

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

FORM 10-Q

(Mark One)

- ☒ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2024
- ☐ 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
(State or Other Jurisdiction of
Incorporation or Organization)

1261 Liberty Way
Vista, CA
(Address of Principal Executive Offices)

20-0434866
(I.R.S. Employer
Identification No.)

92081
(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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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

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

Total shares of common stock outstanding as of the close of business on November 8, 2024 was 17,637,278.

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Part I. Financial Information
Item 1. Unaudited Condensed Financial Statements
Exagen Inc.

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

	September 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	\$ 22,035	\$ 36,493
Accounts receivable, net	9,387	6,551
Prepaid expenses and other current assets	4,135	4,797
Total current assets	35,557	47,841
Property and equipment, net	4,855	5,201
Operating lease right-of-use assets	2,630	3,286
Other assets	563	616
Total assets	\$ 43,605	\$ 56,944
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,105	\$ 3,131
Accrued and other current liabilities	6,177	7,531
Operating lease liabilities	1,065	976
Borrowings-current portion	430	264
Total current liabilities	8,777	11,902
Borrowings-non-current portion, net of discounts and debt issuance costs	19,823	19,231
Operating lease liabilities - non-current portion	1,952	2,760
Other non-current liabilities	185	357
Total liabilities	30,737	34,250
Commitments and contingencies (Note 5)		
Stockholders' equity:		
Preferred stock, \$0.001 par value per share; 10,000,000 shares authorized, no shares issued or outstanding as of September 30, 2024 and December 31, 2023	—	—
Common stock, \$0.001 par value per share; 200,000,000 shares authorized as of September 30, 2024 and December 31, 2023; 17,520,335 and 17,045,954 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	18	17
Additional paid-in capital	303,420	301,893
Accumulated deficit	(290,570)	(279,216)
Total stockholders' equity	12,868	22,694
Total liabilities and stockholders' equity	\$ 43,605	\$ 56,944

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

Exagen Inc.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Revenue	\$ 12,507	\$ 13,416	\$ 41,986	\$ 38,783
Operating expenses:				
Costs of revenue	5,526	5,710	17,351	17,472
Selling, general and administrative expenses	10,163	11,375	31,169	35,212
Research and development expenses	1,481	1,400	3,719	3,789
Total operating expenses	17,170	18,485	52,239	56,473
Loss from operations	(4,663)	(5,069)	(10,253)	(17,690)
Interest expense	(562)	(557)	(1,671)	(1,769)
Interest income	197	211	570	1,343
Net loss	\$ (5,028)	\$ (5,415)	\$ (11,354)	\$ (18,116)
Net loss per share, basic and diluted	\$ (0.28)	\$ (0.31)	\$ (0.63)	\$ (1.03)
Weighted-average number of shares used to compute net loss per share, basic and diluted	18,254,937	17,692,603	18,127,549	17,626,686

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, 2023	17,045,954	\$ 17	\$ 301,893	\$ (279,216)	\$ 22,694
Issuance of stock from vested restricted stock units	217,056	—	—	—	—
Issuance of stock under Employee Stock Purchase Plan	54,605	—	104	—	104
Exercise of stock options	326	—	—	—	—
Stock-based compensation	—	—	553	—	553
Net loss	—	—	—	(3,360)	(3,360)
Balances as of March 31, 2024	17,317,941	17	302,550	(282,576)	19,991
Issuance of stock from vested restricted stock units	62,998	—	—	—	—
Exercise of stock options	636	—	—	—	—
Stock-based compensation	—	—	560	—	560
Net loss	—	—	—	(2,966)	(2,966)
Balances as of June 30, 2024	17,381,575	17	303,110	(285,542)	17,585
Issuance of stock from vested restricted stock units	13,155	—	—	—	—
Issuance of stock under Employee Stock Purchase Plan	41,443	1	71	—	72
Exercise of stock options	84,162	—	22	—	22
Stock-based compensation	—	—	217	—	217
Net loss	—	—	—	(5,028)	(5,028)
Balances as of September 30, 2024	17,520,335	\$ 18	\$ 303,420	\$ (290,570)	\$ 12,868

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	Accumulated	Total
	Shares	Amount	Paid-In Capital	Deficit	Stockholders' Equity
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	—	—	—	—
Exercise of stock options	93,335	—	27	—	27
Issuance of stock under Employee Stock Purchase Plan	70,317	—	152	—	152
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
Issuance of stock from vested restricted stock units	14,424	—	—	—	—
Issuance of stock under Employee Stock Purchase Plan	59,276	—	127	—	127
Stock-based compensation	—	—	890	—	890
Net loss	—	—	—	(5,415)	(5,415)
Balances as of September 30, 2023	16,931,894	\$ 17	\$ 301,130	\$ (273,643)	\$ 27,504

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

Exagen Inc.
Unaudited Condensed Statements of Cash Flows
(in thousands)

	Nine Months Ended September 30,	
	2024	2023
Cash flows from operating activities:		
Net loss	\$ (11,354)	\$ (18,116)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,309	1,661
Amortization of debt discount and debt issuance costs	112	119
Non-cash interest expense	206	294
Loss on disposal of assets	111	209
Non-cash lease expense	656	717
Stock-based compensation	1,330	2,854
Changes in assets and liabilities:		
Accounts receivable, net	(2,836)	(10,967)
Prepaid expenses and other current assets	662	727
Other assets	50	(120)
Operating lease liabilities	(720)	(767)
Accounts payable	(2,028)	(1,422)
Accrued and other current liabilities	(1,140)	2,000
Net cash used in operating activities	(13,642)	(22,811)
Cash flows from investing activities:		
Purchases of property and equipment	(369)	(722)
Proceeds from disposal of property and equipment	—	2
Net cash used in investing activities	(369)	(720)
Cash flows from financing activities:		
Proceeds from exercise of stock options	22	27
Proceeds from common stock issued under Employee Stock Purchase Plan	176	279
Principal payments on finance lease obligations	(379)	(541)
Principal payment on note payable obligations	(266)	(177)
Principal payment on long-term debt	—	(10,000)
Net cash used in financing activities	(447)	(10,412)
Net change in cash, cash equivalents and restricted cash	(14,458)	(33,943)
Cash, cash equivalents and restricted cash, beginning of period	36,693	62,591
Cash, cash equivalents and restricted cash, end of period	\$ 22,235	\$ 28,648
Supplemental disclosure of cash flow information:		
Cash paid for interest	\$ 1,307	\$ 1,336
Supplemental disclosure of non-cash items:		
Equipment purchased under notes payable obligations	\$ 706	\$ 250
Costs incurred, but not paid, in connection with capital expenditures	\$ 20	\$ 81

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. As of September 30, 2024, the Company had cash and cash equivalents of \$22.0 million and had an accumulated deficit of \$290.6 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 may need 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, 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 September 30, 2024, condensed statements of operations and stockholders' equity for the three and nine months ended September 30, 2024 and 2023, cash flows for the nine months ended September 30, 2024 and 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, 2023, included in its Annual Report on Form 10-K filed with the SEC on March 18, 2024. In management's opinion, the unaudited interim condensed financial statements have been prepared on the same basis as the audited financial statements and include all normal adjustments necessary for the fair presentation of the Company's financial position as of September 30, 2024 and its results of operations for the periods presented. The results for the three and nine months ended September 30, 2024 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		Nine Months Ended	
	September 30,		September 30,	
	2024	2023	2024	2023
Medicare Advantage	22 %	15 %	21 %	17 %
Medicare	20 %	37 %	24 %	35 %

* Less than 10%.

	Accounts Receivable, Net			
	September 30, 2024		December 31, 2023	
Medicare	23 %		42 %	
Medicare Advantage	22 %		16 %	

* Less than 10%.

For the three months ended September 30, 2024 and 2023, approximately 93% and 89%, respectively, of the Company's revenue was related to the AVISE® CTD test. Revenue related to the AVISE® CTD test for the nine months ended September 30, 2024 and 2023 was approximately 91% and 88%, respectively.

The Company is dependent on key suppliers for certain laboratory materials. For the three months ended September 30, 2024 and 2023, approximately 98% and 98%, respectively, of the Company's diagnostic testing supplies were purchased from two suppliers. For the nine months ended September 30, 2024 and 2023, approximately 97% and 97%, respectively, of the Company's diagnostic testing supplies were purchased from two suppliers. An interruption in the supply of these materials would impact the Company's ability to perform testing services.

Disaggregation of Revenue

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Revenue:				
Commercial	\$ 6,779	\$ 6,090	\$ 22,314	\$ 17,789
Government	2,633	4,955	10,276	13,570
Client(1)	2,981	2,319	9,175	6,999
Other(2)	114	52	221	425
Total revenue	\$ 12,507	\$ 13,416	\$ 41,986	\$ 38,783

(1) Includes hospitals, other laboratories, etc.

(2) Includes patient self-pay.

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):

	September 30, 2024	December 31, 2023
Cash and cash equivalents	\$ 22,035	\$ 36,493
Restricted cash	200	200
	<u>\$ 22,235</u>	<u>\$ 36,693</u>

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, the Company combines its intangible assets and other long-lived assets, into groupings, a determination which is made principally on the basis of whether the assets are specific to a particular test offered or technology being developed. 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 (hospitals, other laboratories, etc.) and patient self-pay.

The Company recognizes revenue in accordance with Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers* and follows a five-step process to determine the amount and timing of revenue recognized: (1) identify the contract with the customer, (2) identify the performance obligations in the contract, (3) determine the transaction price, (4) allocate the transaction price to performance obligations in the contract, and (5) recognize revenue when (or as) the performance obligation is satisfied. 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 generally billed at the Company's list price unless a separate pricing contract is in place. 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 September 30, 2024 and 2023 was a \$0.6 million net revenue increase and a \$ 2.5 million net revenue increase, respectively, associated with changes in estimated variable consideration related to performance obligations satisfied in previous periods. Included in revenues for the nine months ended September 30, 2024 and 2023 was a \$6.2 million net revenue increase and a \$ 2.6 million net revenue increase, 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, along with any requested medical or other claims-related information to the healthcare insurers. This generally occurs within 30 to 90 days of billing, however, the amount and timing of any reimbursements or collections for the Company's billed tests may vary by payor and other circumstances. 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 September 30, 2024 and 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; depreciation; amortization 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 \$0.5 million for the three months ended September 30, 2024 and 2023, respectively. For the nine months ended September 30, 2024 and 2023, total advertising and marketing costs were approximately \$1.0 million and \$1.2 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 were approximately \$0.9 million and \$0.6 million for the three months ended September 30, 2024 and 2023, respectively. For the nine months ended September 30, 2024 and 2023, shipping and handling costs were approximately \$2.5 million and \$1.9 million, respectively.

Stock-Based Compensation

The Company recognizes compensation expense for all stock-based awards to employees and directors based on the grant-date estimated fair values over the requisite service period of the awards (usually the vesting period) on a straight-line basis. The fair value of stock options and purchases under the Company's 2019 Employee Stock Purchase Plan (ESPP) rights 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, as we have concluded that our stock option exercise history does not provide a reasonable basis upon which to estimate the expected term. 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 (RSU) is determined on the grant date using the closing price of the Company's common stock on that date. The Company's RSUs 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 the RSU is subject to the holder's continued service with the Company. The Company issues new shares of common stock to satisfy the RSUs 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, RSUs outstanding under the Company's 2019 Incentive Award Plan (the 2019 Plan) and shares of the Company's common stock pursuant to the ESPP. For the three and nine months ended September 30, 2024 and 2023, there is no difference in the number of shares used to calculate basic and diluted shares outstanding, as the inclusion of the potentially dilutive securities would be antidilutive.

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

	September 30, 2024	September 30, 2023
Warrants to purchase common stock	325,330	409,108
Common stock options	576,151	1,004,855
Restricted stock units	1,810,468	1,568,112
Employee stock purchase plan	12,570	12,542
Total	2,724,519	2,994,617

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, Accounting Standards Updates (ASU) not included in the Company's disclosures were assessed and determined to be either not applicable or are not expected to have a material impact on the Company's financial statements or disclosures.

In November 2023, the FASB issued ASU No. 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures* (ASU 2023-07), which requires public entities to disclose significant segment expenses that are regularly provided to the Chief Operating Decision Maker (CODM) and details of how the CODM uses financial reporting to assess the performance of a segment. ASU 2023-07 is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. This ASU will likely result in additional required disclosure when adopted.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* (ASU 2023-09), which requires additional income tax disclosures in the rate reconciliation table for federal, state and foreign income taxes, in addition to more details about the reconciling items in some categories when items meet a certain quantitative threshold. ASU 2023-09 is effective for annual periods beginning after December 15, 2024 with early adoption permitted. The Company does not expect that this standard will have a material impact on its 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):

	September 30, 2024	December 31, 2023
Diagnostic testing supplies	\$ 2,934	\$ 2,871
Prepaid product royalties	32	35
Prepaid maintenance and insurance contracts	1,169	1,860
Other prepaid expenses and other current assets	—	31
Prepaid expenses and other current assets	<u>\$ 4,135</u>	<u>\$ 4,797</u>

Property and Equipment

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

	September 30, 2024	December 31, 2023
Furniture and fixtures	\$ 98	\$ 98
Laboratory equipment	4,209	5,312
Computer equipment and software	2,113	2,185
Leasehold improvements	3,089	3,316
Construction in progress	945	59
Total property and equipment	10,454	10,970
Less: accumulated depreciation and amortization	(5,599)	(5,769)
Property and equipment, net	\$ 4,855	\$ 5,201

Depreciation and amortization expense for the three months ended September 30, 2024 and 2023 was approximately \$ 0.4 million and \$0.6 million, respectively. For the nine months ended September 30, 2024 and 2023, depreciation and amortization expense was approximately \$1.3 million and \$1.7 million, respectively.

Accrued and Other Current Liabilities

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

	September 30, 2024	December 31, 2023
Accrued payroll and related expenses	\$ 4,413	\$ 4,738
Accrued purchases of goods and services	547	720
Finance lease obligations, current portion	283	490
Refund liability	266	302
Other accrued liabilities	668	1,281
Accrued and other current liabilities	\$ 6,177	\$ 7,531

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 September 30, 2024, no additional amounts remained available to borrow under the Amended Loan Agreement.

On April 28, 2023, the Company entered into the Amended Loan Agreement. The Amended Loan Agreement was treated as a modification. In connection with the Amended Loan Agreement, the Company repaid \$10.0 million of the principal balance outstanding, for which the prepayment premium was waived. Pursuant to the Amended Loan Agreement, 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%, which is paid-in-kind in the form of additional term loans (PIK Loans). 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. The Company estimated the effective interest rate of this loan to be approximately 10.6% as of September 30, 2024. 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 September 30, 2024 and 2023, the Company issued PIK Loans totaling \$0.1 million. For the nine months ended September 30, 2024 and 2023, the Company issued PIK Loans totaling \$0.2 million and \$0.3 million, respectively. The issuances of the PIK Loans are included in borrowings-non-current portion on the accompanying balance sheet.

The Amended Loan Agreement requires a prepayment premium of 1% of the aggregate outstanding principal for any prepayments made prior to November 1, 2024.

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 Amended Loan Agreement (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 financial plan approved by the Company's board of directors (the Board) 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 September 30, 2024, 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 Amended Loan Agreement due beyond twelve months of the balance sheet date as non-current.

Equipment Notes Payable

In April 2024, the Company purchased additional laboratory equipment using notes payable. At September 30, 2024, the total notes payable balance related to the financed equipment was \$1.2 million, with \$0.4 million classified within borrowings-current portion and \$0.8 million within borrowings-non-current portion, net of discounts and debt issuance costs in the accompanying balance sheets. The notes related to the financed equipment are subject to a 5.28% effective interest rate and will mature between October 1, 2026 and April 1, 2028.

Future Minimum Payments on the Outstanding Borrowings

As of September 30, 2024, future minimum aggregate payments, including interest, for outstanding borrowings are as follows (in thousands):

2024 (remaining)	\$	517
2025		2,097
2026		21,400
2027		215
2028		67
Total		24,296
Less:		
Unamortized debt discount and issuance costs		(80)
Interest		(3,963)
Total borrowings, net of discounts and debt issuance costs		20,253
Less: Borrowings-current portion		(430)
Borrowings-non-current portion, net of discounts and debt issuance costs	\$	19,823

Note 5. Commitments and Contingencies

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 2.0% to 7.0% on net sales of products which incorporate licensed technology, as defined in such agreements. Royalties are accrued when incurred 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 per year. Collaboration expenses under the master research collaboration agreement were \$0.1 million for each of the three months ended September 30, 2024 and 2023. For each of the nine months ended September 30, 2024 and 2023, collaboration expenses under the master research collaboration agreement were \$0.3 million. Collaboration expenses under the AHN collaboration are included in research and development expenses.

Supply Agreements

In August 2024, the Company amended a supply agreement with one supplier for reagents, which includes pricing terms and minimum purchase commitments, through December 31, 2025, for new consumable products related to the Company's launch of the RA Sub-Profile Biomarkers. Aggregate minimum annual purchase commitments related to such agreement for the years ending December 31, 2024 and 2025 are \$8.4 million and \$10.4 million, 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 addition, in October 2023, the Company resolved an investigation with the U.S. Attorney's Office for the District of Massachusetts that was initiated by a qui tam lawsuit. Pursuant to a settlement agreement entered into by and between the Company and the U.S. Department of Justice (the Settlement Agreement), the Company made a single lump-sum remittance to the government in the amount of \$0.7 million, including interest, in connection with specimen processing arrangements that Exagen historically had with physicians. The U.S. Attorney's Office dismissed this "covered conduct" in the qui tam lawsuit with prejudice, while non-covered conduct was dismissed without prejudice. The Department of Justice excused itself from the case in connection with the settlement. In November 2023, the complaint was unsealed by the court and served on Exagen by the relator. Exagen filed a motion to dismiss the complaint. In December 2023, the Company's insurance carrier provided reimbursement for certain defense costs the Company incurred in the October 2023 qui tam lawsuit. In February 2024, the relator filed a motion for leave to amend the complaint. Exagen opposed this motion, and all motions are still pending. The Company cannot predict when these matters will be resolved, the outcome of these matters, or their potential impact, which may materially and adversely affect the Company's business, prospects, and financial condition. The Company intends to vigorously defend against the claims being asserted in the complaint.

The Company's participation in federal healthcare programs is not affected by the Settlement Agreement.

Note 6. 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 September 30, 2024, the 2017 Term Loan had a carrying value of \$19.0 million and a fair value of \$18.5 million. As of December 31, 2023, the 2017 Term Loan had a carrying value of \$18.7 million and a fair value of \$19.7 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 carrying value of the Company's other long-term borrowing at September 30, 2024 was \$1.2 million and approximated its fair value. At December 31, 2023, the carrying value of the Company's other long-term borrowing was \$0.8 million and approximated its fair value.

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 1 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):

	September 30, 2024			
	Total	Level 1	Level 2	Level 3
Assets:				
Money market funds, included in cash and cash equivalents	\$ 14,963	\$ 14,963	\$ —	\$ —

	December 31, 2023			
	Total	Level 1	Level 2	Level 3
Assets:				
Money market funds, included in cash and cash equivalents	\$ 14,386	\$ 14,386	\$ —	\$ —

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

Note 7. Stockholders' Equity

Common Stock

Shelf Registration Statement

On November 17, 2023, the Company filed a registration statement on Form S-3, as amended (the 2023 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. The 2023 Shelf Registration Statement became effective on November 29, 2023, and all \$150.0 million remain available for sale as of September 30, 2024.

At The Market Sales Agreement

On September 15, 2022, the Company entered into a sales agreement, as amended on November 17, 2023 (the Sales Agreement) with Cowen and Company, LLC, as sales agent, pursuant to which the Company may offer and sell, from time to time, shares of Company common stock having an aggregate offering price of up to \$50.0 million. The Company is not obligated to sell any shares of Company common stock in the offering. As of September 30, 2024, 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 September 30, 2024:

	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	20,944	\$ 14.32	December 7, 2018	December 7, 2025
Common stock warrants	804,951	\$ 0.001	June 22, 2021	None
	1,130,281			

During the three and nine months ended September 30, 2024, no warrants to purchase common stock were exercised.

Note 8. Stock Option Plan

2019 Incentive Award Plan

In September 2019, the Board 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, RSUs 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 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. As of September 30, 2024, 2,122,271 shares of common stock remained available for future awards under the 2019 Plan.

Restricted Stock Units

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

	Number of Shares	Weighted- Average Grant Date Fair Value
Outstanding, December 31, 2023	1,387,459	\$ 4.24
Awards granted	1,287,225	\$ 2.09
Awards released	(293,209)	\$ 5.87
Awards canceled	(571,007)	\$ 4.16
Outstanding, September 30, 2024	1,810,468	\$ 2.47

As of September 30, 2024, all of the outstanding RSUs were unvested. The fair value of RSUs vested in the nine months ended September 30, 2024 and 2023 was \$0.5 million and \$0.4 million, respectively. The weighted average grant date fair value for RSUs granted in the nine months ended September 30, 2024 and 2023 was \$2.09 and \$2.42, respectively. As of September 30, 2024, total unrecognized compensation cost related to RSUs was \$3.7 million, which is expected to be recognized over a remaining weighted-average vesting period of 3.0 years.

Stock Options

Stock option activity under the 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, 2023	986,819	\$ 11.87	6.44	\$ 228
Granted	55,500	\$ 1.99		
Exercised	(85,124)	\$ 0.26		
Forfeited	(9,518)	\$ 16.70		
Expired	(371,526)	\$ 15.48		
Outstanding, September 30, 2024	576,151	\$ 10.23	6.57	\$ 197
Vested and expected to vest, September 30, 2024	576,151	\$ 10.23	6.57	\$ 197
Options exercisable, September 30, 2024	552,686	\$ 10.56	6.45	\$ 177

There were 55,500 and 73,500 stock options granted in the nine months ended September 30, 2024 and 2023, respectively. 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 nine months ended September 30, 2024 was \$0.3 million. The aggregate intrinsic value of options exercised during the nine months ended September 30, 2023 was \$0.2 million. As of September 30, 2024, total unrecognized compensation cost related to option awards was less than \$0.1 million, which is expected to be recognized over a remaining weighted-average vesting period of 2.29 years.

2019 Employee Stock Purchase Plan

In September 2019, the Board adopted, and the Company's stockholders approved, the ESPP. The ESPP became effective on the day the ESPP was adopted by the Board. 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. As of September 30, 2024, 523,744 shares of common stock remained available for issuance under the ESPP.

Stock-Based Compensation Expense

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Costs of revenue	\$ 47	\$ 45	\$ 103	\$ 161
Selling, general and administrative	114	792	1,058	2,497
Research and development	56	53	169	196
Total	<u>\$ 217</u>	<u>\$ 890</u>	<u>\$ 1,330</u>	<u>\$ 2,854</u>

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 included in our Annual Report on Form 10-K for the year ended December 31, 2023.

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 (the Exchange Act). All statements other than statements of historical facts contained in this quarterly report, including statements regarding our future results of operations and financial position, estimates regarding profitability and the time that may elapse before we may become profitable, 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 I, Item 1A, "Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2023 and Part II, Item 1A, "Risk Factors" in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2024. 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 allow for the differential diagnosis, prognosis and monitoring of complex autoimmune and autoimmune-related diseases. 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. There is an unmet need for rheumatologists to add clarity in their connective tissue disease (CTD) clinical evaluation, and we believe there is a significant opportunity for our tests in this market, particularly for potentially life-threatening diseases such as systemic lupus erythematosus (SLE).

Since inception we have devoted substantially all of our efforts to developing and marketing products for the diagnosis, prognosis and monitoring of autoimmune diseases. We commercially launched our lead testing product, AVISE® CTD, in 2012. Our proprietary AVISE® Lupus test is included as part of the AVISE® CTD panel and employs a patent-protected method for diagnosing patients with SLE based on levels of CB-CAPs (e.g. EC4d and BC4d), ANA, and ds-DNA. The AVISE® Lupus test also employs patent-protected algorithms used to generate risk scores to diagnose patients with SLE based on the levels of the biomarkers. These proprietary, patent-protected methods vastly improve the diagnostic sensitivity of our test compared to the current standard of care. AVISE® CTD enables differential diagnosis for patients presenting with symptoms indicative of a wide variety of CTDs and other related diseases with overlapping symptoms. Revenue from this product comprised 91% and 88% of our revenue for the nine months ended September 30, 2024 and 2023, respectively. For the nine months ended September 30, 2024 and 2023, we incurred net losses of \$11.4 million and \$18.1 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 September 30, 2024, we had \$22.0 million of cash and cash equivalents and an accumulated deficit of \$290.6 million.

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), client payors (such as hospitals, other laboratories, etc.) and patients. Reimbursement rates vary by product and payor.

All of our AVISE® tests are performed 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

In addition to providing diagnostic testing, we are leveraging our clinical laboratory to enter into agreements in the normal course of business with leading pharmaceutical companies and contract research organizations for the use of our testing products and/or the data generated from such tests. We believe the quality of our testing, proprietary offerings and specialized knowledge give us an advantage in this space. We plan to continue to pursue additional partnerships with leading pharmaceutical companies and academic research centers that are synergistic with our evolving portfolio of testing products, as more of these organizations realize the extent of the service we can provide.

We market our AVISE® testing products using our specialized sales force covering 40 territories in the United States. Many diagnostic sales forces are trained only to understand the comparative benefits of the tests they promote. In contrast, the specialized backgrounds of our sales personnel, coupled with our comprehensive training, enables our sales representatives to interpret results from our de-identified patient test reports and provide unique insights in a highly tailored discussion with rheumatologists. 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.

Recent Developments

TC4d, TIgG and TIgM Biomarkers

Our collaborative efforts with the Allegheny Health Network Research Institute (AHN) have resulted in further development of three innovative biomarkers, TC4d, TIgG, and TIgM (the T-Cell Biomarkers), for which we obtained an exclusive, worldwide license from AHN in May 2021. These biomarkers have been clinically validated, exhibit a high degree of specificity for lupus and are more sensitive for lupus compared to conventional biomarkers. TC4d is patent protected through 2035, representing a proprietary expansion of CB-CAPs, involving a biochemical process wherein complement activation products are measured on T-cells. We currently plan to incorporate these three biomarkers into our AVISE® CTD test towards the end of 2024. Once incorporated, we believe these biomarkers will significantly enhance the diagnostic sensitivity for lupus of our AVISE® CTD tests beyond its current 80% sensitivity.

RA Sub-Profile

Approximately 70% of rheumatoid arthritis (RA) patients show serological evidence of RA, identified by key biomarkers: anti-CCP and Rheumatoid Factor. The remaining 30% of patients, despite lacking these serological markers, are clinically diagnosed with RA; this subgroup is referred to as "seronegative RA." These patients often face delays in diagnosis due to the absence of serological evidence. In cases of early inflammatory arthritis, differential diagnosis is broad, including conditions like reactive arthritis, crystal arthropathy, spondyloarthropathy, and other systemic rheumatic diseases such as SLE and Sjogren's syndrome, alongside seronegative RA. We have identified three unique biomarkers specific to seronegative RA (the RA Sub-Profile Biomarkers) that help bridge this diagnostic gap and would enable AVISE® CTD to correctly identify approximately a third of the traditional seronegative RA subgroup. We currently plan to incorporate these new biomarkers into our AVISE® CTD test toward the end of 2024, allowing for more timely and targeted treatment plans for these patients. We've submitted our validation for our rheumatoid arthritis assay utilizing RA33 antibodies to the New York State Department of Health for conditional approval. We intend to commercialize the assay once conditional approval is received in accordance with the FDA final rule on laboratory developed tests.

We believe that the addition of the biomarkers discussed above will further differentiate our core test offerings in the market and be accretive to our financial performance, as well as have a positive impact on the average sales price of AVISE® CTD and revenue. Additionally, we anticipate progressive incremental improvements in demand for AVISE® CTD over time, as we educate physicians about the benefits these new markers provide. Given the financial impact we expect from the planned launch of these new biomarkers, we estimate that we will achieve positive cash flows within a year of launching both the T-Cell Biomarkers and the RA Sub-Profile Biomarkers. This estimate

assumes, among other things, that we are able to incrementally increase the average selling price per test. This estimate may ultimately be incorrect.

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 payors as a participating provider) or a "non-participating provider" (do not have a contract and are considered a "non-participating provider"). 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. 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. In addition, in connection with our revenue cycle management initiatives, we've held claims in the first half of the year which has resulted in increases in our accounts receivable and an accelerated decrease in our cash in the first half of the year. As expected, this trend has begun to reverse in the third quarter of 2024 and we expect it to continue to reverse, as cash is collected on billed tests through the remainder of the year.
- **Continued Growth of Our Testing Products.** Since the launch of AVISE® CTD in 2012 and through September 30, 2024, we have delivered approximately 980,714 of these tests. During the three months ended September 30, 2024, the number of AVISE® CTD tests delivered declined by approximately 6% over the same period in 2023. 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, in addition to our ability to successfully and timely launch the T-Cell Biomarkers and RA Sub-Profile Biomarkers we plan to add to our AVISE® CTD test.
- **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 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 that supports 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, and 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 our Quarterly Report on Form 10-Q for the six months ended June 30, 2024, filed with the SEC on August 5, 2024 and our Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on March 18, 2024.

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 Accounting Standards Codification 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 and their physician assistants in the United States. The healthcare professionals 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 (insurance companies, health maintenance organizations, etc.), government payors (primarily Medicare and Medicaid), client payors (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 April 2022, we were granted a Proprietary Laboratory Code (PLA) code for our protein-based test, AVISE[®] Lupus. Noridian, our Medicare Administrative Contractor, has set the current pricing for this PLA code at \$840.65 per test 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.

We submitted a formal request to Noridian for coverage of our AVISE[®] Lupus test under the new PLA Code, and on September 27, 2022, we received notice that Noridian has deemed our application for a Local Coverage Determination (LCD) to be valid, but our application is still pending. Ultimately receiving a favorable LCD is uncertain and may be time-consuming, resource intensive and require multiple quarterly or annual periods to

complete and is subject to risks and uncertainties described in the section entitled “*Risk Factors*” in this Quarterly Report on Form 10-Q. In the meantime, we have continued to submit Medicare claims for AVISE® Lupus, appeal denials and respond to requests for additional information. On January 31, 2024, CMS released a coverage article under which all multi-analyte proteomic testing will be considered within the scope of molecular diagnostic services (MoIDX) and reviewed through their technology assessment process. The article listed several such tests, including the AVISE® Lupus test, and requires all laboratories furnishing multi-analyte proteomics testing in MoIDX jurisdictions to register with the DEX® Diagnostics Exchange Registry and obtain a Z-Code® identifier. We were issued a Z-Code® in May 2024. To determine if the submitted tests are compliant with relevant policy requirements, these tests will undergo technical assessment by Palmetto GBA as part of the MoIDX program.

We face consistent challenges relating to commercial payor claim processing and revenue. While collectability has improved with certain plans year-over-year, we continue to experience denials due to unfavorable medical policy with certain plans, and we expect this situation to persist.

During the year ended December 31, 2023, we implemented several revenue cycle management initiatives, including among others, withholding the submission of commercial payor claims for reimbursement until subsequent quarters, increasing appeals efforts, adjusting the documentation required of physicians when ordering our tests and implementing increases to our patient payment rates. Additionally, in November 2023, we increased the list price billed for our tests. These ongoing revenue cycle management initiatives aim to optimize our appeals process and the potential for cash collections. We’ve experienced moderate declines in test volume since the second half of 2023, as rheumatologists and patients adjust to these changes. The number of AVISE® CTD tests delivered during the three months ended September 30, 2024 declined by approximately 6% as compared to the number of AVISE® CTD tests delivered during the three months ended June 30, 2024 due to seasonal factors, including increased out-of-office time for physicians and weather-related events in the south-east of the United States.

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 in the near-term, primarily due to projected increases in cost-per-test resulting from the expected additions of our T-Cell Biomarkers and RA Sub-Profile Biomarkers to AVISE® CTD.

Selling, General and Administrative Expenses

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

We expect that our selling, general and administrative expenses will increase in the near-term, primarily due to expected additions to headcount and associated increases for personnel costs, including stock-based compensation.

Research and Development Expenses

Research and development expenses include costs incurred to develop our technology, test products and product candidates, 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-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). We expense all research and development costs in the periods in which they are incurred.

We expect that our research and development expenses will remain relatively consistent in the near-term.

Interest Expense

Interest expense consists of cash and non-cash interest expense associated with our financing arrangements, including the borrowings under our Amended Loan Agreement with Innovatus.

Interest Income

Interest income consists of interest income earned on our cash and cash equivalents.

Results of Operations

Comparison of the Three Months Ended September 30, 2024 and 2023 (in thousands):

	Three Months Ended September 30,		Change
	2024	2023	
Revenue	\$ 12,507	\$ 13,416	\$ (909)
Operating expenses:			
Costs of revenue	5,526	5,710	(184)
Selling, general and administrative expenses	10,163	11,375	(1,212)
Research and development expenses	1,481	1,400	81
Total operating expenses	17,170	18,485	(1,315)
Loss from operations	(4,663)	(5,069)	406
Interest expense	(562)	(557)	(5)
Interest income	197	211	(14)
Net loss	\$ (5,028)	\$ (5,415)	\$ 387

Revenue

Revenue decreased \$0.9 million, or 6.8%, for the three months ended September 30, 2024 compared to the three months ended September 30, 2023, primarily due to a \$1.2 million decrease related to revenue and accounts receivable adjustments recorded in the third quarter of 2024. Excluding these adjustments, revenue increased \$0.3 million due to improved ASP (including prior period cash collections), partially offset by decreased AVISE® CTD year-over-year volume. The \$1.2 million decrease in revenue and accounts receivable adjustments were comprised of a \$0.9 million reserve recognized related to accounts receivable for AVISE® CTD testing, in addition to a \$0.3 million reversal of other testing revenue relating to a current procedural terminology coding discrepancy for AVISE® Vasculitis. The number of AVISE® CTD tests delivered, which accounted for 93% of revenue and 89% of revenue in the three months ended September 30, 2024 and 2023, respectively, declined by approximately 6% in the three months ended September 30, 2024 as compared to the same period in 2023.

Costs of Revenue

Costs of revenue decreased \$0.2 million, or 3.2%, for the three months ended September 30, 2024 compared to the three months ended September 30, 2023. This decrease was primarily due to a decrease of \$0.3 million in facilities and allocated overhead expenses, a decrease of \$0.2 million in royalty expenses, and a decrease of \$0.1 million in materials and supplies expenses, partially offset by an increase of \$0.3 million in shipping and handling costs resulting from increased cost-per-shipment, offset in-part by reduced shipping volume; and an increase of \$0.1 million in direct labor. Gross margin as a percentage of revenue decreased to 55.8% for the three months ended September 30, 2024, compared to 57.4% for the three months ended September 30, 2023, primarily due to the changes to revenue and costs of revenue described above, including the \$1.2 million in revenue adjustments, which impacted gross margin by approximately 400 basis points.

Selling, General and Administrative Expenses

Selling, general and administrative expenses decreased \$1.2 million, or 10.7%, for the three months ended September 30, 2024 compared to the three months ended September 30, 2023. This decrease was primarily due to decreases of \$0.7 million in employee-related expenses (including salaries, benefits and stock-based

compensation) resulting from reduced headcount, \$0.4 million in professional service expenses, \$0.2 million in facilities and allocated overhead expenses, \$0.2 million in insurance expenses, and \$0.1 million in legal expenses, partially offset by an increase of \$0.4 million in commissions.

Research and Development Expenses

Research and development expenses increased \$0.1 million, or 5.8%, for the three months ended September 30, 2024 compared to the three months ended September 30, 2023, primarily due to an increase of \$0.2 million in employee-related expenses (including salaries, benefits and stock-based compensation), partially offset by a decrease of \$0.1 million in clinical trial expenses.

Interest Expense

Interest expense remained relatively consistent for the three months ended September 30, 2024 compared to the three months ended September 30, 2023.

Interest Income

Interest income remained relatively consistent for the three months ended September 30, 2024 compared to the three months ended September 30, 2023.

Comparison of the Nine Months Ended September 30, 2024 and 2023 (in thousands):

	Nine Months Ended September 30,		Change
	2024	2023	
Revenue	\$ 41,986	\$ 38,783	\$ 3,203
Operating expenses:			
Costs of revenue	17,351	17,472	(121)
Selling, general and administrative expenses	31,169	35,212	(4,043)
Research and development expenses	3,719	3,789	(70)
Total operating expenses	52,239	56,473	(4,234)
Loss from operations	(10,253)	(17,690)	7,437
Interest expense	(1,671)	(1,769)	98
Interest income	570	1,343	(773)
Net loss	\$ (11,354)	\$ (18,116)	\$ 6,762

Revenue

Revenue increased \$3.2 million, or 8.3%, for the nine months ended September 30, 2024 compared to the nine months ended September 30, 2023, primarily due to improved ASP (including prior period cash collections), partially offset by decreased AVISE® CTD year-over-year volume. The number of AVISE® CTD tests delivered, which accounted for 91% of revenue and 88% of revenue in the nine months ended September 30, 2024 and 2023, respectively, declined by approximately 13% in the nine months ended September 30, 2024 as compared to the same period in 2023.

Costs of Revenue

Costs of revenue decreased \$0.1 million, or 0.7%, for the nine months ended September 30, 2024 compared to the nine months ended September 30, 2023. This decrease was primarily due to a decrease of \$1.0 million in materials and supplies expenses, and a decrease of \$0.2 million in facilities and allocated overhead expenses, partially offset by an increase of \$0.6 million in shipping and handling costs resulting from increased cost-per-shipment, offset in-part by reduced shipping volume; and an increase of \$0.5 million in direct labor. Gross margin as a percentage of revenue increased to 58.7% for the nine months ended September 30, 2024, compared to 54.9% for the nine months ended September 30, 2023, primarily due to the changes to revenue and costs of revenue described above.

Selling, General and Administrative Expenses

Selling, general and administrative expenses decreased \$4.0 million, or 11.5%, for the nine months ended September 30, 2024 compared to the nine months ended September 30, 2023. This decrease was primarily due to decreases of \$1.9 million in employee-related expenses (including salaries, benefits and stock-based compensation) resulting from reduced headcount, \$0.9 million in legal expenses and settlement costs, \$0.5 million in insurance expenses, \$0.4 million in professional services, \$0.4 million in facilities and allocated overhead expenses, and \$0.2 million in audit and tax services, partially offset by an increase of \$0.3 million in commissions.

Research and Development Expenses

Research and development expenses decreased \$0.1 million, or 1.8%, for the nine months ended September 30, 2024 compared to the nine months ended September 30, 2023. This decrease was primarily due to a decrease of \$0.4 million in clinical trial expenses and a decrease of \$0.1 million in facilities and allocated overhead expenses, partially offset by an increase of \$0.4 million in employee-related expenses (including salaries, benefits and stock-based compensation).

Interest Expense

Interest expense decreased by \$0.1 million, or 5.5%, for the nine months ended September 30, 2024 compared to the nine months ended September 30, 2023. This decrease was due to interest savings related to the term loan agreement entered into in September 2017 (the 2017 Term Loan), by and between the Company and Innovatus Life Sciences Lending Fund I, LP, as amended.

Interest Income

Interest income decreased by \$0.8 million, or 57.6%, for the nine months ended September 30, 2024 compared to the nine months ended September 30, 2023, primarily due to lower cash and cash equivalents balances of interest-earning accounts.

Liquidity and Capital Resources

We have incurred net losses since our inception. For the nine months ended September 30, 2024 and 2023, we incurred a net loss of \$11.4 million and \$18.1 million, respectively, and we expect to incur additional losses in future periods. To date, we have generated only limited revenue, and, despite any estimates we may make regarding our ability to become profitable, we may never achieve revenue sufficient to offset our expenses. As of September 30, 2024, we had an accumulated deficit of \$290.6 million and cash and cash equivalents of \$22.0 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 and money market funds.

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, Borrowings, 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 financial plan approved by our Board of Directors 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. 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. As of September 30, 2024, we were in compliance with all covenants of the Amended Loan Agreement with Innovatus.

On November 17, 2023, we filed a registration statement on Form S-3 covering the offering, from time to time, of up to \$150.0 million of common stock, preferred stock, debt securities, warrants and units, all of which remained unsold at September 30, 2024.

On September 15, 2022, we entered into a sales agreement, as amended on November 17, 2023 (the Sales Agreement) with Cowen and Company, LLC, as sales agent, pursuant to which the Company may offer and sell, from time to time, shares of Company common stock having an aggregate offering price of up to \$50.0 million. The Company is not obligated to sell any shares of Company common stock in the offering. As of September 30, 2024, the Company has not sold any shares of its common stock pursuant to the Sales Agreement.

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. 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 continue to consist of working capital and general corporate expenses associated with the growth of our business, including payments we may be required to make upon the achievement of previously negotiated milestones associated with intellectual property we have licensed, payments related to non-cancelable purchase obligations for reagents, payments related to our principal and interest under our long term borrowing arrangements, payments for operating leases related to our office and laboratory space in Vista, California and our office space in Carlsbad, California and payments for finance leases related to our laboratory equipment (see Note 4, Borrowings, and Note 5, Commitments and Contingencies, to our unaudited financial statements included in this Quarterly Report on Form 10-Q). 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 (in thousands):

	Nine Months Ended September 30,	
	2024	2023
Net cash used in:		
Operating activities	\$ (13,642)	\$ (22,811)
Investing activities	(369)	(720)
Financing activities	(447)	(10,412)
Net change in cash, cash equivalents and restricted cash	<u>\$ (14,458)</u>	<u>\$ (33,943)</u>

Cash Flows from Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2024 was \$13.6 million, primarily resulting from (i) our net loss of \$11.4 million adjusted for non-cash charges of \$3.7 million primarily related to stock-based compensation, depreciation, amortization and non-cash lease expense and (ii) changes in our net operating assets of \$6.0 million primarily related to net increases in accounts receivable and net decreases in accounts payable, operating lease liabilities and accrued and other current liabilities, partially offset by net decreases in prepaid expenses. The increase in accounts receivable was primarily due to delays in claim submission as part of our revenue cycle management initiatives.

Net cash used in operating activities for the nine months ended September 30, 2023 was \$22.8 million, primarily resulting from (i) our net loss of \$18.1 million adjusted for non-cash charges of \$5.9 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 \$10.5 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.

Cash Flows from Investing Activities

Net cash used in investing activities for the nine months ended September 30, 2024 and 2023 was \$0.4 million and \$0.7 million, respectively, due to purchases of property and equipment.

Cash Flows from Financing Activities

Net cash used in financing activities for the nine months ended September 30, 2024 was \$0.4 million, primarily resulting from payments on finance lease and notes payable obligations, partially offset by proceeds from purchases under the Company's 2019 Employee Stock Purchase Plan.

Net cash used in financing activities for the nine months ended September 30, 2023 was \$10.4 million, primarily resulting from the Term Loan Prepayment of \$10.0 million.

Critical Accounting 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 accounting principles generally accepted in the United States (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 estimates, 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, 2023 filed with the Securities and Exchange Commission (SEC) on March 18, 2024. There have been no significant changes in our critical accounting policies and estimates during the nine months ended September 30, 2024 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, 2023, filed with the SEC on March 18, 2024.

Recent Accounting Pronouncements

Please see Note 2, Summary of Significant Accounting Policies, to the unaudited condensed financial statements included in this Quarterly Report on Form 10-Q for a summary of recent accounting pronouncements.

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" like 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, which will occur on December 31, 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

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that the information 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. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. In addition, the design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate.

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 September 30, 2024, our disclosure controls and procedures were effective at a reasonable level of assurance.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting during the three months ended September 30, 2024 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 October 2023, we resolved an investigation with the U.S. Attorney's Office for the District of Massachusetts that was initiated by a qui tam lawsuit. Pursuant to a settlement agreement entered into by and between us and the U.S. Department of Justice (the Settlement Agreement), we made a single lump-sum remittance to the government in the amount of \$0.7 million, including interest, in connection with specimen processing arrangements that we historically had with physicians. The U.S. Attorney's Office dismissed this "covered conduct" in the qui tam lawsuit with prejudice, while non-covered conduct was dismissed without prejudice. The Department of Justice excused itself from the case in connection with the settlement. In November 2023, the complaint was unsealed by the court and served on us by the relator. We filed a motion to dismiss the complaint. In February 2024, the relator filed a motion for leave to amend the complaint. We opposed this motion, and all motions are still pending. We cannot predict when these matters will be resolved, the outcome of these matters, or their potential impact, which may materially and adversely affect our business, prospects, and financial condition. We intend to vigorously defend against the claims being asserted in the complaint.

Our participation in federal healthcare programs is not affected by the Settlement Agreement.

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, 2023 and Part II, Item 1A, "Risk Factors" of our Quarterly Report on Form 10-Q for the quarter ended June 30, 2024.

Item 5. Other Information

Rule 10b5-1 trading arrangements

During the nine months ended September 30, 2024, none of our directors or officers adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408 of Regulation S-K.

Item 6. Exhibits

Exhibit Number	Exhibit Description	Incorporated by Reference			Exhibit Filing Date	Filed/Furnished Herewith
		Form	File No.	Exhibit		
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	
10.2#	Employment Agreement, dated as of September 1, 2024, by and between the Company and Jeffrey Black.	8-K/A	001-39049	10.1	8/2/2024	
31.1	Certificate of Principal Executive Officer, pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
31.2	Certificate of Principal Financial Officer, pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
32.1*	Certifications Pursuant to U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Public Company Accounting Reform and Investor Protection Act of 2002.					X
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.					X
101.SCH	Inline XBRL Taxonomy Extension Schema Document.					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.					X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.					X
101.LAB	Inline XBRL Taxonomy Extension Labels Linkbase Document.					X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.					X
104	The cover page from the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2024, 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: November 12, 2024

by: /s/ John Aballi
John Aballi
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 12, 2024

by: /s/ Jeffrey G. Black
Jeffrey G. Black
Chief Financial Officer
(Principal Financial and Accounting Officer)

EXAGEN INC.
CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL 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; and
 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
-

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

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

Date: November 12, 2024

/s/ John Aballi

John Aballi

President and Chief Executive Officer

(Principal Executive Officer)

EXAGEN INC.
CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

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

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

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

Date: November 12, 2024

/s/ Jeffrey G. Black

Jeffrey G. Black

Chief Financial Officer

(Principal Financial and Accounting Officer)

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

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

1. The accompanying quarterly report on Form 10-Q of the Company for the quarterly period ended September 30, 2024 (the "Report") fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the periods presented therein.

Dated: November 12, 2024

/s/ John Aballi

John Aballi

President and Chief Executive Officer
(Principal Executive Officer)

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

CERTIFICATION OF CHIEF FINANCIAL OFFICER

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

1. The accompanying quarterly report on Form 10-Q of the Company for the quarterly period ended September 30, 2024 (the "Report") fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the periods presented therein.

Dated: November 12, 2024

/s/ Jeffrey G. Black

Jeffrey G. Black

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.