss of $23.6 million adjusted for non-cash charges of $4.3 million related to stock-based compensation, depreciation, amortization, non-cash lease expense and non-cash interest and (ii) changes in our net operating assets of $0.4 million primarily related to net decreases in accrued and other current liabilities and operating lease liabilities, partially offset by net increases in accounts payable and net decreases in prepaid expenses and other current assets.

Net cash used in operating activities for the six months ended June 30, 2021 was $8.8 million and primarily resulted from (i) our net loss of $12.6 million adjusted for non-cash charges of $3.0 million related to stock-based compensation, depreciation, amortization and non-cash interest and (ii) changes in our net operating assets of $0.8 million primarily related to net decreases in prepaid expenses and other current assets.

Cash Flows from Investing Activities

Net cash used in investing activities for the six months ended June 30, 2022 and 2021 was $3.0 million and $0.9 million, respectively, and was due to net purchases of property and equipment.

Cash Flows from Financing Activities

Net cash used in financing activities for the six months ended June 30, 2022 was $0.3 million and primarily resulted from payment on finance lease obligations and payment of taxes withheld on vested restricted stock units, partially offset by proceeds from ESPP purchases.

Net cash provided by financing activities for the six months ended June 30, 2021 was $64.8 million primarily resulted from the net proceeds received from our public offering in March 2021 of $64.7 million and proceeds from ESPP purchases, partially offset by principal payments on finance lease obligations.

Critical Accounting Policies and Significant Management Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our condensed financial statements, which have been prepared in accordance with United States generally accepted accounting principles (GAAP). The year-end condensed balance sheet data was derived from audited financial statements, but does not include all disclosures required by GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are 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. Actual results may differ from these estimates under different assumptions or conditions, and any such differences may be material.

For a description of our critical accounting policies, please see the section entitled "*Management's Discussion and Analysis of Financial Condition and Results of Operations - Critical Accounting Policies and Significant Management Estimates*" contained in our Annual Report on Form 10-K for the year ended December 31, 2021. Except as disclosed in Note 2 to the unaudited condensed financial statements included in this Quarterly Report on Form 10-Q, there have been no significant changes in our critical accounting policies and estimates during the three months ended June 30, 2022 as compared to the critical accounting policies and estimates disclosed in the Management's Discussion and Analysis of Financial Condition and Operations included in our Annual Report on Form 10-K for the year ended December 31, 2021 filed with the SEC on March 22, 2022.

Recent Accounting Pronouncements

Please see Note 2 to the unaudited condensed financial statements included in this Quarterly Report on Form 10-Q for a summary of changes in significant accounting policies.

JOBS Act Accounting Election

The Jumpstart Our Business Startups Act of 2012 (the JOBS Act), contains provisions that, among other things, reduce certain reporting requirements for an "emerging growth company." The JOBS Act permits an "emerging growth company" such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We have elected to use this extended transition period under the JOBS Act until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our audited financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

We will remain an emerging growth company until the last day of our fiscal year following the fifth anniversary of the date of the first sale of our common equity securities pursuant to an effective registration statement under the Securities Act of 1933, as amended (the Securities Act), which will occur in 2024. However, if certain events occur prior to the end of this five-year period, including if we become a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, our annual gross revenues exceed $1.07 billion or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to this anniversary.

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 reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that the information required to be disclosed by us in such reports is accumulated and communicated to our management, including our principal executive officer and principal financial officer or persons performing similar functions, 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 also is 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, control 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 our principal financial officer, evaluated, as of the end of the period covered by this quarterly report, 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 that 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. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgement in evaluating the cost-benefit relationship of possible controls and procedures.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting during the three months ended June 30, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Part II. Other Information

Item 1. Legal Proceedings

We are currently not a party 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 I, Item 1A, "Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2021, other than those set forth below:

Risks Related to Our Business and Strategy

If third-party payors do not provide coverage and adequate reimbursement for our testing products, or they breach, rescind or modify their contracts or reimbursement policies or delay payments for our tests, or if we or our partners are unable to successfully negotiate payor contracts, our revenues, gross margins and commercial success could be materially adversely affected.

Successful commercialization of our tests depends, in large part, on the availability of coverage and adequate reimbursement from third-party payors, including government payors, such as Medicare and Medicaid, and private insurers. For the tests that we develop and commercialize, each third-party payor decides whether to cover the test, the amount it will reimburse for a test and the specific conditions for reimbursement.

Reimbursement by third-party payors may depend on a number of factors, including the payor's determination that tests using our technologies are:

- not experimental or investigational;
- medically necessary;
- demonstrated to lead to improved patient outcomes;
- appropriate for the specific patient;
- cost-saving or cost-effective;
- supported by peer-reviewed medical journals; and
- included in clinical guidelines.

If we are unable to provide third-party payors with sufficient evidence of the clinical utility and validity of our tests, they may not provide coverage, or may provide limited coverage, which will adversely affect our revenue and our ability to succeed. In addition, clinicians may be less likely to order a test unless a third-party payor pays a substantial portion of the test price. Therefore, coverage determinations and reimbursement levels and conditions are critical to commercial success, and if we are not able to secure positive coverage determinations and reimbursement levels, our business will be materially adversely affected. Moreover, the COVID-19 pandemic may cause a delay in coverage decisions from Medicare and third-party payors, and has delayed ongoing and planned clinical trials involving our tests, the occurrence of which may have a material adverse effect on our business.

Third-party payors and other entities also conduct technology assessments of new medical tests and devices and provide and/or sell the results of their assessments to other parties. These assessments may be used by third-party payors and healthcare providers as grounds to deny coverage for or refuse to use a test or procedure. In addition, third-party payors have increased their efforts to control the cost, utilization and delivery of healthcare services. These measures have resulted in reduced payment rates and decreased utilization for the diagnostics industry.

Effective April 25, 2012, Palmetto GBA, the Medicare molecular diagnostic services program contractor, or MolDX Program, assigned the AVISE® MTX assay a unique identifier and determined that the test meets the applicable

Medicare coverage criteria to support dose optimization and therapeutic decision making for patients diagnosed with RA on methotrexate. Our current Medicare Administrative Contractor, Noridian Healthcare Solutions, LLC, or Noridian, has adopted this coverage policy.

We experienced a disruption in our revenue recognition and cash collection during the quarter ended June 30, 2022 in relation to Medicare Part B reimbursements for our AVISE® Lupus test and may experience future disruptions in this revenue and cash collection. Effective April 1, 2022 CMS recognized a new PLA code for our protein-based test, AVISE® Lupus, and Noridian priced this PLA code at $1,085 per test. The process for establishing reimbursement for new tests can be uncertain, lengthy and time consuming. A pricing determination is not synonymous with a coverage determination. Having a price associated with the PLA code for any particular test does not secure coverage or reimbursement for that PLA code from Medicare or any other third-party payor.

Beginning April 1 2022, we billed Noridian for AVISE® Lupus under its new PLA code. However, to date, we have received few payments, with the substantial majority of these claims either resulting in requests for additional information and denials from Noridian. In order to confirm coverage and payment of claims, we submitted a formal request to Noridian for coverage of our AVISE® Lupus test. This request may not be successful, and we may ultimately be required to pursue additional strategies for reimbursement with Noridian, which may include seeking a local coverage determination or a local coverage article. These alternative strategies may not be successful and, even if successful, may be time-consuming, resource intensive and require multiple quarterly or annual periods to complete. During the pendency of these efforts, we may be unable to collect reimbursement from Noridian for all or some of our AVISE® Lupus claims, which could again result in a disruption in recognizing related revenue for billed AVISE® Lupus claims. If our efforts to seek reimbursement are ultimately unsuccessful, we may not receive any revenue or cash from these claims.

Other third-party payors make their own decisions as to whether to establish a policy to reimburse for our tests. Because approvals must be sought on a payor-by-payor basis, establishing broad coverage is a time-consuming and costly process. There are many third-party payors who have not yet established a coverage policy applicable to our tests. In addition, several Blue Cross Blue Shield plans and Aetna issued non-coverage policies with respect to AVISE® Lupus, determining that AVISE® Lupus does not meet the medical criteria for coverage and is considered investigational and/or experimental.

While our tests are reimbursed by a number of third-party payors, we do not currently have contracts with significant private payors. We have in the past, and will likely in the future, experience delays and temporary interruptions in the receipt of payments from third-party payors due to changes in their internal processes, documentation requirements and other issues, which could cause our revenue and cash to fluctuate from period to period.

If we are not successful in reversing existing non-coverage policies, obtaining and maintaining consistent reimbursement for billed tests or if other third-party payors issue negative coverage policies, these policies could have a material adverse effect on our business and operations. Even if many third-party payors currently reimburse for our testing products, such payors may withdraw coverage at any time, review and adjust the rate of reimbursement, require co-payments from patients or stop paying for our tests altogether, any of which would reduce our revenue.

Risks Related to Regulatory and Compliance Matters

We conduct business in a heavily regulated industry. Complying with the numerous statutes and regulations pertaining to our business is expensive and time-consuming, and any failure by us, our consultants or commercial partners to comply could result in substantial penalties.

Our industry and our operations are heavily regulated by various federal, state, local and foreign laws and regulations, and the regulatory environment in which we operate could change significantly and adversely in the future. These laws and regulations currently include, among others:

- CLIA's and CAP's regulation of our laboratory activities;
- FDA laws and regulations, including but not limited to requirements for offering LDTs;
- federal and state laws and standards affecting reimbursement by government payors, including certain coding requirements to obtain reimbursement and certain changes to the payment mechanism for clinical laboratory services resulting from the Protecting Access to Medicare Act of 2014, or PAMA;

- HIPAA and HITECH, which establish comprehensive federal standards with respect to the privacy and security of PHI, and requirements for the use of certain standardized electronic transactions with respect to transmission of such information, as well as similar laws protecting other types of personal information;
- state laws governing the maintenance of personally identifiable information of state residents, including medical information, and which impose varying breach notification requirements, some of which allow private rights of action by individuals for violations and also impose penalties for such violations;
- the federal Anti-Kickback Statute, which generally prohibits knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, in return for or to induce a person to refer to an individual any good, facility, item or service that is reimbursable under a federal healthcare program;
- the federal Stark Law, which generally prohibits a physician from making a referral for certain designated health services covered by the Medicare program, including laboratory and pathology services, if the physician or an immediate family member has a financial relationship with the entity providing the designated health services;
- the federal False Claims Act, which imposes civil penalties, and provides for civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Civil Monetary Penalties Law, which generally prohibits, among other things, the offering or transfer of remuneration to a Medicare or Medicaid beneficiary if it is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of services reimbursable by Medicare or Medicaid;
- EKRA, which imposes criminal penalties for knowing or willful payment or offer, or solicitation or receipt, of any remuneration, whether directly or indirectly, overtly or covertly, in cash or in kind, in exchange for the referral or inducement of laboratory testing (among other healthcare services) covered by healthcare benefit programs (including commercial insurers) unless a specific exception applies;
- the ACA, which, among other things, establishes a requirement for providers and suppliers to report and return any overpayments received from the Medicare and Medicaid programs;
- other federal and state fraud and abuse laws, such as anti-kickback laws, prohibitions on self-referral, fee-splitting restrictions, insurance fraud laws, anti-markup laws, prohibitions on the provision of tests at no or discounted cost to induce physician or patient adoption and false claims acts, some of which may extend to services reimbursable by any third-party payor, including private payors;
- the prohibition on reassignment of Medicare claims and other Medicare and Medicaid billing and coverage requirements;
- state laws that prohibit other specified healthcare practices, such as billing physicians for tests that they order, waiving coinsurance, copayments, deductibles and other amounts owed by patients, business corporations practicing medicine or employing or engaging physicians to practice medicine and billing a state Medicaid program at a price that is higher than what is charged to one or more other payors;
- the FCPA, and applicable foreign anti-bribery laws;
- federal, state and local regulations relating to the handling and disposal of regulated medical waste, hazardous waste and biohazardous waste and workplace safety for healthcare employees;
- laws and regulations relating to health and safety, labor and employment, public reporting, taxation and other areas applicable to businesses generally, all of which are subject to change, including, for example, the significant changes to the taxation of business entities were enacted in December 2017; and
- similar foreign laws and regulations that apply to us in the countries in which we operate or may operate in the future.

Any future growth of our business, including, in particular, continued reliance on consultants, commercial partners and other third parties, may increase the potential for violating these laws. In some cases, our risk of violating these

or other laws and regulations is further increased because of the lack of their complete interpretation by applicable regulatory authorities or courts, and their provisions are thus open to a variety of interpretations.

We have adopted policies and procedures designed to comply with these laws and regulations, and, in the ordinary course of our business, we conduct internal reviews of our compliance with these laws. Our compliance is also subject to review by applicable government agencies. However, these laws and regulations are subject to change and additional interpretation and guidance from regulatory authorities. For instance, in April 2022, the Department of Health and Human Services Office of Inspector General issued a new advisory opinion indicating that a particular clinical laboratory's practice of contracting with hospitals for the collection of samples for testing could, based on the facts provided and assuming the requisite intent, be a violation of the federal Anti-Kickback Statute. If this Advisory Opinion ultimately limits our ability to collect samples in a hospital setting, we may be required to contract for sample collection with other collection sites or sources, such as mobile phlebotomists, that could be more expensive and less convenient for patients, which could adversely affect both demand for our tests and the margins and profitability of our tests.

Given the complexity of these existing and changing rules and regulations, it is not always possible to identify and deter misconduct by employees, distributors, consultants and commercial partners and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with applicable laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. Any action brought against us for violation of these or other laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention from the operation of our business and harm our reputation. If our operations, including the conduct of our employees, consultants and commercial partners, are found to be in violation of any of these laws and regulations, we may be subject to applicable penalties associated with the violation, including administrative, civil and criminal penalties, damages, fines, individual imprisonment, exclusion from participation in federal healthcare programs, refunding of payments received by us and curtailment or cessation of our operations. Any of these consequences could seriously harm our business and our financial results.

It is possible that some of our business activities could be subject to challenge under one or more of such laws. Such a challenge, regardless of the outcome, could have a material adverse effect on our business, business relationships, reputation, financial condition and results of operations. Although an effective compliance program can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with these laws may prove costly. If we or our operations, or any of the rheumatologists or entities with whom we do business are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to significant penalties, including administrative, civil and/or criminal penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation in U.S. federal or state healthcare programs, such as Medicare and Medicaid in the U.S. and similar programs outside the U.S., a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could materially adversely affect our ability to operate our business and our financial results. To the extent that any of our testing products are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

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

Use of Proceeds

On September 18, 2019, the SEC declared effective our registration statement on Form S-1 (File No. 333-233446), as amended, filed in connection with our IPO. At the closing of the offering on September 23, 2019, we issued and sold 4,140,000 shares of our common stock at the initial public offering price to the public of $14.00 per share, which included the exercise in full of the underwriters' option to purchase additional shares. We received gross proceeds from the IPO of $58.0 million, before deducting underwriting discounts, commissions and other offering expenses, which resulted in net proceeds of approximately $50.4 million and offering-related transaction costs of

approximately $7.5 million. Cowen and Company, LLC, Cantor Fitzgerald & Co. and William Blair & Company, L.L.C. acted as joint book-running managers for the offering. No offering expenses were paid or are payable, directly or indirectly, to our directors or officers, to persons owning 10% or more of any class of our equity securities or to any of our affiliates.

As of June 30, 2022, we have used all of the proceeds from our IPO primarily related to selling and marketing activities. There has been no material change in the planned use of such proceeds from that described in the final prospectus filed by us with the SEC on September 20, 2019.

Recent Sales of Unregistered 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/Furnished Herewith
		Form	File No.	Exhibit	Exhibit Filing Date	
3.1	Amended and Restated Certificate of Incorporation.	8-K	001-39049	3.1	9/23/2019	
3.2	Amended and Restated Bylaws.	8-K	001-39049	3.1	3/22/2021	
4.1	Specimen stock certificate evidencing the shares of common stock.	S-1/A	333-233446	4.1	9/9/2019	
4.2	Amended and Restated Investors' Rights Agreement, dated July 12, 2019, by and among the Company and certain of its stockholders.	S-1/A	333-233446	4.2	9/9/2019	
4.3	Amended and Restated Stockholders' Agreement, dated July 12, 2019, by and among the Company and certain of its stockholders.	S-1/A	333-233446	4.3	9/9/2019	
4.4	Form of Common Stock Purchase Warrant issued to investors by the Company in connection with private placement financings.	S-1/A	333-233446	4.4	9/9/2019	
4.5	Form of Common Stock Purchase Warrant to purchase common stock issued to investors by the Company in 2016.	S-1/A	333-233446	4.8	9/9/2019	
4.6	Form of Exchange Warrant	10-Q	001-39049	4.5	8/9/2021	
31.1	Certificate of Principal Executive Officer, pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
31.2	Certificate of Principal Financial Officer, pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
32.1*	Certifications Pursuant to U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Public Company Accounting Reform and Investor Protection Act of 2002.					X
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its 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 Labels Linkbase Document.					X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.					X
104	The cover page from the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, has been formatted in Inline XBRL.					X

* 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 hereunto duly authorized.

EXAGEN INC.

Date: August 4, 2022 by: /s/ Fortunato Ron Rocca

Fortunato Ron Rocca
President and Chief Executive Officer
(Principal Executive Officer)

Date: August 4, 2022 by: /s/ Kamal Adawi

Kamal Adawi
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 31.1

EXAGEN INC.

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Fortunato Ron Rocca, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Exagen 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 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 (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. The registrant's other certifying officer 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 4, 2022

/s/ Fortunato Ron Rocca

Fortunato Ron Rocca

President and Chief Executive Officer

(Principal Executive Officer)

Exhibit 31.2

EXAGEN INC.

CERTIFICATION OF CHIEF FINANCIAL OFFICER

PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Kamal Adawi, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Exagen 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 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 (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. The registrant's other certifying officer 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 4, 2022

/s/ Kamal Adawi

Kamal Adawi

Chief Financial Officer

(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Exagen Inc. (the "Company") hereby certifies, to such officer's knowledge, that:

1. The accompanying quarterly report on Form 10-Q of the Company for the quarterly period ended June 30, 2022 (the "Report") fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the periods presented therein.

Dated: August 4, 2022

/s/ Fortunato Ron Rocca
Fortunato Ron Rocca
President and Chief Executive Officer
(Principal Executive Officer)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. Section 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing. A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

CERTIFICATION OF CHIEF FINANCIAL OFFICER

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Exagen Inc. (the "Company") hereby certifies, to such officer's knowledge, that:

1. The accompanying quarterly report on Form 10-Q of the Company for the quarterly period ended June 30, 2022 (the "Report") fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the periods presented therein.

Dated: August 4, 2022

/s/ Kamal Adawi

Kamal Adawi

Chief Financial Officer (Principal Financial and Accounting Officer)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. Section 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing. A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.