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 September 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 November 18, 2022 was 16,319,488.

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Exagen Inc.

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

	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 68,704	$ 99,442
Accounts receivable, net	10,639	9,654
Prepaid expenses and other current assets	2,717	3,638
Total current assets	82,060	112,734
Property and equipment, net	8,331	4,772
Operating lease right-of-use assets	5,114	—
Goodwill	5,506	5,506
Other assets	586	433
Total assets	$ 101,597	$ 123,445
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,669	$ 2,492
Operating lease liabilities	1,009	—
Accrued and other current liabilities	6,654	6,826
Total current liabilities	11,332	9,318
Borrowings-non-current portion, net of discounts and debt issuance costs	28,008	27,478
Non-current operating lease liabilities	4,766	—
Deferred tax liabilities	306	306
Other non-current liabilities	999	1,407
Total liabilities	45,411	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 September 30, 2022 and December 31, 2021	—	—
Common stock, $0.001 par value; 200,000,000 shares authorized as of September 30, 2022 and December 31, 2021; 16,305,475 and 16,164,994 shares issued and outstanding as of September 30, 2022 and December 31, 2021, respectively	16	16
Additional paid-in capital	297,343	293,060
Accumulated deficit	(241,173)	(208,140)
Total stockholders' equity	56,186	84,936
Total liabilities and stockholders' equity	$ 101,597	$ 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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenue	$ 14,726	$ 12,251	$ 32,726	$ 35,610
Operating expenses:				
Costs of revenue	6,010	5,487	17,905	15,649
Selling, general and administrative expenses	14,151	11,528	39,206	32,739
Research and development expenses	2,382	1,740	7,175	5,035
Total operating expenses	22,543	18,755	64,286	53,423
Loss from operations	(7,817)	(6,504)	(31,560)	(17,813)
Interest expense	(618)	(678)	(1,822)	(1,986)
Other income, net	339	3	349	1
Net loss	$ (8,096)	$ (7,179)	$ (33,033)	$ (19,798)
Net loss per share, basic and diluted	$ (0.47)	$ (0.42)	$ (1.94)	$ (1.27)
Weighted-average number of shares used to compute net loss per share, basic and diluted	17,080,959	16,945,591	17,044,623	15,636,150

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 (As Restated)	Total Stockholders' Equity (As Restated)
	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 (As Restated)	—	—	—	(14,665)	(14,665)
Balances as of June 30, 2022 (As Restated)	16,258,807	16	295,885	(233,077)	62,824
Issuance of stock from vested restricted stock units and payment of employees' taxes	5,336	—	(2)	—	(2)
Exercise of stock options	1,273	—	—	—	—
Issuance of stock under Employee Stock Purchase Plan	40,059	—	154	—	154
Stock-based compensation	—	—	1,306	—	1,306
Net loss	—	—	—	(8,096)	(8,096)
Balances as of September 30, 2022	16,305,475	$ 16	$ 297,343	$ (241,173)	$ 56,186

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, 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
Exercise of stock options	1,752	—	1	—	1
Issuance of stock under Employee Stock Purchase Plan	17,977	—	215	—	215
Stock-based compensation	—	—	1,354	—	1,354
Exercise of common stock warrants	17,719	—	32	—	32
Net loss	—	—	—	(7,179)	(7,179)
Balances at September 30, 2021	16,164,232	$ 16	$ 291,874	$ (201,087)	$ 90,803

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

Exagen Inc.

Unaudited Condensed Statements of Cash Flows
(in thousands)

	Nine Months Ended September 30,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$ (33,033)	$ (19,798)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,037	656
Amortization of debt discount and debt issuance costs	119	226
Non-cash interest expense	411	403
Non-cash lease expense	738	—
Stock-based compensation	4,122	3,551
Other	33	—
Changes in assets and liabilities:		
Accounts receivable, net	(985)	(300)
Prepaid expenses and other current assets	921	1,754
Other assets	(100)	(167)
Operating lease liabilities	(613)	—
Accounts payable	1,061	(1,085)
Accrued and other current liabilities	(121)	538
Net cash used in operating activities	(26,410)	(14,222)
Cash flows from investing activities:		
Purchases of property and equipment	(3,912)	(1,306)
Purchase of other assets	—	(50)
Net cash used in investing activities	(3,912)	(1,356)
Cash flows from financing activities:		
Proceeds from exercise of stock options	—	80
Payments of taxes withheld on vested restricted stock units	(224)	—
Proceeds from common stock issued under Employee Stock Purchase Plan	385	390
Proceeds from exercise of common stock warrants	—	32
Principal payments on finance lease obligations	(477)	(343)
Proceeds from the issuance of common stock in public offering	—	69,144
Payment of issuance costs related to public offering	—	(4,407)
Net cash (used in) provided by financing activities	(316)	64,896
Net change in cash, cash equivalents and restricted cash	(30,638)	49,318
Cash, cash equivalents and restricted cash, beginning of period	99,542	57,548
Cash, cash equivalents and restricted cash, end of period	$ 68,904	$ 106,866
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 1,297	$ 1,362
Supplemental disclosure of non-cash items:		
Equipment purchased under finance lease obligations	$ 709	$ 1,111
Costs incurred, but not paid, in connection with capital expenditures	$ 645	$ 135
Deferred offering costs reclassified to equity	$ —	$ 28

The accompanying notes are an integral part of these 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 September 30, 2022, the Company had cash and cash equivalents of $68.7 million and had an accumulated deficit of $241.2 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.

Note 1A. Restatement of Previously Issued Financial Statements

The Company has restated previously issued financial statements and related disclosures as of and for the three and six months ended June 30, 2022 included in our Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission (the SEC) on August 4, 2022 (the Original Quarterly Report), in order to correct misstatements resulting from erroneous and duplicate billings included in revenue. The applicable Notes to Condensed Financial Statements were also updated to reflect the restatement.

Impact of Restatement

In November 2022 management determined that the Company made certain errors in revenue resulting from erroneous and duplicate billings related to changes in billing practices. The errors were due to the inadequate design and implementation and precision of internal controls and procedures to evaluate and monitor the accounting for revenue recognition. As a result, the Company determined that there were material errors in the financial statements that required a restatement of the financial statements for the three and six months ended June 30, 2022 in the Original Quarterly Report. The effect of these errors was a $1.4 million overstatement of revenue for the three and six months ended June 30, 2022; in addition to, a $0.9 million overstatement of accounts receivable and a $0.5 million understatement of other liabilities as of June 30, 2022.

The following tables reflect the impact of the restatement adjustments to the specific line items presented in our previously reported financial statements for the periods indicated. The amounts originally reported were derived from the Original Quarterly Report (in thousands, except per share amounts):

Condensed Balance Sheet	June 30, 2022		
	As Originally Reported	Adjustments	As Restated
Assets			
Accounts receivable, net	$ 9,590	$ (875)	$ 8,715
Total current assets	89,039	(875)	88,164
Total assets	107,724	(875)	106,849
Liabilities and Stockholders' Equity			
Accrued and other current liabilities	5,489	481	5,970
Total current liabilities	9,573	481	10,054
Total liabilities	43,544	481	44,025
Accumulated deficit	(231,721)	(1,356)	(233,077)
Total stockholders' equity	64,180	(1,356)	62,824
Total liabilities and stockholders' equity	107,724	(875)	106,849

Condensed Statement of Operations	Three Months Ended June 30, 2022		
	As Originally Reported	Adjustments	As Restated
Revenue	$ 8,962	$ (1,356)	$ 7,606
Loss from operations	(12,708)	(1,356)	(14,064)
Net loss	(13,309)	(1,356)	(14,665)
Net loss per share, basic and diluted	(0.78)	(0.08)	(0.86)

Condensed Statement of Operations	Six Months Ended June 30, 2022		
	As Originally Reported	Adjustments	As Restated
Revenue	$ 19,356	$ (1,356)	$ 18,000
Loss from operations	(22,387)	(1,356)	(23,743)
Net loss	(23,581)	(1,356)	(24,937)
Net loss per share, basic and diluted	(1.39)	(0.07)	(1.46)

Condensed Statement of Cash Flows	Six Months Ended June 30, 2022		
	As Originally Reported	Adjustments	As Restated
Cash flows from operating activities:			
Net loss	$ (23,581)	$ (1,356)	$ (24,937)
Changes in assets and liabilities:			
Accounts receivable, net.	64	875	939
Accrued and other current liabilities	(1,232)	481	(751)
Net cash used in operating activities	(19,728)	—	(19,728)

Note 2. Summary of Significant Accounting Policies

Basis of Presentation and Use of Estimates

The accompanying interim condensed balance sheet as of September 30, 2022, the condensed statements of operations and the condensed statements of stockholders' equity for the three and nine months ended September 30, 2022 and 2021, cash flows for the nine months ended September 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 September 30, 2022 and its results of operations for the three and nine month periods presented. The results for the nine months ended September 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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Medicare	62 %	19 %	37 %	19 %
Medicare Advantage	12 %	13 %	15 %	13 %
Blue Shield	*	12 %	*	12 %

* Less than 10%.

	Accounts Receivable, Net	
	September 30, 2022	December 31, 2021
Medicare	53 %	*
Blue Shield	*	19 %
United Healthcare	*	18 %

* Less than 10%.

For the three months ended September 30, 2022 and 2021, approximately 87% and 81%, respectively, of the Company's revenue was related to the AVISE® CTD test. For the nine months ended September 30, 2022 and 2021, approximately 84% 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 the three months ended September 30, 2022 and 2021, approximately 97% and 95%, respectively, of the Company's diagnostic testing supplies were purchased from two suppliers. For each of the nine months ended September 30, 2022 and 2021, approximately 96% 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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenue:				
Healthcare insurers	$ 3,216	$ 6,910	$ 14,259	$ 20,318
Government	9,228	2,330	12,242	6,733
Client(1)	2,046	2,346	5,496	6,738
Other(2)	236	265	729	821
Janssen (SIMPONI®)	—	400	—	1,000
Total revenue	$ 14,726	$ 12,251	$ 32,726	$ 35,610

(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.

In connection with it's corporate credit card program, the Company is required to maintain a certificate of deposit of $0.2 million and $0.1 million at September 30, 2022 and December 31, 2021, respectively, as collateral for amounts borrowed on the 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 consist of the following (in thousands):

	September 30, 2022	September 30, 2021	December 31, 2021
Cash and cash equivalents	$ 68,704	$ 106,766	$ 99,442
Restricted cash	200	100	100
	$ 68,904	$ 106,866	$ 99,542

Long-lived Assets

The Company’s long-lived assets are comprised principally of its property and equipment, finite lived intangible assets, and goodwill.

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

Goodwill is tested for impairment annually (during the fourth quarter) or more frequently if indicators of impairment exist. As the Company operates in a single operating segment and reporting unit, the Company first assesses qualitative factors to determine whether it is more likely than not that the fair value of the reporting unit is less than its carrying amount as a basis for determining whether it is necessary to perform a quantitative assessment. The Company considered the current and expected future economic and market conditions, the current market capitalization and forecasts. The Company determined that it was not more likely than not that the fair value of the reporting unit was less than the carrying value as of September 30, 2022. Therefore, an interim quantitative impairment test was not performed.

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 September 30, 2022 was a $3.7 million revenue increase for tests delivered in a prior period due to the reassessment of the constraint on variable consideration and a $1.9 million net revenue decrease associated with other changes in estimated variable consideration related to performance obligations satisfied in previous periods. Included in revenues for the three months ended September 30, 2021 was a $0.1 million net revenue increase, associated with changes in estimated variable consideration related to performance obligations satisfied in previous periods. Included in revenues for the nine months ended September 30, 2022 and 2021 was a net revenue decrease of $2.5 million and a net revenue increase of $0.2 million, respectively, associated with changes in estimated variable consideration related to performance obligations satisfied in previous periods. The transaction price is estimated using an expected value method on a portfolio basis.

Variable consideration is included in the transaction price only to the extent it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainties with respect to the amount are resolved. 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. 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. Additionally, from time to time, the Company may issue refunds to payors for overpayments or amounts billed in error. Any refunds are accounted for as reductions in revenues in the statement of operations as an element of variable consideration. The estimated expected refunds are accrued as a liability on the Company’s balance sheet.

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. The Company recognized no co-promotion revenue and $0.4 million during the three months ended September 30, 2022 and 2021, respectively. The Company recognized no co-promotion revenue and $1.0 million during the nine months ended September 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, the Company was 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 Accounting Standards Codification (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 $1.3 million and $0.6 million for the three months ended September 30, 2022 and 2021, respectively, and $2.2 million and $1.3 million for the nine months ended September 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 September 30, 2022 and 2021, respectively, and $2.1 million and $1.6 million for the nine months ended September 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 nine months ended September 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):

	September 30,	
	2022	2021
Warrants to purchase common stock	409,108	409,108
Common stock options	1,820,555	2,067,057
Restricted stock units	805,496	403,100
Employee stock purchase plan	17,204	4,130
Total	3,052,363	2,883,395

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):

	September 30, 2022	December 31, 2021
Diagnostic testing supplies	$ 1,364	$ 1,091
Prepaid product royalties	42	49
Prepaid maintenance and insurance contracts	1,001	2,008
Other prepaid expenses and other current assets	310	490
Prepaid expenses and other current assets	$ 2,717	$ 3,638

Property and Equipment, Net

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

	September 30, 2022	December 31, 2021
Furniture and fixtures	$ 98	$ 83
Laboratory equipment	5,488	4,361
Computer equipment and software	1,461	1,206
Leasehold improvements	3,230	1,151
Construction in progress	2,961	1,855
Total property and equipment	13,238	8,656
Less: accumulated depreciation and amortization	(4,907)	(3,884)
Property and equipment, net	$ 8,331	$ 4,772

Depreciation and amortization expense for the three months ended September 30, 2022 and 2021 was approximately $0.4 million and $0.3 million, respectively, and for the nine months ended September 30, 2022 and 2021, was approximately $1.0 million and $0.7 million, respectively.

Accrued and Other Current Liabilities

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

	September 30, 2022	December 31, 2021
Accrued payroll and related expenses	$ 3,353	$ 4,048
Accrued interest	136	139
Accrued purchases of goods and services	1,227	510
Accrued royalties	69	180
Accrued clinical study activity	165	254
Finance lease obligations, current portion	730	587
Refund liability	445	—
Other accrued liabilities	529	1,108
Accrued and other current liabilities	$ 6,654	$ 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 September 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 September 30, 2022 and 2021, the Company issued PIK Loans totaling $0.1 million. For each of the nine months ended September 30, 2022 and 2021, the Company issued PIK Loans totaling $0.4 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 September 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 September 30, 2022, future minimum aggregate payments, including interest, for outstanding borrowings under the 2017 Loan Amendment are as follows (in thousands):

2022 (remaining)	$	420
2023		1,686
2024		2,980
2025		16,152
2026		14,786
Total		36,024
Less:		
Unamortized debt discount and issuance costs		(170)
Interest		(7,846)
Total borrowings, net of discounts and debt issuance costs	$	28,008

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	September 30, 2022
Lease Assets		
Operating	Operating lease right-of-use assets	$ 5,114
Finance	Property and equipment, net	$ 1,696
Lease Liabilities		
Current		
Operating	Operating lease liabilities	$ 1,009
Finance	Accrued and other current liabilities	$ 730
Non-current		
Operating	Non-current operating lease liabilities	$ 4,766
Finance	Other non-current liabilities	$ 974

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

Lease Cost	Three months ended September 30, 2022	Nine months ended September 30, 2022
Operating leases		
Operating lease cost[(1)]	$ 384	$ 1,156
Finance lease cost		
Amortization of lease assets	174	487
Interest on finance lease liabilities	20	60
Total lease cost	$ 578	$ 1,703

(1) Includes variable lease cost of $41,000 and $124,000 for the three and nine months ended September 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	Nine months ended September 30, 2022
Operating cash out flows from operating leases	$ 907
Operating cash out flows from interest paid on finance leases	$ 60
Financing cash out flows from finance leases	$ 477

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

	September 30, 2022
Weighted-average remaining lease term (years)	
Operating leases	4.6
Finance leases	2.29
Weighted-average discount rate	
Operating leases	8.0 %
Finance leases	5.3 %

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

	Operating Leases	Finance Leases
2022 (remaining)	$ 356	$ 227
2023	1,446	827
2024	1,489	573
2025	1,533	247
2026	1,584	127
Thereafter	539	28
Total minimum lease payments	6,947	2,029
Less: imputed interest	(1,172)	(325)
Total lease liabilities	5,775	1,704
Less: current portion	(1,009)	(730)
Lease obligations, net of current portion	$ 4,766	$ 974

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 nine months ended September 30, 2021, rent expense was $0.2 million and $0.5 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 September 30, 2022 and 2021. Collaboration expenses under the master research collaboration agreement were $0.3 million and $0.2 million, for the nine months ended September 30, 2022 and 2021, respectively. Collaboration expenses under the AHN collaboration are included in research and development expenses.

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):

	September 30, 2022			
	Total	Level 1	Level 2	Level 3
Assets:				
Money market funds, included in cash and cash equivalents	$ 35,328	$ 35,328	$ —	$ —

	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

Shelf Registration Statement

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.

At The Market Sales Agreement

On September 15, 2022, the Company entered into a sales agreement (the Sales Agreement) with Cowen and Company, LLC (the Sales Agent), pursuant to which the Company may offer and sell, from time to time, shares of Company common stock having an aggregate offering price of up to $50.0 million. The Company is not obligated to sell any shares of Company common stock in the offering. As of September 30, 2022, the Company has not sold any shares of its common stock pursuant to the Sales Agreement.

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 September 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 September 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 nine months ended September 30, 2022, no warrants to purchase common stock were 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 or, for grants to new hires, date of hire. As of September 30, 2022, 1,528,877 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 September 30, 2022, 413,425 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		
Exercised	(1,273)	$ 0.33		
Forfeited	(114,182)	$ 13.74		
Expired	(141,320)	$ 13.79		
Outstanding, September 30, 2022	1,820,555	$ 11.63	7.19	$ 1,150
Vested and expected to vest, September 30, 2022	1,820,555	$ 11.63	7.19	$ 1,150
Options exercisable, September 30, 2022	1,321,485	$ 10.59	6.93	$ 1,126

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 September 30, 2022, total unrecognized compensation cost related to option awards was $3.5 million, which is expected to be recognized over a remaining weighted-average vesting period of 1.36 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	604,100	$ 8.61	
Awards released	(99,624)	$ 16.62	
Awards canceled	(114,305)	$ 11.72	
Outstanding, September 30, 2022	805,496	$ 11.27	$ 2,183

As of September 30, 2022, total unrecognized compensation cost related to restricted stock units was $7.7 million, which is expected to be recognized over a remaining weighted-average vesting period of 3.1 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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Expected volatility	—%	86%	54%	83%-86%
Risk-free interest rate	—%	0.9%	3.4%	0.8%-1.1%
Dividend yield	—	—	—	—
Expected term (in years)	0	5.77	5.5	5.50-6.08

There were no stock options granted in the three months ended September 30, 2022.

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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Expected volatility	45%	45%	45%-57%	45%-60%
Risk-free interest rate	0.6%	0.1%	0.6%-3.3%	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 nine months ended September 30, 2022 and 2021. As of September 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 0.41 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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Costs of revenue	$ 56	$ 64	$ 159	$ 136
Selling, general and administrative	1,085	1,115	3,406	2,955
Research and development	165	175	557	460
Total	$ 1,306	$ 1,354	$ 4,122	$ 3,551

Note 10. Subsequent Events

In October 2022, in connection with the appointment of its new Chief Executive Officer, the Company granted 350,000 restricted stock units which will vest in equal annual installments over four years.

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 (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 84% and 81% of our revenue for the nine months ended September 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, Parexel International, LLC and IMVT Corporation (Immunovant), 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. The conversion of the research and development facility space was substantially completed in the third quarter of 2022 and will be placed into service in the fourth quarter 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, and lupus nephritis.

We market our AVISE® testing products using our specialized sales force. As of September 30, 2022, we have a sales force of 54 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 institutions 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. We have never been profitable and, as of September 30, 2022, we had an accumulated deficit of $241.2 million. We incurred net losses of $33.0 million and $19.8 million for the nine months ended September 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 September 30, 2022, we had $68.7 million of cash and cash equivalents.

On September 15, 2022, the Company entered into a sales agreement (the Sales Agreement) with Cowen and Company, LLC, as sales agent, pursuant to which the Company may offer and sell, from time to time, shares of Company common stock having an aggregate offering price of up to $50.0 million. The Company is not obligated to sell any shares of Company common stock in the offering and, as of September 30, 2022, the Company had not sold any shares of its common stock pursuant to the Sales Agreement.

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.

In the quarter ended March 31, 2022 we disclosed that the 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 Healthcare Solutions, LLC (Noridian), our Medicare Administrative Contractor, priced this PLA code at $1,085 per test. To determine pricing beyond 2022, the CMS pricing process resulted in a recommendation that AVISE Lupus (0312U) be crosswalked to Vectra (81490), at a rate of $840.65 per test. We expect pricing to be finalized on the Clinical Laboratory Fee Schedule by the end of 2022 and that such new pricing for the AVISE Lupus PLA code would be effective from January 1st, 2023 through the end of 2025, in light of the current reporting timelines under the Protecting Access to Medicare Act of 2014. 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.

In the second quarter 2022, we deemed variable consideration with respect to unpaid AVISE Lupus Medicare claims fully constrained due to uncertainty in the outcome of such claims arising from claims processing issues, including an unexpectedly high number of denied claims and claims made subject to requests from Noridian for additional information (such as medical records). We have been working with Noridian to resubmit claims and respond to its requests for information. Medicare has since resumed its reimbursement of our claims, including claims originally made in the second quarter of 2022, at the PLA Code price of $1,085 per test. Accordingly, we have reassessed the constraint on variable consideration related to claims from the second and third quarters of 2022 and recognized $3.7 million in additional revenue and $3.6 million accounts receivable from the second quarter period in the third quarter of 2022.

We continue to see headwinds relating to commercial payor claim processing and revenue. Now that we are billing under our PLA code, we are experiencing an increase in denials due to unfavorable medical policy with certain plans, and we expect this to persist. This has resulted in net revenue decreases of $1.9 million and $2.5 million, respectively, during the three and nine months ended September 30, 2022 associated with changes in estimated variable consideration related to performance obligations with these payors that were satisfied in previous periods.

In an effort to improve transparency regarding Medicare support of AVISE Lupus, on July 29, 2022, we submitted a formal request to Noridian for coverage of our AVISE® Lupus test under the new PLA Code. On September 27, 2022 we received notice that Noridian has deemed our application for a Local Coverage Determination (LCD) to be valid. Ultimately receiving a favorable LCD is uncertain and may be time-consuming, resource intensive and require multiple quarterly or annual periods to complete. In the meantime, we will continue to submit Medicare claims for AVISE® Lupus, appeal denials and respond to requests for additional information.

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.

In September 2022, we announced that our collaboration with Dr. Iñaki Sanz at Emory University has led to a publication in Nature. Our clinical test offerings, run on samples from severe COVID-19 patients, helped researchers from Emory characterize the autoimmune profiles induced by SARS-CoV-2 infection. In addition, these retrospective analyses laid the groundwork for recent longitudinal studies of so-called post-acute COVID syndrome (PACS), as well as other post-severe pulmonary infection sequelae, including the incorporation of Exagen's proprietary CB-CAPs technology. These efforts will assess the importance of long-term autoimmune monitoring in those patients experiencing lasting symptoms following acute pulmonary infection, including those caused by SARS-CoV-2.

Impact of Hurricane Ian

Hurricane Ian made landfall at the Southwestern Florida coast in late September 2022, causing significant damage within the state. Historically, a significant number of orders for our tests have come from clinicians and healthcare providers based in Florida. Demand for our tests was impacted during the last week of the quarter ended September 30, 2022 and continued through the first weeks of the subsequent quarter. We are unable to predict the extent to which our future test report volumes, and our results of operations, financial condition and cash flows, will ultimately be impacted by Hurricane Ian.

Impact of COVID-19

The full extent to which the COVID-19 pandemic may directly or indirectly continue to impact our business, results of operations and financial condition will depend on future developments that are highly uncertain. We have implemented business continuity plans designed to address the COVID-19 pandemic and minimize disruptions to ongoing operations.

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 September 30, 2022, we have delivered over 700,000 of these tests. Through the third quarter of 2022, 101,391 AVISE® CTD tests were delivered, representing approximately 7.7% growth over the same period in 2021. The number of ordering healthcare providers in the third quarter of 2022 was a record 2,287, representing an approximate 4% increase over the same period in 2021, and we had 772 adopting healthcare providers (defined as those who previously prescribed at least 11 diagnostic tests in the corresponding period) compared to 714 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 second quarter of 2022 ordered at least one diagnostic test in the third 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 $1.0 million in revenue during the nine months ended September 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 may continue to invest in research and development in order to develop additional testing products and, if so, we 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. 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*."

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. As Medicare payments have now resumed, we have reassessed the constraint on variable consideration related to claims from the second and third quarter of 2022 and recognized $3.7 million in additional revenue and $3.6 million in additional accounts receivable from the second quarter period in the third quarter of 2022 when the uncertainty was resolved.

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.

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.

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.

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.

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.

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.

Other Income, Net

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

Results of Operations

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

	Three Months Ended September 30,		
	2022	2021	Change
	(in thousands)		
Revenue	$ 14,726	$ 12,251	$ 2,475
Operating expenses:			
Costs of revenue	6,010	5,487	523
Selling, general and administrative expenses	14,151	11,528	2,623
Research and development expenses	2,382	1,740	642
Total operating expenses	22,543	18,755	3,788
Loss from operations	(7,817)	(6,504)	(1,313)
Interest expense	(618)	(678)	60
Other income, net	339	3	336
Net loss	$ (8,096)	$ (7,179)	$ (917)

Revenue

Revenue increased $2.5 million, or 20.2%, for the three months ended September 30, 2022 compared to the three months ended September 30, 2021, primarily due to an increase of $3.7 million from the reassessment of the constraint on variable consideration related to AVISE® Lupus Medicare claims from the second quarter of 2022, partially offset by a net revenue decrease of $1.9 million associated with changes in estimated variable consideration related to performance obligations satisfied in previous periods. The number of AVISE® CTD tests delivered, which accounted for 87% of revenue in each of the three months ended September 30, 2022 and 2021, increased to 35,569 tests delivered in the three months ended September 30, 2022 compared to 31,742 tests delivered in the same 2021 period. The number of AVISE® CTD ordering healthcare providers increased to 2,287 for the three months ended September 30, 2022 as compared to 1,969 ordering healthcare providers in the same 2021 period. Revenue resulting from the Janssen Agreement contributed no revenue for the three months ended September 30, 2022 compared to $0.4 million for the three months ended September 30, 2021.

Costs of Revenue

Costs of revenue increased $0.5 million, or 9.5%, for the three months ended September 30, 2022 compared to the three months ended September 30, 2021. This increase was primarily due to increased direct costs, such as labor and shipping and handling; and allocated overhead. Gross margin as a percentage of revenue increased to 59.2% for the three months ended September 30, 2022, compared to 55.2% for the three months ended September 30, 2021. This was primarily attributable to increased revenues and increased volume partially offset by decreases in Simponi revenue and increased direct costs, such as labor and shipping and handling; and allocated overhead.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased $2.6 million, or 22.8%, for the three months ended September 30, 2022 compared to the three months ended September 30, 2021. This increase was primarily due to a net increase of $1.0 million of employee related expenses, including stock-based compensation and recruitment expenses, increases related to marketing expenses of $0.7 million, audit and professional services of $0.4 million, allocated overhead of $0.3 million, legal fees of $0.1 million and third-party billing expenses of $0.1 million.

Research and Development Expenses

Research and development expenses increased $0.6 million for the three months ended September 30, 2022 compared to the three months ended September 30, 2021. This increase was primarily due to increases in expenses related to current and potential future employees, including stock-based compensation and recruitment expenses of $0.3 million, increases related to allocated overhead of $0.2 million and laboratory supplies expense of $0.3 million, partially offset by decreases in clinical trial expenses of $0.1 million.

Interest Expense

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

Other Income, Net

Other income, net, increased by $0.3 million for the three months ended September 30, 2022 compared to the three months ended September 30, 2021. This increase was primarily due to increases in interest income due to rising interest rates.

Comparison of the Nine Months Ended September 30, 2022 and 2021:

	Nine Months Ended September 30,		
	2022	2021	Change
	(in thousands)		
Revenue	$ 32,726	$ 35,610	$ (2,884)
Operating expenses:			
Costs of revenue	17,905	15,649	2,256
Selling, general and administrative expenses	39,206	32,739	6,467
Research and development expenses	7,175	5,035	2,140
Total operating expenses	64,286	53,423	10,863
Loss from operations	(31,560)	(17,813)	(13,747)
Interest expense	(1,822)	(1,986)	164
Other income, net	349	1	348
Net loss	$ (33,033)	$ (19,798)	$ (13,235)

Revenue

Revenue decreased $2.9 million, or 8.1%, for the nine months ended September 30, 2022 compared to the nine months ended September 30, 2021, primarily due a decrease in AVISE® CTD revenue of $1.4 million resulting from a decrease in average reimbursement per AVISE® CTD test, a $1.0 million decrease due to the termination of the SIMPONI agreement and a $0.5 million decrease from other testing. The number of AVISE® CTD tests delivered, which accounted for 84% and 81% of revenue in the nine months ended September 30, 2022 and 2021, respectively, increased to 101,391 tests delivered in the nine months ended September 30, 2022 compared to 94,099 tests delivered in the same 2021 period. The number of ordering healthcare providers increased to 3,127 for the nine months ended September 30, 2022 compared to 2,595 in the same 2021 period. Revenue resulting from the Janssen Agreement contributed no revenue for the nine months ended September 30, 2022 compared to $1.0 million during the nine months ended September 30, 2021.

Costs of Revenue

Costs of revenue increased $2.3 million, or 14.4%, for the nine months ended September 30, 2022 compared to the nine months ended September 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 in 2022 compared to 2021. Gross margin as a percentage of revenue decreased to 45.3% for the nine months ended September 30, 2022, compared to 56.1% for the nine months ended September 30, 2021. This was primarily attributable to a decrease in average reimbursement per AVISE® CTD test, a decrease in revenue from the

Janssen Agreement and increased direct costs, such as labor and shipping and handling; partially offset by increased AVISE® CTD volume.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased $6.5 million, or 19.8%, for the nine months ended September 30, 2022 compared to the nine months ended September 30, 2021. This increase was primarily due to an increase of $3.3 million of employee related expenses, including stock-based compensation and recruitment expenses, increases related to allocated overhead of $0.7 million, legal fees of $0.5 million, audit and professional services of $0.6 million, marketing expenses of $0.9 million and third-party billing expenses of $0.2 million.

Research and Development Expenses

Research and development expenses increased $2.1 million, or 42.5%, for the nine months ended September 30, 2022 compared to the nine months ended September 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 $1.4 million, collaboration expenses of $0.1 million, allocated overhead of $0.4 million, laboratory supplies expense of $0.6 million and consulting fees of $0.1 million, partially offset by decreases in clinical trial expenses of $0.5 million.

Interest Expense

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

Other Income, Net

Other income, net, increased by $0.3 million for the nine months ended September 30, 2022 compared to the nine months ended September 30, 2021. This increase was primarily due to increases in interest income due to rising interest rates.

Liquidity and Capital Resources

We have incurred net losses since our inception. For the nine months ended September 30, 2022 and 2021, we incurred a net loss of $33.0 million and $19.8 million, respectively, and we expect to incur additional losses and increased operating expenses in future periods. As of September 30, 2022, we had an accumulated deficit of $241.2 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.

In September 2017, we entered into the 2017 Term Loan 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 2017 Term Loan 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 September 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.

On September 15, 2022, the Company entered into the Sales Agreement, pursuant to which the Company may offer and sell, from time to time, shares of Company common stock having an aggregate offering price of up to $50.0 million. The Company is not obligated to sell any shares of Company common stock in the offering. As of September 30, 2022, the Company has not sold any shares of its common stock pursuant to the Sales Agreement.

As of September 30, 2022, we had $68.7 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.

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 may 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 may continue to increase to the extent 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 have made significant investments for laboratory equipment and capital expenditures related to our laboratory facilities and expansion of research capabilities. This includes converting 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 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. The conversion of the research and development space was substantially completed in the third quarter of 2022 and will be placed into service in the fourth quarter 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 facilities are expected to allow us to enhance our testing capacity and improve efficiencies. Additionally, we expect that it will enable us to pursue development of molecular and multiomic capabilities and advance our product pipeline, including support of the development of tests for fibromyalgia, RA 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. 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, potentially including 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:

	Nine Months Ended September 30,	
	2022	2021
(in thousands)		
Net cash (used in) provided by:		
Operating activities	$ (26,410)	$ (14,222)
Investing activities	(3,912)	(1,356)
Financing activities	(316)	64,896
Net change in cash, cash equivalents and restricted cash	$ (30,638)	$ 49,318

Cash Flows from Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2022 was $26.4 million and primarily resulted from (i) our net loss of $33.0 million adjusted for non-cash charges of $6.4 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 $0.2 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 nine months ended September 30, 2021 was $14.2 million and primarily resulted from (i) our net loss of $19.8 million adjusted for non-cash charges of $4.8 million related to stock-based compensation, depreciation, amortization and non-cash interest and (ii) changes in our net operating assets of $0.7 million primarily related to net decreases in prepaid expenses and other current assets, partially offset by net decreases in accounts payables.

Cash Flows from Investing Activities

Net cash used in investing activities for the nine months ended September 30, 2022 and 2021 was $3.9 million and $1.4 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 nine months ended September 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 nine months ended September 30, 2021 was $64.9 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 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 September 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

At the end of the period covered by this Quarterly Report on Form 10-Q, our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures. Disclosure controls and procedures include, without limitation, controls and procedures 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 period 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 recognizes 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 is 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.

On November 13, 2022, management and the audit committee of our board of directors determined that we made certain errors in revenue resulting from erroneous and duplicate billings related to changes in billing practices. The errors were due to the inadequate design and implementation and precision of internal controls and procedures to evaluate and monitor the accounting for revenue recognition. As a result, revenue and accounts receivable were overstated and other liabilities was understated for the quarter and year to date periods ended June 30, 2022.

We have concluded that these were material errors in the financial statements requiring a restatement of the Form 10-Q for the three and six months ended June 30, 2022.

Accordingly, management has determined that this control deficiency constituted a material weakness and, as a result, management has concluded that, as of September 30, 2022, our internal control over financial reporting was not effective based on the criteria in Internal Control Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria).

Based on that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were not effective to ensure that the information required to be disclosed by us in 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.

Remediation Plan to Address the Material Weaknesses

Management is actively engaged in the planning for, and implementation of, remediation efforts to address the material weakness. The remediation plan includes: (i) evaluating the staffing level, skills and qualification of accounting department personnel, (ii) enhancement of our existing control structure and processes for revenue recognition and (iii) improving the detailed review process of our revenue recognition models. The elements of our remediation plan can only be accomplished over time, and we can offer no assurance that these initiatives will ultimately have the intended effects.

The elements of our remediation plan can only be accomplished over time, and we can offer no assurance that these initiatives will ultimately have the intended effects. The weakness will not be considered remediated, however, until the applicable controls operate for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively.

Changes in Internal Control Over Financial Reporting

Other than the material weakness and remediation plan discussed above, there were no changes in our internal control over financial reporting (as such term is defined by Rules 13a-15(f) and 15d-15(f) of the Exchange Act)

during the most recent fiscal quarter ended September 30, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls and Procedures

Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. 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 judgment in evaluating the cost-benefit relationship of possible controls and procedures.

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 and in Part II, Item 1A of our Quarterly Report on Form 10-Q for the three and six months ended June 30, 2022, as amended:

We have identified a material weakness in our internal control over financial reporting and determined that our disclosure controls and procedures were ineffective as of September 30, 2022, in connection with the restatement of our financial statements as of and for the three and six months ended June 30, 2022. In the future, we may identify additional material weaknesses or otherwise fail to maintain an effective system of internal control over financial reporting or adequate disclosure controls and procedures, which may result in material errors in our financial statements or cause us to fail to meet our period reporting obligations.

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in our reports that we file or submit under the Securities and Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the time period 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 recognizes 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 is 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.

On November 13, 2022, management and the audit committee of our board of directors determined that we made certain errors in revenue resulting from erroneous and duplicate billings related to changes in billing practices. The errors were due to the inadequate design and implementation and precision of internal controls and procedures to evaluate and monitor the accounting for revenue recognition. As a result, revenue and accounts receivable were overstated and other liabilities was understated for the quarter and year to date periods ended June 30, 2022.

We then determined that there were material errors in the financial statements requiring a restatement of the Form 10-Q for the three and six months ended June 30, 2022.

Accordingly, management has determined that this control deficiency constituted a material weakness and, as a result, management has concluded that, as of September 30, 2022, our internal control over financial reporting was not effective based on the criteria in Internal Control Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria).

Management is actively engaged in the planning for, and implementation of, remediation efforts to address the material weakness. The remediation plan includes: (i) evaluating the staffing level, skills and qualification of accounting department personnel, (ii) enhancement of our existing control structure and processes for revenue recognition and (iii) improving the detailed review process of our revenue recognition models. The elements of our

remediation plan can only be accomplished over time, and we can offer no assurance that these initiatives will ultimately have the intended effects.

If we are not able to comply with the applicable requirements of the Sarbanes-Oxley Act of 2002 or if we are unable to maintain effective internal control over financial reporting, we may not be able to produce timely and accurate financial statements or guarantee that information required to be disclosed by us in the reports that we file with the SEC, is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms. Any failure of our internal control over financial reporting or disclosure controls and procedures could cause our investors to lose confidence in our publicly reported information, cause the market price of our stock to decline, expose us to sanctions or investigations by the SEC or other regulatory authorities, or impact our results of operations.

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	
10.1#	Employment Agreement, dated as of October 16, 2022, by and between the Company and John Aballi.	8-K	001-39049	10.1	10/16/2022	
10.2#	Severance Agreement, dated as of October 14, 2022, by and between the Company and Ron Rocca.	8-K	001-39049	10.2	10/16/2022	
10.3	Sales Agreement, dated as of September 15, 2022, by and between the Company and Cowen and Company, LLC	8-K	001-39049	1.1	9/15/2022	
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 September 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.

\# Management Compensation Plan or Arrangement.

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: November 21, 2022 by: /s/ John Aballi

John Aballi
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 21, 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, John Aballi, 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: November 21, 2022

/s/ John Aballi

John Aballi

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: November 21, 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 September 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: November 21, 2022

/s/ John Aballi
John Aballi
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 September 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: November 21, 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.