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

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2023

☐ **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 such files). Yes ☒ No ☐

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the 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 August 3, 2023 was 16,858,764.

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Exagen Inc.

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

	June 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 31,466	$ 62,391
Accounts receivable, net	16,235	6,077
Prepaid expenses and other current assets	3,570	4,143
Total current assets	51,271	72,611
Property and equipment, net	7,875	8,197
Operating lease right-of-use assets	4,412	4,885
Other assets	620	528
Total assets	$ 64,178	$ 86,221
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,309	$ 3,046
Accrued and other current liabilities	5,933	5,347
Operating lease liabilities	1,104	1,040
Borrowings-current portion	257	190
Total current liabilities	8,603	9,623
Borrowings-non-current portion, net of discounts and debt issuance costs	19,153	28,778
Non-current operating lease liabilities	3,923	4,493
Other non-current liabilities	597	867
Total liabilities	32,276	43,761
Commitments and contingencies (Note 5)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized, no shares issued or outstanding as of June 30, 2023 and December 31, 2022	—	—
Common stock, $0.001 par value; 200,000,000 shares authorized as of June 30, 2023 and December 31, 2022; 16,858,194 and 16,549,984 shares issued and outstanding as of June 30, 2023 and December 31, 2022, respectively	17	17
Additional paid-in capital	300,113	297,970
Accumulated deficit	(268,228)	(255,527)
Total stockholders' equity	31,902	42,460
Total liabilities and stockholders' equity	$ 64,178	$ 86,221

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

Exagen Inc.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Revenue	$ 14,137	$ 7,606	$ 25,367	$ 18,000
Operating expenses:				
Costs of revenue	5,836	6,078	11,762	11,895
Selling, general and administrative expenses	11,953	12,903	23,837	25,055
Research and development expenses	1,263	2,689	2,389	4,793
Total operating expenses	19,052	21,670	37,988	41,743
Loss from operations	(4,915)	(14,064)	(12,621)	(23,743)
Interest expense	(574)	(606)	(1,212)	(1,204)
Other income, net	476	5	1,132	10
Net loss	$ (5,013)	$ (14,665)	$ (12,701)	$ (24,937)
Net loss per share, basic and diluted	$ (0.28)	$ (0.86)	$ (0.72)	$ (1.46)
Weighted-average number of shares used to compute net loss per share, basic and diluted	17,655,483	17,058,516	17,591,478	17,025,636

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, 2022	16,549,984	$ 17	$ 297,970	$ (255,527)	$ 42,460
Issuance of stock from vested restricted stock units	113,378	—	—	—	—
Issuance of stock under Employee Stock Purchase Plan	70,317	—	152	—	152
Exercise of stock options	93,335	—	27	—	27
Stock-based compensation	—	—	986	—	986
Net loss	—	—	—	(7,688)	(7,688)
Balances as of March 31, 2023	16,827,014	17	299,135	(263,215)	35,937
Issuance of stock from vested restricted stock units	31,180	—	—	—	—
Stock-based compensation	—	—	978	—	978
Net loss	—	—	—	(5,013)	(5,013)
Balances as of June 30, 2023	16,858,194	$ 17	$ 300,113	$ (268,228)	$ 31,902

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

Exagen Inc.

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

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balances as of December 31, 2021	16,164,994	$ 16	$ 293,060	$ (208,140)	$ 84,936
Issuance of stock from vested restricted stock units and payment of employees' taxes	30,523	—	(115)	—	(115)
Issuance of stock under Employee Stock Purchase Plan	35,681	—	231	—	231
Stock-based compensation	—	—	1,376	—	1,376
Net loss	—	—	—	(10,272)	(10,272)
Balances as of March 31, 2022	16,231,198	16	294,552	(218,412)	76,156
Issuance of stock from vested restricted stock units and payment of employees' taxes	27,609	—	(107)	—	(107)
Stock-based compensation	—	—	1,440	—	1,440
Net loss	—	—	—	(14,665)	(14,665)
Balances as of June 30, 2022	16,258,807	$ 16	$ 295,885	$ (233,077)	$ 62,824

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

Exagen Inc.

Unaudited Condensed Statements of Cash Flows
(in thousands)

	Six Months Ended June 30,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (12,701)	$ (24,937)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,056	597
Amortization of debt discount and debt issuance costs	80	78
Non-cash interest expense	226	272
Loss on disposal of assets	129	—
Non-cash lease expense	473	514
Stock-based compensation	1,964	2,816
Changes in assets and liabilities:		
Accounts receivable, net	(10,158)	939
Prepaid expenses and other current assets	573	576
Other assets	(101)	(201)
Operating lease liabilities	(506)	(382)
Accounts payable	(1,750)	751
Accrued and other current liabilities	812	(751)
Net cash used in operating activities	(19,903)	(19,728)
Cash flows from investing activities:		
Purchases of property and equipment	(720)	(3,033)
Proceeds from disposal of property and equipment	2	—
Net cash used in investing activities	(718)	(3,033)
Cash flows from financing activities:		
Proceeds from exercise of stock options	27	—
Payments of taxes withheld on vested restricted stock units	—	(222)
Proceeds from common stock issued under Employee Stock Purchase Plan	152	231
Principal payments on finance lease obligations	(369)	(303)
Principal payment on note payable obligations	(114)	—
Principal payment on long-term debt	(10,000)	—
Net cash used in financing activities	(10,304)	(294)
Net change in cash, cash equivalents and restricted cash	(30,925)	(23,055)
Cash, cash equivalents and restricted cash, beginning of period	62,591	99,542
Cash, cash equivalents and restricted cash, end of period	$ 31,666	$ 76,487
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 898	$ 860
Supplemental disclosure of non-cash items:		
Equipment purchased under finance lease obligations	$ —	$ 293
Equipment purchased under notes payable obligations	$ 250	$ —
Costs incurred, but not paid, in connection with capital expenditures	$ 61	$ 391

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

Exagen Inc.

Notes to Unaudited Interim Condensed Financial Statements

Note 1. Organization

Description of Business

Exagen Inc. (the Company) is a commercial-stage diagnostics company which exists to provide clarity in autoimmune disease decision making with the goal of improving patients' clinical outcomes.

Liquidity

The Company has incurred recurring losses and negative cash flows from operating activities since inception. The Company anticipates that it will continue to incur net losses into the foreseeable future. As of June 30, 2023, the Company had cash and cash equivalents of $31.5 million and had an accumulated deficit of $268.2 million. Since inception, the Company has financed its operations primarily through a combination of equity financings, 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 2. Summary of Significant Accounting Policies

Basis of Presentation and Use of Estimates

The accompanying interim condensed balance sheet as of June 30, 2023, condensed statements of operations and stockholders' equity for the three and six months ended June 30, 2023, cash flows for the six months ended June 30, 2023 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. These unaudited condensed financial statements and related footnote disclosures should be read in conjunction with the Company’s audited financial statements for the fiscal year ended December 31, 2022, included in its Annual Report on Form 10-K filed with the SEC on March 20, 2023. In management's opinion, the unaudited interim condensed financial statements have been prepared on the same basis as the audited financial statements and include all normal adjustments, necessary for the fair presentation of the Company's financial position as of June 30, 2023 and its results of operations for the periods presented. The results for the three and six months ended June 30, 2023 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.

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, the recoverability of its long-lived assets 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. The Company has not experienced any losses on its cash or cash equivalents.

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

	Revenue			
	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Medicare	29 %	15 %	34 %	18 %
Medicare Advantage	19 %	23 %	18 %	19 %
Blue Shield	10 %	*	*	*
Aetna	*	10 %	*	*

* Less than 10%.

	Accounts Receivable, Net	
	June 30, 2023	December 31, 2022
Medicare	49 %	21 %
Medicare Advantage	14 %	13 %

For the three months ended June 30, 2023 and 2022, approximately 88% and 77%, respectively, of the Company's revenue was related to the AVISE® CTD test. Revenue related to the AVISE® CTD test for the six months ended June 30, 2023 and 2022 was approximately 88% and 81%, respectively.

The Company is dependent on key suppliers for certain laboratory materials. For the three months ended June 30, 2023 and 2022, approximately 95% and 97%, respectively, of the Company's diagnostic testing supplies were purchased from two suppliers. For each of the six months ended June 30, 2023 and 2022, 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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Revenue:				
Commercial	$ 7,484	$ 4,510	$ 11,699	$ 10,933
Government	4,189	1,139	8,615	3,259
Client(1)	2,273	1,755	4,680	3,346
Other(2)	191	202	373	462
Total revenue	$ 14,137	$ 7,606	$ 25,367	$ 18,000

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

Fair Value Measurements

The carrying value of the Company's cash, cash equivalents and restricted cash, accounts receivable, prepaid expenses and other current assets, accounts payable and accrued and other current liabilities approximate their fair values due to their short-term nature, which are determined to be a Level 1 measurement. The estimated fair value of the Company's long-term borrowings is determined by Level 2 inputs and based primarily on quoted market prices for the same or similar issues. As of June 30, 2023, the 2017 Term Loan (as defined below) had a carrying value of $18.5 million and a fair value of $19.1 million. As of December 31, 2022, the 2017 Term Loan had a carrying value of $28.3 million and a fair value of $26.9 million. The estimated fair value of the 2017 Term Loan was determined based on a discounted cash flow approach using available market information on discount and borrowing rates with similar terms, maturities, and credit ratings. The recorded value of the Company's other long-term borrowing was $0.9 million and approximated its fair value as of June 30, 2023. As of December 31, 2022, the recorded value of the Company's other long term borrowing was $0.8 million and approximated its fair value.

Cash, Cash Equivalents and Restricted Cash

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

The Company has an arrangement with a financial institution with which it has an existing banking relationship, whereby in exchange for the issuance of corporate credit cards, the Company agreed to obtain a certificate of deposit with this financial institution in the amount of $0.2 million as collateral for the balances borrowed on these cards. The Company has classified the value of this certificate of deposit (including all interest earned thereon) within other assets in the accompanying balance sheets. The Company has the right to terminate the credit card program at any time. Upon termination of the credit card program and repayment of all outstanding balances owed, the Company may redeem the certificate of deposit (and all interest earned thereon).

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

	June 30, 2023	December 31, 2022
Cash and cash equivalents	$ 31,466	$ 62,391
Restricted cash	200	200
	$ 31,666	$ 62,591

Long-lived Assets

The Company’s long-lived assets are comprised principally of its property and equipment and operating lease assets. The Company amortizes all finite lived intangible assets over their respective estimated useful lives. Operating lease assets are amortized over the term of the leases. In considering whether long-lived assets are impaired, we combine our intangible assets and other long-lived assets, into groupings, a determination which we principally make on the basis of whether the assets are specific to a particular test we offer or technology we are developing. If the Company identifies a change in the circumstances related to its long-lived assets that indicates the carrying value of any such asset may not be recoverable, the Company will perform an impairment analysis. A

long-lived asset is 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. Management's estimates of future cash flows are impacted by projected test volume and levels of reimbursement, as well as expectations related to the future cost structure of the entity. Any required impairment loss would be measured as the amount by which the asset's carrying value exceeds its fair value, and would be recorded as a reduction in the carrying value of the related asset and a charge to operating expense.

Revenue Recognition

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, a payor) consist of commercial payors (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. Adjustments are recorded in the current period as changes in estimates occur. Further adjustments to the allowances, based on actual receipts, are recorded upon settlement. Included in revenues for the three months ended June 30, 2023 and 2022 was a $1.5 million net revenue increase and a $1.2 million net revenue decrease, respectively, associated with changes in estimated variable consideration related to performance obligations satisfied in previous periods. Included in revenues for the six months ended June 30, 2023 and 2022 was a $1.8 million net revenue increase and a $1.6 million net revenue decrease, 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 commercial payor, Medicare, Medicaid, 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.

Accounts Receivable and Allowance for Credit Losses

We accrue an allowance for credit losses against our accounts receivable based on management's current estimate of amounts that will not be collected. Management's estimates are typically based on historical loss information adjusted for current conditions. We generally do not perform evaluations of the financial condition of our customers and generally do not require collateral. The allowance for credit losses was zero as of June 30, 2023. Adjustments for implicit price concessions attributable to variable consideration, as discussed above, are incorporated into the measurement of the accounts receivable balances and are not part of the allowance for credit losses.

Research and Development

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

Advertising and Marketing Costs

Costs associated with advertising and marketing activities are expensed as incurred. Total advertising and marketing costs were approximately $0.4 million and $0.6 million for the three months ended June 30, 2023 and 2022, respectively. For the six months ended June 30, 2023 and 2022, total advertising and marketing costs were approximately $0.7 million and $0.9 million, respectively. These costs 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 $0.6 million and $0.7 million for the three months ended June 30, 2023 and 2022, respectively. For each of the six months ended June 30, 2023 and 2022, shipping and handling costs were approximately $1.3 million.

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 is 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 BSM option pricing model incorporates various inputs, including the fair value of the Company's common stock, expected volatility, expected term and risk-free interest rates. Volatility is based on the Company's historical calculated volatility since being publicly traded. The weighted-average expected term of options was calculated using the simplified method. The risk-free interest rate for periods within the contractual term of the option is based on the U.S. Treasury yield in effect at the time of grant. The dividend yield is zero, as the Company has never declared or paid dividends and has no plans to do so in the foreseeable future.

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 that date. The Company's restricted stock units generally vest in equal annual installments over four years from the date of grant or, for grants to new hires, date of hire. Vesting of restricted stock units is 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 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, stock options, restricted stock units outstanding under the Company's 2019 Incentive Award Plan (the 2019 Plan) and shares of the Company's common stock pursuant to the ESPP. For the three and six months ended June 30, 2023 and 2022,

there is no difference in the number of shares used to calculate basic and diluted shares outstanding, as the inclusion of the potentially dilutive securities would be antidilutive.

Potentially dilutive securities not included in the calculation of diluted net loss per share, because to do so would be anti-dilutive, are as follows (in common stock equivalent shares):

	June 30, 2023	June 30, 2022
Warrants to purchase common stock	409,108	409,108
Common stock options	994,526	1,949,374
Restricted stock units	1,598,578	784,940
Employee stock purchase plan	60,719	30,303
Total	3,062,931	3,173,725

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

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. 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.

Recently Adopted Accounting Standards

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 (based on historical experience, current conditions and reasonable forecasts) for financial instruments (such as accounts receivable) held at the reporting date which are carried at amortized cost. 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 emerging growth companies, ASU 2016-13 is effective for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. The Company adopted this pronouncement on January 1, 2023. The adoption did not have an impact on its condensed financial statements.

In August 2020, the FASB issued ASU 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40)*. ASU 2020-06 eliminates the beneficial conversion and cash conversion accounting models for convertible instruments. It also amends the accounting for certain contracts in an entity's own equity that are currently accounted for as derivatives because of specific settlement provisions. In addition, ASU 2020-06 modifies how particular convertible instruments and certain contracts that may be settled in cash or shares impact the diluted EPS computation. The amendments in ASU 2020-06 are effective for smaller reporting companies as defined by the SEC for fiscal years beginning after December 15, 2023, including interim periods within those fiscal years. The Company early adopted ASU 2020-06 as of January 1, 2023. The adoption did not have an impact on its condensed financial statements.

Note 3. Other Financial Information

Prepaid Expenses and Other Current Assets

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

	June 30, 2023	December 31, 2022
Diagnostic testing supplies	$ 1,653	$ 1,795
Prepaid product royalties	39	40
Prepaid maintenance and insurance contracts	1,860	2,072
Other prepaid expenses and other current assets	18	236
Prepaid expenses and other current assets	$ 3,570	$ 4,143

Property and Equipment

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

	June 30, 2023	December 31, 2022
Furniture and fixtures	$ 98	$ 98
Laboratory equipment	6,458	5,136
Computer equipment and software	1,557	1,482
Leasehold improvements	5,284	5,223
Construction in progress	641	1,382
Total property and equipment	14,038	13,321
Less: accumulated depreciation and amortization	(6,163)	(5,124)
Property and equipment, net	$ 7,875	$ 8,197

Depreciation and amortization expense for the three months ended June 30, 2023 and 2022 was approximately $0.5 million and $0.3 million, respectively. For the six months ended June 30, 2023 and 2022, depreciation and amortization expense was approximately $1.1 million and $0.6 million, respectively.

Accrued and Other Current Liabilities

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

	June 30, 2023	December 31, 2022
Accrued payroll and related expenses	$ 3,284	$ 2,355
Accrued interest	130	142
Accrued purchases of goods and services	435	803
Accrued royalties	62	514
Accrued clinical study activity	121	162
Finance lease obligations, current portion	595	700
Legal accrual	700	—
Refund liability	254	445
Other accrued liabilities	352	226
Accrued and other current liabilities	$ 5,933	$ 5,347

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), as amended (the Amended Loan Agreement), pursuant to which the Company borrowed $25.0 million. As of June 30, 2023, no additional amounts remained available to borrow under the 2017 Term Loan.

On April 28, 2023, the Company entered into the Third Loan Amendment to the 2017 Term Loan (the Third Loan Amendment). The Third Loan Amendment was treated as a modification. Pursuant to the Third Loan Amendment, the interest rate on all borrowings under the Amended Loan Agreement is the sum (the Basic Rate) of (a) the greater of 8.0% or The Wall Street Journal prime rate (the Prime Rate), plus (b) 2.0%. Under the Amended Loan Agreement, an amount equal to 1.5% of the Basic Rate will be payable in-kind and capitalized to the principal amount of the outstanding term loan on a monthly basis until April 1, 2026, after which interest is scheduled to accrue at the Basic Rate. The maturity date of the loan was extended to December 31, 2026. As of June 30, 2023, the Company estimated the effective interest rate of this loan to be approximately 10.8%. Accrued interest is due and payable monthly, unless the Company elects to pay paid-in-kind interest. The outstanding principal and accrued interest under the Amended Loan Agreement is to be repaid in ten equal monthly installments commencing in April 2026. Upon repayment of the final installment under the Amended Loan Agreement, 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 loan using the effective interest method. For each of the three months ended June 30, 2023 and 2022, the Company issued PIK Loans totaling $0.1 million. For the six months ended June 30, 2023 and 2022, the Company issued PIK Loans totaling $0.2 million and $0.3 million, respectively.

The Amended Loan Agreement requires a prepayment premium of 2% of the aggregate outstanding principal and decreases by 1% on each of November 1, 2023 and 2024. However, this fee was waived on April 28, 2023, at which time the Company prepaid $10.0 million of principal (the Term Loan Prepayment).

The Amended Loan Agreement is collateralized by a first priority security interest in substantially all of the Company's assets, including intellectual property. The affirmative covenants of the Amended Loan Agreement 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, however the Company is not required to comply with the revenue covenant for any quarter during which it maintains a minimum aggregate cash balance equal to fifty percent of the aggregate principal amount of the 2017 Term Loan (excluding any capitalized interest paid-in-kind) at all times during such quarter. The consequences of failing to achieve the performance covenants, when applicable, will be cured if, (i) within thirty days of failing to achieve the performance covenant, the Company submits a new Board approved financial plan to Innovatus under which the Company is expected to break even on a cash flow basis prior to the maturity date, and (ii) within thirty days of the submission of such financial plan, the Company issues 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. The Amended Loan Agreement 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 Amended Loan Agreement provides that an event of default will occur if, among other triggers, (i) the Company defaults in the payment of any amount payable under the agreement when due, (ii) there occurs any circumstance(s) that could reasonably be expected to result in a material adverse effect on the Company's business, operations or condition, or on the Company's ability to perform its obligations under the agreement, (iii) the Company becomes insolvent, (iv) the Company undergoes a change in control or (v) the Company breaches any negative covenants or certain affirmative covenants in the agreement or, subject to a cure period, otherwise neglects to perform or observe any material item in the agreement.

As of June 30, 2023, the Company was in compliance with all covenants of the Amended Loan Agreement.

Upon an event of default in any of the Amended Loan Agreement covenants, the repayment of the 2017 Term Loan may be accelerated, and the applicable interest rate will be increased by 4.0% until the default is cured. Although repayment of the 2017 Term Loan 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 Third Loan Amendment due beyond twelve months of the balance sheet date as non-current.

2022 Equipment Notes Payable

In May 2022, the Company purchased laboratory equipment using notes payable. At June 30, 2023, the total notes payable balance related to this financed equipment was $1.0 million, with $0.3 million classified within borrowings-current portion and $0.7 million within borrowings-non-current portion, net of discounts and debt issuance costs in the accompanying balance sheets. The financed equipment is subject to a 5.28% effective interest rate and will mature on October 1, 2026.

Future Minimum Payments on the Outstanding Borrowings

As of June 30, 2023, future minimum aggregate payments, including interest, for outstanding borrowings are as follows (in thousands):

2023 (remaining)	$ 950
2024	1,908
2025	1,928
2026	21,215
Total	26,001
Less:	
Unamortized debt discount and issuance costs	(134)
Interest	(6,457)
Total borrowings, net of discounts and debt issuance costs	19,410
Less: Borrowings-current portion	(257)
Borrowings-non-current portion, net of discounts and debt issuance costs	$ 19,153

Note 5. 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 has ongoing royalty payment obligations 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, 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.

Collaboration Obligations

In May 2021, the Company entered into a master research collaboration agreement with Allegheny Health Network Research Institute (AHN), pursuant to which the Company is required to pay AHN a collaboration fee of $0.4 million for each year during the initial term of the agreement. Collaboration expenses under the master research collaboration agreement were $0.1 million for each of the three months ended June 30, 2023 and 2022. For each of the six months ended June 30, 2023 and 2022, collaboration expenses were $0.2 million. Collaboration expenses under the AHN collaboration are included in research and development expenses.

Supply Agreements

In December 2021, the Company entered into an amended supply agreement with one supplier for reagents which includes minimum annual purchase commitments of $6.9 million, $8.0 million and $9.2 million for the years ending December 31, 2023, 2024 and 2025, respectively.

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 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.

In February 2022, the Company received a subpoena issued by the U.S. Department of Justice (DOJ) requesting documents related to an investigation of potential federal regulatory healthcare offenses. The Company has fully cooperated with the DOJ in connection with the investigation. The DOJ revealed that there is a suit under seal in the Commonwealth of Massachusetts. The suit will remain under seal until a definitive settlement agreement is executed. In July 2023, the Company reached an agreement in principle with the DOJ to resolve this matter and recorded a charge of $0.7 million for the three and six months ended June 30, 2023 as a result. This amount is included in selling, general and administrative expenses. There can be no assurance that a definitive agreement will be executed or that the material terms of the definitive agreement will remain the same as the agreement in principle.

Note 6. Fair Value Measurements

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. Techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs.

The three-levels of the valuation hierarchy for disclosure of fair value measurements are defined 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. The following table sets forth the Company's financial instruments that were measured at fair value on a recurring basis within the fair value hierarchy (in thousands):

	June 30, 2023			
	Total	Level 1	Level 2	Level 3
Assets:				
Money market funds, included in cash and cash equivalents	$ 4,082	$ 4,082	$ —	$ —
Certificate of deposit, included in cash and cash equivalents	24,000	24,000	—	—
Total	$ 28,082	$ 28,082	$ —	$ —

	December 31, 2022			
	Total	Level 1	Level 2	Level 3
Assets:				
Money market funds, included in cash and cash equivalents	$ 29,438	$ 29,438	$ —	$ —
Certificate of deposit, included in cash and cash equivalents	30,100	30,100	—	—
Total	$ 59,538	$ 59,538	$ —	$ —

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

Note 7. Stockholders' Equity

Common Stock

At The Market Sales Agreement

On September 15, 2022, the Company entered into a sales agreement (the Sales Agreement) with Cowen and Company, LLC, 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 June 30, 2023, the Company has not sold any shares of its common stock pursuant to the Sales Agreement.

Outstanding Warrants

The following equity classified warrants to purchase common stock were outstanding as of June 30, 2023:

	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	804,951	$ 0.001	June 22, 2021	None
	1,214,059			

During the three and six months ended June 30, 2023, no warrants to purchase common stock were exercised.

Note 8. Stock Option Plan

2019 Incentive Award Plan

In September 2019, the 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. The 2019 Plan contains an "evergreen provision" that allows annual increases in the number of shares available for issuance on the first day of

each calendar year through January 1, 2029 in an amount equal to the lesser of: (i) 4% of the outstanding capital stock on each December 31st, or (ii) such lesser amount determined by the Board of Directors. As of June 30, 2023, 1,740,628 shares of common stock remained available for future awards under the 2019 Plan.

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. The number of shares of common stock available for issuance under the ESPP will be annually increased on the first day of each calendar year during the term of the ESPP through January 1, 2029 in an amount equal to the lesser of (i) 1% of the outstanding capital stock on each December 31st, or (ii) such lesser amount determined by the Board of Directors. As of June 30, 2023, 508,608 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, 2022	1,421,235	$ 12.94	7.09	$ 483
Granted	58,500	$ 3.15		
Exercised	(93,335)	$ 0.26		
Forfeited	(32,426)	$ 14.38		
Expired	(359,448)	$ 17.02		
Outstanding, June 30, 2023	994,526	$ 12.03	6.90	$ 349
Vested and expected to vest, June 30, 2023	994,526	$ 12.03	6.90	$ 349
Options exercisable, June 30, 2023	825,513	$ 12.24	6.66	$ 349

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. The aggregate intrinsic value of options exercised during the six months ended June 30, 2023 was $0.2 million. There were no options exercised during the six months ended June 30, 2022. As of June 30, 2023, total unrecognized compensation cost related to option awards was $0.9 million, which is expected to be recognized over a remaining weighted-average vesting period of 0.91 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, 2022	1,036,208	$ 7.28	$ 2,487
Awards granted	796,400	$ 2.42	
Awards released	(144,985)	$ 12.01	
Awards canceled	(89,045)	$ 9.53	
Outstanding, June 30, 2023	1,598,578	$ 4.30	$ 4,636

As of June 30, 2023, all of the outstanding restricted stock units were unvested. The fair value of restricted stock units vested in the six months ended June 30, 2023 and 2022 was $0.4 million and $0.6 million, respectively. The weighted average grant date fair value for restricted stock units granted in the six months ended June 30, 2023 and 2022 was $2.42 and $8.66, respectively. As of June 30, 2023, total unrecognized compensation cost related to restricted stock units was $6.0 million, which is expected to be recognized over a remaining weighted-average vesting period of 3.3 years.

Stock-Based Compensation Expense

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Costs of revenue	$ 63	$ 59	$ 116	$ 103
Selling, general and administrative	874	1,203	1,705	2,321
Research and development	41	178	143	392
Total	$ 978	$ 1,440	$ 1,964	$ 2,816

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, 2022 included in our Annual Report on Form 10-K for the year ended December 31, 2022.

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, current and future product offerings, reimbursement and coverage, the expected benefits from our partnership or promotion arrangements with third parties, 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 exist to provide clarity in autoimmune disease decision making with the goal of improving patients' clinical outcomes. We have developed and are commercializing a portfolio of innovative testing products under our AVISE® brand which demonstrate excellent quality and performance. We believe our focus on and experience in the field of rheumatology, combined with our commitment to excellent customer service and support, position us very well to respond to the needs of rheumatologists and the patients they serve.

Marketed under our AVISE® brand, our testing products allow for the differential diagnosis, prognosis and monitoring of complex autoimmune and autoimmune-related diseases, including systemic lupus erythematosus (SLE) and rheumatoid arthritis (RA). We commercially launched our lead testing product, AVISE® CTD, in 2012. 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. Revenue from this product comprised 88% and 81% of our revenue for the six months ended June 30, 2023 and 2022, 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 perform all of our AVISE® tests in our approximately 13,000 square foot laboratory located in Vista, California, which is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and accredited by the College of American Pathologists (CAP). Our laboratory is certified for performance of high-complexity testing by the Centers for Medicare & Medicaid Services (CMS) in accordance with CLIA and is licensed by all states requiring out-of-state licensure. Our clinical laboratory typically reports all AVISE® testing product results within five business days.

Reimbursement for our testing services comes from several sources, including commercial payors (such as insurance companies and health maintenance organizations), government payors (such as Medicare and Medicaid), and patients. Reimbursement rates vary by product and payor.

Since inception we have devoted substantially all of our efforts to developing and marketing products for the diagnosis, prognosis and monitoring of autoimmune diseases. For the six months ended June 30, 2023 and 2022, we incurred net losses of $12.7 million and $24.9 million, respectively, and we expect to continue to incur operating losses in the near term. Our operations have been funded primarily through equity financings, debt financings and revenue from product sales. We have never been profitable and, as of June 30, 2023, we had $31.5 million of cash and cash equivalents and an accumulated deficit of $268.2 million.

Our initial public offering (IPO) was completed in September 2019, raising net proceeds of approximately $50.4 million. In March 2021, we completed a secondary public offering of common stock for net proceeds of approximately $64.7 million.

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 our common stock having an aggregate offering price of up to $50.0 million. The Company is not obligated to sell any shares of common stock in the offering and, as of June 30, 2023, the Company had not sold any shares of its common stock pursuant to the Sales Agreement.

Recent Developments

During the quarter ended June 30, 2023 and in connection with our previously announced revenue cycle management initiatives, we began releasing claims previously withheld from prior periods. These revenue cycle management initiatives aim to optimize our appeals process and the potential for cash collections. The implementation of these initiatives contributed to increased accounts receivables for the three and six months ended March 31, 2023 and June 30, 2023. Commencing in July 2023, we began to receive payments related to these withheld claims for both commercial and government payors, including Medicare.

Specific to Medicare claims, our Proprietary Laboratory Analysis (PLA) for AVISE Lupus (0312U) was finalized on the Clinical Laboratory Fee Schedule (CLFS) in January of 2023. During the three months ended June 30, 2023, the claims we submitted to our Medicare Administrative Coordinator (MAC), Noridian, were subjected to a utilization review with a greater-than-typical proportion of these claims requiring additional medical records for approval. To date, we have submitted the requested medical records to Noridian for over 80% of the requested claims. We are pending final claim adjudication on the majority of submitted claims, but, to date, payments for these Medicare claims have been consistent with our CLFS established price for testing performed in 2023.

In April 2023, we discontinued development of our AVISE® RADR platform, including the associated clinical trials.

Factors Affecting Our Performance

We believe there are several important factors that have impacted, and that we expect will impact, our operating performance and results of operations, including:

- ***Reimbursement for Our Testing Products***. Our revenue depends on achieving broad coverage and reimbursement for our tests from third-party payors, including both commercial payors and government payors. Payment from third-party payors differs depending on whether we are considered a "participating provider" (have entered into a contract with the payor) or a "non-participating provider" (do not have a contract with the payor). Payors will often reimburse non-participating providers at a lower amount than participating providers, if at all. We have received a substantial portion of our revenue from a limited number of 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" in this Quarterly Report on Form 10-Q, 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, changes in our estimated reimbursements for tests

performed in prior periods can positively or negatively impact our revenue in the current period and cause our financial results to fluctuate.

- ***Continued Growth of Our Testing Products.*** Since the launch of AVISE® CTD in 2012 and through June 30, 2023, we have delivered approximately 825,000 of these tests. During the second quarter of 2023, 37,749 AVISE® CTD tests were delivered, representing approximately 8% growth over the same period in 2022. Revenue growth for our testing products will depend, in part, on our ability to continue to expand our base of ordering healthcare providers and increase our penetration with existing healthcare providers.
- ***Development of Additional Testing Products.*** We rely on sales of our AVISE® CTD test to generate the significant majority of our revenue. We expect to continue to invest in research and development in order to develop additional testing products. Our success in developing new testing products will be important in our efforts to grow our business by expanding the potential market for our products and diversifying our sources of revenue.
- ***Maintain Meaningful Margin***. We seek to maintain meaningful margin through a continued focus on increasing operating leverage through the implementation of certain internal initiatives, such as leveraging validation, utility and reimbursement oriented clinical studies to facilitate payor coverage of our testing products. We plan to center our efforts around long-term reimbursement and average sales price (ASP) growth and seek to improve our per-test costs by focusing on profitable, core test offerings and limiting fixed costs and overhead.
- ***Timing of Our Research and Development Expenses***. 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. We also expend funds to secure clinical samples that can be used in discovery, product development, clinical validation, utility and outcome studies. Our spending on experiments and clinical studies may vary substantially from quarter to quarter, as 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.
- ***How We Recognize Revenue***. We record revenue on an accrual basis, using an estimate of the amount that we will ultimately realize, as determined based on a historical analysis of amounts collected by test and by payor, among other factors. Changes to such estimates may increase or decrease revenue recognized in future periods.

While each of these areas present 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*." in this Quarterly Report on Form 10-Q, as well as in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2023 and our Annual Report on Form 10-K for the year ended December 31, 2022, filed with the SEC on March 30, 2023.

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 (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.

Inflationary Environment

The current inflationary environment has resulted in higher prices, which have impacted our costs incurred to generate revenue from our laboratory testing services, costs to attract and retain personnel, and other operating costs. The severity and duration of the current inflationary environment remains uncertain and may continue to impact our financial condition and results of operations.

Financial Overview

Revenue

We recognize revenue in accordance with the provisions of ASC Topic 606, *Revenue from Contracts with Customers.* We record revenue on an accrual basis, using an estimate of the amount we will ultimately receive, as determined based on a historical analysis of amounts collected by test and by payor, among other factors. These assessments require significant judgment by management.

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 (payors) consist of commercial payors (e.g. insurance companies, health maintenance organizations, etc.), 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.

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.

In the quarter ended March 31, 2022, CMS agreed, effective April 1, 2022, to recognize a new PLA code for our protein-based test, AVISE® Lupus. Noridian, our MAC, priced this PLA code at $1,085 per test. To determine pricing beyond 2022, CMS recommended crosswalking AVISE® Lupus (0312U) to Vectra (81490) at a rate of $840.65 per test. This pricing was finalized on the 2023 CLFS and is effective from January 1, 2023 through December 31, 2025. The process for obtaining and maintaining consistent reimbursement for new tests can be uncertain, lengthy and time consuming. A pricing determination is not synonymous with a coverage determination. Having a price associated with the PLA code for any particular test does not secure coverage or reimbursement for that PLA code from Medicare or any other third-party payor.

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 have continued to submit Medicare claims for AVISE® Lupus, appeal denials and respond to requests for additional information.

We face challenges relating to commercial payor claim processing and revenue. Now that we are billing under our PLA code, we are experiencing denials due to unfavorable medical policy with certain plans, and we expect this situation to persist.

In July 2023, we implemented increases to our patient payment rates. Although it is difficult to estimate the effect these changes will have on our operations, we anticipate the possibility of a short-term impact to revenue, as rheumatologists and patients adjust to these changes.

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, infrastructure expenses, shipping charges to transport specimens, blood specimen collections fees, royalties, depreciation and allocated overhead (including rent and utilities).

Each payor, whether commercial, 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 year-over-year in the near-term as test volume increases.

Selling, General and Administrative Expenses

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

We expect that our selling, general and administrative expenses will decrease year-over-year in the near-term as a result of cost saving initiatives which began in the fourth quarter of 2022.

Research and Development Expenses

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

We expect that our research and development expenses will increase year-over-year in the near-term as a result of product development initiatives.

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

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

Results of Operations

Comparison of the Three Months Ended June 30, 2023 and 2022 (in thousands):

	Three Months Ended June 30,		
	2023	**2022**	**Change**
Revenue	$ 14,137	$ 7,606	$ 6,531
Operating expenses:			
Costs of revenue	5,836	6,078	(242)
Selling, general and administrative expenses	11,953	12,903	(950)
Research and development expenses	1,263	2,689	(1,426)
Total operating expenses	19,052	21,670	(2,618)
Loss from operations	(4,915)	(14,064)	9,149
Interest expense	(574)	(606)	32
Other income, net	476	5	471
Net loss	$ (5,013)	$ (14,665)	$ 9,652

Revenue

Revenue increased $6.5 million, or 85.9%, for the three months ended June 30, 2023 compared to the three months ended June 30, 2022, primarily due to increased test volume, increased ASP and increased accrual rates due to improved collections from prior periods, in addition to a $4.0 million increase related to constraining revenue related to certain claims in the three months ended June 30, 2022. The number of AVISE® CTD tests delivered, which accounted for 88% of revenue and 77% of revenue in the three months ended June 30, 2023 and 2022, respectively, increased to 37,749 tests delivered in the three months ended June 30, 2023 compared to 34,919 tests delivered in the same 2022 period.

Costs of Revenue

Costs of revenue decreased $0.2 million, or 4.0%, for the three months ended June 30, 2023 compared to the three months ended June 30, 2022. This decrease was primarily due to decreases of $0.2 million in materials and supplies and $0.1 million in shipping and handling costs. Gross margin as a percentage of revenue increased to 58.7% for the three months ended June 30, 2023, compared to 20.1% for the three months ended June 30, 2022.

Selling, General and Administrative Expenses

Selling, general and administrative expenses decreased $1.0 million, or 7.4%, for the three months ended June 30, 2023 compared to the three months ended June 30, 2022. This decrease was primarily due to decreases of $1.0 million in employee-related expenses (including salaries, benefits and stock based compensation), $0.4 million in professional services, $0.2 million in commissions and $0.1 million in marketing expenses, partially offset by increases of $0.5 million in legal expenses, $0.2 million in allocated overhead and $0.1 million in audit expenses.

Research and Development Expenses

Research and development expenses decreased $1.4 million, or 53.0%, for the three months ended June 30, 2023 compared to the three months ended June 30, 2022. This decrease was primarily due to decreases of $0.8 million in employee-related expenses (including salaries, benefits and stock based compensation), $0.3 million in collaboration expenses and $0.3 million in laboratory expenses.

Interest Expense

Interest expense remained substantially consistent for the three months ended June 30, 2023 compared to the three months ended June 30, 2022.

Other Income

Other income increased by $0.5 million for the three months ended June 30, 2023 compared to the three months ended June 30, 2022, primarily due to rising interest rates earned on invested cash and cash equivalents.

Comparison of the Six Months Ended June 30, 2023 and 2022 (in thousands):

	Six Months Ended June 30,		
	2023	**2022**	**Change**
Revenue	$ 25,367	$ 18,000	$ 7,367
Operating expenses:			
Costs of revenue	11,762	11,895	(133)
Selling, general and administrative expenses	23,837	25,055	(1,218)
Research and development expenses	2,389	4,793	(2,404)
Total operating expenses	37,988	41,743	(3,755)
Loss from operations	(12,621)	(23,743)	11,122
Interest expense	(1,212)	(1,204)	(8)
Other income, net	1,132	10	1,122
Net loss	$ (12,701)	$ (24,937)	$ 12,236

Revenue

Revenue increased $7.4 million, or 40.9%, for the six months ended June 30, 2023 compared to the six months ended June 30, 2022, primarily due to increased test volume and increased accrual rates due to improved collections from prior periods, in addition to a $4.0 million increase related to constraining revenue related to certain claims in the three months ended June 30, 2022. The number of AVISE® CTD tests delivered, which accounted for 88% of revenue and 81% of revenue in the six months ended June 30, 2023 and 2022, respectively, increased to 75,061 tests delivered in the six months ended June 30, 2023 compared to 65,822 tests delivered in the same 2022 period.

Costs of Revenue

Costs of revenue decreased $0.1 million, or 1.1%, for the six months ended June 30, 2023 compared to the six months ended June 30, 2022. This decrease was primarily due to decreases of $0.3 million in materials and supplies and $0.1 million in royalties, partially offset by an increase of $0.3 million in labor costs. Gross margin as a percentage of revenue increased to 53.6% for the six months ended June 30, 2023, compared to 33.9% for the six months ended June 30, 2022.

Selling, General and Administrative Expenses

Selling, general and administrative expenses decreased $1.2 million, or 4.9%, for the six months ended June 30, 2023 compared to the six months ended June 30, 2022. This decrease was primarily due to decreases of $2.2 million in employee related expenses (including salaries, benefits and stock-based compensation), $0.2 million in marketing expenses, $0.1 million in professional services and $0.1 million in third-party billing expenses, partially offset by increases of $0.5 million in commissions, $0.4 million in legal expenses, $0.3 million in allocated overhead and $0.2 million in audit expenses.

Research and Development Expenses

Research and development expenses decreased $2.4 million, or 50.2%, for the six months ended June 30, 2023 compared to the six months ended June 30, 2022. This decrease was primarily due to decreases of $1.5 million in employee-related expenses (including salaries, benefits and stock based compensation), $0.4 million in laboratory expenses, $0.4 million in collaboration expenses and $0.2 million in clinical trial expenses, partially offset by an increase of $0.1 million in allocated overhead.

Interest Expense

Interest expense remained substantially consistent for the six months ended June 30, 2023 compared to the six months ended June 30, 2022.

Other Income

Other income increased by $1.1 million for the six months ended June 30, 2023 compared to the six months ended June 30, 2022, primarily due to rising interest rates earned on invested cash and cash equivalents.

Liquidity and Capital Resources

We have incurred net losses since our inception. For the six months ended June 30, 2023 and 2022, we incurred a net loss of $12.7 million and $24.9 million, respectively, and we expect to incur additional losses and increased operating expenses in future periods. To date, we have generated only limited revenue, and we may never achieve revenue sufficient to offset our expenses. As of June 30, 2023, we had an accumulated deficit of $268.2 million and cash and cash equivalents of $31.5 million. 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, money market funds and certificates of deposit.

Since becoming a public company, our primary sources of capital have been cash inflows from product sales, sales of our common stock and, to a lesser extent, borrowings under our 2017 Term Loan. In April 2023, we further amended the 2017 Term Loan, pursuant to which we prepaid $10.0 million of principal and amended additional terms of the agreement. See Note 4 to the unaudited condensed financial statements included in this Quarterly Report on Form 10-Q for additional information.

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 minimum liquidity of $2.0 million, 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. Per the Amended Loan Agreement, we are not required to comply with the revenue covenant for any quarter during which we maintain a minimum aggregate cash balance equal to fifty percent of the aggregate principal amount of the 2017 Term Loan funded (excluding any capitalized interest paid-in-kind) at all times during such quarter. The consequences of failing to achieve the performance covenants, when

applicable, will be cured if, (i) within thirty days of failing to achieve the performance covenant, we submit a new Board approved financial plan to Innovatus under which we are expected to break even on a cash flow basis prior to the maturity date, and (ii) within thirty days of the submission of such financial plan, we issue additional equity securities or subordinated debt with net proceeds sufficient to fund any cash flow deficiency generated from operations, as defined in the Amended Loan Agreement. As of June 30, 2023, we were in compliance with all covenants of the Amended Loan Agreement with Innovatus. 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 June 30, 2023, the Company has not sold any shares of its common stock pursuant to the Sales Agreement.

On November 10, 2020, we filed a registration statement on Form S-3 (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. In March 2021, we completed a public offering of shares of our common stock, which shares were sold under the Shelf Registration Statement. Net proceeds from the offering were approximately $64.7 million.

Funding Requirements

Our primary use of cash is to fund our operations as we continue to grow our business. We expect to continue to incur operating losses in the near term. In the short-term, we expect costs of revenue to increase year-over-year as test volume increases. We expect selling, general and administrative expenses to decrease year-over-year as a result of cost saving initiatives which began in the fourth quarter of 2022 and expect research and development expenses to increase year-over-year as a result of product development initiatives. We believe we have sufficient laboratory capacity to support increased test volume. 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 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 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, payments for finance leases related to our laboratory equipment and costs associated with legal proceedings and government investigations. 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:

- 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;
- 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;
- 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; and
- 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.

Until such time, if ever, as we can generate revenue to support our costs structure, we expect to finance our operations through equity offerings, debt financings or other capital sources, including potentially collaborations, licenses and other similar arrangements. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital

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

Cash Flows

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

	Six Months Ended June 30,	
	2023	2022
(in thousands)		
Net cash used in:		
Operating activities	$ (19,903)	$ (19,728)
Investing activities	(718)	(3,033)
Financing activities	(10,304)	(294)
Net change in cash, cash equivalents and restricted cash	$ (30,925)	$ (23,055)

Cash Flows from Operating Activities

Net cash used in operating activities for the six months ended June 30, 2023 was $19.9 million, primarily resulting from (i) our net loss of $12.7 million adjusted for non-cash charges of $3.9 million primarily related to stock-based compensation, depreciation, amortization, non-cash lease expense and non-cash interest and (ii) changes in our net operating assets of $11.1 million primarily related to net increases in accounts receivable and accrued and other current liabilities, partially offset by net decreases in accounts payable, prepaid expenses, other current assets and operating lease liabilities. The increase in accounts receivable was primarily due to delays in claim submission as part of our revenue cycle management initiatives and delayed claim processing by Medicare due to a request for medical records on submitted claims.

Net cash used in operating activities for the six months ended June 30, 2022 was $19.7 million and primarily resulted from (i) our net loss of $24.9 million adjusted for non-cash charges of $4.3 million primarily related to stock-based compensation, depreciation, amortization, non-cash lease expense and non-cash interest and (ii) changes in our net operating assets of $0.9 million primarily related to net decreases in accounts receivable, prepaid expenses and other current assets, accrued and other current liabilities and operating lease liabilities, partially offset by net increases in accounts payable.

Cash Flows from Investing Activities

Net cash used in investing activities for the six months ended June 30, 2023 and 2022 was $0.7 million and $3.0 million, respectively, due to net purchases of property and equipment.

Cash Flows from Financing Activities

Net cash used in financing activities for the six months ended June 30, 2023 was $10.3 million, primarily resulting from the Term Loan Prepayment of $10.0 million.

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

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 sheets 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 Estimates*" contained in our Annual Report on Form 10-K for the year ended December 31, 2022. There have been no significant changes in our critical accounting policies and estimates during the six months ended June 30, 2023 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, 2022 filed with the Securities and Exchange Commission (SEC) on March 20, 2023.

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 $1.235 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

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that the information we are required to disclose 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.

Our management, with the participation of our principal executive officer and our principal financial officer, evaluated, as of the end of the period covered by this Quarterly Report on Form 10-Q, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Based on that evaluation, our principal executive officer and principal financial officer have concluded that as of June 30, 2023, our disclosure controls and procedures were not effective at a reasonable level of assurance, to ensure that the information we are required to disclose 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, due to the material weakness in our internal control over financial reporting described below.

Material Weakness

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, 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 were understated for the quarter and year to date periods ended June 30, 2022.

We 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 June 30, 2023, 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).

Remediation Plan to Address the Material Weaknesses

Management has prepared and implemented the following remediation plan to address the material weakness as described below:

- Evaluated the staffing level, skills and qualification of accounting department personnel and hired additional personnel in our accounting department;
- Enhanced our existing control structure and processes for revenue recognition; and
- Improved 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 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

There have been no changes in our internal control over financial reporting during the three months ended June 30, 2023 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

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 our business resulting from defense and settlement costs, diversion of resources and other factors. There can be no assurances that favorable outcomes will be obtained.

In February 2022, the Company received a subpoena issued by the U.S. Department of Justice (DOJ) requesting documents related to an investigation of potential federal regulatory healthcare offenses. The Company has fully cooperated with the DOJ in connection with the investigation. The DOJ revealed that there is a suit under seal in the Commonwealth of Massachusetts. The suit will remain under seal until a definitive settlement agreement is executed. In July 2023, the Company reached an agreement in principle with the DOJ to resolve this matter and recorded a charge of $0.7 million for the three and six months ended June 30, 2023 as a result. This amount is included in selling, general and administrative expenses. There can be no assurance that a definitive agreement will be executed or that the material terms of the definitive agreement will remain the same as the agreement in principle.

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, 2022, other than those set forth below:

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 June 30, 2023, 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 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, 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 June 30, 2023, our internal control over financial reporting was not effective based on 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 and hiring additional personnel in our accounting department, (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.

We may, and with respect to certain matters are likely to, be required to modify our business practices, pay fines, incur significant expenses or experience losses due to litigation or governmental investigations.

From time to time and in the ordinary course of our business, we have been and may be subject to litigation or governmental investigation on a variety of matters in the United States or foreign jurisdictions, including, without limitation, regulatory, intellectual property, product liability, antitrust, consumer, false claims, whistleblower, Qui Tam, privacy, anti-kickback, anti-bribery, environmental, commercial, securities and employment litigation and claims and other legal proceedings that may arise from the conduct of our business. Our activities relating to our products and services are subject to extensive regulation in the United States and foreign jurisdictions. Like many companies in our industry, we have in the ordinary course of business received inquiries, subpoenas, civil investigative demands, and other types of information requests from government authorities. For example, in February 2022, we received a subpoena issued by the DOJ requesting documents related to an investigation of potential federal regulatory healthcare offenses. We fully cooperated with the DOJ in connection with the investigation. In July 2023 we reached an agreement in principle with the DOJ to resolve this matter. Pursuant to the agreement in principle, we agreed to make a settlement payment of approximately $0.7 million including fees and costs and admitted to certain facts, although we did not concede liability, and the DOJ did not require an outside compliance monitor to oversee our operations going forward. The DOJ revealed that there is a suit under seal in the Commonwealth of Massachusetts. The suit will remain under seal until a definitive settlement agreement is executed. The definitive settlement agreement is subject to further negotiations and therefore there is no assurance it will be completed in accordance with our agreement in principle or at all. We cannot predict when the investigation will be finally resolved, the final outcome of the investigation or its potential impact on our business which may ultimately be greater than we expect. In addition, responding to this subpoena, and any litigation or government investigation generally, diverts the attention of our management team and resources from our core business and limits the time and attention of our management team otherwise available to devote to our business. Government investigation and litigation in general may cause us to incur significant expenses, to experience significant losses, and, as a result of such matters, we may also be required to materially alter the conduct of our operations or pay significant penalties. Any of these circumstances may adversely affect our business, prospects, reputation and 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	
3.3	Amendment to Amended and Restated Bylaws, dated January 19, 2023	8-K	001-39049	3.1	1/23/2023	
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	Third Amendment to Loan and Security Agreement dated April 28, 2023, by and among Innovatus Life Sciences Lending I, LP, other lenders and the Company.	8-K	001-39049	10.1	5/4/2023	
31.1	Certificate of Principal Executive Officer, pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
31.2	Certificate of Principal Financial Officer, pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
32.1*	Certifications Pursuant to U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Public Company Accounting Reform and Investor Protection Act of 2002.					X
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.					X
101.SCH	Inline XBRL Taxonomy Extension Schema Document.					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.					X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.					X
101.LAB	Inline XBRL Taxonomy Extension Labels Linkbase Document.					X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.					X
104	The cover page from the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2023, has been formatted in Inline XBRL.					X

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

Signatures

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

EXAGEN INC.

Date: August 7, 2023 by: /s/ John Aballi

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

Date: August 7, 2023 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: August 7, 2023

/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: August 7, 2023

/s/ Kamal Adawi

Kamal Adawi

Chief Financial Officer

(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

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

1. The accompanying quarterly report on Form 10-Q of the Company for the quarterly period ended June 30, 2023 (the "Report") fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

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

Dated: August 7, 2023

/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 June 30, 2023 (the "Report") fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

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

Dated: August 7, 2023

/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.