UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2024

OR

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

Commission File Number: 001-40606

SERA PROGNOSTICS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**26-1911522**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
2749 East Parleys Way, Suite 200 Salt Lake City, Utah	**84109**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (801) 990-0520

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Class A Common Stock, $0.0001 par value per share	**SERA**	**The Nasdaq Stock Market LLC**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No o

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes x No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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	o	Accelerated filer	o
Non-accelerated filer	x	Smaller reporting company	x
		Emerging growth company	x

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

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

As of August 2, 2024, the registrant had 32,400,832 and 967,759 shares of Class A and Class B common stock, $0.0001 par value per share, outstanding, respectively.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This discussion contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. In some cases, you can identify forward-looking statements by words such as “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “seek,” “should,” “target,” “will,” “would,” or the negative of these words or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- estimates of our addressable market, market growth, future revenue, key performance indicators, expenses, capital requirements, and our needs for additional financing;
- our expectations regarding the rate and degree of market acceptance of our products and services, including our PreTRM test;
- the impact of our PreTRM test, including the results of any studies of the test, on the field of bioinformatics and proteomics and the size and growth of the addressable bioinformatics and proteomics market;
- our ability to obtain funding for our operations;
- our ability to manage and grow our business and commercialize our PreTRM test;
- our ability to develop and commercialize new products and services;
- our ability to retain the continued service of our key professionals and to identify, hire, and retain additional qualified professionals;
- the pricing and reimbursement of our products and services;
- the implementation of our business model, strategic plans for our business, products, services, and technology;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology;
- developments relating to our competitors and our industry;
- the accuracy of our estimates regarding expenses, capital requirements, and needs for additional financing;
- the expected impact of global business, political, and macroeconomic conditions, including inflation, increasing interest rates, and volatile market conditions, uncertainty with respect to the federal budget and debt ceiling and potential government shutdowns related thereto, cybersecurity events, instability in the global banking system, and global events, including regional conflicts around the world, on our business, clinical trials, financial condition, liquidity, and results of operations; and
- our financial performance.

These forward-looking statements are subject to a number of risks, uncertainties, and assumptions, including those described in the “Risk Factors” section and elsewhere in this report. Moreover, we operate in a very competitive and rapidly changing environment, and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties, and assumptions, the forward-looking events and circumstances discussed in this report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable as of the date of this report, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this report to conform these statements to new information, actual results or to changes in our expectations, except as required by law.

PART I — FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited)

SERA PROGNOSTICS, INC.

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

	June 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 4,664	$ 3,880
Marketable securities	46,276	45,199
Accounts receivable	101	160
Other receivables	—	11,310
Prepaid expenses and other current assets	502	795
Total current assets	51,543	61,344
Property and equipment, net	1,607	1,999
Long-term marketable securities	30,006	30,841
Other assets	1,705	1,257
Total assets	$ 84,861	$ 95,441
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 952	$ 1,046
Accrued and other current liabilities	3,181	2,722
Finance lease obligation, current portion	396	440
Deferred revenue	20,228	20,235
Total current liabilities	24,757	24,443
Finance lease obligation, net of current portion	23	196
Operating lease obligation, net of current portion	328	644
Total liabilities	25,108	25,283
Commitments and contingencies (Note 13)		
Stockholders' equity:		
Common stock, $0.0001 par value; 150,000,000 Class A shares authorized; 32,386,088 and 30,736,513 Class A shares issued and outstanding as of June 30, 2024 and December 31, 2023, respectively; 1,500,000 Class B shares authorized; 1,405,259 Class B shares issued as of June 30, 2024 and December 31, 2023;967,759 Class B shares outstanding as of June 30, 2024 and December 31, 2023.	3	3
Additional paid-in capital	323,257	317,066
Accumulated other comprehensive loss	(211)	(15)
Accumulated deficit	(263,296)	(246,896)
Total stockholders' equity	59,753	70,158
Total liabilities and stockholders' equity	$ 84,861	$ 95,441

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

SERA PROGNOSTICS, INC.

Condensed Statements of Operations and Comprehensive Loss
(unaudited)
(in thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Revenue	$ 24	$ 123	$ 24	$ 223
Operating expenses:				
Cost of revenue	20	80	37	142
Research and development	4,406	3,688	8,089	7,791
Selling and marketing	1,099	2,872	2,326	5,690
General and administrative	3,752	4,943	7,922	9,389
Total operating expenses	9,277	11,583	18,374	23,012
Loss from operations	(9,253)	(11,460)	(18,350)	(22,789)
Interest expense	(8)	(14)	(17)	(30)
Other income, net	958	932	1,967	1,712
Net loss	$ (8,303)	$ (10,542)	$ (16,400)	$ (21,107)
Net loss per share, basic and diluted	$ (0.25)	$ (0.34)	$ (0.50)	$ (0.68)
Weighted-average shares outstanding, basic and diluted	32,932,903	31,077,420	32,576,470	31,048,526
Other comprehensive (loss) income:				
Unrealized (loss) gain on available-for-sale debt securities, net of tax	$ (30)	$ (215)	$ (196)	$ 309
Total other comprehensive (loss) income	(30)	(215)	(196)	309
Comprehensive loss	$ (8,333)	$ (10,757)	$ (16,596)	$ (20,798)

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

SERA PROGNOSTICS, INC.

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

	Common Stock (Class A and B)		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of December 31, 2023	31,704,272	$ 3	$ 317,066	$ (15)	$ (246,896)	$ 70,158
Issuance of common stock upon exercise of stock options	425,749	—	1,162	—	—	1,162
Issuance of restricted stock units	431,152	—	—	—	—	—
Common stock warrant exercises	6,168	—	—	—	—	—
Stock-based compensation expense	—	—	1,693	—	—	1,693
Other comprehensive loss	—	—	—	(166)	—	(166)
Net loss	—	—	—	—	(8,097)	(8,097)
Balance as of March 31, 2024	32,567,341	3	319,921	(181)	(254,993)	64,750
Issuance of common stock upon exercise of stock options	464,305	—	1,258	—	—	1,258
Issuance of restricted stock units	287,729	—	—	—	—	—
Issuance of common stock under employee stock purchase plan	32,669	—	55	—	—	55
Common stock warrant exercises	1,803	—	—	—	—	—
Stock-based compensation expense	—	—	2,023	—	—	2,023
Other comprehensive loss	—	—	—	(30)	—	(30)
Net loss	—	—	—	—	(8,303)	(8,303)
Balance as of June 30, 2024	33,353,847	$ 3	$ 323,257	$ (211)	$ (263,296)	$ 59,753

	Common Stock (Class A and B)		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of December 31, 2022	31,017,946	$ 3	$ 310,575	$ (981)	$ (210,654)	$ 98,943
Issuance of common stock upon exercise of stock options	4,094	—	4	—	—	4
Stock-based compensation expense	—	—	1,304	—	—	1,304
Other comprehensive income	—	—	—	524	—	524
Net loss	—	—	—	—	(10,565)	(10,565)
Balance as of March 31, 2023	31,022,040	3	311,883	(457)	(221,219)	90,210
Issuance of common stock upon exercise of stock options	117,839	—	178	—	—	178
Issuance of common stock under employee stock purchase plan	58,626	—	66	—	—	66
Stock-based compensation expense	—	—	1,440	—	—	1,440
Other comprehensive loss	—	—	—	(215)	—	(215)
Net loss	—	—	—	—	(10,542)	(10,542)
Balance as of June 30, 2023	31,198,505	$ 3	$ 313,567	$ (672)	$ (231,761)	$ 81,137

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

SERA PROGNOSTICS, INC.

Condensed Statements of Cash Flows
(unaudited)
(in thousands)

	Six Months Ended June 30,	
	2024	**2023**
Cash flows from operating activities		
Net loss	$ (16,400)	$ (21,107)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	421	472
Stock-based compensation	3,716	2,744
Non-cash lease expense	278	259
Non-cash investment income, net	(632)	(426)
Other	16	12
Changes in operating assets and liabilities:		
Accounts receivable	59	(50)
Other receivables	11,310	6,000
Prepaid expenses and other assets	203	872
Accounts payable	(42)	(289)
Accrued and other current liabilities	144	(1,284)
Deferred revenue	(7)	(32)
Net cash used in operating activities	(934)	(12,829)
Cash flows from investing activities		
Purchases of marketable securities	(26,556)	(23,068)
Proceeds from maturities and sales of marketable securities	26,735	38,113
Purchases of property and equipment	(22)	(86)
Proceeds from disposal of property and equipment	—	269
Purchase of intangible assets	(697)	—
Net cash (used in) provided by investing activities	(540)	15,228
Cash flows from financing activities		
Proceeds from exercise of stock options	2,420	182
Proceeds from employee stock purchase plan	55	66
Finance lease principal payments	(217)	(240)
Net cash provided by financing activities	2,258	8
Net increase in cash and cash equivalents	784	2,407
Cash and cash equivalents at beginning of period	3,880	29,878
Cash and cash equivalents at end of period	$ 4,664	$ 32,285
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 17	$ 30
Supplemental disclosure of non-cash investing and financing information		
Purchases of property and equipment in accounts payable and accrued and other current liabilities	$ 8	$ —

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

SERA PROGNOSTICS, INC.
Notes to Condensed Financial Statements
(Unaudited)

1. Description of Business and Financial Condition

Sera Prognostics, Inc. (the "Company") is a women's health company utilizing its proprietary proteomics and bioinformatics platform, and significant data resources, to improve maternal and neonatal health by discovering, developing, and commercializing blood-based biomarker tests and predictive analytic products and services. The Company was incorporated in the State of Delaware on January 17, 2008 and its operations are located in Salt Lake City, Utah, including a Clinical Laboratory Improvement Amendments ("CLIA")-certified laboratory.

Since its inception, the Company's activities have consisted of performing research and development and conducting clinical studies for its pipeline products and services, acquiring product rights, raising capital, establishing facilities, and organizing commercial operations to market its testing and analytics products, primarily the PreTRM test.

Liquidity and Capital Resources

The accompanying condensed financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business.

The Company has incurred net losses and negative cash flows from operations since inception and had an accumulated deficit of $ 263.3 million as of June 30, 2024. The Company's management expects the Company to incur significant additional operating losses and negative cash flows for the foreseeable future, principally as a result of the Company's activities relating to the PreTRM test and the Company's other pipeline products and services, including clinical and preclinical trials and anticipated research and development activities as well as commercialization activities. There can be no assurance that the Company will eventually achieve significant revenues or profitability to sustain operations, or if achieved, can sustain either on a continuing basis. If the Company is unable to achieve significant revenues or raise additional funds, when needed, it may not be able to continue the development or commercialization of its products and services and could be required to delay, scale back, or abandon some or all of its operations. No assurance can be given that the Company will be successful in raising the required capital on reasonable terms and at the required times, or at all. Any additional equity financing, if available to the Company, may not be available on favorable terms and may be dilutive to current stockholders, and any debt financing, if available, may involve restrictive covenants and dilutive financing instruments. The Company's future operations are highly dependent on a combination of factors, including (i) the commercialization and market acceptance of the PreTRM test and the successful development, commercial launch, marketing, and distribution of other pipeline products and services; (ii) the success of scientific and clinical studies and other research and development programs that support current and future products and services; (iii) the development of competitive products by other biotechnology and laboratory companies; (iv) the Company's ability to manage growth of the organization; (v) the Company's ability to protect its intellectual property, technology, products and services; and, ultimately (vi) the timely and successful completion of any additional financing.

The principal sources of the Company's working capital to date have been the proceeds from the sale and issuance of convertible preferred stock and convertible notes, bank loans, and the sale and issuance of Class A common stock in an initial public offering ("IPO"), which was completed in July 2021. As of June 30, 2024, the Company had aggregate cash, cash equivalents, and available-for-sale securities of $80.9 million. See Note 3—Cash, Cash Equivalents and Marketable Securities.

The Company believes that its existing financial resources are sufficient to continue operating activities at least 12 months from the issuance date of these unaudited condensed financial statements.

2. Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") and applicable rules and regulations of the U.S. Securities and Exchange Commission (the "SEC") regarding interim financial reporting. Certain information and note disclosures normally included in the financial statements prepared in accordance with U.S. GAAP have been condensed or

omitted pursuant to such rules and regulations. As such, these unaudited condensed financial statements should be read in conjunction with the audited financial statements and accompanying notes included in the Company's Annual Report on Form 10-K for the year ended December 31, 2023. The unaudited interim condensed financial statements have been prepared on a basis consistent with the audited annual financial statements as of and for the year ended December 31, 2023, and, in the opinion of the Company's management, reflect all adjustments, consisting solely of normal recurring adjustments, necessary for the fair presentation of the Company's financial results. The balance sheet as of December 31, 2023 has been derived from the audited financial statements at that date but does not include all information and footnotes required by U.S. GAAP for complete financial statements. The results of the three and six months ended June 30, 2024 are not necessarily indicative of the results to be expected for the full year ending December 31, 2024, or any other period.

There have been no significant changes in the Company's significant accounting policies during the six months ended June 30, 2024, as compared with those disclosed in its Annual Report on Form 10-K for the year ended December 31, 2023 filed with the SEC on March 20, 2024.

Any reference in these notes to applicable accounting guidance is meant to refer to the authoritative U.S. GAAP included in the Accounting Standards Codification ("ASC"), and Accounting Standards Updates ("ASU") issued by the Financial Accounting Standards Board ("FASB").

Use of Estimates

The preparation of the condensed financial statements in conformity with U.S. GAAP requires the Company's management to make estimates and assumptions that affect the amounts reported in the condensed financial statements and accompanying notes. The Company evaluates these estimates on an ongoing basis. The Company bases these estimates on historical and anticipated results, trends, and various other assumptions that the Company believes are reasonable under the circumstances, including assumptions as to future events. Actual results could differ materially from those estimates.

The Company's financial statements as of and for the three and six months ended June 30, 2024 reflect the Company's estimates of the impact of the current macroeconomic environment, including the impact of inflation and higher interest rates. The extent to which these conditions will directly or indirectly impact the Company's business, results of operations, and financial condition is uncertain. The Company is not aware of any specific event or circumstance that would require an update to its estimates, judgments and assumptions or a revision of the carrying value of the Company's assets or liabilities as of the date of this filing.

Recently Issued Accounting Pronouncements Not Yet Adopted

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* , which is intended to improve the transparency of income tax disclosures by requiring consistent categories and greater disaggregation of information in the effective tax rate reconciliation and income taxes paid by jurisdiction. The ASU is effective for public business entities' annual periods beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the impact of adopting this guidance on its financial statements.

In November 2023, the FASB issued ASU No. 2023-07, *Improvements to Reportable Segments Disclosures.* While ASU 2023-07 requires incremental disclosures, it does not change how an entity identifies its operating segments, aggregates those operating segments, or applies the quantitative thresholds to determine reportable segments. This ASU is effective for all public business entities for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Entities must adopt the changes to the segment reporting guidance on a retrospective basis. The Company is currently evaluating the impact of adopting this guidance on its financial statements. Early adoption is permitted; however, the Company is not early adopting the standard.

3. Cash, Cash Equivalents and Marketable Securities

The Company has classified its marketable securities as available-for-sale. The Company's cash, cash equivalents and marketable securities by major security type as of June 30, 2024 and December 31, 2023 were as follows (in thousands):

	June 30, 2024			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and cash equivalents:				
Cash	$ 1,761	$ —	$ —	$ 1,761
Money market funds	2,903	—	—	2,903
Total cash and cash equivalents	4,664	—	—	4,664
Current marketable securities:				
Commercial paper	7,939	—	(9)	7,930
Corporate debt securities	11,823	—	(23)	11,800
U.S. federal agency securities	20,331	—	(78)	20,253
U.S. government securities	6,321	—	(28)	6,293
Total current marketable securities	46,414	—	(138)	46,276
Long-term marketable securities:				
Corporate debt securities	26,998	21	(92)	26,927
Municipal debt securities	3,081	—	(2)	3,079
Total long-term marketable securities	30,079	21	(94)	30,006
Total cash, cash equivalents and marketable securities	$ 81,157	$ 21	$ (232)	$ 80,946

	December 31, 2023			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and cash equivalents:				
Cash	$ 2,608	$ —	$ —	$ 2,608
Money market funds	1,272	—	—	1,272
Total cash and cash equivalents	3,880	—	—	3,880
Current marketable securities:				
Commercial paper	11,769	6	(2)	11,773
Corporate debt securities	1,155	—	(2)	1,153
U.S. federal agency securities	19,644	—	(102)	19,542
U.S. government securities	12,812	—	(81)	12,731
Total current marketable securities	45,380	6	(187)	45,199
Long-term marketable securities:				
U.S. federal agency securities	9,406	27	(17)	9,416
U.S. government securities	4,388	3	(5)	4,386
Corporate debt securities	16,880	159	—	17,039
Total long-term marketable securities	30,674	189	(22)	30,841
Total cash, cash equivalents and marketable securities	$ 79,934	$ 195	$ (209)	$ 79,920

The following tables summarize the Company's available-for-sale debt securities and cash equivalents with unrealized losses as of June 30, 2024 and December 31, 2023, aggregated by major security type and the length of time that individual securities have been in a continuous loss position (in thousands):

	June 30, 2024					
	Less than 12 months		12 months or greater		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
Commercial paper	$ 7,930	$ (9)	$ —	$ —	$ 7,930	$ (9)
Corporate debt securities	29,129	(111)	1,151	(4)	30,280	(115)
U.S. federal agency securities	4,790	(14)	14,357	(64)	19,147	(78)
U.S. government securities	1,475	(3)	4,818	(25)	6,293	(28)
Municipal debt securities	$ 3,079	$ (2)	$ —	$ —	3,079	(2)
Total	$ 46,403	$ (139)	$ 20,326	$ (93)	$ 66,729	$ (232)

	December 31, 2023					
	Less than 12 months		12 months or greater		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
Commercial paper	$ 5,453	$ (2)	$ —	$ —	$ 5,453	$ (2)
Corporate debt securities	1,153	(2)	—	—	1,153	(2)
U.S. federal agency securities	15,308	(52)	8,751	(67)	24,059	(119)
U.S. government securities	4,769	(13)	10,895	(73)	15,664	(86)
Total	$ 26,683	$ (69)	$ 19,646	$ (140)	$ 46,329	$ (209)

As of June 30, 2024 and December 31, 2023, the Company had not recorded any allowance for credit losses related to its available-for-sale securities. The Company attributes the declines in the fair value of its available-for-sale securities to normal market and interest rate fluctuations. The declines in fair value are not attributed to declines in credit quality. The Company does not intend to sell investments while they are in an unrealized loss position and does not believe that it is more likely than not that the Company will be required to sell the investments before recovery of their amortized cost basis, which may be maturity. All of the Company's investments mature in less than three years.

The Company's marketable securities classified by contractual maturities as of June 30, 2024 were as follows (in thousands):

	Amortized Cost	Fair Value
Due within one year	$ 46,414	$ 46,276
Due after one year through five years	30,079	30,006
Total	$ 76,493	$ 76,282

4. Property and Equipment

The following table presents the components of property and equipment, net, as of June 30, 2024 and December 31, 2023 (in thousands):

	June 30, 2024	December 31, 2023
Laboratory equipment	$ 5,742	$ 5,734
Computer equipment	1,074	1,054
Leasehold improvements	772	772
Software	1,141	1,141
Furniture and fixtures	320	320
Total property and equipment	9,049	9,021
Less accumulated depreciation and amortization	(7,442)	(7,022)
Property and equipment, net	$ 1,607	$ 1,999

Depreciation and amortization expense was $ 0.2 million for each of the three months ended June 30, 2024 and 2023. Depreciation and amortization expense was $0.4 million and $0.5 million for the six months ended June 30, 2024 and 2023, respectively.

5. Other Assets

The following table presents the components of other assets as of June 30, 2024 and December 31, 2023 (in thousands):

	June 30, 2024	December 31, 2023
Operating right-of-use asset	$ 902	$ 1,180
Intangible assets	697	—
Other assets	106	77
Total other assets	$ 1,705	$ 1,257

During the six months ended June 30, 2024, the Company acquired domain names resulting in capitalized intangible assets of $ 697,000. The Company determined that the domain names have an indefinite useful life and are therefore not subject to amortization. The Company assesses its intangible assets for impairment annually, or more frequently if circumstances dictate.

6. Accrued and Other Current Liabilities

The following table presents the components of accrued and other current liabilities as of June 30, 2024 and December 31, 2023 (in thousands):

	June 30, 2024	December 31, 2023
Accrued compensation	$ 513	$ 779
Accrued vacation	466	365
Accrued 401(k) matching contributions	216	74
Operating lease liability, current portion	610	578
Other current liabilities	1,376	926
Total accrued and other current liabilities	$ 3,181	$ 2,722

7. Other Income, net

The following table presents the components of other income, net, for the three and six months ended June 30, 2024 and 2023 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Interest income	$ 671	$ 337	$ 1,341	$ 593
Investment income, net	287	595	626	1,119
Other income, net	$ 958	$ 932	$ 1,967	$ 1,712

8. Fair Value Measurements

As of June 30, 2024 and December 31, 2023, the carrying amounts of the Company's receivables, prepaid and other current assets, accounts payable, and accrued and other current liabilities approximate their fair values, principally due to the short-term nature of the assets and liabilities. The recorded values of the finance leases approximate fair value as the interest rates approximate market interest rates.

Money market funds are highly liquid investments and are actively traded. The pricing information on money market funds is readily available and can be independently validated as of the measurement date. This approach results in the classification of these securities as Level 1 of the fair value hierarchy.

U.S. government agency bonds, U.S. government bonds, commercial paper, corporate debt securities, and municipal debt securities are measured at fair value using Level 2 inputs. The Company reviews trading activity and pricing for these investments as of each measurement date.

The Company follows a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. Fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. The three levels of the fair value hierarchy are as follows:

Level 1 inputs are observable, quoted prices (unadjusted) in active markets for identical assets or liabilities that the Company can access at the measurement date.

Level 2 inputs are observable inputs other than quoted prices included in Level 1 that are observable either directly or indirectly or quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 inputs are unobservable inputs in which there is little or no market data, which require the Company to develop its own assumptions.

The following table shows the Company's assets measured at fair value on a recurring basis by level within the fair value hierarchy (in thousands) as of June 30, 2024:

	Level 1	Level 2	Level 3
Assets:			
Cash equivalents:			
Money market funds	$ 2,903	$ —	$ —
Marketable securities:			
Commercial paper	—	7,930	—
Corporate debt securities	—	38,727	—
Municipal debt securities	—	3,079	—
U.S. federal agency securities	—	20,253	—
U.S. government securities	—	6,293	—
Total assets	$ 2,903	$ 76,282	$ —

The following table shows the Company's assets measured at fair value on a recurring basis by level within the fair value hierarchy (in thousands) as of December 31, 2023:

	Level 1	Level 2	Level 3
Assets:			
Cash equivalents:			
Money market funds	$ 1,272	$ —	$ —
Marketable securities:			
Commercial paper	—	11,773	—
Corporate debt securities	—	18,192	—
U.S. federal agency securities	—	28,958	—
U.S. government securities	—	17,117	—
Total assets	$ 1,272	$ 76,040	$ —

9. Related Party Transactions

In June 2019, the Company entered into a master services agreement with Carelon Research, a subsidiary of Elevance Health, Inc. ("Elevance Health"). This agreement covers a range of research projects, including Carelon Research's role as a contract research organization for the **P**rematurity **R**isk Assessment Combined With Clinical **I**nterventions for Improving Neonatal outco**ME**s ("PRIME") study. The Company paid fees related to this agreement of $0.8 million for each of the three months ended June 30, 2024 and 2023, and $ 1.4 million and $1.7 million for the six months ended June 30, 2024 and 2023, respectively, which were recorded in research and development expenses in the Company's condensed statements of operations and comprehensive loss. In November 2020, the Company entered into a Laboratory Services Agreement with Elevance Health related to the PRIME study. This agreement provides a contracted rate for certain tests performed pursuant to the study. In December 2023, enrollment in the PRIME study was stopped due to efficacy, and as such, there was an immaterial amount of revenue recognized related to this agreement for the three and six months ended June 30, 2024. The Company recognized revenue related to this agreement of $14 thousand and $34 thousand for the three and six months ended June 30, 2023.

In February 2021, the Company entered into a commercial collaboration agreement with Elevance Health and its affiliates (the "Commercial Collaboration Agreement"). The Commercial Collaboration Agreement provides defined payment within a defined period for use of the PreTRM test within Elevance Health's network of covered members. Pursuant to the Commercial Collaboration Agreement, Elevance Health agreed to purchase a certain minimum number of tests for each of the first three years of the term of the agreement. Additionally, Elevance Health agreed to pay a certain minimum amount per year for the first three years of the term of the Commercial Collaboration Agreement. The Company received $11.2 million during the six months ended June 30, 2024, which amount related to the minimum payments for the year ended December 31, 2023. Such minimum payments were initially recorded as deferred revenue. Deferred revenue is recognized as revenue when the Company delivers PreTRM test results to Elevance Health patients pursuant to the Commercial Collaboration Agreement. The Company also agreed to develop a sales, marketing, and customer service program, and to provide training and marketing to duly licensed physicians specializing in obstetrics and gynecology or family medicine, or licensed nurse midwives, at the reasonable request of Elevance Health.

Elevance Health has been participating in the Company's PRIME study, and at the conclusion of the PRIME study, under the Commercial Collaboration Agreement, the parties agreed to use commercially reasonable efforts to enter into Elevance Health's standard lab provider agreement. Unless earlier terminated due to breach, the Commercial Collaboration Agreement will remain in effect until the later of (a) the third anniversary of the effective date or (b) the date on which Elevance Health has purchased a fixed number of PreTRM tests as agreed by the parties.

The Commercial Collaboration Agreement with Elevance Health is considered to be within the scope of ASC Topic 808, Collaborative Arrangements ("ASC 808"), as the parties are active participants and exposed to the risks and rewards of the collaborative activity. The Company determined the PreTRM tests to be a performance obligation for which Elevance Health is a customer and a unit of account within the scope of ASC 606. The associated transaction price is based on the contractual minimum number of tests and the agreed upon defined payment amount per test. The transaction price was allocated to this single performance obligation, which will be recognized upon delivery of test results expected to occur over the term of the agreement. All other items promised to Elevance Health are immaterial in the context of the Commercial Collaboration Agreement. There were no material revenues related to the Commercial Collaboration Agreement for the three and six months ended June 30, 2024 and 2023.

10. Capital Structure

The Company has two authorized classes of common stock, Class A and Class B. The rights of the holders of Class A and Class B common stock are identical, except with respect to voting and conversion. Each share of Class A common stock is entitled to one vote and shares of Class B common stock are non-voting. Each share of Class B common stock may be converted at any time to one share of Class A common stock at the option of its holder, subject to the ownership limitations provided for in the Company's amended and restated certificate of incorporation.

The following shares of Class A common stock were reserved for future issuance:

	June 30, 2024	December 31, 2023
Warrants to purchase Class A common stock	2,649,720	2,775,978
Options to purchase Class A common stock	6,336,742	7,251,663
Restricted stock units outstanding	2,118,834	2,692,459
Class A common stock available for future grants under the 2021 Equity Incentive Plan	2,111,162	1,002,091
Class A common stock available for future grants under the 2021 Employee Stock Purchase Plan	1,076,364	801,668
Total	14,292,822	14,523,859

11. Stock-Based Compensation

Equity Incentive Plans

In November 2011, the Company established the 2011 Employee, Director and Consultant Equity Incentive Plan (the "2011 Plan") and reserved shares of the Company's common stock for sale and issuance under the 2011 Plan. Options granted under the 2011 Plan generally vest over a four-year period and generally expire ten years from the date of grant. Options are exercisable only to the extent vested. The 2011 Plan terminated in November 2021, and accordingly, no

additional shares are available for grant under the 2011 Plan. The 2011 Plan continues to govern outstanding awards granted under the 2011 Plan.

The 2021 Equity Incentive Plan (the "2021 Plan") was established in July 2021. The 2021 Plan provides for the grant of incentive and non-statutory stock options as well as other stock rights to employees, directors, and consultants of the Company. Options generally vest over a four-year period, are exercisable only to the extent vested, and generally expire ten years from the date of grant. Restricted stock units ("RSUs") generally vest over either a two-year or four-year period. The 2021 Plan includes provisions for annual automatic increases to the number of shares of Class A common stock reserved for issuance under the 2021 Plan. In addition, any shares that otherwise would be returned to the 2011 Plan as a result of the expiration or cancellation of stock options may be added to the 2021 Plan. As of June 30, 2024, there were 2,111,162 shares of the Company's Class A common stock that were available for future grants under the 2021 Plan.

The 2021 Employee Stock Purchase Plan (the "2021 ESPP") was established in July 2021. The 2021 ESPP includes provisions for annual automatic increases to the number of shares of Class A common stock reserved for issuance under the 2021 ESPP. As of June 30, 2024, there were 1,076,364 shares of the Company's Class A common stock that were available for future grants under the 2021 ESPP.

Stock Options

Unless otherwise noted, references to "options" in the subsequent disclosures, refers to the combined incentive and non-statutory stock options issued as employee and non-employee stock-based compensation, and authorized under the 2011 Plan and the 2021 Plan. The following table summarizes information about these options granted and outstanding:

	Number of Shares Subject to Options Outstanding	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Life (In Years)	Aggregate Intrinsic Value (In Thousands)
Outstanding — December 31, 2023	7,251,663	$ 3.66	6.9	$ 20,014
Granted	73,843	8.43		
Expired	—	—		
Cancelled	(98,710)	3.62		
Exercised	(890,054)	2.72		
Outstanding — June 30, 2024	6,336,742	$ 3.84	6.7	$ 16,497
Vested and expected to vest at June 30, 2024	6,257,911	$ 3.83	6.7	$ 16,355
Vested and exercisable at June 30, 2024	5,174,134	$ 3.54	6.5	$ 14,747

RSUs

The following table summarizes information about RSUs granted and outstanding under the 2021 Plan:

	Number of Awards	Weighted-Average Grant Date Fair Value
Outstanding — December 31, 2023	2,692,459	$ 2.01
Granted	188,173	9.00
Forfeited	(42,917)	2.05
Vested	(718,881)	2.53
Outstanding — June 30, 2024	2,118,834	$ 2.46

Stock-Based Compensation Expense

The following table presents the impact of stock-based compensation expense in the statements of operations for the periods indicated (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Research and development expense	$ 918	$ 382	$ 1,444	$ 732
Sales and marketing expense	92	294	177	477
General and administrative expense	1,013	764	2,095	1,535
Total employee stock-based compensation	$ 2,023	$ 1,440	$ 3,716	$ 2,744

The information about unrecognized stock-based compensation expense for outstanding unvested stock options and RSUs as of June 30, 2024 was as follows (in thousands, except years):

	Unrecognized Stock-Based Compensation Expense	Weighted-Average Period of Recognition (in years)
Stock Options	$ 3,550	1.3
RSUs	3,969	2.0
Total unrecognized stock-based compensation expense	$ 7,519	

12. Warrants

All outstanding common stock warrants were exercisable immediately when granted. All outstanding common stock warrants are exercisable for shares of Class A common stock. The Company's common stock warrants outstanding were as follows:

	Number of Warrants Outstanding as of:	
Exercise Price	June 30, 2024	December 31, 2023
$ 5.20	3,473	3,473
9.03	969,275	1,032,404
10.84	946,666	1,009,795
12.38	8,083	8,083
20.77	722,223	722,223
	2,649,720	2,775,978

During the six months ended June 30, 2024, 126,258 common stock warrants were net exercised, resulting in the issuance of 7,971 shares of Class A common stock.

13. Commitments and Contingencies

Leases

The Company is the lessee in all of its lease arrangements. The Company did not enter into any leases with related parties during the presented periods. The Company makes assumptions and judgments when assessing contracts for lease components, determining lease classifications, and calculating right-of-use asset and lease liability values. These assumptions and judgments may include the useful lives and fair values of the leased assets, the implicit rate underlying the Company's leases, the Company's incremental borrowing rate or the Company's intent to exercise or not exercise options available in lease contracts.

The following table shows right-of-use assets and lease liabilities, and the associated financial statement line items as of June 30, 2024 and December 31, 2023 (in thousands):

Lease-Related Assets and Liabilities	Financial Statement Line Items	June 30, 2024	December 31, 2023
Right-of-use assets:			
Operating leases	Other assets	$ 902	$ 1,180
Finance leases	Property and equipment, net	855	1,008
Total right-of-use assets		$ 1,757	$ 2,188
Lease liabilities:			
Operating leases	Accrued and other current liabilities	$ 610	$ 578
	Operating lease obligation, net of current portion	328	644
Finance leases	Finance lease obligation, current portion	396	440
	Finance lease obligation, net of current portion	23	196
Total lease liabilities		$ 1,357	$ 1,858

Lease costs and other information consisted of the following (in thousands, except terms and rates):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Lease cost				
Finance lease cost:				
Amortization of right-of-use assets	$ 78	$ 83	$ 157	$ 166
Interest on lease liabilities	8	14	17	30
Operating lease cost	159	159	318	318
Total lease cost	$ 245	$ 256	$ 492	$ 514
Other information				
Finance leases:				
Operating cash outflows	$ 8	$ 14	$ 17	$ 30
Financing cash outflows	$ 109	$ 120	$ 217	$ 240
Right-of-use assets obtained in exchange for lease liabilities	$ —	$ 18	$ —	$ 18
Weighted-average remaining lease term (in years)	0.9	1.8	0.9	1.8
Weighted-average discount rate	6.6%	6.5%	6.6%	6.5%
Operating leases:				
Operating cash outflows	$ 162	$ 157	$ 323	$ 314
Right-of-use assets obtained in exchange for lease liabilities	$ —	$ —	$ —	$ —
Weighted-average remaining lease term (in years)	1.5	2.5	1.5	2.5
Weighted-average discount rate	7.5%	7.5%	7.5%	7.5%

Future minimum lease payments for the Company's leases as of June 30, 2024 were as follows (in thousands):

	Operating Leases	Finance Leases	Total
2024	$ 323	$ 233	$ 556
2025	666	197	863
2026	—	2	2
2027 and thereafter	—	—	—
Total minimum lease payments	989	432	1,421
Less: imputed interest	(51)	(13)	(64)
Present value of future lease payments	938	419	1,357
Less: current portion	610	396	1,006
Long-term portion	$ 328	$ 23	$ 351

Operating Leases

The Company leases a total of approximately 24,300 square feet of office and laboratory space under a single non-cancelable operating lease with a termination date of December 31, 2025 (as amended, the "Office Lease"). The Office Lease includes an early termination right which termination would occur under certain circumstances, as provided in the amended Office Lease, after July 1, 2024, if exercised. The Company is not currently reasonably certain it will exercise the termination right. The implicit rate provided in the Company's operating lease is not readily determinable. As such, the Company uses its incremental borrowing rate to calculate the present value of its operating lease liabilities.

Finance Leases

The Company leases certain equipment related to its information technology infrastructure and laboratory operations. All of the Company's current finance leases include bargain purchase options that the Company is reasonably certain to exercise. The Company has elected not to separate lease and non-lease components for its equipment leases. The rates implicit in the Company's finance leases are determinable, and the Company uses those rates to calculate the present value of its finance lease liabilities.

Indemnification

The Company has agreed to indemnify its officers and directors for certain events or occurrences while the officer or director is or was serving at the Company's request in such capacity. The maximum amount of potential future indemnification is unlimited; however, the Company purchases director and officer insurance coverage that provides for corporate reimbursements of covered obligations that limits the Company's exposure and enables it to recover a portion of potential future amounts paid. The Company is unable to reasonably estimate the maximum amount that could be payable under these arrangements since these obligations are not capped but are conditional to the unique facts and circumstances involved. Accordingly, the Company has no liabilities recorded for these agreements as of June 30, 2024 and December 31, 2023. The Company has never incurred costs to defend lawsuits or settle claims related to these indemnification agreements.

Employee Agreements

The Company has signed various employment agreements with key executives pursuant to which, if their employment is terminated by the Company without cause or by the employees for good reason, or following a change of control of the Company, the employees are entitled to receive certain benefits, including severance payments, accelerated vesting of stock and stock options, and certain insurance benefits.

Legal Matters

The Company is not currently a party to any material litigation or other material legal proceedings. The Company may, from time to time, be involved in various legal proceedings arising from the normal course of business activities, and an unfavorable resolution of any of these matters could materially affect the Company's future results of operations, cash flows, or financial position.

14. Net loss per share

The Company calculates net loss per share of Class A and Class B common stock using the two-class method. For periods in which the Company reports a net loss, all potentially dilutive shares are anti-dilutive and are therefore excluded from the calculation of diluted net loss per share. For the three and six months ended June 30, 2024 and 2023, the Company reported net losses and as such, basic and diluted net loss per share are the same.

As the liquidation and dividend rights are identical for Class A and Class B common stock, the undistributed earnings are allocated on a proportionate basis and the resulting amount per share for Class A and Class B common stock was the same for the three and six months ended June 30, 2024 and 2023.

The Company excluded the following potentially dilutive securities, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share for the periods indicated because their impact would have been anti-dilutive:

	June 30,	
	2024	2023
Warrants to purchase Class A common stock	2,649,720	2,775,978
Options to purchase Class A common stock	6,336,742	8,062,442
Restricted stock units outstanding	2,118,834	240,832
Total	11,105,296	11,079,252

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

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q. Some of the information contained in this discussion and analysis or set forth elsewhere in this Form 10-Q, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Form 10-Q, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Investors and others should note that we routinely use the Investors section of our website to announce material information to investors and the marketplace. While not all of the information that we post on the Investors section of our website is of a material nature, some information could be deemed to be material. Accordingly, we encourage investors, the media, and others interested in us to review the information that we share on the Investors section of our website, investors.seraprognostics.com.

Overview

We are a women's health company utilizing our proprietary proteomics and bioinformatics platform, and significant data resources, to improve maternal and neonatal health by discovering, developing, and commercializing blood-based biomarker tests and predictive analytic products and services. Our vision is to deliver pivotal and actionable information to pregnant women, their physicians, and health care payers to significantly enhance a mother's pregnancy journey, improve maternal and neonatal health, and dramatically reduce health care costs. We believe that our method of combining the disciplines of proteomics and bioinformatics with rigorous clinical testing, data, and economic analysis enables us to provide physicians and expectant mothers with personally insightful, clinically meaningful, and economically impactful information designed to improve the pregnancy experience and outcomes for mothers and babies.

There are approximately 140 million births globally each year, and approximately 3.7 million births annually in the United States. Of these, it is estimated that as many as 30% are affected by various complications (*i.e.*, a high-risk pregnancy), including: preterm birth, preeclampsia, fetal growth restriction, stillbirth, hypertension of pregnancy, gestational diabetes, and others. In many cases these complications have profound short- and long-term health consequences for the mother and baby. These health consequences of preterm birth alone are estimated to be approximately $25 billion annually in the United States. This underscores that existing methods to predict adverse pregnancy outcomes are insufficient for timely and effective proactive management for the vast majority of high-risk pregnancies. We believe that positive patient outcomes are the result of appropriate care, and the primary differentiator of patient care should be based on a determination of risk informed by a number of factors including our novel diagnostic tests.

Our first commercial product, the PreTRM test, is the only broadly validated, commercially available blood-based biomarker test to accurately predict the risk of a premature delivery, also known as preterm birth. The PreTRM test is a non-invasive blood test given to a pregnant woman, carrying a single fetus, during weeks 18 through 20 of gestation that provides an accurate prediction of the expectant mother's risk of delivering spontaneously before 37 weeks' gestation. Our commercialization strategy includes conducting clinical trials to demonstrate the health and economic benefits of early and accurate detection of preterm birth risk coupled with well-recognized interventions in higher risk patients, illustrating these benefits to healthcare providers and insurance payers, and providing convenient access to the test through streamlined specimen collection options. Beyond demonstration of efficacy, we look forward to studying the effectiveness and implementation of the PreTRM test in a real-world setting. Clinical trials conducted to date include the Prediction and Prevention of Preterm Birth, or the PREVENT-PTB Study, Serum Assessment of Preterm Birth Outcomes Compared to Historical Controls study, or the AVERT PRETERM TRIAL, and the **P**rematurity **R**isk Assessment Combined With Clinical **I**nterventions for Improving Neonatal outco**ME**s study, or the PRIME study. Manuscript results of these studies demonstrate consistency in the reported beneficial impact of the PreTRM test-and-treat strategy. Specifically, this includes evidence of a prolongation of gestation, shortened hospital or neonatal intensive care unit, or NICU, length of stay, and improvements in measures of neonatal morbidity/mortality. Our studies demonstrate a model indicating that by identifying and intervening in at-risk pregnancies, not identifiable by other approaches, babies destined for premature delivery remain in utero longer. This prolongation of gestation in the preterm period leads to more mature babies that require shorter hospital/NICU stays due to improved neonatal health. The PRIME study, for which enrollment was stopped due to efficacy at the interim analysis and is being prepared for publication, includes the same Primary and Secondary outcomes as the AVERT PRETERM TRIAL and affords the continued assessment of this model.

We believe market adoption by both health care providers and payers should be aided by the publications of our PREVENT-PTB study sub-analysis and the peer-reviewed positive data from our AVERT PRETERM TRIAL, as well as upcoming publications, including the results of our PRIME study and other real-world evidence studies. We believe the data that will be published in coming years, together with our current body of evidence, will further demonstrate the clinical and economic utility of our test.

In December 2023, we announced that the Data Safety Monitoring Board, or DSMB, overseeing our PRIME study recommended stopping enrollment due to efficacy, reporting that either co-primary endpoints, neonatal hospital length of stay and composite neonatal morbidity and mortality, met the stopping criteria for statistical significance at the pre-planned interim analysis. We adopted the DSMB's recommendation and stopped PRIME study enrollment to focus on analyzing and reporting the available data. In May 2024, deliveries of all PRIME study participants were complete, inclusive of the approximately 2,000 remaining participants who were enrolled but had not delivered before enrollment was stopped in December 2023 per DSMB recommendation. All mothers and babies within the study have left the hospital and data monitoring for the final PRIME dataset is in progress. Manuscripts reporting study results, including top-line and exploratory analyses, are being prepared for submission and peer review after final analysis expected in fall 2024.

We have built an advanced, proprietary, and scalable proteomics and bioinformatics platform to characterize the biology of pregnancy and to discover and validate key protein biomarkers found in blood that are highly accurate predictors of dynamic changes that occur during pregnancy. By incorporating our proprietary technology platform into our rigorous data-driven development process, we have created a differentiated approach for effectively addressing major milestones, conditions, and features of pregnancy. We believe our large and growing pregnancy dataset (clinical, demographic, proteomic) is a substantial asset for understanding pregnancy complications, health inequities, and the personal pregnancy journey. We envision that our comprehensive approach will enable us to fully characterize one of the most important periods in the lives of women and their babies, and will help to improve their well-being.

We are actively discovering and developing several additional biomarker tests to predict other specific major conditions of pregnancy, such as a pregnancy risk prediction panel test. We believe these tests have the potential to offer significant health benefits to women and their babies. Among other products, we are developing a test designed to provide a more accurate estimate of the delivery date for expectant mothers for the purposes of planning maternity leave, required support, travel arrangements, and related considerations.

Our operations are headquartered in Salt Lake City, Utah, including a CLIA-certified laboratory. Since our inception, we have devoted the majority of our efforts and resources to performing research and development, acquiring product rights, raising capital, establishing facilities, conducting clinical trials, and establishing commercial operations to develop and commercialize our testing and analytics products, primarily the PreTRM test. During this period, we have incurred annual net losses. We have largely funded our operations with proceeds from the sale and issuance of convertible preferred stock, debt financings, bank loans, and the sale and issuance of Class A common stock in our initial public offering, or IPO, which was completed in July 2021.

We have incurred significant operating losses since inception. Our net losses were $8.3 million and $10.5 million for the three months ended June 30, 2024 and 2023, respectively and $16.4 million and $21.1 million for the six months ended June 30, 2024 and 2023, respectively. We expect to incur significant additional operating losses and negative cash flows for the foreseeable future, principally as a result of our commercialization activities for the PreTRM test, and to support additional clinical studies, publications, and anticipated research and development of our other pipeline products and services.

We have taken steps to significantly reduce our annual operating expenses across all aspects of our business and we believe our cash runway is sufficient to enable us to operate into 2027 based on our existing operating plans. We will continue to evaluate the allocation of our resources as we focus our efforts to accelerate the market adoption of our PreTRM test and the development and launch of additional pipeline products and services. Our evidence portfolio continues to grow with the publication of the PREVENT-PTB study sub-analysis of the potential benefit of care coordination and low-dose aspirin paired with PreTRM test results.

We recently announced the publication of the positive results from the AVERT PRETERM TRIAL in *Diagnostics*, an international, peer-reviewed, open access journal on medical diagnosis. *Diagnostics* highlighted this study on the cover of the journal issue. Notable results indicated an 18% reduction in severe neonatal morbidity and mortality. Additionally, there was a 7-day reduction in the mean neonatal hospital length of stay among neonates with the longest stays. The trial also showed an increase in the average gestational age at birth before 32 weeks by 2.48 weeks. Furthermore, there was a

28-day reduction in the neonatal length of hospital stay for babies born before 32 weeks' gestation, significantly reducing the time spent in the hospital for those at risk of the earliest delivery. Significant reductions in neonatal morbidity and mortality were also reported, as well as hospital and NICU lengths of stay, in the entire intent-to-treat population. The test-and-treat strategy was linked to decreased odds of preterm birth and spontaneous preterm birth at various gestational ages.

Our real-world evidence implementation programs, targeting to expand PreTRM clinical utility data and replicate randomized controlled trial evidence in the real world, have been developed for study launches anticipated in the second half of 2024 and in 2025.

We recently completed validation of certain whole-blood collection and whole-blood compatible testing technologies, and have begun marketing and processing whole-blood specimens. This evolution to whole-blood collection will remove laborious specimen processing steps such as centrifugation and enable in-office physician or at-home consumer collection channels. We believe that whole-blood collection technologies, paired with ambient specimen shipment approaches, may enable greater market penetration and an optimal customer experience, while also potentially lowering costs.

We will continue to opportunistically pursue contracts with private and governmental payers and health systems with new positive data from the PREVENT-PTB study, the AVERT PRETERM TRIAL, and the PRIME study, along with real-world evidence studies and other data we plan to generate, and we believe these efforts may eventually result in material revenues. However, if we are unable to secure payer contracts and generate significant market adoption by providers resulting in significant revenues, or if we fail to develop and successfully market our additional tests that generate additional revenues, we may be required to delay, scale back or abandon some, or all, of our development programs and other operations. Until such time as we can generate significant revenue from the sales of our products, if ever, we may need to continue to finance our cash needs through equity offerings, debt financings or other capital sources, potentially including collaborations or other similar arrangements. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends and may require the issuance of warrants. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may have to significantly delay, reduce, or eliminate some or all of our product development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Our ability to access capital when needed is not assured and, if not achieved on a timely basis, will materially harm our business, financial condition, and results of operations.

Key Components of Our Results of Operations

Revenues

Substantially all of our revenue in the near term is expected to come from sales of the PreTRM test. We expect to derive future revenues from PreTRM and other pipeline tests. As we continue to engage with payers and health systems using our latest evidence, we aim to close additional contracts which are expected to eventually result in additional revenues when health care providers order the PreTRM test. We believe market adoption by both health care providers and payers could be aided by the publication of the PREVENT-PTB study sub-analysis, the recent publication of the AVERT PRETERM TRIAL results, the future publication of positive PRIME study data, and other evidence generated within the next three years. We believe market accessibility of the test could be improved by our recent developments in diversifying our specimen collection methods and enhanced awareness and engagement with patients. Revenue from our other pipeline products and services is expected to be dependent on our ability to successfully market them to patients, providers, payers, and, in most cases, a combination of the three.

Operating Expenses

Cost of Revenue

Cost of revenue reflects the aggregate costs incurred in delivering products to customers (e.g., proteomic testing results to clinicians) and includes expenses related to third-party specimen collection and shipping costs, as well as our lab personnel, materials and supplies, equipment, and infrastructure expenses associated with clinical testing, and allocated overhead including rent and equipment depreciation. Some of these components can vary significantly in cost and reliability of supply, and we periodically seek ways to make our supplier network more robust. For example, to address the

risk posed by potential disruptions in specimen collection services described in the “Risk Factors” section of this report, we have contracted with alternative specimen collection providers beyond those that have traditionally supplied the majority of our needs, and have developed additional collection methods. We expect costs of revenue will generally move in line with the sales of our products.

Research and Development Expenses

Research and development expenses consist of costs incurred for our research activities and development of our product candidates. These expenses include:

- clinical and real-world studies;
- laboratory processes;
- research and bioinformatic activities;
- biobanking and publication efforts;
- personnel-related expenses, including salaries, payroll taxes, employee benefits, and stock-based compensation charges for employees engaged in these research and development activities;
- direct study expenses incurred under agreements with study sites or contract research organizations;
- consultants engaged in our research and development efforts;
- laboratory materials and supplies;
- facilities costs; and
- depreciation, amortization, and other direct and allocated expenses, including insurance, and other operating costs, incurred as a result of our research and development activities.

We expense all research and development costs, both internal and external, in the period in which they are incurred. We expect that our research and development expenses will increase slightly in 2024 compared to 2023 due to increased product development activities, offset by decreased clinical study costs following our ending enrollment in the PRIME study due to efficacy at the interim analysis at the end of 2023. Research and development costs may continue to increase in the medium to long-term as we support current and additional clinical studies, publications, and other product development activities.

Selling and Marketing Expenses

Selling and marketing expenses consist primarily of salaries, payroll taxes, employee benefits, and stock-based compensation charges for sales, marketing, and payer access personnel. Other significant costs include travel, consulting, public relations, and legal costs related to commercial efforts. We expect selling and marketing expenses will decrease in 2024 compared to 2023 as we recently took steps to further streamline our near-term commercial strategy to refocus on institutional sales as we generate additional clinical data. We expect selling and marketing expenses to accelerate as early as the second half of 2024 and further increase in the medium to long-term as we expand our investment in pursuit of PreTRM commercial opportunities, and as we increase our commercial investments in our product portfolio.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries, payroll taxes, employee benefits, and stock-based compensation charges for personnel in executive, finance, information technology, human resources, and other administrative functions. Other significant costs include facilities, corporate and intellectual property legal fees, accounting, insurance, consulting, and other professional fees.

We expect general and administrative expenses in 2024 could remain consistent or decrease slightly compared to 2023, but such expenses could increase in the medium to long-term as needed to support future operations and anticipated revenue growth.

Interest Expense

Interest expense represents interest incurred on our finance leases.

Other Income, Net

Other income, net consists of interest income and other investment income earned on our cash, cash equivalents, and marketable securities, and other gains and losses.

Results of Operations

The results of operations presented below should be reviewed in conjunction with the condensed financial statements and related notes included elsewhere in this report.

Comparison of the Three Months Ended June 30, 2024 and 2023

The following table summarizes our results of operations for the three months ended June 30, 2024 and 2023:

	Three Months Ended June 30,		
	2024	2023	$ Change
		(in thousands)	
		(unaudited)	
Revenue	$ 24	$ 123	$ (99)
Operating expenses:			
Cost of revenue	20	80	(60)
Research and development	4,406	3,688	718
Selling and marketing	1,099	2,872	(1,773)
General and administrative	3,752	4,943	(1,191)
Total operating expenses	9,277	11,583	(2,306)
Loss from operations	(9,253)	(11,460)	2,207
Interest expense	(8)	(14)	6
Other income, net	958	932	26
Net loss	$ (8,303)	$ (10,542)	$ 2,239

Research and Development Expenses

The following table summarizes our research and development expenses for the three months ended June 30, 2024 and 2023:

	Three Months Ended June 30,		
	2024	2023	$ Change
		(in thousands)	
		(unaudited)	
Research and development expenses:			
Clinical studies	$ 1,131	$ 1,540	$ (409)
Research and bioinformatics	2,465	1,079	1,386
Laboratory operations	810	1,069	(259)
Total research and development expenses	$ 4,406	$ 3,688	$ 718

The $0.7 million increase in total research and development expenses was due to a $1.4 million increase in research and bioinformatics costs, partially offset by a $0.4 million decrease in clinical study costs and a $0.3 million decrease in laboratory operations costs. The $1.4 million increase in research and bioinformatics costs was primarily due to a $0.7 million increase in consulting and outside processing expenses related to product development activities, a $0.5 million increase in stock-based compensation expense, and a $0.1 million increase in personnel costs due to increased average headcount. The $0.4 million decrease in clinical study costs was primarily due to a $0.3 million decrease in PRIME study costs resulting from stopping enrollment in December 2023 due to efficacy and a $0.2 million decrease in personnel costs due to decreased average headcount. The $0.3 million decrease in laboratory operations costs was primarily

due to a $0.2 million decrease in personnel costs due to decreased average headcount and a $0.1 million decrease in lab supplies.

Selling and Marketing Expenses

The $1.8 million decrease was due primarily to decreases of $1.2 million in personnel-related costs driven by decreased average headcount, $0.2 million in stock-based compensation expense, $0.2 million in marketing programs and materials, and $0.1 million in travel expenses. These decreases are largely a result of steps we took to further streamline our near-term commercial strategy to refocus on institutional sales as we generate additional clinical data.

General and Administrative Expenses

The $1.2 million decrease was due primarily to decreases of $0.7 million related to one-time personnel costs, $0.3 million in personnel-related costs driven by decreased average headcount, $0.1 million of director and officer insurance costs, and $0.1 million in professional services fees. The decreases in personnel-related costs are largely a result of steps we took to streamline our general and administrative expenses to maintain the appropriate level of support for our current level of operations.

Comparison of the Six Months Ended June 30, 2024 and 2023

The following table summarizes our results of operations for the six months ended June 30, 2024 and 2023:

	Six Months Ended June 30,		
	2024	2023	$ Change
	(in thousands) (unaudited)		
Revenue	$ 24	$ 223	$ (199)
Operating expenses:			
Cost of revenue	37	142	(105)
Research and development	8,089	7,791	298
Selling and marketing	2,326	5,690	(3,364)
General and administrative	7,922	9,389	(1,467)
Total operating expenses	18,374	23,012	(4,638)
Loss from operations	(18,350)	(22,789)	4,439
Interest expense	(17)	(30)	13
Other income, net	1,967	1,712	255
Net loss	$ (16,400)	$ (21,107)	$ 4,707

Research and Development Expenses

The following table summarizes our research and development expenses for the six months ended June 30, 2024 and 2023:

	Six Months Ended June 30,		
	2024	2023	$ Change
	(in thousands) (unaudited)		
Research and development expenses:			
Clinical studies	$ 2,145	$ 3,370	$ (1,225)
Research and bioinformatics	4,271	2,175	2,096
Laboratory operations	1,673	2,246	(573)
Total research and development expenses	$ 8,089	$ 7,791	$ 298

The $0.3 million increase in total research and development expenses was due to a $2.1 million increase in research and bioinformatics costs, partially offset by a $1.2 million decrease in clinical study costs and a $0.6 million decrease in laboratory operations costs. The $2.1 million increase in research and bioinformatics costs was primarily due to a $1.2 million increase in consulting and outside processing expenses related to product development activities, a $0.7 million increase in stock-based compensation expense, and a $0.2 million increase in personnel costs due to increased average headcount. The $1.2 million decrease in clinical study costs was primarily due to a $0.9 million decrease in PRIME study costs resulting from stopping enrollment in December 2023 due to efficacy and a $0.5 million decrease in personnel costs due to decreased average headcount, partially offset by a $0.1 million increase in consulting costs. The $0.6 million decrease in laboratory operations costs was primarily due to a $0.5 million decrease in personnel costs due to decreased average headcount and a $0.2 million decrease in lab supplies.

Selling and Marketing Expenses

The $3.4 million decrease was due primarily to decreases of $2.4 million in personnel-related costs driven by decreased average headcount, $0.4 million in travel expenses, $0.3 million in stock-based compensation expense, and $0.3 million in marketing programs and materials. These decreases are largely a result of steps we took to further streamline our near-term commercial strategy to refocus on institutional sales as we generate additional clinical data.

General and Administrative Expenses

The $1.5 million decrease was due primarily to decreases of $0.8 million in personnel-related costs driven by decreased average headcount, $0.6 million related to one-time personnel costs, $0.2 million of director and officer insurance costs, $0.2 million in professional services fees, and $0.2 million in other miscellaneous costs (such as facilities and equipment depreciation), partially offset by an increase of $0.6 million in stock-based compensation expense. The decreases in personnel-related and other miscellaneous costs are largely a result of steps we took to streamline our general and administrative expenses to maintain the appropriate level of support for our current level of operations.

Other Income, Net

The $0.3 million increase in other income, net was due to a $0.8 million increase related primarily to interest income on our marketable securities, partially offset by a $0.5 million decrease in investment income related primarily to our marketable securities.

Liquidity and Capital Resources

Sources of Liquidity

Since inception, we have not generated a significant amount of commercial revenue from product sales or any other sources and have incurred significant operating losses and negative cash flows from operations. We anticipate that we will continue to incur net losses for the foreseeable future. We have financed our operations primarily through proceeds from the sale and issuance of convertible preferred stock and convertible notes, bank loans, and the sale and issuance of Class A common stock in our IPO, which was completed in July 2021. As of June 30, 2024, we had aggregate cash, cash equivalents, and available-for-sale securities of $80.9 million, and an accumulated deficit of $263.3 million.

Cash Flows

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

	Six Months Ended June 30,	
	2024	2023
	(in thousands)	
	(unaudited)	
Net cash provided by (used in):		
Operating activities	$ (934)	$ (12,829)
Investing activities	(540)	15,228
Financing activities	2,258	8
Net increase in cash and cash equivalents	$ 784	$ 2,407

Operating Activities

The net cash used in operating activities during the six months ended June 30, 2024 was primarily due to a net loss of $16.4 million, partially offset by an increase in operating assets and liabilities of $11.7 million and non-cash charges of $3.8 million. The net cash used in operating activities during the six months ended June 30, 2023 was primarily due to a net loss of $21.1 million partially offset by non-cash charges of $3.1 million and an increase in operating assets and liabilities of $5.2 million.

Investing Activities

Net cash used in investing activities for the six months ended June 30, 2024 was primarily due to $26.6 million in purchases of marketable securities and $0.7 million in purchases of intangible assets, partially offset by $26.7 million in proceeds from maturities and sales of marketable securities. Net cash provided by investing activities for the six months ended June 30, 2023 was primarily due to $38.1 million in proceeds from maturities and sales of marketable securities, partially offset by $23.1 million in purchases of marketable securities.

Financing Activities

Net cash provided by financing activities for the six months ended June 30, 2024 was primarily due to $2.5 million in proceeds from employee equity transactions, partially offset by $0.2 million of finance lease principal payments. Net cash provided by financing activities for the six months ended June 30, 2023 was primarily due to $0.2 million in proceeds from employee equity transactions, partially offset by $0.2 million of finance lease principal payments.

Future Funding Requirements

We expect to incur significant additional operating losses and negative cash flows for the foreseeable future. We expect our losses in the future to arise principally as a result of our commercialization activities for the PreTRM test and the development, commercialization, marketing, and distribution of our other pipeline products and services, especially the costs of evidence-generating initiatives. There can be no assurance that we will eventually achieve significant revenues or profitability, or if achieved, can sustain either on a continuing basis. If we are unable to achieve significant revenues or raise additional funding, when needed, we may not be able to continue the development or commercialization of our products and services and could be required to delay, scale back, or abandon some or all of our development programs and other operations. No assurance can be given that we will be successful in raising the required capital at reasonable cost and at the required times, or at all. Any additional equity financing may not be available on favorable terms, most likely will be dilutive to our current stockholders, and debt financing, if available, may involve restrictive covenants and dilutive financing instruments. Further, our operating plan may change, and we may need additional funds to meet operational needs and capital requirements for product development and commercialization sooner than planned. We currently have no credit facility or committed sources of capital. Our future funding requirements will depend on many factors, including the following:

- the timing, receipt, and amount of sales from the PreTRM test and other pipeline products and services;
- the cost and timing of establishing sales, marketing, and other commercialization capabilities in the United States and abroad;
- our ability to develop and commercialize other products and services;
- the terms and timing of any collaborative, licensing, and other arrangements that we may establish;
- the cost, timing, and outcomes of regulatory approvals;
- the scope, rate of progress, results, and cost of our clinical, scientific, and real-world studies, and other related activities;
- the cost of preparing, filing, prosecuting, defending, and enforcing any patent claims and other intellectual property rights;
- the extent to which we acquire or invest in businesses, products, services, or technologies, although we currently have no commitments or agreements relating to any of these types of transactions;
- partnerships and other strategic options for our PreTRM test and other product candidates; and
- other factors described in the “Risk Factors” section and elsewhere in this report.

We believe that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months.

Contractual Obligations and Commitments

Our contractual obligations and commitments for the year ended December 31, 2023 are set forth in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in our Annual Report on Form 10-K for the year ended December 31, 2023 filed with the SEC on March 20, 2024. No material changes have occurred during the six months ended June 30, 2024.

Critical Accounting Policies and Estimates

A summary of our critical accounting policies and estimates is included in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in our Annual Report on Form 10-K for the year ended December 31, 2023 filed with the SEC on March 20, 2024. There have been no significant changes in the application of our critical accounting policies, significant judgments and use of estimates during the six months ended June 30, 2024.

Emerging Growth Company and Smaller Reporting Company Status

We are an emerging growth company, or EGC, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. We elected to use the extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that we (1) are no longer an EGC

or (2) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies, reduce disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and are exempt from the requirements of holding a nonbinding advisory vote on executive compensation and any golden parachute payments not previously approved. As an EGC, we are also not required to have our internal control over financial reporting audited by our independent registered public accounting firm pursuant to Section 404 of the Sarbanes-Oxley Act. As a result, our financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates and we are not required to provide auditor attestation regarding requirements of Section 404(b) of Sarbanes-Oxley.

We will remain an EGC until the earliest to occur of: (1) the last day of the fiscal year in which we have at least $1.235 billion in annual revenue; (2) the last day of the fiscal year in which we are deemed to be a “large accelerated filer,” as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common stock held by non-affiliates exceeded $700.0 million as of the last business day of the second fiscal quarter of such year; (3) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period; and (4) December 31, 2026.

We are also a “smaller reporting company” as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies until the fiscal year following the determination that the market value of our voting and non-voting common stock held by non-affiliates is more than $250 million measured on the last business day of our second fiscal quarter, or our annual revenues are less than $100 million during the most recently completed fiscal year and the market value of our voting and non-voting common stock held by non-affiliates is more than $700 million measured on the last business day of our second fiscal quarter.

Recent Accounting Pronouncements

A description of recent accounting pronouncements that may potentially impact our financial position, results of operations or cash flows is disclosed in Note 2—Significant Accounting Policies.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Risk

Our exposure to changes in interest rates relates primarily to interest earned and market value on our cash and cash equivalents and marketable securities.

Our cash and cash equivalents and marketable securities consist of cash held in banks, money market funds, commercial paper, U.S. government securities, U.S. federal agency securities and investment grade corporate securities. Our investment policy and strategy are focused on preservation of capital and supporting our liquidity requirements. Changes in U.S. interest rates affect the interest earned on our cash and cash equivalents and marketable securities, and the market value of those securities. A hypothetical 100 basis point increase in interest rates would have resulted in a decrease of $0.6 million in the market value of our available-for-sale debt securities as of June 30, 2024. Any realized gains or losses resulting from such interest rate changes would only occur if we sold the investments prior to maturity. We do not intend to sell investments while they are in an unrealized loss position and do not believe we will be required to sell the investments before recovery, which may be maturity.

Foreign Currency

We do not regularly incur expenses with vendors outside the United States or that are denominated in currencies other than the U.S. dollar. We may incur such expenses in the future at which point exchange rate fluctuations might adversely affect our expenses, results of operations, financial position and cash flows. To date, exchange rate fluctuations have not had a material effect on our results of operations.

Effects of Inflation

We do not believe inflation has had a material effect on our results of operations during the periods presented. However, the current inflationary environment could affect us by increasing our costs of labor, laboratory supplies, and clinical trials and could adversely affect our business, results of operations, financial position and cash flows. In addition, increased inflation has had, and if it continues to increase, may have, an effect on interest rates and may adversely affect our borrowing rate and our ability to obtain any potential additional funding.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, that are designed to ensure that information required to be disclosed in the 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. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Our 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.

Our management, with the participation of our Chief Executive Officer (our principal executive officer) and Chief Financial Officer (our principal financial officer and principal accounting officer), evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2024. Based on the evaluation of our disclosure controls and procedures as of June 30, 2024, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the period covered by this Quarterly Report on Form 10-Q that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings

We are not currently a party to any material litigation or other material legal proceedings. We may, from time to time, be involved in various legal proceedings arising from the normal course of business activities, and an unfavorable resolution of any of these matters could materially affect our future results of operations, cash flows, or financial position.

Item 1A. Risk Factors

Investing in our Class A common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, the section of this Quarterly Report Form 10-Q entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes, before investing in our Class A common stock. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that affect us. If any of the following risks occur, our business, operating results and prospects could be materially harmed. In that event, the price of our Class A common stock could decline, and you could lose part or all of your investment.

Summary of Risk Factors

Our business is subject to numerous risks and uncertainties, including those highlighted in this section below, that represent challenges that we face in connection with the successful implementation of our strategy. The occurrence of one or more of the events or circumstances described in more detail in the risk factors below, alone or in combination with other events or circumstances, may have an adverse effect on our business, cash flows, financial condition, and results of operations. Such risks include, but are not limited to:

- We have incurred net losses since our inception and we anticipate that we will continue to incur losses for the foreseeable future, which could harm our future business prospects.
- Operating our business requires a significant amount of cash, and our ability to generate sufficient cash depends on many factors, some of which are beyond our control and if we cannot raise additional capital when needed, we may have to curtail or cease operations.
- Our quarterly and annual results may fluctuate from period to period, which could adversely impact the value of our Class A common stock.
- We have derived substantially all of our revenues to date from the PreTRM test, and if our efforts to further increase the use and adoption of the PreTRM test or to develop new products and services in the future do not succeed, our business will be harmed.
- In the near future, we expect to rely on sales to a limited number of direct customers for a significant portion of our revenue and cash flows related to the sale of the PreTRM test, making us subject to customer concentration risk.
- If we are unable to establish and maintain sales and marketing capabilities, we may not be successful in commercializing the PreTRM test.
- Competition in the life science industry, including companies engaged in molecular diagnostics and proteomics, is intense. If we are unable to compete successfully with respect to our current or future products or services, we may not be able to increase or sustain our revenues or achieve profitability.
- If our CLIA-certified laboratory facility becomes inoperable, we will be unable to perform our tests and our business will be harmed.
- Interim, top-line and preliminary data from our clinical trials that we announce or publish from time to time may change as additional data become available and are subject to confirmation, audit, and verification procedures that could result in material changes in the final data.
- Our business would be materially harmed if our proprietary biobank were to become contaminated, lost or destroyed.
- Some of our products and services rely heavily on access to internal and external databases, and loss of access to such databases could materially harm our business.

- We rely on third parties for specimen collection, including phlebotomy services, and commercial courier delivery services, and if these services are disrupted, our business will be harmed.
- We rely on a limited number of suppliers or, in some cases, single suppliers, for some of our laboratory instruments and materials and may not be able to find replacements or immediately transition to alternative suppliers on a cost-effective basis, or at all.
- Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.
- Our estimates of total addressable market opportunity and forecasts of market growth may prove to be inaccurate, and even if the market in which we compete achieves the forecasted growth, our business could fail to grow at a similar rate.
- The inflationary environment could materially adversely impact our business and results of operations.
- If third-party payers do not adequately reimburse for the PreTRM test or any new products we may develop, such products may not be purchased or used, which may adversely affect our revenue and profits.
- New reimbursement methodologies applicable to the PreTRM test, and other future products, including new CPT codes, may decrease reimbursement rates from third-party payers.
- Billing disputes with third-party payers, including disagreement regarding the selection and use of CPT codes when submitting claims, may decrease realized revenue and may lead to requests for recoupment of past amounts paid.
- When third-party payers deny coverage, we are often unable to collect from the patient or any other source and risk disputes if we attempt to do so.
- Our revenues may be adversely impacted if third-party payers withdraw coverage or provide lower levels of reimbursement due to changing policies, billing complexities or other factors.
- Status as an out-of-network provider with a large commercial insurer may cause health care providers to avoid recommending our tests.
- If the validity of an informed consent from a patient is challenged, we could be precluded from billing for such patient's testing, be forced to stop performing certain tests, forced to exclude the patient's data or specimens from clinical trial results or be subject to lawsuits or regulatory enforcement.
- Changes in the way the FDA regulates the reagents, other consumables, and testing equipment we use when developing, validating, and performing our tests could result in delay or additional expense in bringing our tests to market or performing such tests for our customers.
- If we fail to comply with federal and/or state laboratory licensing requirements, we could lose the ability to perform our tests or experience disruptions to our business.
- Any failure to obtain, maintain, and enforce our intellectual property rights could impair our ability to protect our proprietary technology and our brand.
- Issued patents covering our tests and technology could be found invalid or unenforceable, if challenged.
- Our intellectual property may be infringed by a third party.
- If we are not able to prevent disclosure of our trade secrets and other proprietary information, the value of our tests and technology could be significantly diminished.
- The price of our Class A common stock may be volatile, and you could lose all or part of your investment.
- Sales of a substantial number of shares of our Class A common stock by our existing stockholders in the public market could cause our stock price to fall.
- Our inability to maintain effective disclosure controls and procedures could adversely affect our results of operations, liquidity and financial positions, as well as our stock price and investor confidence in us.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred net losses since our inception and we anticipate that we will continue to incur losses for the foreseeable future, which could harm our future business prospects.

We have incurred net losses each year since our inception in 2008. To date, we have financed our operations primarily through private placements of our equity and debt securities, bank loans and the sale and issuance of Class A common stock in our initial public offering ("IPO"), which was completed in July 2021. Our net loss for the six months ended June 30, 2024 and 2023 was $16.4 million and $21.1 million, respectively. As of June 30, 2024, we had an accumulated deficit of $263.3 million. Our losses may continue to increase in the future as we continue to devote a substantial portion of our resources to efforts to increase the adoption of, and reimbursement for, the PreTRM test, make improvements to this product, and research, develop, and commercialize new products and services.

We currently receive substantially all of our revenues from the sales of the PreTRM test and expect to continue to receive revenue from sales of the PreTRM test and our other pipeline products and services in the future. It is possible that we will not generate sufficient revenue from the sales of any of our products and services to cover our costs, including research and development expenses related to furthering our product pipeline, and achieve or sustain profitability. A significant element of our business strategy is to increase and maintain our in-network coverage with third-party payers. However, third-party payers, such as commercial insurers and government health care programs, may decide not to reimburse for the PreTRM test or other tests we may develop, may not reimburse for uses of the PreTRM test or our other tests for the pregnant patient population, or may set the amounts of such reimbursements at prices that do not allow us to cover our expenses. Many third-party payers currently either have negative coverage determinations or otherwise do not reimburse for low-risk patient preterm birth screening tests. State Medicaid programs currently do not reimburse for our tests; third-party payers are increasingly requiring that prior authorization be obtained prior to conducting testing as a condition to reimbursing for it, which may reduce and/or delay the reimbursement amounts.

As there is a possibility that our Company, any collaborators and/or licensees may not successfully develop additional products, obtain required regulatory authorizations for such products, manufacture such products at an acceptable cost or with sufficient quality or successfully market and sell such products with desired margins, our expenses may continue to exceed any revenues we may receive. Our operating expenses also will increase as, or if, among other factors:

- our earlier-stage products move into later-stage development, which is generally more expensive than early-stage development;
- we select additional technologies or products for development;
- we increase the number of patents we are prosecuting or otherwise expend additional resources on patent prosecution or defense; or
- we acquire or in-license additional technologies, product candidates, products or businesses.

Operating our business requires a significant amount of cash, and our ability to generate sufficient cash depends on many factors, some of which are beyond our control and if we cannot raise additional capital when needed, we may have to curtail or cease operations.

In the future, we expect to incur significant costs in connection with our operations, including, but not limited to, the development, marketing authorization, and commercialization of new tests, new services, and other products. These development activities generally require a substantial investment before we can determine commercial viability. We expect to need to raise additional funds through public or private equity or debt financings, collaborations or licensing arrangements to continue to fund or expand our operations.

Our actual liquidity and capital funding requirements will depend on numerous factors, including:

- our ability to achieve broad commercial success with the PreTRM test and other pipeline products and services;
- the scope and duration of, and expenditures associated with, our discovery efforts and research and development programs, including for our proprietary proteomics and bioinformatics platform;
- the costs to fund our commercialization strategies for any product candidates which we launch and to prepare for potential product marketing authorizations, as required;
- the costs of any acquisitions of complementary businesses or technologies that we may pursue;

- potential licensing or partnering transactions, if any;
- our facility expenses, which will vary depending on the time and terms of any facility lease or sublease we may enter into, and other operating expenses;
- the scope and extent of the expansion of our sales and marketing efforts;
- the commercial success of our other products and services;
- our ability to obtain more extensive coverage and reimbursement for the PreTRM test and other products and services, if any; and
- our ability to collect our accounts receivable.

The availability of additional capital, whether from private capital sources, such as banks, or the public capital markets, may fluctuate as our financial condition and market conditions in general change. There may be times when the private capital sources and the public capital markets lack sufficient liquidity or when our securities cannot be sold at attractive prices, or at all, in which case we would not be able to access capital from these sources. In addition, any weakening of our financial condition or deterioration in our credit ratings could adversely affect our ability to obtain necessary funds. Even if available, additional financing could be costly or have adverse consequences.

Additional capital, if needed, may not be available on satisfactory terms or at all. Furthermore, any additional capital raised through the sale of equity or equity-linked securities will dilute our stockholders' ownership interests and may have an adverse effect on the price of our Class A common stock. In addition, the terms of any financing may adversely affect stockholders' holdings or rights. Debt financing, if available, may include restrictive covenants. To the extent that we raise additional funds through collaborations and licensing arrangements, it may be necessary to relinquish some rights to our technologies or grant licenses on terms that may not be favorable to us.

If we are not able to obtain adequate funding when needed, we may be required to delay development programs or sales and marketing initiatives. If we are unable to raise additional capital in sufficient amounts or on satisfactory terms, we may have to reduce our workforce and may be prevented from continuing our discovery, development and commercialization efforts and leveraging other corporate opportunities. In addition, it may be necessary to work with a partner on one or more of our tests or products under development, which could lower our economic value of those products. Each of the foregoing factors may harm our business, operating results, and financial condition and may impact our ability to continue as a going concern.

Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults or non-performance by financial institutions or transactional counterparties, could adversely affect our current and projected business operations and our financial condition and results of operations.

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank, or SVB, was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation, or the FDIC, as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership. In addition, on May 1, 2023, the FDIC announced that First Republic had been closed by the California Department of Financial Protection and Innovation and its assets seized by the FDIC. If any of our partners, suppliers, or other parties with whom we conduct business are unable to access funds pursuant to such instruments or lending arrangements with such a financial institution, such parties' ability to pay their obligations to us or to enter into new commercial arrangements requiring additional payments to us could be adversely affected. Similar impacts have occurred in the past, such as during the 2008-2010 financial crisis.

Inflation and rapid increases in interest rates have led to a decline in the trading value of previously issued government securities with interest rates below current market interest rates. Although the U.S. Department of Treasury, FDIC and Federal Reserve Board have announced a program to provide up to $25 billion of loans to financial institutions secured by certain of such government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments, widespread demands for customer withdrawals or other liquidity needs of financial institutions for immediate liquidity may exceed the capacity of such program. There is no guarantee that the U.S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions, or that they would do so in a timely fashion.

Although we assess our banking relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect us, the financial institutions with which we have arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could involve financial institutions or financial services industry companies with which we have financial or business relationships, but could also include factors involving financial markets or the financial services industry generally.

The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to, the following:

- Delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets;
- Loss of access to revolving existing credit facilities or other working capital sources and/or the inability to refund, roll over or extend the maturity of, or enter into new credit facilities or other working capital resources;
- Potential or actual breach of contractual obligations that require us to maintain letters or credit or other credit support arrangements; or
- Termination of cash management arrangements and/or delays in accessing or actual loss of funds subject to cash management arrangements.

In addition, investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and/or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and/or projected business operations and financial condition and results of operations.

In addition, any further deterioration in the macroeconomic landscape or financial services industry could lead to losses or defaults by parties with whom we conduct business, which in turn, could have a material adverse effect on our current and/or projected business operations and results of operations and financial condition.

Our quarterly and annual results may fluctuate from period to period, which could adversely impact the value of our Class A common stock.

Our quarterly and annual results of operations, including our revenues, gross margin, net loss, and cash flows, may vary from period to period as a result of a variety of factors, many of which are outside of our control, including those listed elsewhere in this “Risk Factors” section, and as a result, period-to-period comparisons of our operating results may not be meaningful. Our quarterly and annual results should not be relied upon as an indication of future performance. In addition, to the extent that we continue to spend considerably on our internal sales and marketing and research and development efforts, we expect to incur costs in advance of achieving the anticipated benefits of such efforts. We also face competitive pricing and reimbursement pressures, and we may not be able to maintain our premium pricing in the future, which would adversely affect our operating results. Fluctuations in quarterly and annual results and key metrics may cause our results to fall below our financial guidance, if any, or other projections or goals, or the expectations of analysts or investors, which could adversely affect the price of our Class A common stock.

Risks Related to Our Business and Industry

We have derived substantially all of our revenues to date from the PreTRM test, and if our efforts to further increase the use and adoption of the PreTRM test or to develop new products and services in the future do not succeed, our business will be harmed.

We currently receive and expect to continue to receive substantially all of our revenues from the sales of the PreTRM test in the near term. We intend to establish reimbursement for the PreTRM test by collaborating with payers to perform rigorous analysis to demonstrate the health and economic benefits of our biomarker tests within their own network using customized inputs based on the plan's patient population. We plan to leverage early payer reimbursement decisions to obtain widespread commercial coverage of the PreTRM test from many regional and national plans and medical groups with doctors ordering the PreTRM test. If we are unable to execute on this commercial strategy and increase our revenues from the sale of the PreTRM test, our business may be materially adversely impacted. Our ability to increase sales of the PreTRM test and establish greater levels of adoption and reimbursement for the PreTRM test is uncertain for many reasons, including, among others:

- we may be unable to demonstrate to clinics, clinicians, physicians, payers, and patients that the PreTRM test is superior to alternatives with respect to value, convenience, accuracy, scope of coverage, and other factors;
- third-party payers may set the amounts of reimbursement at prices that reduce our profit margins or do not allow us to cover our expenses;
- we may not be able to maintain and grow effective sales and marketing capabilities;
- our sales and marketing efforts may fail to effectively reach customers or communicate the benefits of the PreTRM test;
- superior alternatives to the PreTRM test may be developed and commercialized and we may not be able to compete against these alternatives;
- we may face competitive pressures;
- we may experience supply constraints, including due to the failure of our key suppliers to provide laboratory supplies, instruments, and reagents;
- we may encounter difficulties with transportation logistics, regulations and quality associated with shipping blood specimens, including infrastructure conditions, transportation delays and temperature stress;
- we may encounter laboratory process difficulties that impact the quality and timeliness of reporting of test results;
- U.S. or foreign regulatory or legislative bodies may adopt new regulations or policies or take other actions that impose significant restrictions on, or other challenges to, our ability to sell or market our products and services;
- news media organizations, medical societies, or industry groups may issue publications, guidance, or analyses that negatively impact patients' and/or health care providers' perception or utilization of the PreTRM test (or certain types of prenatal testing and related health care services, generally) and thereby negatively impact our ability to sell or market the PreTRM test;
- we may be unable to compete successfully with respect to our current or future products or services, as a result of which we may not be able to increase or sustain our revenues or achieve profitability; and
- we may not be able to protect our intellectual property position.

If our market share for the PreTRM test fails to grow or grows more slowly than expected, or if our efforts to develop new products and services in the future do not succeed, our business, operating results, and financial condition would be adversely affected.

Our success depends on broad scientific and market acceptance of the PreTRM test and our other pipeline products and services, which we may fail to achieve.

Our ability to achieve and maintain scientific and commercial market acceptance of the PreTRM test will depend on a number of factors. We expect that the PreTRM test will be subject to the market forces and adoption curves common to other new technologies. The market for proteomics and bioinformatics technologies and products is in its early stages of development. If widespread adoption of the PreTRM test or any other products and services that we commercialize in the future takes longer than anticipated, we will continue to experience operating losses. The success of life sciences

technologies and products is due, in large part, to acceptance by the scientific and medical communities and their adoption of certain products in the applicable field of research. The life sciences scientific community is often led by a small number of early adopters and key opinion leaders who significantly influence the rest of the community through publications in peer-reviewed journals. In such journal publications, the researchers will describe their discoveries, and also the methods, and typically the products used, to fuel such discoveries. Mentions in peer-reviewed journal publications may be a driver for the general acceptance of products for the life sciences industry, such as the PreTRM test. In addition, continuing collaborative relationships with opinion leaders will be vital to maintaining any market acceptance we achieve. If too few researchers describe the use of our products or services, too many researchers shift to a competing product or service and publish research outlining their use of that product or service, or too many researchers negatively describe the use of our products or services in publications, it may drive customers away from our products or services. Other factors in achieving commercial market acceptance include:

- our ability to market and increase awareness of the capabilities of the PreTRM test;
- the ability of the PreTRM test to demonstrate comparable performance in intended use applications broadly in the hands of customers;
- our customers' willingness to adopt new products, services, and workflows;
- the PreTRM test's ease of use and whether it reliably provides advantages over other alternative technologies;
- the rate of adoption of the PreTRM test by patients, physicians, payers and the medical community at large;
- medical society guidelines supporting the use of the PreTRM test and clinical interventions based on it;
- the prices we charge for the PreTRM test;
- our ability to develop new products, services, and solutions for customers;
- whether competitors develop and commercialize products that perform similar functions as the PreTRM test; and
- the impact of our investments in product and service innovation and commercial growth.

We cannot assure that we will be successful in addressing each of these criteria or other criteria that might affect the market acceptance of any products or services we commercialize, particularly the PreTRM test. If we are unsuccessful in achieving and maintaining market acceptance of the PreTRM test, our business, financial condition, and results of operations would be adversely affected.

In the near future, we expect to rely on sales to a limited number of direct customers for a significant portion of our revenue and cash flows related to the sale of the PreTRM test, making us subject to customer concentration risk.

We expect that a significant portion of our revenue and cash flows in the near future will be related to sales to a limited number of customers, including Elevance Health, the loss of any of which could adversely affect our business, financial condition, cash flows, and results of operations. Accordingly, we are subject to customer concentration risk. Furthermore, any termination of our relationship with Elevance Health would also adversely impact our strategy to rapidly accelerate commercialization of the PreTRM test and help incentivize broader market adoption.

If we are unable to establish and maintain sales and marketing capabilities, we may not be successful in commercializing the PreTRM test.

We have limited experience as a company in sales and marketing and our ability to achieve profitability depends on our being able to attract customers for the PreTRM test and our future products or services, once approved. Although members of our management team have considerable industry experience, successfully commercializing the PreTRM test will require adapting our sales, marketing, distribution, and customer service and support capabilities to current and ever-changing market conditions. To perform sales, marketing, distribution, and customer service and support successfully, we will face a number of risks, including:

- our ability to attract, retain, and manage the sales, marketing, and customer service and operations workforce necessary to commercialize and gain market acceptance for our technology;
- the time and cost of establishing a specialized sales, marketing, and customer service and operations workforce; and
- our sales, marketing, and customer service and support team may be unable to initiate and execute successful commercialization activities.

We may seek to enlist one or more third parties to assist with sales, distribution, and customer service and support. There is no guarantee, if we do seek to enter into such arrangements, that we will be successful in attracting desirable sales and distribution partners or that we will be able to enter into such arrangements on favorable terms. If our sales and marketing efforts, or those of any third-party sales and distribution partners, are not successful, the PreTRM test may not gain market acceptance, which could materially impact our business operations.

Even if the PreTRM test achieves broad scientific and market acceptance, if we fail to improve it or introduce compelling new products and services, our future revenues and prospects could be harmed.

Even if we are able to achieve broad scientific and market acceptance for the PreTRM test, our ability to grow our business will depend in large part on our ability both to enhance and improve the PreTRM test and to introduce compelling new products and services, including for major pregnancy related conditions beyond preterm birth. The success of any enhancement to the PreTRM test or introduction of new products or services depends on several factors, including completion of certain clinical development requirements, timely completion and delivery of the product or service, competitive pricing, adequate quality testing, integration with existing technologies, appropriately timed and staged product or service introductions, and overall market acceptance. Any new product, new service, or enhancement to the PreTRM test that we develop may not be introduced in a timely or cost-effective manner, may contain defects, errors or vulnerabilities or may not achieve the market acceptance necessary to generate significant revenue.

The typical development cycle of new life sciences products or services can be lengthy and complicated and may require new scientific discoveries or advancements, considerable resources, and complex technology and engineering. Such developments may involve external suppliers and service providers, making the management of development projects complex and subject to risks and uncertainties regarding timing, timely delivery of required components or services and satisfactory technical performance of such components or assembled products. If we do not achieve the required technical specifications or successfully manage development processes of the new product or service, or if development work is not performed according to schedule, then such new technologies, products, or services may be adversely impacted. To date, we have only completed the development process for one product. We cannot assure you that we will ever succeed in completing that process for another product, including for major pregnancy related conditions beyond preterm birth, or that even if we do, it will be launched successfully in the market and find commercial acceptance. If we are unable to successfully develop new products or services, enhance the PreTRM test to meet customer requirements, compete with alternative products and services or otherwise gain and maintain market acceptance, our business, results of operations, and financial condition could be harmed.

Competition in the life science industry, including companies engaged in molecular diagnostics and proteomics, is intense. If we are unable to compete successfully with respect to our current or future products or services, we may not be able to increase or sustain our revenues or achieve profitability.

We are a women's health diagnostic company utilizing our proprietary proteomics and bioinformatics platform to discover, develop, and commercialize biomarker tests, and our first commercial product, the PreTRM test, is designed to accurately predict the risk of premature delivery. The proteomics and bioinformatics industry is characterized by rapid technological changes, frequent new product introductions, reimbursement challenges, emerging competition, intellectual property disputes and litigation, price competition, aggressive marketing practices, evolving industry standards and changing customer preferences. We cannot guarantee that research, discoveries or other advancements by other companies will not render our existing or potential products and services uneconomical or result in products and services that are superior or otherwise preferable to our current or future products and services.

We face competition with respect to the PreTRM test and expect to face competition with respect to any product candidates that we may seek to develop or commercialize in the future. Many of the companies against which we are competing or may compete against in the future have significantly greater financial resources and expertise in research and development, manufacturing, and commercialization. Mergers and acquisitions in our industry may result in even more resources being concentrated among a smaller number of our competitors. Smaller and early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel and conducting clinical trials, as well as in acquiring technologies complementary to, or necessary for, our products and services.

To remain competitive over time, we will need to continually research and develop improvements to our products and services. However, we cannot assure you that we will be able to develop and commercialize any improvements to our

products and services on a timely basis. Our competitors may develop and commercialize competing or alternative products and services and improvements faster than we are able to do so, which would negatively affect our ability to increase or sustain our revenue or achieve profitability.

If our products do not perform as expected, our operating results, reputation, and business will suffer.

Our success depends on the market's confidence that we can provide reliable, high-quality testing results. There is no guarantee that the accuracy and reproducibility we have demonstrated to date will continue as our test volumes continue to increase and our product portfolio continues to expand. We believe that patients that rely on our tests are particularly sensitive to test limitations and errors, including inaccurate test results. As a result, if our tests do not perform as expected or favorably in comparison to competing tests, our operating results, reputation, and business will suffer. We may also become subject to legal claims arising from such limitations, errors or inaccuracies.

The PreTRM test uses, and our future tests will use, a number of complex and sophisticated proteomic and bioinformatics processes and advanced mass spectrometry techniques, which are highly sensitive to external factors. An operational, technological or other failure in one of these complex processes may result in sensitivity or specificity rates that are lower than we anticipate. In addition, we regularly evaluate and refine our testing processes, and any refinements we make may not improve our tests as we expect and may result in unanticipated issues that may adversely affect our test performance as described above. Such operational, technical, and other difficulties adversely affect test performance, may impact the commercial attractiveness of our products and may increase our costs or divert our resources, including management's time and attention, from other projects and priorities. Furthermore, any changes to our testing process may require us to use new or different suppliers or materials with whom or which we are unfamiliar, and which may not perform as we anticipate, and could cause delays, downtime or other operational issues.

If our CLIA-certified laboratory facility becomes inoperable, we will be unable to perform our tests and our business will be harmed.

We currently operate a CLIA-certified laboratory facility in Salt Lake City, Utah, which processes the PreTRM test and likely any other future test, if approved, that is or will be the source of substantially all of our revenues. Our facility could be harmed or rendered inoperable, or our supplies or other assets could be damaged or destroyed, by natural or man-made disasters, including earthquakes, severe weather, flooding, power outages, and contamination, including as a result of a public health threat, which may render it difficult or impossible for us to operate our business and/or perform our tests for some period of time. The inability to perform our tests or the backlog of tests that could develop if our facility is inoperable — for even a short period of time — may harm our reputation and result in a material adverse effect on our revenues.

The marketing, sale, and use of the PreTRM test and any other products that we develop in the future could result in substantial damages arising from product liability or professional liability claims, associated with product recalls or otherwise, that exceed our resources.

The marketing, sale, and use of the PreTRM test and any other products that we develop and commercialize in the future could lead to product liability claims against us if someone were to allege that the PreTRM test or any future product failed to perform as it was designed or as claimed in our promotional materials, was performed pursuant to incorrect or inadequate laboratory procedures, if we delivered incorrect or incomplete test results or if someone were to misinterpret test results. In addition, we may be subject to liability for errors in, a misunderstanding of, or inappropriate reliance upon, the information we provide, or for failure to provide such information, in connection with our marketing and promotional activities or as part of the results generated by the PreTRM test and other future products or services. Even though the PreTRM test is highly accurate, no test is 100% accurate, and we may report false results. In such a scenario, the patient or her family may file a lawsuit against us claiming product or professional liability. In addition, any manufacturing or design defects in our products could lead to product recalls, either voluntary or as required by government authorities, which could result in the removal of a product from the market.

A product liability or professional liability claim could result in substantial damages and be costly and time-consuming for us to defend. Although we maintain product and professional liability insurance, our insurance may not fully protect us from the financial impact of defending against product liability or professional liability claims or any judgments, fines or settlement costs arising out of any such claims, or the financial and reputational consequences of a product recall. Any product liability or professional liability claim brought against us, with or without merit, could increase our insurance rates, cause our insurance coverage to be terminated or prevent us from securing insurance coverage in the future. As we attempt

to bring new products to market, we may need to increase our product liability coverage, which would be a significant additional expense that we may not be able to afford. Additionally, any product liability or professional liability lawsuit could harm our reputation, result in a cessation of PreTRM testing or cause our partners to terminate our agreements with them, any of which could adversely impact our results of operations.

The results of our clinical trials and studies may not support the use of our tests and other product candidates, or may not be replicated in later studies.

We have conducted and are currently conducting a variety of observational and interventional studies for the PreTRM test and our other tests in development that involve clinical investigators at multiple sites in the United States. We may need to conduct additional studies for the PreTRM test, as well as other tests we may offer in the future, to drive test adoption in the marketplace and reimbursement. Should we not be able to perform these studies, or should their results not provide clinically meaningful data and value for clinicians, or if our results are unfavorable, adoption of our tests could be impaired.

The administration of clinical and economic utility studies is expensive and demands significant attention from certain members of our management team. Data collected from these studies may not be positive or consistent with our existing data, or may not be statistically significant or compelling to the medical community or payers. If the results obtained from our ongoing or future studies are inconsistent with certain results obtained from our previous studies, adoption of our products would suffer and our business would be harmed.

Peer-reviewed publications regarding our products and product candidates may be limited by many factors, including delays in the completion of, poor design of, or lack of compelling data from clinical studies, as well as delays in the review, acceptance, and publication process. If our products or product candidates or the technology underlying our current or future products or product candidates do not receive sufficient favorable exposure in peer-reviewed publications, or are not published, the rate of health care provider adoption of our tests and positive reimbursement coverage decisions for our tests and other products could be negatively affected. The publication of clinical data in peer-reviewed journals can be a crucial step in commercializing and obtaining reimbursement for tests, and our inability to control when, if ever, results are published may delay or limit our ability to derive sufficient revenues from any test that is the subject of a study. The performance achieved in published studies may not be repeated in later studies that may be required to obtain FDA marketing authorizations should we decide to do so for business reasons, or should we be required to submit applications to the FDA or other health authorities seeking such authorizations.

In addition, clinical trials must be conducted in accordance with applicable laws and subject to the oversight of Institutional Review Boards, or IRBs. We rely on clinical trial sites to ensure the proper and timely conduct of our clinical trials and while we have agreements governing their committed activities, we have limited influence over their actual performance. We depend on our collaborators and on medical institutions to conduct our clinical trials in compliance with applicable human subject protection regulations and Good Clinical Practice, or GCP, requirements. To the extent our collaborators fail to enroll participants for our clinical trials, fail to conduct our trials in compliance with applicable law and GCP requirements, or are delayed for a significant time in the execution of trials, including achieving full enrollment, we may be affected by increased costs, program delays, or both.

Interim, top-line and preliminary data from our clinical trials that we announce or publish from time to time may change as additional data become available and are subject to confirmation, audit, and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose interim, top-line or preliminary data from our clinical trials, which is based on a preliminary analysis of then-available data, and these results and related findings and conclusions may be subject to change following a more comprehensive review of the data. We also make assumptions, estimations, calculations, and conclusions as part of our analyses of data, and we may not have received or have had the opportunity to fully and carefully evaluate all data. As a result, the interim, top-line or preliminary data that we report may differ from future results of the same trials, or different conclusions or considerations may qualify such results once additional data have been received and fully evaluated. Interim data from clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary, interim or top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary top-line data we previously published. As a result, preliminary, interim, and top-line data should be viewed with caution until the final data are available. Adverse differences between

preliminary, interim, and top-line data and final data could significantly harm our business prospects and may cause the price of our Class A common stock to fluctuate or decline.

Further, payers, physicians, and others may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could adversely impact the potential of the particular product or program, the prospects for commercialization of any product, and the business prospects of our Company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is derived from information that is typically extensive, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

If the preliminary, interim or top-line data that we report differ from later or final results, or if payers, physicians or others disagree with the conclusions reached, our ability to commercialize our product candidates may be significantly impaired, which could materially harm our business, operating results, prospects or financial condition.

Our business would be materially harmed if our proprietary biobank were to become contaminated, lost or destroyed.

A fundamental component of our platform is our proprietary biobank, consisting of comprehensive, clinically and demographically annotated blood specimens collected from thousands of pregnant U.S. women, representing the broad demographic and geographic diversity inherent in the U.S. population. This biobank is maintained at our facility in Salt Lake City, Utah, in a secure environment. If the specimens and information contained in the biobank were to become compromised or destroyed, through contamination, theft, a cybersecurity breach, a natural disaster or otherwise, our ability to rely on the data represented in the biobank could be significantly impaired, which could materially harm our business, operating results, prospects or financial condition.

Some of our products and services rely heavily on access to internal and external databases, and loss of access to such databases could materially harm our business.

Data is a critical driver of our business, and access to large amounts of data housed in both internal and external databases is essential for our existing and future products and services. We maintain much of this data in our own proprietary databases. While we take reasonable measures to protect such internal databases, those measures may be unsuccessful, which could lead to a temporary loss of access to or permanent loss of data, or to other unavailability or modification of such data. Other data used in or essential to our products and services is stored in databases controlled by third parties, including governmental databases. Continued access to such data depends on the third party maintaining such databases and continuing to allow our access on reasonable terms. Loss of access to either internal or external data or databases, or other unavailability or modification of such data could materially harm our business, including the possibility of us needing to discontinue certain products or services.

International expansion of our business will expose us to business, regulatory, political, operational, financial, and economic risks associated with doing business outside the United States.

To the extent that we decide to market our products and services outside the United States, our business will be subject to the risks associated with doing business outside the United States, including an increase in our expenses and diversion of our management's attention from the development of future products and services. Accordingly, our business and financial results in the future could be adversely affected due to a variety of factors, including:

- multiple, conflicting and changing laws and regulations such as data privacy, information security, and data use regulations, tax laws, export and import restrictions, economic sanctions and embargoes, employment laws, anti-corruption laws, regulatory requirements, reimbursement or payer regimes and other governmental approvals, permits, and licenses;
- failure by us or our distributors to obtain any necessary regulatory clearance, authorization or approval for the use of our products and services in various countries;
- additional potentially relevant third-party patent rights;
- complexities and difficulties in obtaining intellectual property protection and maintaining, defending, and enforcing our intellectual property outside the United States;
- difficulties in staffing and managing foreign operations;
- employment risks related to hiring employees outside the United States;

- complexities associated with managing multiple payer reimbursement regimes, government payers or patient self-pay systems;
- difficulties in negotiating favorable reimbursement negotiations with governmental authorities;
- logistics and regulations associated with shipping specimens, including infrastructure conditions and transportation delays;
- limits in our ability to penetrate international markets if we are not able to sell our products or conduct services locally;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products and services and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political and economic instability, including wars, terrorism, and political unrest, outbreak of disease, boycotts, curtailment of trade, and other business restrictions;
- regulatory and compliance risks that relate to maintaining accurate information and control over sales and distributors' activities that may fall within the purview of the U.S. Foreign Corrupt Practices Act, or FCPA, its books and records provisions, or its anti-bribery provisions, or laws similar to the FCPA in other jurisdictions in which we may operate, such as the United Kingdom Bribery Act of 2010, or the U.K. Bribery Act; and
- onerous anti-bribery requirements of several member states in the European Union, the United Kingdom, Japan, and other countries that are constantly changing and require disclosure of information to which U.S. legal privilege may not extend.

Any of these factors could significantly harm our future international expansion and operations and, consequently, our revenue and results of operations.

We may not be able to obtain and maintain the third-party relationships that are necessary to develop and commercialize some or all of our tests.

We expect to depend on collaborators, partners, licensees, and other third parties to support our test development and validation efforts, to deliver needed supplies, and to transport specimens for testing, among other things. Any problems we experience with any of these third parties could delay the development, validation, commercialization, and performance of our testing, which could harm our results of operations.

We cannot guarantee that we will be able to successfully negotiate agreements for, or maintain relationships with, collaborators, partners, licensees, and other third parties on favorable terms, if at all. If we are unable to obtain or maintain these agreements, we may not be able to develop, validate, obtain regulatory authorizations for, or commercialize any future tests, which will in turn adversely affect our business.

We expect to expend substantial management time and effort to enter into relationships with third parties and, if we successfully enter into such relationships, to manage these relationships. In addition, substantial amounts will be paid to third parties in these relationships. However, we cannot control the amount or timing of resources our future contract partners will devote to our business endeavors, and we cannot guarantee that these parties will fulfill their obligations to us under these arrangements in a timely fashion, if at all. In addition, while we manage the relationships with third parties, we cannot control all of the operations of and protection of intellectual property by such third parties.

We rely on third parties for specimen collection, including phlebotomy services, and commercial courier delivery services, and if these services are disrupted, our business will be harmed.

We rely on third parties to perform specimen collection, including phlebotomy services, and to transport specimens to our laboratory facility in a timely and cost-efficient manner. Disruptions in these services, whether due to any natural or other disasters, pandemics, acts of war or terrorism, shipping embargoes, labor unrest, political instability or similar events could adversely affect specimen integrity and our ability to process specimens in a timely manner and to service our customers, and ultimately our reputation and our business. In addition, if we are unable to continue to obtain expedited delivery services on commercially reasonable terms, our operating results may be adversely affected.

In addition, our relationships with these service providers could be scrutinized under federal and state health care laws such as the federal Anti-Kickback Statute and the Stark Law, and their implementing regulations, to the extent, for

example, that these services provide a financial benefit to or relieve a financial burden for a potential referral source. If our operations are found to be in violation of any of these (or other) laws and regulations, we may be subject to administrative, civil and/or criminal penalties, damages, fines, individual imprisonment, refunding of payments received by us, exclusion from government health care programs, and/or curtailment or cessation of our operations, among other potential penalties, any of which could harm our reputation and adversely affect our business, operating results, and financial condition.

We rely on a limited number of suppliers or, in some cases, single suppliers, for some of our laboratory instruments and materials and may not be able to find replacements or immediately transition to alternative suppliers on a cost-effective basis, or at all.

We source components of our technology from third parties and certain components are sole sourced. Obtaining substitute components may be difficult or require us to re-design our products. We expect to continue to depend on third-party contract suppliers for the foreseeable future. Any natural or other disasters, pandemics, acts of war or terrorism, shipping embargoes, labor unrest or political instability or similar events at our third-party suppliers' facilities that cause a loss of manufacturing capacity or a reduction in the quality of the items manufactured would heighten the risks that we face. In addition, inflation and/or global supply chain disruptions may have a negative impact on our third-party contract suppliers' ability to acquire the materials necessary for our business and we could incur higher costs for certain goods or services due to inflation or increased freight costs. Changes to, failure to renew or termination of our existing agreements or our inability to enter into new agreements with other suppliers could result in the loss of access to important components of our tests and could impair, delay or suspend our commercialization efforts. Our failure to maintain a continued and cost-effective supply of high-quality components could materially and adversely harm our business, operating results, and financial condition.

If we are unable to successfully scale our operations, or attract and retain highly skilled employees, our business could suffer.

As our test volumes grow and we develop future product offerings, we will need to continue to ramp up our testing capacity and implement increases in scale, such as increased headcount, additional or upgraded equipment, additional qualified laboratory personnel, increased office and laboratory space, expanded customer service capabilities, improved billing and systems processes, enhanced controls and procedures and expanded or internal quality assurance program and technology platform. The value of the PreTRM test and our other testing products that we may develop in the future depends on our ability to perform, and our reputation for performing, these tests on a timely basis and with an exceptionally high standard of quality. Failure to implement necessary procedures, transition to new facilities, purchase and maintain equipment, establish processes, or hire the necessary personnel in a timely and effective manner could result in higher processing costs or an inability to meet market demand or could otherwise affect our operating results.

To execute our growth plan, we must attract and retain highly qualified personnel. Competition for these personnel is intense, especially for sales, scientific, medical, laboratory, research and development, and other technical personnel. The turnover rate of such personnel can be high. We may, from time to time, experience difficulty in hiring and retaining employees with appropriate qualifications. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time due to the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of, and commercialize products. Competition to hire from the limited pool referred to above is intense, and we may be unable to hire, train, retain, or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. Many of the companies with which we compete for highly qualified personnel have greater resources than we have. If we hire employees from competitors or other companies, their former employers may attempt to assert that these employees or our Company have breached their legal obligations to their former employers, which occurs from time to time. Furthermore, to the extent that we are unable to retain our employees and they leave our Company to join one of our competitors, we cannot assure you that any invention, non-disclosure or non-compete agreements we have in place will provide meaningful protection against a departing employee's unauthorized use or disclosure of our confidential information.

In addition, our growth may place a significant strain on our operating and financial systems and our management, sales, marketing, and administrative resources. As a result of our growth, our operating costs may escalate faster than we anticipate, we may face difficulties in obtaining additional office or laboratory space and some of our internal systems may need to be enhanced or replaced. If we cannot effectively manage our expanding operations and our costs, we may not be able to grow successfully or we may grow at a slower pace, and our business could be adversely affected.

Any headcount reductions undertaken to extend our cash runway and focus more of our capital resources on our prioritized research and development programs as well as commercialization activities may not achieve our intended outcome.

From time to time, we have made select headcount reductions to more effectively allocate costs toward a refined focus on those opportunities deemed most promising in the near-term from a product adoption and revenue generation perspective. Such headcount reductions may result in unintended consequences and costs, such as the loss of institutional knowledge and expertise, attrition beyond the intended number of employees, decreased morale among our remaining employees, and the risk that we may not achieve the anticipated benefits of the headcount reductions. In addition, while positions have been eliminated, certain functions necessary to our operations remain, and we may be unsuccessful in distributing the duties and obligations of departed employees among our remaining employees. The headcount reductions could also make it difficult for us to pursue, or prevent us from pursuing, new opportunities and initiatives due to insufficient personnel, or require us to incur additional and unanticipated costs to hire new personnel to pursue such opportunities or initiatives. If we are unable to realize the anticipated benefits from the headcount reductions, or if we experience significant adverse consequences from the headcount reductions, our business, financial condition, and results of operations may be materially adversely affected.

We may engage in acquisitions, dispositions or other strategic transactions that could disrupt our business, cause dilution to our stockholders or reduce our financial resources.

From time to time, we may enter into transactions to acquire or dispose of businesses, products or technologies or to engage in other strategic transactions. Because we have not made any such acquisitions to date, our ability to do so successfully is unproven. Even if we identify suitable transactions, we may not be able to complete such transactions on favorable terms or at all. Any acquisitions or other strategic transactions we consummate may not strengthen our competitive position, and these transactions may be viewed negatively by customers or investors. We may decide to incur debt in connection with an acquisition or issue shares of our common stock or other equity securities to the stockholders of the acquired company, which would cause dilution to our existing stockholders. We could incur losses resulting from such strategic transactions, including undiscovered liabilities of an acquired business that are not covered by any indemnification we may obtain from the seller. In addition, we may not be able to successfully integrate any acquired personnel, technologies, and operations into our existing business in an effective, timely and non-disruptive manner. Any dispositions may also cause us to lose revenue and may not strengthen our financial position. Strategic transactions may also divert management attention from day-to-day responsibilities, increase our expenses, result in accounting charges, and reduce our cash available for operations and other uses. We cannot predict the number, timing or size of future strategic transactions or the effect that any such transactions might have on our operating results.

We may need to raise additional funds through equity or debt financings, corporate collaborations or licensing arrangements to continue to fund or expand our operations. Additional capital, if needed, may not be available on satisfactory terms or at all. Furthermore, any additional capital raised through the sale of equity or equity-linked securities, or grant of equity or equity-linked securities in connection with any debt financing, will dilute stockholders' ownership interests in us and may have an adverse effect on the price of our Class A common stock. In addition, the terms of any financing may adversely affect stockholders' holdings or rights. To the extent that we raise capital through collaborations and licensing arrangements, it may be necessary to relinquish some rights to our technologies or grant licenses on terms that may not be favorable to us.

If we are not able to obtain adequate funding when needed, we may have to delay development programs or sales and marketing initiatives. In addition, we may have to work with a partner on one or more of our tests or programs, which could lower the economic value of those programs to our Company.

Public health threats, such as COVID-19, could materially affect our operations, as well as the business or operations of third parties with whom we conduct business. Our business could be adversely affected by the effects of other future public health threats in regions where we, or third parties on which we rely, have significant business operations.

Our business and operations, including, but not limited to, our laboratory operations, sales and marketing efforts, supply chain operations, research and development activities, and fundraising activities, could be adversely affected by public health disruptions in regions where we have business operations, and such health disruptions could cause significant disturbance in the operations of third parties upon whom we rely. As a recent example, in March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic, and the U.S. government imposed restrictions on travel between the United States, Europe, and certain other countries. In the years following the initial outbreak, numerous state

and local jurisdictions, including the jurisdictions where our headquarters and laboratory are located, imposed quarantines, shelter-in-place orders, executive orders, and similar government orders for their residents to control the spread of COVID-19. A new serious public health threat could result in similar restrictions being imposed. The future impact of a public health threat is highly uncertain and subject to change. We cannot predict the full extent of potential delays or impacts on our business, our clinical trials, health care systems or the global economy as a whole.

We cannot ensure that our employees will fully adhere to compliance policies and procedures.

We have implemented and strive to continuously develop and improve compliance policies and procedures intended to train our sales, billing, marketing, and other personnel regarding compliance with state and federal laws applicable to our business. Our efforts to implement appropriate monitoring of compliance with such policies and procedures are likewise ongoing. Despite our compliance policies and procedures, and related training and monitoring, we may experience situations in which employees may have failed to fully adhere to our policies and/or applicable laws in the past or in which they fail to adhere to applicable policies and/or laws in the future. Such failures may subject us to administrative, civil, and criminal actions, penalties, damages, fines, individual imprisonment, exclusion from participation in state and/or federal health care programs, refunding of payments received by us, and curtailment or cessation of our operations. In addition, commercial third-party payers may refuse to provide all or any reimbursement for tests administered, seek repayment from us of amounts previously reimbursed and harm our ability to secure network contracts with third-party payers. Any of the foregoing could adversely affect our revenue, cash flow, and financial condition, and reduce our growth prospects. As of the date hereof, we are not aware of any noncompliance with any state and federal laws applicable to our business.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

We have a significant amount of net operating loss, or NOL, carryforwards that can be used to offset potential future taxable income and related income taxes. As of December 31, 2023, we had federal NOL carryforwards of approximately $211.6 million, of which, $70.3 million, if not utilized, begin to expire in 2028. Approximately $141.3 million of these federal NOLs can be carried forward indefinitely. Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an “ownership change” (generally defined as a greater than 50% change, by value, in equity ownership over any three-year period), the corporation’s ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. We may experience ownership changes in the future as a result of shifts in our stock ownership, some of which may not be within our control. Our ability to use these carryforwards could be limited if we experience an “ownership change.”

Our estimates of total addressable market opportunity and forecasts of market growth may prove to be inaccurate, and even if the market in which we compete achieves the forecasted growth, our business could fail to grow at a similar rate.

Total addressable market opportunity estimates and growth forecasts are subject to significant uncertainty and are based on assumptions and estimates that may not prove to be accurate. Our publicly announced estimates and forecasts relating to the size and expected growth of our market may prove to be inaccurate. Even if the market in which we compete meets our size estimates and forecasted growth, our business could fail to grow at similar rates.

The inflationary environment could materially adversely impact our business and results of operations.

Our operating results could be materially impacted by changes in the overall macroeconomic environment and other economic factors that impact customer confidence and spending, including capital spending. Changes in economic conditions, supply chain constraints, logistics challenges, labor shortages, global conflicts, and steps taken by governments and central banks, particularly in response to public health threats as well as other stimulus and spending programs, have led to higher inflation, which is likely, in turn, to lead to an increase in costs and may cause changes in fiscal and monetary policy, including increased interest rates. In a higher inflationary environment, we may be unable to raise the prices of our products sufficiently to keep up with the rate of inflation. Impacts from inflationary pressures could be more pronounced and materially adversely impact aspects of our business where revenue streams and cost commitments are linked to contractual agreements that extend further into the future, as we may not be able to quickly or easily adjust pricing, reduce costs, or implement counter measures.

Risks Related to Reimbursement

If third-party payers do not adequately reimburse for the PreTRM test or any new products we may develop, such products may not be purchased or used, which may adversely affect our revenue and profits.

In the United States and markets in some other countries, patients generally rely on third-party payers to reimburse all or part of the costs associated with their treatment or tests. Adequate coverage and reimbursement from third-party payers such as federal and state health care programs (e.g., Medicare and Medicaid) and commercial insurers is critical to new product acceptance. Our business depends on our ability to obtain or maintain adequate reimbursement from third-party payers. We expect third-party payers such as commercial insurers to be our most significant source of payment in the near future. In particular, we believe that for our Company to achieve commercial success, it will be necessary to gain acceptance from third-party payers for the PreTRM test, and to obtain positive coverage determinations and favorable reimbursement rates from third-party payers for our tests over time. We do not yet know, however, whether and to what extent certain of our products, including those under development, will be covered or reimbursed. If we are unable to obtain or maintain coverage or adequate reimbursement from, or achieve in-network status with, third-party payers for our existing or future tests or other products, our ability to generate revenues will be limited. For example, health care providers may be reluctant to order our tests or other products due to the possibility that a patient may incur substantial costs if third-party payer coverage or reimbursement is unavailable or insufficient. Such coverage and reimbursement may depend upon a number of factors, including the determination that the test and its use or administration for a particular patient are:

- a covered benefit;
- safe, effective, and medically necessary;
- appropriate for the specific patient;
- supported by guidelines established by the relevant professional societies;
- approved in any states where specific assay approval is necessary;
- cost-effective; and
- neither experimental nor investigational.

In the United States, the Centers for Medicare & Medicaid Services, or CMS, an agency within the United States Department of Health and Human Services, or HHS, and its Medicare Administrative Contractors make decisions regarding Medicare coverage for new tests. Other third-party payers, including commercial insurers, often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and both CMS and certain commercial insurers may have sufficient market power to demand significant price reductions.

Obtaining coverage and reimbursement approval for a test from each third-party payer is a time-consuming and costly process that could require us to provide to each payer supporting scientific and clinical information, as well as information about patient insurance eligibility and benefits, and billing. We may not be able to provide data sufficient to satisfy third-party payers that they should cover and pay for the test. There is substantial uncertainty whether any particular payer will cover and reimburse the use of any test incorporating new technology. Even when a payer determines that a test is eligible for reimbursement, the payer may impose coverage limitations that preclude payment under certain circumstances or for certain patient populations. Moreover, eligibility for coverage does not mean that any test will be reimbursed in all cases or at a rate that allows us to make a profit or even cover our costs. Interim payments for new tests, if applicable, may also not be sufficient to cover our costs and may not be made permanent. In addition, some payers may require prior authorization before they will pay for a test. We may also have to engage in lengthy and costly appeals in order to overturn payers' coverage and reimbursement determinations and ultimately obtain payment. Furthermore, reimbursement rates may vary, for example, according to the use of the test and the clinical setting in which it is used, and may reflect budgetary constraints and/or imperfections in Medicare, Medicaid or other data used to calculate these rates.

There have been, and we expect that there will continue to be, federal and state proposals to constrain expenditures for health care products and services, which may affect payments for our tests. Third-party payers, including the Medicare program, frequently change coverage policies, product and service codes and payment methodologies and reimbursement amounts. Due in part to actions by third-party payers, the health care industry is experiencing a trend toward containing or reducing costs through various means, including lowering reimbursement rates and negotiating reduced payment schedules with service providers for certain products and/or services.

Our inability to promptly obtain coverage and profitable reimbursement rates from third-party payers for our tests could have a material and adverse effect on our business, operating results, and financial condition.

In addition, leading professional societies may not recommend our products or services or may recommend alternatives to our tests, which may provide a basis for third-party payers not to cover or reimburse our tests. In making coverage determinations, third-party payers often rely on practice guidelines issued by professional societies. Test-ordering providers may also rely on such guidelines when deciding whether to order testing for their patients. If any relevant professional societies issue guidelines suggesting, or otherwise make recommendations, that providers not use our tests or instead use alternatives to our tests, payers may make unfavorable coverage and reimbursement decisions and test-ordering providers may not order our tests. Any such outcomes could have a material and adverse effect on our business, operating results, and financial condition.

New reimbursement methodologies applicable to the PreTRM test, and other future products, including new CPT codes, may decrease reimbursement rates from third-party payers.

Generally, two types of coding systems may be used to describe laboratory testing services: (i) CMS's Healthcare Common Procedure Coding System, or HCPCS, and (ii) the American Medical Association's, or AMA, Current Procedural Terminology, or CPT, coding systems. Both coding systems use alphanumeric codes to describe the services at issue. Third-party payers, including Medicare, determine which CPT or HCPCS codes they will cover, as well as the circumstances under which they will (or will not) cover those codes and the amount they will reimburse for each code. In some circumstances (such as when a laboratory becomes an in-network provider with a commercial insurer), the third-party payer will negotiate reimbursement amounts with the provider. We use CPT codes to submit claims to payers for our testing and those payers use those same codes to make payments to us.

One type of CPT code is a Proprietary Laboratory Analysis, or PLA, code. PLA codes describe proprietary clinical laboratory analyses. The AMA has issued a unique CPT® PLA code for the PreTRM test. CMS priced this code at $750 in November 2021. Before the AMA issued a PLA code for the PreTRM test, we submitted claims for reimbursement using CPT codes existing at the time based on the guidance of external coding experts.

We cannot guarantee that we will be able to negotiate favorable rates for our unique code, nor can we guarantee that we will receive reimbursement at all, especially if we are unable to collect and publish additional data and obtain positive coverage determinations for the PreTRM test or our other future tests.

We do not currently have specific CPT codes assigned for any of our other tests under development, and there is a risk that we may not be able to obtain such codes or, if obtained, we may not be able to negotiate favorable rates for such codes.

Finally, third-party payers may not establish positive coverage policies for our tests or adequately reimburse for any CPT code we may use, or seek recoupment for testing previously performed, which is a common occurrence in our industry.

Billing disputes with third-party payers, including disagreement regarding the selection and use of CPT codes when submitting claims, may decrease realized revenue and may lead to requests for recoupment of past amounts paid.

It is possible that payers could dispute our billing or coding from time to time. Payers may likewise seek to recoup reimbursements already paid, and we expect that such disputes and requests for recoupment may arise. Third-party payers may also decide to deny payment or recoup payment for testing that they contend to have been not medically necessary, against their coverage determinations, or for which they have otherwise overpaid. There is also a risk that the CPT codes we previously submitted, are currently submitting, or will submit in the future on claims will be rejected or withdrawn or that third-party payers will seek refunds of amounts that they claim were inappropriately billed based on, for example, the CPT code used, the modifier attached, or the number of units billed. Claims for recoupment require the time and attention of our management and other key personnel, which can be a distraction from operating our business.

If third-party payers deny payment for testing, reimbursement revenue for our testing could decline. If a third-party payer successfully challenges that payment for prior testing was in breach of contract or otherwise contrary to policy or law, they may recoup payment, which amounts could be significant and would impact our operating results and financial condition, and it may decrease reimbursement going forward. We may also decide to negotiate and settle with a third-party payer in order to resolve an allegation of overpayment. Any of these outcomes, including recoupment or reimbursements,

might also require us to restate our financials from a prior period, any of which could have a material and adverse effect on our business, operating results, and financial condition.

Failure to comply with laws and regulations related to submission of claims for our services could result in substantial financial penalties and/or potential civil or criminal liability.

We are subject to a variety of complex federal and state laws and regulations applicable to the submission of claims for payment for our services. If a third-party payer or a regulatory or enforcement agency, or, in some cases, a *qui tam* relator, believes or alleges that we engaged in improper billing practices—including, but not limited to, not adequately pursuing patient cost share responsibilities or submitting improper CPT codes, multipliers or modifiers on our claims—we may be subject to investigation and/or enforcement actions under federal and/or state law.

Responding to and defending such investigations and/or enforcement actions may require significant time and attention from management and key personnel, include significant expenditures, and result in significant penalties, damages, fees, and reputational harm, all of which could have a material adverse effect on our business, operating results, and financial condition. *See "— Risks Related to Government Regulation — If we, or our employees or contractors on our behalf, engage in conduct that violates health care laws, are suspected or accused of engaging in such conduct, or are subject to investigation for actual or alleged such conduct, we could face substantial penalties and damage to our reputation, and our business operations and financial condition could be adversely affected*."

"Most favored nation" provisions in contracts with third-party payers may limit potential for revenue growth and may lead to claims for recoupment.

Some of our contracts with third-party payers may in the future contain "most favored nation" provisions, pursuant to which we typically agree that we will not bill the third-party payer more than we bill any other third-party payer. These contract provisions limit the amount we are able to charge for our products and can negatively impact revenue. We monitor our billing and claims submissions for compliance with these contractual requirements with third-party payers. If we do not successfully manage compliance with these most favored nation provisions, we may be required to forego revenues from some third-party payers or reduce the amount we bill to each third-party payer with a most favored nation clause in its contract that is violated, which would adversely affect our business, operating results, and financial condition. This situation could also subject us to claims for recoupment, which could ultimately result in an obligation to repay amounts previously earned.

When third-party payers deny coverage, we are often unable to collect from the patient or any other source and risk disputes if we attempt to do so.

If a third-party payer denies coverage, or if the patient has a large deductible or co-insurance amount, it may be difficult for us to collect from the patient, and we may not be successful in doing so. If we are in-network, we may be contractually prohibited from seeking payment beyond applicable deductibles, co-insurance, or co-payments from the patient. If we are out-of-network, we may be unable to collect the full amount of a patient's responsibility, despite our good faith efforts to collect. As a result, we may not always be able to collect the full amount due for our tests if third-party payers deny coverage or cover only a portion of the billed amount or if the patient has a large deductible, which could cause payers to raise questions regarding our billing policies and patient collection practices.

We believe that our practices with respect to billing and collecting patient responsibility amounts are compliant with applicable laws; however, we may in the future receive inquiries from third-party payers regarding our practices in these areas. There is no guarantee that we will be successful in addressing such concerns, and if we are unsuccessful, this may result in a third-party payer deciding to reimburse for our tests at a lower rate or not at all, seeking recoupment of amounts previously paid to us, or bringing legal action to seek reimbursement of previous amounts paid. Any such occurrences could cause reimbursement revenue for our testing, which constitutes the large majority of our revenue, to decline. Additionally, if we were required to make a repayment, such repayment could be significant, which could have a material and adverse effect on our business, operating results, and financial condition.

Our revenues may be adversely impacted if third-party payers withdraw coverage or provide lower levels of reimbursement due to changing policies, billing complexities or other factors.

If we become an in-network provider by entering into an agreement with any of the third-party payers from which we receive reimbursement, this means that we will have an agreement that governs approval or payment terms. However, such a contract would not guarantee reimbursement for all testing we perform.

In addition, the terms of any such agreement may require a physician or qualified practitioner's signature on test requisitions or require other controls and procedures prior to conducting a test. In particular, third-party payers have been increasingly requiring prior authorization to be obtained prior to conducting a test as a condition to reimbursing for the test. If the payers were to do so for the PreTRM test, it could place a burden on our billing operations and require us to dedicate resources to monitoring that these prior authorization requirements are met. To the extent we or the health care providers ordering our tests do not follow the prior authorization requirements, we may be subject to claims for recoupment of reimbursement amounts previously paid to us, or may not receive some or all of the reimbursement amounts to which we would otherwise be entitled. This may occur in the future, which could have a material and adverse effect on our business, operating results, and financial condition.

If we are considered to be an out-of-network provider, which we expect to be the case with at least some of the largest third-party payers from which we may receive reimbursement in the future, such third-party payers could withdraw coverage and decline to reimburse for our tests, for any reason. They can also impose prior authorization requirements through the terms of the patients' health plans. Managing reimbursement on a case-by-case basis is time-consuming and contributes to an increase in the number of days it takes us to collect on accounts, which also increases our risk of non-payment. Negotiating reimbursement on a case-by-case basis also typically results in the receipt of reimbursement at a significant discount to the list price of our tests.

Even if we are being reimbursed for our tests, third-party payers may unilaterally review and adjust the rate of reimbursement, require co-payments from patients or stop paying for our tests. Federal and state health care programs as well as commercial insurers continue to increase their efforts to control the cost, utilization, and delivery of health care services by demanding price discounts or rebates and limiting coverage of, and amounts they will pay for, molecular tests. These measures have resulted in reduced payment rates and decreased utilization in the clinical laboratory industry. Because of these cost-containment measures, third-party payers — including those that may reimburse our tests in the future — may reduce, suspend, revoke or discontinue payments or coverage at any time. Reduced reimbursement of our tests may harm our business, operating results, and financial condition.

Billing for clinical laboratory testing services is complex. We perform tests in advance of payment and without certainty as to the outcome of the billing process. In cases where we expect to receive a fixed fee per test due to our reimbursement arrangements, we may nevertheless encounter variable reimbursement, leading to disputes over pricing and billing. Each third-party payer typically has different billing requirements, and the billing requirements of many payers have become increasingly difficult to meet. Among the factors complicating our billing of third-party payers are:

- disparity in coverage among various payers;
- disparity in information and billing requirements among payers, including with respect to prior authorization requirements and procedures and establishing medical necessity; and
- incorrect or missing billing information, which is required to be provided by the ordering health care provider.

These risks related to billing complexities, and the associated uncertainty in obtaining payment for our tests, could harm our business, operating results, and financial condition.

Status as an out-of-network provider with a large commercial insurer may cause health care providers to avoid recommending our tests.

We may be considered to be an out-of-network provider with respect to the large commercial insurers from which we may receive reimbursement in the future. Physician groups and other health care providers may view this negatively and may insist upon only using laboratories that are in-network with their patients' insurance companies. These types of decisions could reduce our revenue and harm our financial condition.

Changes in government health care policy could increase our costs and negatively impact coverage and reimbursement for our tests by governmental and other third-party payers.

The U.S. government is pursuing health care reform and aiming to reduce health care costs. Government health care policy has been, and will likely continue to be, a topic of extensive legislative and executive activity in the U.S. federal government and many U.S. state governments. As a result, our business could be affected by significant and potentially unanticipated changes in government health care policy, which could in turn substantially impact our revenues, increase costs, and divert management attention from our business strategy. We cannot predict the impact of governmental health care policy changes on our future business, operating results, and financial condition.

In the United States, the Affordable Care Act, or ACA, was signed into law in March 2010 and significantly impacted the U.S. pharmaceutical and medical device industries, including the diagnostics sector, in a number of ways. The ACA restricts insurers from charging higher premiums or denying coverage to individuals with pre-existing conditions, and requires insurers to cover certain preventative services without charging any copayment or coinsurance, including screening for lung, breast, colorectal and cervical cancers. The ACA also created a new system of health insurance “exchanges” designed to make health insurance available to individuals and certain groups through state- or federally-administered marketplaces in addition to existing channels for obtaining health insurance coverage. In connection with such exchanges, certain “essential health benefits” are intended to be made more consistent across plans, setting a baseline coverage level. The states (and the federal government) have some discretion in determining the definition of “essential health benefits” and we do not know whether our tests or other products will fall into a benefit category deemed “essential” for coverage purposes across the plans offered in any or all of the exchanges. If any of our tests are not covered by plans offered in the health insurance exchanges, our business, operating results and financial condition could be adversely affected.

There have been multiple attempts to repeal the ACA or significantly scale back its applicability, as a result of which, certain sections of the ACA have not been fully implemented or were effectively repealed. This could negatively impact reimbursement for our testing, adversely affect our test volumes and adversely affect our business, operating results, and financial condition. However, following several years of litigation in the federal courts, in June 2021, the United States Supreme Court upheld the ACA when it dismissed a legal challenge to the Act’s constitutionality. Further legislative and regulatory changes to federal health care laws and policies remain possible. Future changes or additions to the ACA, the Medicare and Medicaid programs, and changes stemming from other health care reform measures, especially with regard to health care access, financing or other legislation in individual states, could have a material adverse effect on the health care industry in the U.S. The uncertainty around the future of the ACA and other health care legislation, and in particular the impact to reimbursement levels and the number of insured individuals, may lead to delay in the purchasing decisions of our customers.

In addition to the ACA, various health care reform proposals have also emerged from federal and state governments. The Protecting Access to Medicare Act of 2014, or PAMA, for example, introduced a multi-year pricing program for services payable under the Clinical Laboratory Fee Schedule, or CLFS, that is designed to bring Medicare allowable amounts in line with the amounts paid by commercial insurers. The rule issued by CMS to implement PAMA required certain laboratories to report third-party payer rates and test volumes, though these reporting requirements have been delayed.

The implementation of Medicare rates pursuant to PAMA has negatively impacted overall pricing and reimbursement for many clinical laboratory testing services and may do so in the future. Since January 1, 2018, the Medicare payment rate for such tests is equal to the weighted median private payer rate reported to CMS, which for many tests is lower than the previous CLFS payment rates due to the often lower negotiated commercial insurer rates applicable to large commercial laboratories that were required to report data to CMS. Likewise, because commercial insurers often base their pricing for laboratory testing on a percentage of the price set on the CLFS, PAMA has in turn affected rates paid by commercial insurers.

The rates paid by Medicare and other state and federal health care programs have been the subject of controversy in the industry, including a lawsuit by the American Clinical Laboratory Association, and it is unclear whether and to what extent the new rates may change.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion

for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several state and federal health care programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year, and, due to subsequent legislative amendments, will remain in effect through 2032 unless additional Congressional action is taken (with the exception of a temporary suspension from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic). As another example, in January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which among other things, increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

We cannot predict whether future health care initiatives will be implemented at the federal or state level or how any such future legislation, regulation, or initiative may affect us. Current or potential future federal legislation and the expansion of government's role in the U.S. health care industry, as well as changes to the reimbursement amounts paid by third-party payers for our current and future tests, may adversely affect our test volumes and adversely affect our business, operating results, and financial condition.

If the validity of an informed consent from a patient is challenged, we could be precluded from billing for such patient's testing, be forced to stop performing certain tests, forced to exclude the patient's data or specimens from clinical trial results or be subject to lawsuits or regulatory enforcement.

We are required to ensure that all clinical data and blood specimens that we receive have been collected from subjects who have provided appropriate informed consent for us to perform our testing, both commercially and in clinical trials. Among other things, in our consent forms, we seek to ensure that the subjects from whom the data and specimens are collected do not retain or have conferred on them any proprietary or commercial rights to the data or any discoveries derived from them. A subject's informed consent could be challenged in the future, and the informed consent could prove invalid, unlawful or otherwise inadequate for our purposes. Any such findings against us, or our partners, could deny us access to, or force us to stop, testing specimens in a particular territory or could call into question the results of our clinical trials. We could also be precluded from billing third-party payers for tests for which the underlying informed consents are challenged, or we could be requested to refund amounts previously paid by third-party payers for such tests. We could become involved in legal challenges or regulatory enforcement, which could require significant management and financial resources and adversely affect our operating results.

Risks Related to Government Regulation

We may be adversely impacted by changes in laws and regulations, or in their application.

The health care industry in which we operate is highly regulated, and failure to comply with applicable regulatory, supervisory, accreditation, registration, or licensing requirements may adversely affect our business, operating results, and financial condition. The laws and regulations governing our research and marketing efforts are extremely complex and in many instances there are no clear regulatory or judicial interpretations of these laws and regulations, which increases the risk that we may be found to be in violation of these laws.

Furthermore, the industry is growing, and regulatory agencies such as HHS or the FDA may apply heightened scrutiny to new developments. While we have taken steps to ensure compliance with current regulatory frameworks in all material respects as historically enforced by the applicable regulatory agencies, given the highly complex and often unclear guidelines, there could be areas where we are unintentionally and unknowingly noncompliant. Any change in the federal or state laws or regulations relating to our business may require us to implement changes to our business or practices, and we may not be able to do so in a timely or cost-effective manner. Should we be found to be noncompliant with current or future regulatory requirements, we may be subject to sanctions that could include changes to our operations, adverse publicity, substantial financial penalties, exclusion from state and federal health care programs, and criminal proceedings, which may adversely affect our business, operating results, and financial condition by increasing our cost of compliance or limiting our ability to develop, market, and commercialize our products.

In addition, there has been a longstanding trend of heightened U.S. federal and state scrutiny of payments made to physicians and other referral sources, which are governed by various state and federal laws and regulations including the Stark Law, the federal Anti-Kickback Statute, the Physician Payments Sunshine Act, the Eliminating Kickbacks in Recovery Act of 2018, and the federal False Claims Act, as well as state equivalents of such laws.

While we have implemented and strive to continuously develop and improve compliance policies and procedures intended to address compliance with applicable federal and state laws and regulations, including applicable fraud and abuse laws and regulations such as those described in this risk factor, the evolving compliance environment and the need to build and maintain robust and scalable systems to comply with regulations in multiple jurisdictions with different compliance and reporting requirements increases the possibility that we could inadvertently violate one or more of these requirements.

Changes in the way the FDA regulates the reagents, other consumables, and testing equipment we use when developing, validating, and performing our tests could result in delay or additional expense in bringing our tests to market or performing such tests for our customers.

Many of the sequencing instruments, reagents, kits, and other consumable products used to perform our testing, as well as the instruments and other capital equipment that enable the testing, are offered for sale as analyte specific reagents, or ASRs, or for research use only, or RUO. ASRs are medical devices and must comply with FDA quality system requirements provisions and other device requirements, but most are exempt from premarket review by the FDA as an *in vitro* diagnostic product. Products that are intended for RUO and are labeled as RUO are exempt from compliance with most FDA requirements, including the approval or clearance and other product quality requirements for medical devices. A product labeled RUO but which is actually intended for clinical diagnostic use may be viewed by the FDA as adulterated and misbranded under the Federal Food, Drug and Cosmetic Act, or the FD&C Act, and subject to FDA enforcement action. The FDA has said that when determining the intended use of a product labeled RUO, it will consider the totality of the circumstances surrounding distribution and use of the product, including how the product is marketed and to whom. The FDA could disagree with a supplier's assessment that the supplier's products are RUOs, or could conclude that products labeled as RUO are actually intended for clinical diagnostic use, and could take enforcement action against the supplier, including requiring the supplier to cease offering the product while it seeks appropriate marketing authorization from FDA. Suppliers of ASRs and RUO products that we employ in our tests may cease selling their respective products, and we may be unable to obtain an acceptable substitute on commercially reasonable terms or at all, which could significantly and adversely affect our ability to provide timely testing results to our customers or could significantly increase our costs of conducting business.

If we fail to comply with federal and/or state laboratory licensing requirements, we could lose the ability to perform our tests or experience disruptions to our business.

As a clinical laboratory, our business is subject to regulation by CMS through its Clinical Laboratory Improvement Amendments of 1988, or CLIA, program. The CLIA program regulates the quality of most laboratory testing performed on human specimens in the United States. CLIA regulations establish quality standards for laboratory testing in an effort to ensure the accuracy, reliability, and timeliness of patient results. To that same end, CLIA regulations require clinical laboratories to obtain a CLIA certificate and to meet specific standards with respect to operations, personnel, facilities, quality control and assurance, administration, participation in proficiency testing, and patient test management. CLIA certification is also required in order for us to be eligible to bill federal and state health care programs, as well as commercial insurers for our tests. To renew and maintain our CLIA certification, we are subject to survey and inspection every two years. Our laboratory holds a CLIA Certificate of Accreditation.

Our laboratory is also accredited by the College of American Pathologists, or CAP. CMS has deemed CAP standards to be equally or more stringent than CLIA regulations and has approved CAP as a recognized accrediting organization. Inspection by CAP is performed in lieu of inspection by CMS for CAP-accredited laboratories. Because we are accredited by CAP, we are deemed to also comply with CLIA. Many commercial insurers require CAP accreditation as a condition to contracting with clinical laboratories to cover their tests.

In the event of any CLIA-related violations, CMS has the authority to impose a wide range of sanctions, including revocation of the CLIA certification, directed plans of correction, onsite monitoring, civil monetary penalties, civil injunctive suits, a bar on the ownership or operation of a CLIA-certified laboratory by any owners or operators of the deficient laboratory, and many others, depending on the nature of the CLIA violation. Any sanction imposed under CLIA and its implementing regulations, including but not limited to those applicable to proficiency testing, or our failure to renew a CLIA certificate, could have a material and adverse effect on our business, operating results and financial condition. If we were to lose our CLIA certification, we would not be able to operate our clinical laboratory or conduct our testing, which would adversely impact our business, operating results, and financial condition. In such case, even if we were able to bring our laboratory back into compliance, we could incur significant expenses and lose revenue while doing so. Failure to maintain CAP accreditation could likewise have a material adverse effect on the sales of our tests and the results of our operations.

Our laboratory is located in Salt Lake City, Utah. Utah requires that laboratories located in this state hold a CLIA certificate (which we do), as well as approval from the Utah Department of Health, or UT DOH, to operate a laboratory. In addition to meeting CLIA requirements and holding a valid CLIA certificate, Utah requires that our laboratory timely notify the UT DOH of certain changes and demonstrate successful performance of proficiency testing in an approved proficiency testing program or approved alternative testing program. If our clinical laboratory is out of compliance with these standards, the UT DOH may revoke our approval to perform testing or potentially impose other remedial measures, any of which could materially affect our business. We maintain an approval in good standing with the UT DOH.

Moreover, several states require that out-of-state laboratories hold laboratory licenses from those states in order to test specimens from patients, or accept specimens from laboratories, in those states. One such state is New York. As part of the laboratory licensure process, the New York Department of Health, or NY DOH, requires that laboratories seeking licensure establish the analytic and clinical performance characteristics of all tests performed, and also imposes specific review and approval requirements on certain categories of testing, including laboratory developed tests, or LDTs. As an LDT, our PreTRM test is thus subject to this NY DOH review and approval process.

We have obtained licenses from states where we believe we are required to be licensed. From time to time, we may become aware of other states that require out-of-state laboratories to obtain licensure in order to accept specimens from those states, and it is possible that other states do have such requirements or will have such requirements in the future. If we identify any other state with such requirements or if we are contacted by any other state advising us of such requirements, we expect to seek to comply with such requirements. However, there is no assurance that we will be able to obtain any such required license for the particular state.

If a clinical laboratory is out of compliance with state laboratory licensure laws and regulations, the state authority may suspend, restrict or revoke the license to operate the clinical laboratory, assess substantial civil money penalties, or impose specific corrective action plans. If we were to lose a required state license, we would not be able to operate our clinical laboratory and conduct our tests, in full or in particular states, which would adversely impact our business, operating results, and financial condition. Any such actions could materially affect our business.

The FDA recently finalized its rulemaking to regulate Laboratory Developed Tests, and Congress continues to debate whether to take action to reform the current legal requirements applicable to LDTs. In either case we may become subject to extensive regulatory requirements and may be required to conduct additional clinical trials prior to continuing to sell our existing tests or launching any other tests we may develop, which may increase the cost of conducting, or otherwise harm, our business.

We currently market the PreTRM test as an LDT and may in the future market other tests as LDTs. Although historically the FDA applied a policy of enforcement discretion with respect to LDTs whereby the agency does not generally actively enforce its regulatory requirements for such tests, in October 2023, the FDA issued a proposed rule aimed at regulating LDTs under the current medical device framework and phasing out its current enforcement discretion policy over several years. This FDA rulemaking was initiated after years of failed congressional attempts to harmonize the regulatory paradigms applicable to LDTs and other *in vitro* diagnostic tests, as discussed further below. The agency's final rule was released to the public on April 29, 2024 and was officially published in the Federal Register on May 6, 2024, with an effective date of July 5, 2024.

FDA's final rule provides that the LDT enforcement policy phase-out process will occur in gradual stages over a total period of four years, with premarket approval applications for high-risk tests to be submitted by the 3.5-year mark. Moderate-risk and low-risks tests are expected to be in compliance at the 4-year mark, although the FDA has stated that if premarket submissions are pending review it will continue to exercise enforcement discretion with respect to those tests. The FDA's final rule is complex and, concurrently, the agency announced several exceptions from the requirement to comply with full medical device regulatory controls, depending upon the specific nature of the LDT and the clinical laboratory that is offering such LDT for use by health care providers. We have begun the process of evaluating the final rule's potential impact on our PreTRM tests, our operations, and our business more generally.

On May 29, 2024, the American Clinical Laboratory Association (ACLA) and one of its members filed a complaint against the FDA in the Eastern District of Texas, alleging that the agency does not have authority to promulgate the LDT final rule and seeking to vacate the FDA's action. The outcome of such litigation is uncertain. The ongoing litigation could potentially affect FDA's plans to implement these new LDT requirements, making the potential implementation timeline somewhat uncertain. Affected stakeholders also continue to press for a comprehensive legislative solution to create a harmonized paradigm for oversight of LDTs by both the FDA and CMS, instead of administrative agency action via FDA's

final rule approach, which may be disruptive to the industry and to patient access to certain diagnostic tests. However, it is unclear whether any future legislative efforts would be successful.

If there are changes in FDA regulations or legislative authorities such that the agency begins to exercise oversight over LDTs, as has now been initiated through the LDT final rule, or if the FDA disagrees that our marketed tests are within the scope of its criteria used for defining LDTs, we may become subject to extensive regulatory requirements and may be required to stop selling our existing test or launching any other tests we may develop and to conduct additional clinical trials or take other actions prior to continuing to market our tests. If the FDA allows our tests to remain on the market but there is uncertainty about our tests, if they are labeled investigational by the FDA or if labeling claims the FDA allows us to make are very limited, orders from health care providers or reimbursement for our tests may decline.

As part of the medical device authorization process, to the extent we become subject to those requirements under FDA's LDT final rule and new enforcement direction policies applicable to currently marketed tests, we may be required to conduct additional clinical testing before applying for commercial marketing authorization. Clinical trials must be conducted in compliance with FDA regulations in order to support a marketing submission to the agency for a regulated product, or the FDA may take certain enforcement actions or reject the data. Performing additional, new clinical studies and trials in order to obtain product approval from the FDA, if any were to become necessary, would take a significant amount of time and would substantially delay our ability to commercialize the PreTRM test, any or all of which would adversely impact our business. Any such clinical trial may need to comply with recent amendments to the FD&C Act requiring sponsors of most clinical studies of investigational devices to develop and submit a diversity action plan to the FDA. If we were to be required to develop a diversity action plan for any future clinical trial, such an obligation could result in further costs and potentially delay our ability to begin such a clinical trial.

In addition, as noted above, Congress has been working on legislation to create an LDT and In Vitro Diagnostic, or IVD, regulatory framework that would be separate and distinct from the existing medical device regulatory framework. For example, as drafted and re-introduced for consideration by the current Congress, reform legislation called the Verifying Accurate, Leading-edge IVCT Development (VALID) Act would codify the term "in vitro clinical test," or IVCT, and create a new medical product category separate from medical devices to include products currently regulated as IVDs as well as LDTs, among other provisions. The VALID Act would also create a new system for laboratories to use to submit their tests electronically to the FDA for approval, which is aimed at reducing the amount of time it would take for the agency to approve such tests, and establish a new program to expedite the development of diagnostic tests that can be used to address a current unmet need for patients. On March 21, 2024, the House Energy and Commerce held a subcommittee hearing titled "Evaluating Approaches to Diagnostic Test Regulation and the Impact of the FDA's Proposed Rule." The private witnesses testifying at the hearing expressed broad support for the bipartisan VALID Act instead of the FDA's plan to use its medical devices authorities. More recently, following FDA's release of the final rule at the end of April, certain members of Congress have objected strenuously to the agency's action. The FY2025 funding bill for FDA that was passed by the House Appropriations Committee on July 17, 2024 also recommends that the agency suspend its efforts to implement the rule and to instead partner with Congress on developing legislation for the field.

If Congress were to pass the VALID Act or any other legislation applicable to the FDA's regulation of LDTs, or if the FDA were to successfully implement new regulations for such products following resolution of the pending ACLA lawsuit or any other litigation challenging the agency's underlying authority to issue the May 2024 LDT final rule, we will likely be subject to increased regulatory burdens such as registration and listing requirements, adverse event reporting requirements, and quality control requirements. Any legislation or formal FDA regulatory framework affecting LDTs is also likely to have premarket application requirements prohibiting commercialization without FDA authorization and controls regarding modification to the tests that may require further FDA submissions. Any such process would likely be costly and time-consuming.

The outcome and ultimate impact on our business of any changes to the federal government's regulation of LDTs is difficult to predict. Potential future increased regulation of our LDTs could result in increased costs and administrative and legal actions for noncompliance, including warning letters, fines, penalties, product suspensions, product recalls, injunctions and other civil and criminal sanctions, which could have a material and adverse effect upon our business, operating results, and financial condition. In addition, at this time it is unclear what testing and data may be required to support any required FDA clearance or approval of our tests, should the final rule be fully implemented as envisioned by FDA and HHS.

Furthermore, should it be required in the future, we cannot be sure that the PreTRM test, any new tests that we may develop, or new uses for our products that we may develop, will be reviewed and authorized for marketing by the FDA in a

timely or cost-effective manner, if authorized at all. Even if such tests are authorized for marketing by the FDA, the agency could limit the test's indications for use, which may significantly limit the market for that product and may adversely affect our business and financial condition. In addition, failure to comply with any applicable FDA requirements could trigger a range of governmental enforcement actions, including but not limited to warning letters, civil monetary penalties, injunctions, criminal prosecution, recall or seizure, operating restrictions, partial suspension or total shutdown of operations and denial of or challenges to applications for marketing authorization, as well as significant adverse publicity.

If we were to be required by the FDA to conduct additional clinical studies before continuing to offer the PreTRM test or future tests that we may develop as LDTs, those studies could lead to delays or failure to obtain necessary regulatory authorization, which could cause significant delays in commercializing any future products and harm our ability to achieve profitability.

If the FDA decides to require that we obtain any form or type of premarket authorization in order for us to commercialize our current PreTRM test or any future tests developed as LDTs, whether as a result of new legislative authority or following implementation of the May 2024 final rule or based on its determination that the PreTRM test does not meet the definition of an LDT, we may be required to conduct additional clinical testing before submitting a regulatory submission for commercial marketing authorization. Clinical trials to support marketing authorization from the FDA must be conducted in compliance with various regulatory requirements, including investigational device exemption regulations and good clinical practices, or else the FDA may take certain enforcement actions or reject the data. Such clinical trials may take several years to design and conduct, and they are often expensive and resource-driven.

Further, even if clinical trials are completed as planned, we cannot be certain that their results would be able to support the PreTRM test's claims or that the FDA will agree with our conclusions regarding the results of our clinical trials. If we are required to conduct clinical trials to support a premarket submission to the FDA, whether using prospectively acquired samples or archival samples, delays in the commencement or completion of clinical testing could significantly increase the development costs for the PreTRM test or any future tests and delay commercialization. Many of the factors that may cause or lead to a delay in the commencement or completion of clinical trials may also ultimately lead to delay or denial of regulatory authorization. See related risks described above at "***The results of our clinical trials and studies may not support the use of our tests and other product candidates, or may not be replicated in later studies.***"

The Federal Trade Commission and/or state enforcement or regulatory agencies may object to the methods and materials we use to promote our tests and initiate enforcement against us, which could adversely affect our business and financial condition.

The Federal Trade Commission, or FTC, and/or state enforcement or regulatory agencies (including but not limited to the offices of state attorneys general) may object to the materials and methods we use to promote our current tests or other LDTs we may develop in the future, including with respect to the product claims in our promotional materials, and may initiate enforcement actions against us. Enforcement actions by the FTC may include, among others, injunctions, civil penalties, and equitable monetary relief. Recently the FTC has become more active in its scrutiny of health claims used in advertising goods and services, including through its publication of a sweeping "health products compliance guidance" document in December 2022.

Medical product manufacturers' use of social media platforms presents new risks.

We believe that our customer base and potential patient populations are active on social media and we have begun engaging through those platforms to elevate our national marketing presence. Social media practices in the diagnostic, pharmaceutical, biotechnology, and medical device industries are evolving, which creates uncertainty and risk of noncompliance with regulations applicable to our business. For example, patients may use social media platforms to comment on the effectiveness of, or adverse experiences with, the PreTRM test or any future products we may develop, which could result in reporting obligations or the need for us to conduct an investigation. In addition, there is a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us or our testing products on any social networking website. If any of these events were to occur or we otherwise fail to comply with any applicable regulations, we could incur liability, face restrictive regulatory actions, or incur other harm to our business.

Actual or perceived failures to comply with applicable data protection, data privacy and information security laws, regulations, standards, and other requirements could adversely affect our business, results of operations, and financial condition.

The global data protection landscape is rapidly evolving, and we are or may become subject to numerous state, federal, and international laws, requirements, and regulations governing the collection, use, disclosure, retention, and security of personal information. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, or standards or perception of their requirements may have on our business. This evolution may create uncertainty in our business, affect our ability to operate in certain jurisdictions or to collect, store, transfer, use and share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability, or impose additional costs on us. The cost of compliance with these laws, regulations, and standards is high and is likely to increase in the future. Any failure or perceived failure by us to comply with federal or state laws or regulations, our internal policies and procedures, or our contracts governing our use and disclosures of personal information could result in negative publicity, government investigations and enforcement actions, claims by third parties, and damage to our reputation, any of which could have a material adverse effect on our operations, financial performance, and business.

As our operations and business grow, we may become subject to or affected by new or additional privacy and security laws and regulations and face increased scrutiny or attention from regulatory authorities. In the United States, HIPAA requires organizations like ours to develop and implement policies and procedures with respect to information that is protected under HIPAA, called protected health information, or PHI, that is used or disclosed in connection with our testing services, including the adoption of administrative, physical, and technical safeguards to protect such information.

HIPAA further requires organizations subject to HIPAA, called “covered entities” to notify affected individuals without unreasonable delay and in no case later than 60 calendar days following discovery, of certain unauthorized access, uses, or disclosures of PHI. If a breach affects 500 individuals or more in a particular state or jurisdiction, covered entities must report it to the HHS and local media contemporaneously with notice to affected individuals, and HHS will post information regarding the breach, including the name of the entity reporting the breach, on its public website. If a breach affects fewer than 500 individuals, the covered entity must notify HHS within the first 60 days of the following calendar year in which the breach occurred.

Penalties for failure to comply with HIPAA are substantial and could include corrective action plans, and/or the imposition of civil monetary or criminal penalties. HIPAA also authorizes state attorneys general to enforce HIPAA on behalf of state residents. Courts can award damages, costs, and attorneys’ fees related to violations of HIPAA in such cases. While HIPAA does not create a private right of action allowing individuals to sue us in civil court for HIPAA violations, its standards have been used as the basis for a duty of care claim in state civil suits such as those for negligence or recklessness in the misuse or breach of PHI.

Certain states have also adopted privacy and security laws and regulations, some of which may be more stringent than HIPAA and/or regulate information other than PHI. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. At the state level, for example, California has enacted the California Consumer Privacy Act, or CCPA, an extremely comprehensive and stringent privacy law. The CCPA took effect on January 1, 2020, and became enforceable by the California Attorney General on July 1, 2020. It creates individual privacy rights for California consumers (as that term is broadly defined) and increases the privacy and security obligations of entities handling certain personal data, including obligations to provide disclosures to California consumers that include detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches. CCPA does not apply to health information that is protected by HIPAA or the California Confidentiality of Medical Information Act, but CCPA still applies to other types of personal information held by HIPAA covered entities, such as personnel or marketing information. The regulations issued under the CCPA have been modified several times, and there is still some uncertainty about how the law will be interpreted and enforced.

In addition, California voters also approved the California Privacy Rights Act, or CPRA, on November 3, 2020 which went into effect in January 2023 with enforcement commencing in July 2023. CPRA modifies the CCPA significantly, resulting in further uncertainty, additional costs and expenses stemming from efforts to comply, and additional potential for harm and liability for failure to comply. The CPRA imposes additional obligations on companies covered by the legislation and expands consumers’ rights with respect to certain sensitive personal information. The CPRA also creates a new regulatory entity, the California Privacy Protection Agency, which is vested with authority to implement and enforce the

CCPA and the CPRA. In addition to California, more U.S. states are enacting similar legislation, increasing compliance complexity and increasing risks of failures to comply. In 2023, comprehensive privacy laws in Virginia, Colorado, Connecticut, and Utah all took effect, and laws in Montana, Oregon, and Texas will take effect in 2024. In addition, laws in other U.S. states are set to take effect beyond 2024, and additional U.S. states have proposals under consideration.

The CCPA, the CPRA, and similar laws may increase our compliance costs and potential liability. Any liability from failure to comply with the requirements of these laws could adversely affect our financial condition. All U.S. states have implemented data breach notification laws that overlap and often conflict with HIPAA and apply simultaneously. Additionally, various U.S. state and federal consumer protection laws and regulations govern the collection, use, disclosure and protection of health-related and other personal information. We must comply with all of these laws simultaneously in the event of a data breach which is a complicated and expensive proposition.

The collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the European Union (EU), including personal health data, is subject to the EU's General Data Protection Regulation, or GDPR, which became effective on May 25, 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the EU, including the U.S., and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. Our operations currently do not subject us to the GDPR. However, contemplated new initiatives, e.g., marketing the PreTRM test in a member country of the EU, may subject us to and require us to comply with the GDPR.

In July 2023, the European Commission adopted an adequacy decision for a new mechanism for transferring personal data from the EU to the United States – the EU-U.S. Data Privacy Framework, which provides EU individuals with several new rights, including the right to obtain access to their data, or obtain correction or deletion of incorrect or unlawfully handled data. In addition, the EU-U.S. Data Privacy Framework offers additional redress avenues for violations, including free of charge independent dispute resolution mechanisms and an arbitration panel. The European Commission will continually review developments in the United States along with its adequacy decision. Adequacy decisions can be adapted or even withdrawn in the event of developments affecting the level of protection in the applicable jurisdiction. Future actions of EU data protection authorities are difficult to predict. If we become subject to the GDPR and its transfer restrictions, some customers or other service providers may respond to these evolving laws and regulations by asking us to make certain privacy or data-related contractual commitments that we are unable or unwilling to make. This could lead to the loss of current or prospective customers or other business relationships.

The regulatory framework governing the collection, storage, use, and sharing of certain information, particularly financial and other personal information, is rapidly evolving and is likely to continue to be subject to uncertainty and varying interpretations. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our existing practices. Any failure or perceived failure by us, or any third parties with which we do business, to comply with our privacy policies, changing expectations, evolving laws, rules and regulations, industry standards, or contractual obligations to which we or such third parties are or may become subject, may result in actions or other claims against us by governmental entities or private actors, the expenditure of substantial costs, time and other resources or the incurrence of significant fines, penalties or other liabilities. In addition, any such action, particularly to the extent we were found to be guilty of violations or otherwise liable for damages, would damage our reputation and adversely affect our business, financial condition, and results of operations.

Although we strive to comply with applicable laws, regulations and standards, our contractual obligations, and other legal obligations, these requirements are evolving and may be modified, interpreted, and applied in an inconsistent manner from one jurisdiction to another, and may conflict with one another or other legal obligations with which we must comply. Any failure or perceived failure by us or our employees, representatives, contractors, consultants, Contract Research Organizations, or CROs, collaborators, or other third parties to comply with such requirements or adequately address privacy and security concerns, even if unfounded, could result in additional cost and liability to us, damage our reputation, and adversely affect our business and results of operations.

Security breaches, losses of data, and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and reputation.

In the ordinary course of our business, we collect and store sensitive data, including PHI (such as patient medical records, including test results), and personally identifiable information. We also store business and financial information, intellectual property, research and development information, trade secrets, and other proprietary and business critical information, including that of our customers, payers and collaboration partners. We manage and maintain our data utilizing a combination of on-site systems, managed data center systems and cloud-based data center systems. We are highly dependent on information technology networks and systems, including the internet, to securely process, transmit and store critical information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure, and that of our third-party billing and collections provider and other service providers, may be vulnerable to attacks by hackers, viruses, disruptions and breaches due to employee error or malfeasance.

A security breach or privacy violation that leads to unauthorized access, disclosure or modification of, or prevents access to, patient information, including PHI, could implicate state and federal breach notification laws, subject us to fines and mandatory corrective action and require us to verify the correctness of, or to reconstruct, database contents. Such a breach or violation also could result in legal claims or proceedings brought by a private party or a governmental authority, liability under laws and regulations that protect the privacy of personal information, such as HIPAA and laws and regulations of various U.S. states, as well as penalties imposed by the Payment Card Industry Security Standards Council for violations of the Payment Card Industry Data Security Standards. If we are unable to prevent such security breaches or privacy violations or implement satisfactory remedial measures, we may suffer loss of reputation, financial loss, and civil or criminal fines or other penalties. In addition, these breaches and other forms of inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above.

Unauthorized access, loss, or dissemination of information could disrupt our operations, including our ability to perform tests, provide test results, bill payers or patients, process claims and appeals, provide customer assistance services, conduct research and development activities, develop and commercialize tests, collect, process and prepare company financial information, provide information about our tests, educate patients and health care providers about our service, and manage the administrative aspects of our business, any of which could damage our reputation and adversely affect our business. Any cybersecurity incident could also result in the compromise of our trade secrets and other proprietary information, which could adversely affect our competitive position.

In addition, health-related, privacy, and data protection laws and regulations in the United States and elsewhere are subject to interpretation and enforcement by various governmental authorities and courts, resulting in complex compliance issues and the potential for varying or even conflicting interpretations, particularly as laws and regulations in this area are in flux. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business and our reputation. Complying with these laws could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business, operating results, and financial condition.

Any failure or perceived failure by us or any third-party collaborators, service providers, contractors or consultants to comply with privacy, confidentiality, cybersecurity or similar obligations, or any cybersecurity incidents or other security breaches that result in the accidental, unlawful or unauthorized access to, use of, release of, or transfer of sensitive information, including personally identifiable information, or PHI, may result in negative publicity, harm to our reputation, governmental investigations, enforcement actions, regulatory fines, litigation or public statements against us, could cause third parties to lose trust in us or could result in claims by third parties, including class action lawsuits, any of which could have a material adverse effect on our reputation, business, financial condition or results of operations. While we have implemented cybersecurity measures intended to protect our information, data, information technology systems, applications and infrastructure, there can be no assurance that such measures will successfully detect or prevent service interruptions or cybersecurity incidents or that these measures will be satisfactory to regulatory authorities in the event of an audit, investigation or complaint.

Our internal information technology systems, or those of any of our third party service providers, or potential future collaborators, may fail or suffer security or data privacy breaches or other unauthorized or improper access to, use of, or destruction of our proprietary or confidential data, employee data or personal data, which could result in additional costs, loss of revenue, significant liabilities, harm to our brand and material disruption of our operations.

In the ordinary course of our business, we and the third parties upon which we rely collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process) proprietary, confidential, and sensitive data, including personal data, intellectual property, trade secrets, and other sensitive data (collectively, sensitive information). We may implement a variety of security measures designed to protect systems that store our information, given their size and complexity and the increasing amounts of information maintained on our internal information technology systems and those of our third-party service providers and suppliers, and consultants, these systems are potentially vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, natural disasters, terrorism, war, and telecommunication and electrical failures, as well as cybersecurity incidents from inadvertent or intentional actions by our employees, contractors, consultants, business partners, and/or other third parties, or from cyber-attacks by malicious third parties, which may compromise our system infrastructure or lead to the loss, destruction, alteration or dissemination of, or damage to, our data.

The recent IT outage experienced by CrowdStrike Holdings, Inc. (“CrowdStrike”) serves as a pertinent example of such vulnerabilities. This outage, caused by a defective update to CrowdStrike’s Falcon Sensor for Windows, led to widespread system crashes and “blue screen of death” errors. The incident was further complicated for devices with BitLocker disk encryption enabled, as recovery required keys stored on crashed servers. The faulty update was not subjected to the usual patch management procedures before its release, highlighting the risks associated with inadequate testing. The outage had a global impact, disrupting critical services across various sectors, including airlines, airports, banks, hospitals, and stock markets. Over 5,000 flights were canceled, significantly affecting air travel operations worldwide. Although CrowdStrike provided remediation steps and continuous support, the incident underscores the potential for significant operational disruptions and the extensive efforts required for recovery. Our operations could have been similarly affected by such an IT outage, resulting in disruptions to our services and significant recovery efforts.

Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we, and the third parties upon which we rely, may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services. In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, ability to provide our products or services, loss of sensitive data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

To the extent that any disruption or cybersecurity incident were to result in, or be perceived to result in, loss, destruction, unavailability, alteration or dissemination of, or damage to, our data or applications, we could incur liability and reputational damage and the development and commercialization of our programs could be delayed. Further, our insurance policies may not be adequate to compensate us for the potential losses arising from any such disruption in, or failure or cybersecurity incident impacting, our systems or third-party systems where information important to our business operations or commercial development is stored.

While we have implemented security measures designed to protect against cybersecurity incidents, there can be no assurance that these measures will be effective. We may be unable in the future to detect vulnerabilities in our information technology systems because such threats and techniques change frequently, are often sophisticated in nature, and may not be detected until after a cybersecurity incident has occurred. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities. Applicable data privacy and security obligations may require us to notify relevant stakeholders of cybersecurity incidents. Such disclosures may be costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences.

We rely on third-party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts. Our ability to monitor these third parties’ information security practices is limited, and these third parties may not have adequate information security measures in place. If our third-party service providers experience a cybersecurity incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any

award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised.

If we (or a third party upon whom we rely) experience a cybersecurity incident or are perceived to have experienced a cybersecurity incident, we may experience adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive information (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms. Cybersecurity incidents and attendant consequences may cause stakeholders (including investors and potential customers) to stop supporting our platform, products and services, deter new customers from products and services, and negatively impact our ability to grow and operate our business.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

Artificial intelligence presents risks and challenges that can impact our business including by posing security risks to our confidential information, proprietary information, and personal data.

Issues in the development and use of artificial intelligence, combined with an uncertain and evolving regulatory environment, may result in reputational harm, liability, or other adverse consequences to our business operations. As with many technological innovations, artificial intelligence presents risks and challenges that could impact our business. Additionally, our vendors and suppliers may incorporate generative artificial intelligence tools into their offerings without disclosing this use to us, and the providers of these generative artificial intelligence tools may not meet existing or rapidly evolving regulatory or industry standards with respect to privacy and data protection, which may inhibit our or our vendors' and suppliers' ability to maintain an adequate level of service and experience. Additionally, we expect to see increasing government and supranational regulation related to artificial intelligence use and ethics, which may also significantly increase the burden and cost of research, development and compliance in this area. For example, the European Union's Artificial Intelligence Act ("AI Act") — the world's first comprehensive law regulating the development and use of artificial intelligence—entered into force on August 1, 2024 and, with some exceptions, will become fully effective from August 2, 2026. The AI Act regulates artificial intelligence systems based on risk level, has extraterritorial reach in certain circumstances, and imposes obligations on providers, manufacturers, importers, distributors, and deployers of artificial intelligence systems. The AI Act also prohibits certain uses of artificial intelligence. If we develop or use artificial intelligence systems that are governed by the AI Act, we may be required to ensure higher standards of data quality, transparency, and human oversight, and adhere to specific and potentially burdensome and costly ethical, accountability, and administrative requirements.

If we, our vendors, our suppliers, or our third-party partners experience an actual or perceived breach of privacy or other cybersecurity incident because of the use of generative artificial intelligence, we may lose valuable intellectual property, personal information, and confidential information, and our reputation and the public perception of the effectiveness of our privacy and security measures could be harmed. These events could also result in obligations pursuant to, and subject us to liability under, applicable laws and contracts that we have entered into. Further, bad actors around the world use increasingly sophisticated methods, including the use of artificial intelligence, to engage in illegal activities involving the theft and misuse of personal information, confidential information, and intellectual property. Any of these outcomes could damage our reputation, result in the loss of valuable property and information, and adversely impact our business.

If we, or our employees or contractors on our behalf, engage in conduct that violates health care laws, are suspected or accused of engaging in such conduct, or are subject to investigation for actual or alleged such conduct, we could face substantial penalties and damage to our reputation, and our business operations and financial condition could be adversely affected.

We operate in one of the most highly regulated industries in the United States. Our business activities are, or may in the future be, subject to comprehensive compliance obligations under state and federal laws and regulations, including:

- Federal and state laws governing laboratory testing, including but not limited to the Clinical Laboratory Improvement Amendments of 1988 and state laboratory licensure and related laws.
- FDA laws and regulations, including but not limited to requirements for offering LDTs.
- The federal Anti-Kickback Statute, or AKS, which generally prohibits, among other things knowingly and willfully offering, paying, soliciting, or receiving any remuneration, directly or indirectly, covertly or overtly, in cash or in kind in return for (i) referring an individual to a person for the furnishing or arranging of any item or service, or (ii) purchasing, leasing, ordering, or arranging for or recommending the purchasing, leasing, or ordering of any good, facility, service, or item, for which payment may be made by federal health care programs. A person or entity does not need to have actual knowledge of the AKS or specific intent to violate it to have committed a violation. Safe harbors and exceptions to the AKS protect specified arrangements and conduct if every element of the applicable safe harbor or exception is met. However, failure to satisfy each such requirement does not necessarily mean that the arrangement or conduct at issue violates the AKS. In such circumstances, a facts-and-circumstances analysis is necessary to determine AKS compliance or lack thereof. Violations of the AKS are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from federal health care programs. In addition, claims submitted to federal health care programs for items or services resulting from a violation of the AKS are deemed to be false or fraudulent claims for purposes of the False Claims Act, or FCA.
- The Stark Law, also known as the physician self-referral prohibition, which, unless an exception applies, generally prohibits physicians or an immediate family member from making referrals for certain designated health services covered by Medicare or Medicaid, including clinical laboratory services, if the physician or an immediate family member has a prohibited financial relationship with the entity providing the services at issue. Many states have statutes that are similar to the Stark Law. Federal enforcement agencies may assert that a claim including items or services resulting from a violation of the Stark Law constitutes a false or fraudulent claim for purposes of the federal FCA.
- The federal False Claims Act imposes civil liability on any person or entity that, among other things, knowingly presents, or causes to be presented, to the federal government, claims for payment that are false or fraudulent; and/or knowingly makes, uses, or causes to be made or used, a false statement or record material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government. The FCA also prohibits the knowing retention of overpayments (sometimes referred to as “reverse false claims”) and permits private individuals acting as “whistleblowers” (also referred to as *qui tam* relators) to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery. The federal government may elect or decline to intervene in such matters, but if the government declines intervention, the whistleblower may still proceed with the litigation on the government’s behalf.
- The federal Civil Monetary Penalties Law, or CMP Law, which prohibits, among other things, (1) the offering or transfer of remuneration to a beneficiary of Medicare or a state health care program, if the person knows or should know it is likely to influence the beneficiary’s selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state health care program; (2) employing or contracting with an individual or entity that the provider knows or should know is excluded from participation in a federal health care program; (3) billing for services requested by an unlicensed physician or an excluded provider; and (4) billing for medically unnecessary services. Violations of the CMP Law may result in the imposition of civil monetary penalties, as well as damages and possible exclusion from participation in state and federal health care programs.
- The federal health care fraud statute, which imposes criminal liability for knowingly and willfully executing or attempting to execute a scheme to defraud any health care benefit program (which includes commercial insurers). Violations of this statute are punishable by imprisonment, fines, or both.
- The federal statute prohibiting false statements relating to health care matters, which criminalizes knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious, or fraudulent statements or representations in connection with the delivery of, or payment for,

health care benefits, items or services relating to health care matters. Violations of this statute are punishable by imprisonment, fines, or both.

- HIPAA, as amended by HITECH and its respective implementing regulations, including the Final Omnibus Rule published in January 2013, which impose requirements on certain covered health care providers, health plans, and health care clearinghouses as well as their respective business associates. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions. There are additional federal, state, and non-U.S. laws which govern the privacy and security of health and other personal information, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.
- The Eliminating Kickbacks in Recovery Act of 2018, or EKRA, which is an all-payer anti-kickback law that criminalizes the offer, payment, solicitation, or receipt of any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in return for referring, to induce referrals of, or in exchange for referring patients to recovery homes, clinical treatment facilities, or laboratories, unless an exception applies. Most of the safe harbors applicable under the AKS are not reiterated under EKRA's exceptions. Therefore, compliance with an AKS safe harbor may not guarantee protection under the EKRA. EKRA thus could be interpreted to potentially expand the universe of arrangements that could be subject to enforcement under federal fraud and abuse laws, as well as substantial penalties.
- State data privacy and security laws, which may be more stringent than HIPAA. For example, the CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of certain entities handling certain personal data. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches. The CCPA is expected to increase data breach litigation and may increase our compliance costs and potential liability. Many similar laws have been proposed at the federal level and in other states; in the event that we are subject to or affected by any such privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.
- Federal, state, and local regulations relating to the handling and disposal of regulated medical waste, hazardous waste, and biohazardous waste and workplace safety for health care employees.
- Laws and regulations relating to health and safety, labor and employment, public reporting, taxation, and other areas applicable to businesses generally, all of which are subject to change, including, for example, the significant changes to the taxation of business entities were enacted in December 2017.
- Additionally, we are subject to state equivalents of each of the health care laws and regulations described above, among others, some of which may be broader in scope and may apply regardless of the payer. Many U.S. states have adopted laws similar to the AKS, Stark Law, and FCA, which may apply to our business practices, including, but not limited to, research, distribution, sales or marketing arrangements, and claims involving health care items or services reimbursed by commercial insurers. In addition, many states have fraud and abuse laws, such as fee-splitting restrictions, insurance fraud laws, anti-markup laws, prohibitions on waiving coinsurance, copayments, deductibles and other amounts owed by patients, and prohibitions on the provision of tests at no or discounted cost to induce physician or patient adoption. Some states also prohibit certain health care practices, such as billing physicians for tests that they order and business corporations practicing medicine or employing or engaging physicians to practice medicine. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable state law requirement, we could be subject to penalties. Finally, there are state and foreign laws governing the privacy and security of health information, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because we develop our LDTs solely for use by or within our own laboratory, we believe we are exempt from the reporting requirements imposed under the federal Physician Payments Sunshine Act, or the Sunshine Act. The Sunshine Act requires, among other things, certain manufacturers of drugs, devices, biologics, and medical supplies reimbursed under Medicare, Medicaid or the Children's Health Insurance Program to collect and report annually to CMS certain data and information related to payments and other transfers of value provided to physicians, teaching hospitals, and advanced non-physician health care practitioners, as well as ownership and investment interests, including such ownership and investment interests held by a physician's immediate family members. A number of states also have laws similar to the Sunshine Act.

While we believe that the Sunshine Act does not apply to our business, we cannot guarantee that the federal government or other regulators will agree with our determination. Moreover, we could become subject to Sunshine Act reporting requirements if the FDA requires us to obtain premarket authorization for our tests as medical devices (whether because the agency determines that the PreTRM test does not fall within the scope of the agency's existing LDT definition or because of its recently issued final rule to exercise authority over LDTs as medical devices) or Congress enacts legislative reforms to the federal oversight of LDTs to subject them to FDA regulation and/or the reporting requirements of the Sunshine Act. A determination that we have violated these laws and related CMS regulations, or a public announcement that we are being investigated for possible violations, could adversely affect our business. It is presently unknown how CMS will respond to the recently finalized FDA policy change to effectively render all LDTs medical device products under federal law, and whether or when it will assert that the Sunshine Act's reporting requirements will begin to apply to the manufacturers of such LDTs. Given that litigation is expected between members of the clinical laboratory industry and FDA/HHS in relation to the May 2024 LDT final rule, it may be many months or even years before we have clarity on the applicability of state and federal Sunshine Act laws to our business.

In addition, rapid growth and expansion of our business may increase the risk of violating applicable health care laws or related internal compliance policies and procedures, as well as the possibility that we may be accused of and/or investigated for violating these laws, regulations, and related internal policies and procedures. We likewise may be accused of, and subject to investigation and/or enforcement for, violating these laws on the basis of conduct engaged in by our employees, contractors and/or other related third parties. Such accusations and investigations may stem from allegations made by whistleblowers under the *qui tam* provisions of the FCA or state law equivalents, as well as investigative efforts undertaken by state and federal regulatory and enforcement agencies. The evolving interpretations of these laws and regulations by courts and regulators increase the risk that we may be alleged to be, or in fact found to be, in violation of these or other laws and regulations.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge and may not comply under one or more of such laws, regulations, and guidance. Law enforcement authorities are increasingly focused on enforcing fraud and abuse laws, and it is possible that some of our practices may be challenged under these laws. Efforts to ensure that our current and future business arrangements with third parties, and our business generally, will comply with applicable health care laws and regulations will involve substantial costs. If our operations, including our arrangements with physicians and other health care providers, are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, the curtailment or restructuring of our operations, exclusion from participation in federal and state health care programs (such as Medicare and Medicaid), and imprisonment, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, any of which could adversely affect our ability to operate our business and our financial results.

Companies in our industry occasionally receive civil investigative demands, subpoenas, or other requests for information from state and federal governmental agencies. We cannot predict the occurrence, timing, outcome, or impact of any such investigations. Any adverse outcome in one or more of these investigations could include the commencement of civil and/or criminal proceedings, substantial fines, penalties, administrative remedies and/or entry into corporate integrity agreements with governmental agencies, among other penalties. In addition, resolution of any of these matters could involve the imposition of additional costly compliance obligations. These potential consequences, as well as any adverse outcome from government investigations, could have a material and adverse effect on our business, operating results, and financial condition.

Risks Related to Intellectual Property

Any failure to obtain, maintain, and enforce our intellectual property rights could impair our ability to protect our proprietary technology and our brand.

Our success and ability to compete depend, in part, on our ability to obtain, maintain, and enforce patents, trade secrets, trademarks, and other intellectual property rights and to operate without having third parties infringe, misappropriate, or circumvent the rights that we own or license. If we are unable to obtain, maintain, and enforce intellectual property protection covering our current and future tests or technology, others may be able to make, use or sell tests or technology that are substantially the same as ours without incurring the sizeable development costs that we have incurred, which would adversely affect our ability to compete in the market. Our ability to stop third parties from making,

using, selling, offering to sell or importing our tests or technology is dependent upon the extent to which we have rights under valid and enforceable patents that cover these activities. However, the patent positions of diagnostic companies, including ours, can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. The U.S. Supreme Court and U.S. Court of Appeals for the Federal Circuit have in recent years issued a number of decisions relating to the patent-eligibility of diagnostic method claims. We cannot predict what impact these decisions may have on our ability to obtain or enforce patents relating to diagnostic methods in the future. We believe that no consistent policy regarding the scope of valid patent claims in these fields has emerged to date in the United States. The patent situation in the diagnostics industry outside the United States also is uncertain at least in a number of countries. Moreover, U.S. patent laws frequently change, including changes regarding how patent laws are interpreted, and the U.S. Patent and Trademark Office, or USPTO, frequently issues new procedures to the patent system. We cannot accurately predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law. Those changes may materially affect our patents or our ability to obtain patents. Therefore, there can be no assurance that any current or future patent applications will result in the issuance of patents or that we will develop additional proprietary tests or technology which are patentable. Moreover, patents or pending applications that may issue in the future may not provide us with any competitive advantage. Our patent position is subject to numerous additional risks, including the following:

- we may fail to seek patent protection for inventions that are important to our success;
- any current or future patent applications may not result in issued patents;
- we cannot be certain that we were the first to file patent applications for the inventions covered by pending patent applications and, if we are not, we may be subject to priority or derivation disputes;
- we may be required to disclaim part or all of the term of certain patents or part or all of the term of certain patent applications;
- we may file patent applications but have claims restricted or we may not be able to supply sufficient data to support our claims and, as a result, may not obtain the original claims desired or we may receive restricted claims. Alternatively, it is possible that we may not receive any patent protection from an application;
- we could inadvertently abandon a patent or patent application, resulting in the loss of protection of certain intellectual property rights in a particular country. We or our patent counsel may take action resulting in a patent or patent application becoming abandoned which may not be able to be reinstated or if reinstated, may suffer patent term adjustments;
- the claims of our issued patents or patent applications when issued may not cover our tests or technology;
- no assurance can be given that our patents would be declared by a court to be valid and enforceable or that a competitor’s test or technology would be found by a court to infringe our patents. Our patents or patent applications may be challenged by third parties in patent litigation or in proceedings before the USPTO or its foreign counterparts, and may ultimately be declared invalid or unenforceable, or narrowed in scope;
- there may be prior art of which we are not aware that may affect the validity of a patent claim. There also may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, which may, nonetheless, ultimately be found to do so;
- third parties may develop tests or technology that have the same or similar effect as our tests and technology without infringing our patents. Such third parties may also intentionally circumvent our patents by means of alternate designs or processes or file applications or be granted patents that would block or hurt our efforts;
- there may be patents relevant to our tests or technology of which we are not aware;
- certain of our intellectual property was partly supported by a U.S. government grant awarded by the National Institutes of Health, and the government accordingly has certain rights in this intellectual property, including a non-exclusive, non-transferable, irrevocable worldwide license to use applicable inventions for any governmental purpose. Such rights also include “march-in” rights, which refer to the right of the U.S. government to require us to grant a license to the technology to a responsible applicant if we fail to achieve practical application of the technology or if action is necessary to alleviate health or safety needs, to meet requirements of federal regulations or to give preference to U.S. industry;
- our patent counsel, lawyers or advisors may have given us, or may in the future give us incorrect advice or counsel;

- the patent and patent enforcement laws of some foreign jurisdictions may not protect intellectual property rights to the same extent as laws in the United States, and many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions. If we encounter such difficulties or we are otherwise precluded from effectively protecting our intellectual property rights in foreign jurisdictions, our business prospects could be substantially harmed, and we may not pursue or obtain patent protection in all major markets; and
- we may not develop additional tests or technology that are patentable.

Any of these factors could hurt our ability to gain patent protection for our tests and technology.

Issued patents covering our tests and technology could be found invalid or unenforceable, if challenged.

Our patents and patent applications may be subject to validity, enforceability and priority disputes. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability. Some of our patents or patent applications may be challenged at a future point in time in opposition, derivation, reexamination, *inter partes* review, post-grant review or interference or other similar proceedings. Any successful third-party challenge to our patents in this or any other proceeding could result in the unenforceability or invalidity of such patents, which may lead to increased competition to our business, which could have a material adverse effect on our business, financial condition, results of operations, and prospects. In addition, if we initiate legal proceedings against a third party to enforce a patent covering our tests or technology, the defendant could counterclaim that such patent covering our tests or technology, as applicable, is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. There are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the relevant patent office, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include *ex parte* re-examination, *inter partes* review, post-grant review, derivation and equivalent proceedings in non-U.S. jurisdictions, such as opposition proceedings. Such proceedings could result in revocation of or amendment to our patents in such a way that they no longer cover and protect our tests or technology. With respect to the validity of our patents, for example, we cannot be certain that there is no invalidating prior art of which we, our licensor, our or its patent counsel and the patent examiner were unaware during prosecution. The outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. If a defendant or other third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on certain aspects of our tests and technology, which could have a material adverse effect on our business, financial condition, results of operations, and prospects. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license intellectual property or develop or commercialize current or future tests and technology.

We may not be aware of all third-party intellectual property rights potentially relating to our tests or technology. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until approximately 18 months after filing or, in some cases, not until such patent applications issue as patents. We might not have been the first to make the inventions covered by each of our pending patent applications and we might not have been the first to file patent applications for these inventions. To determine the priority of these inventions, we may have to participate in interference proceedings, derivation proceedings or other post-grant proceedings declared by the USPTO, or other similar proceedings in non-U.S. jurisdictions, that could result in substantial cost to us and the loss of valuable patent protection. The outcome of such proceedings is uncertain. No assurance can be given that other patent applications will not have priority over our patent applications. In addition, changes to the patent laws of the United States allow for various post-grant opposition proceedings that have not been extensively tested, and their outcome is therefore uncertain. Furthermore, if third parties bring these proceedings against our patents, regardless of the merit of such proceedings and regardless of whether we are successful, we could experience significant costs and our management may be distracted. Any of the foregoing events could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Our intellectual property may be infringed by a third party.

Third parties may infringe one or more of our patents, trademarks or other intellectual property rights. We cannot predict if, when or where a third party may infringe our intellectual property rights. To counter infringement, we may be

required to file infringement lawsuits, which can be expensive and time consuming. There is no assurance that we would be successful in a court of law in proving that a third party is infringing one or more of our issued patents or trademarks. Any claims we assert against perceived infringers could also provoke these parties to assert counterclaims against us, alleging that we infringe their intellectual property. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly and/or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question, any of which may adversely affect our business. Even if we are successful in proving in a court of law that a third party is infringing our intellectual property rights, there can be no assurance that we would be successful in halting their infringing activities, for example, through a permanent injunction, or that we would be fully or even partially financially compensated for any harm to our business. We may be forced to enter into a license or other agreement with the infringing third party at terms less profitable or otherwise commercially acceptable to us than if the license or agreement were negotiated under conditions between those of a willing licensee and a willing licensor. We may not become aware of a third-party infringer within legal timeframes for compensation or at all, thereby possibly losing the ability to be compensated for any harm to our business. Such a third party may be operating in a foreign country where the infringer is difficult to locate and/or the intellectual property laws may be more difficult to enforce. Some third-party infringers may be able to sustain the costs of complex infringement litigation more effectively than we can because they have substantially greater resources. Any inability to stop third-party infringement could result in loss in market share of some of our tests and technology or even lead to a delay, reduction and/or inhibition of the development, manufacture or sale of certain tests and technology by us. There is no assurance that a test or technology produced and sold by a third-party infringer would meet our or other regulatory standards or would be safe for use. Such third-party infringer tests or technology could irreparably harm the reputation of our tests or technology thereby resulting in substantial loss in our market share and profits.

Developments or uncertainty in the patent statute, patent case law or USPTO rules and regulations may impact the validity of our patent rights.

Our patent rights may be affected by developments or uncertainty in the patent statute, patent case law or USPTO rules and regulations. For example, the patent position of companies engaged in the development and commercialization of diagnostic tests are particularly uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States or in other jurisdictions could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. For instance, under the Leahy-Smith America Invents Act, or the America Invents Act, enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application is entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. These changes include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to challenge the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review and derivation proceedings. The America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Various courts, including the U.S. Supreme Court, have rendered decisions that impact the scope of patentability of certain inventions or discoveries relating to the life sciences technology. Specifically, these decisions stand for the proposition that patent claims that recite laws of nature are not themselves patentable unless those patent claims have sufficient additional features that provide practical assurance that the processes are genuine inventive applications of those laws rather than patent drafting efforts designed to monopolize the law of nature itself. What constitutes a "sufficient" additional feature is uncertain. Furthermore, in view of these decisions, since December 2014, the USPTO has published and continues to publish revised guidelines for patent examiners to apply when examining process claims for patent eligibility.

In addition, U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that may have a material adverse effect on our ability to obtain new patents and to defend and enforce our existing patents and patents that we might obtain in the future.

We cannot assure you that our patent portfolio will not be negatively impacted by the current uncertain state of the law, new court rulings or changes in guidance or procedures issued by the USPTO or other similar patent offices around the world. From time to time, the U.S. Supreme Court, other federal courts, the U.S. Congress or the USPTO may change

the standards of patentability, scope and validity of patents within the life sciences technology and any such changes, or any similar adverse changes in the patent laws of other jurisdictions, could have a negative impact on our business, financial condition, prospects, and results of operations.

We may be subject to claims challenging the inventorship of our patents and other intellectual property.

We may be subject to claims that former employees, collaborators or other third parties have an interest in our patents, trade secrets or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our tests and technology. In addition, counterparties to our consulting, sponsored research, software development and other agreements may assert that they have an ownership interest in intellectual property developed under such arrangements. In particular, certain software development agreements pursuant to which certain third parties have developed parts of our proprietary software may not include provisions that expressly assign to us ownership of all intellectual property developed for us by such third parties. As such, we may not have the right to use all such developed intellectual property under such agreements, we may be required to obtain licenses from third parties and such licenses may not be available on commercially reasonable terms or at all, or may be non-exclusive. If we are unable to obtain such licenses and such licenses are necessary for the development, manufacture, and commercialization of our tests and technology, we may need to cease the development, manufacture, and commercialization of our tests and technology. Litigation may be necessary to defend against these and other claims challenging inventorship of our patents, trade secrets or other intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our business, including our software, workflows, consumables, and reagent kits. In such an event, we may be required to obtain licenses from third parties and such licenses may not be available on commercially reasonable terms or at all, or may be non-exclusive. If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture, and commercialization of our tests and technology. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees, and certain customers or partners may defer engaging with us until the particular dispute is resolved. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We employ individuals who were previously employed at other biotechnology or diagnostic companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we do not prevail, we could be required to pay substantial damages and could lose rights to important intellectual property. Even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees.

If we are not able to prevent disclosure of our trade secrets and other proprietary information, the value of our tests and technology could be significantly diminished.

We rely on trade secret protection to protect our interests in proprietary know-how and in processes for which patents are difficult to obtain or enforce, including the proprietary algorithm that we use for our tests and technology, including the PreTRM test. We may not be able to protect our trade secrets adequately. We have a policy of requiring our consultants, advisors, and collaborators to enter into confidentiality agreements and our employees to enter into invention, non-disclosure, and non-compete agreements. However, no assurance can be given that we have entered into appropriate agreements with all parties that have had access to our trade secrets, know-how or other proprietary information. There is also no assurance that such agreements will provide for a meaningful protection of our trade secrets, know-how or other proprietary information in the event of any unauthorized use or disclosure of information. Furthermore, we cannot provide assurance that any of our employees, consultants, contract personnel or collaborators, either accidentally or through willful misconduct, will not cause serious damage to our programs and our strategy, for example by disclosing important trade secrets, know-how or proprietary information to our competitors.

It is also possible that our trade secrets, know-how or other proprietary information could be obtained by third parties as a result of breaches of our physical or electronic security systems. Any disclosure of confidential data into the public domain or to third parties could allow our competitors to learn our trade secrets and use the information in competition

against us. In addition, others may independently discover our trade secrets and proprietary information. Any action to enforce our rights is likely to be time consuming and expensive, and may ultimately be unsuccessful, or may result in a remedy that is not commercially valuable. These risks are accentuated in foreign countries where laws or law enforcement practices may not protect proprietary rights as fully as in the United States or Europe. Any unauthorized disclosure of our trade secrets or proprietary information could harm our competitive position.

Risks Related to Our Class A Common Stock

The price of our Class A common stock may be volatile, and you could lose all or part of your investment.

The trading price of our Class A common stock is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this report, these factors include:

- our ability to successfully execute under our commercial agreement with Elevance Health and obtain broader market adoption of our PreTRM test;
- actual or anticipated variations in our and our competitors' results of operations, as well as how those results compare to analyst and investor expectations;
- our failure to successfully commercialize our product candidates;
- announcements by us or our competitors of new products and services, significant acquisitions, other strategic transactions, including strategic and commercial partnerships and relationships, joint ventures, divestitures, collaborations or capital commitments;
- changes in reimbursement practices by current or potential payers;
- failure of analysts to initiate or maintain coverage of our Company, issuance of new securities analysts' reports or changed recommendations for our Class A common stock;
- forward-looking statements related to our financial guidance or projections, our failure to meet or exceed our financial guidance or projections or changes in our financial guidance or projections;
- actual or anticipated changes in regulatory oversight of our products and services;
- development of disputes concerning our intellectual property or other proprietary rights;
- commencement of, or our involvement in, litigation;
- announcement or expectation of additional debt or equity financing efforts;
- any major change in our management;
- our inability to establish collaborations, if needed;
- additions or departures of key scientific or management personnel;
- our ability to effectively manage our growth;
- overall performance of the equity markets;
- sales of our common stock by us, our directors and officers, or our other stockholders in the future;
- trading volume of our Class A common stock;
- changes in accounting practices;
- ineffectiveness of our internal controls;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and the market for diagnostics companies in particular, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of the companies, including as a result of inflationary pressures, supply chain disruptions and geopolitical instability. Broad market and industry factors may negatively affect the market price of our Class A common stock, regardless of our actual operating performance. In the past, securities class action litigation has often been instituted against companies following

periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources.

We do not intend to pay dividends on our Class A common stock, so any returns will be limited to the value of our Class A common stock.

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Furthermore, future debt or other financing arrangements may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our Class A common stock. Any return to stockholders will therefore be limited to the appreciation of their stock.

Our executive officers, directors and their affiliates and our stockholders holding 5% or more of our common stock own a significant percentage of our Class A common stock and will be able to exert significant control over matters subject to stockholder approval.

Our executive officers, directors and our stockholders holding 5% or more of our common stock and their affiliates beneficially hold a significant percentage of our outstanding Class A common stock. These stockholders, acting together, would be able to significantly influence our management and affairs and the outcome of matters submitted to our stockholders for approval, including the election of directors and any sale, merger, consolidation, or sale of all or substantially all of our assets. This concentration of ownership control may adversely affect the market price of our Class A common stock by:

- delaying, deferring or preventing a change in control;
- entrenching our management and the board of directors;
- impeding a merger, consolidation, takeover or other business combination involving us that other stockholders may desire; and/or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

The dual class structure of our common stock may limit your ability to influence corporate matters and may limit your visibility with respect to certain transactions.

The dual class structure of our common stock may limit your ability to influence corporate matters. Holders of our Class A common stock are entitled to one vote per share, while holders of our Class B common stock are not entitled to any votes per share. Nonetheless, each share of our Class B common stock may be converted at any time into one share of our Class A common stock at the option of its holder by providing written notice to us, subject to the limitations provided for in our amended and restated certificate of incorporation. Consequently, if holders of our Class B common stock exercise their option to make this conversion, this will have the effect of increasing the relative voting power of those prior holders of our Class B common stock, and correspondingly decreasing the voting power of the holders of our Class A common stock, which may limit your ability to influence corporate matters. Additionally, stockholders who hold, in the aggregate, more than 10% of our Class A common stock and Class B common stock, but 10% or less of our Class A common stock, and are not otherwise an insider, may not be required to report changes in their ownership due to transactions in our Class B common stock pursuant to Section 16(a) of the Exchange Act, and may not be subject to the short-swing profit provisions of Section 16(b) of the Exchange Act.

We are an emerging growth company and a smaller reporting company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our Class A common stock less attractive to investors.

We are an emerging growth company, or EGC, as defined in the JOBS Act. For as long as we continue to be an EGC, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not EGCs, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in this report and our periodic reports and proxy statements and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We may remain an EGC until the earliest to occur of: (1) the last day of the fiscal year in which we have at least $1.235 billion in annual revenue; (2) the last day of the fiscal year in which we are deemed to be a "large accelerated filer," as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common stock held by non-affiliates

exceeded $700.0 million as of the last business day of the second fiscal quarter of such year; (3) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period; and (4) December 31, 2026.

We are also a smaller reporting company, meaning that the market value of our Class A common stock held by non-affiliates is less than $700.0 million and our annual revenue is less than $100.0 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (1) the market value of our Class A common stock held by non-affiliates is less than $250.0 million or (2) our annual revenue is less than $100.0 million during the most recently completed fiscal year and the market value of our Class A common stock held by non-affiliates is less than $700.0 million. If we are a smaller reporting company at the time we cease to be an EGC we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company, we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

We may choose to take advantage of some, but not all, of the available exemptions. We have taken advantage of reduced reporting burdens in this report. In particular, we have not included all of the executive compensation information that would be required if we were not an EGC. We cannot predict whether investors will find our Class A common stock less attractive if we rely on certain or all of these exemptions. If some investors find our Class A common stock less attractive as a result, there may be a less active trading market for our Class A common stock and our stock price may be more volatile.

Under the JOBS Act, EGCs can also delay adopting new or revised accounting standards until such time as those standards apply to private companies, which may make our financial statements less comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

Sales of a substantial number of shares of our Class A common stock by our existing stockholders in the public market could cause our stock price to decline.

Substantially all of our shares of Class A common stock and Class B common stock are eligible for public sale, if they are registered under the Securities Act of 1933, as amended, or the Securities Act, or if they qualify for an exemption from registration under the Securities Act, including under Rules 144 or 701. If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our Class A common stock in the public market, the trading price of our Class A common stock could decline.

Certain holders of shares of our common stock will be entitled to rights with respect to the registration of their shares under the Securities Act as provided under the terms of an investors' rights agreement between us and the holders of our stock. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

We have registered on Form S-8 all shares of common stock that are issuable under our existing equity compensation plan, including the 2011 Employee, Director and Consultant Equity Incentive Plan, as amended, or the 2011 Plan, which expired in 2021, the 2021 Equity Incentive Plan, or the 2021 Plan, and the 2021 Employee Stock Purchase Plan, or the 2021 ESPP, as well as the shares of common stock underlying option awards outstanding under the 2011 Plan. Additionally, the number of shares of our Class A common stock reserved for issuance under our 2021 Equity Plan automatically increases on January 1 of each year, beginning on January 1, 2022, by 4% of the total number of shares of our capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by our board of directors or compensation committee. Furthermore, the number of shares of our Class A common stock reserved for issuance under our 2021 ESPP automatically increases on January 1 of each year, beginning on January 1, 2022, by 1% of the total number of shares of our capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by our board of directors or compensation committee. Unless our board of directors elects not to increase the number of shares available for future grant each year, our stockholders may experience additional dilution. As a consequence, these shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates.

Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change in control which could limit the market price of our Class A common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent a change in control of our Company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of stockholders be called only by the board of directors acting pursuant to a resolution approved by the affirmative vote of a majority of the directors then in office;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;
- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds of all outstanding shares of our voting stock then entitled to vote in the election of directors;
- a requirement of approval of not less than two-thirds of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation; and
- the authority of the board of directors to issue convertible preferred stock on terms determined by the board of directors without stockholder approval and which convertible preferred stock may include rights superior to the rights of the holders of common stock.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These anti-takeover provisions and other provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our Company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change in control transaction or changes in our board of directors could cause the market price of our Class A common stock to decline.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our Class A common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. If few analysts commence coverage of us, the trading of our stock would likely decrease. Even if we do obtain sufficient analyst coverage, there can be no assurance that analysts will provide favorable coverage. If one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our Company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

Our amended and restated certificate of incorporation designates certain courts as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Our amended and restated certificate of incorporation provides that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any state law claims for (i) any derivative action or proceeding brought on our behalf, (ii) any action or proceeding asserting a claim of breach of fiduciary duty owed by any of our current or former directors, officers and employees, to us or our stockholders, (iii) any action or proceeding asserting a claim arising pursuant to any provision of the General Corporation Law of the State of Delaware, our amended and restated certificate of incorporation or our bylaws (in each case, as they may be amended from time to time), (iv) any action or proceeding to interpret, apply, enforce or determine the validity of our amended and

restated certificate of incorporation or bylaws, (v) any action or proceeding as to which the Delaware General Corporation Law confers jurisdiction to the Court of Chancery of the State of Delaware, or (vi) any action asserting a claim against us or any of our directors, officers or employees that is governed by the internal affairs doctrine; provided, however, that this exclusive forum provision will not apply to any causes of action arising under the Exchange Act. Our amended and restated certificate of incorporation will further provide that, unless we consent in writing to an alternative forum, the United States District Court for the District of Utah will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. We have chosen the United States District Court for the District of Utah as the exclusive forum for such Securities Act causes of action because our principal executive offices are located in Salt Lake City, Utah. In addition, our amended and restated certificate of incorporation will provide that any person or entity purchasing or otherwise acquiring any interest in shares of our Class A common stock is deemed to have notice of and consented to the foregoing provisions. We recognize that the forum selection clause in our amended and restated certificate of incorporation may impose additional litigation costs on stockholders in pursuing any such claims, particularly if the stockholders do not reside in or near the State of Delaware or the State of Utah, as applicable. Additionally, the forum selection clause in our amended and restated certificate of incorporation may limit our stockholders' ability to bring a claim in a forum that they find favorable for disputes with us or our directors, officers, or employees, which may discourage such lawsuits against us and our directors, officers, and employees even though an action, if successful, might benefit our stockholders. The Court of Chancery of the State of Delaware or the United States District Court for the District of Utah may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders. Alternatively, if a court were to find the choice of forum provisions contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations, and financial condition.

Because the applicability of the exclusive forum provision is limited to the extent permitted by applicable law, we do not intend that the exclusive forum provision would apply to suits brought to enforce any duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. We also acknowledge that Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder and that there is uncertainty as to whether a court would enforce an exclusive forum provision for actions arising under the Securities Act.

Our inability to maintain effective disclosure controls and procedures could adversely affect our results of operations, liquidity and financial positions, as well as our stock price and investor confidence in us.

As a public company, we are subject to certain reporting requirements of the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected.

As management continues to work with outside counsel to adopt formal training procedures to periodically educate the Company's officers as to the Company's SEC reporting responsibilities, our principal executive and principal financial officers have concluded that we had effective disclosure controls and procedures as of June 30, 2024. However, we cannot provide assurance that we will not have further lapses in our disclosure controls and procedures, which could result in our failure to provide accurate and timely disclosure to our investors.

We expect to continue incurring significant costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives.

As a public company, we expect to continue incurring significant legal, accounting, and other expenses that we did not incur as a private company. We are subject to the reporting requirements of the Exchange Act, which require, among other things that we file with the SEC annual, quarterly, and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and The Nasdaq Global Market to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including

requiring establishment and maintenance of effective disclosure and financial reporting controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act concerning areas such as “say on pay” and proxy access. EGCs are permitted to implement many of these requirements over a longer period, which may be up to five years from the pricing of our IPO. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

Rules and regulations applicable to public companies have substantially increased and are expected to increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have an adverse effect on our business. The increased costs will decrease our net income or increase our net loss, and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance and we incur substantial costs to maintain the same or similar coverage as when we were a private company. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our Class A common stock.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock.

We are required to disclose changes made in our internal controls and procedures on a quarterly basis and our management are required to assess the effectiveness of these controls annually. However, for as long as we are an EGC, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. We could be an EGC for up to five years. An independent assessment of the effectiveness of our internal controls over financial reporting could detect problems that our management’s assessment might not. Undetected material weaknesses in our internal controls over financial reporting could lead to restatements of our financial statements and require us to incur the expense of remediation.

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

None.

Item 5. Other Information

Insider Adoption or Termination of Trading Arrangements:

The following table provides information concerning Rule 10b5-1 trading arrangements (as defined in Item 408 of Regulation S-K under the Exchange Act) adopted in the second quarter of 2024 by any director or officer who is subject to the filing requirements of Section 16 of the Exchange Act (“Section 16 Director or Officer”). These trading arrangements are intended to satisfy the affirmative defense of Rule 10b5-1(c). Certain of the Company's Section 16 Directors or Officers may participate in the Company’s 2021 Employee Stock Purchase Plan (the “2021 ESPP”) that has been designed to comply with Rule 10b5-1(c). No non-Rule 10b5-1 trading arrangements (as defined in Item 408 of Regulation S-K under the Exchange Act) were adopted by any Section 16 Director or Officer during the second quarter of 2024. Additionally, no

Rule 10b5-1 or non-Rule 10b5-1 trading arrangements were terminated by any Section 16 Director or Officer in the second quarter of 2024.

Name and Position	Action	Adoption Date	Duration/Expiration Date [1]	Aggregate Number of Shares to be Sold
Zhenya Lindgardt, President and Chief Executive Officer	Adoption	6/15/2024	7/31/2025 [2]	Up to 104,979
Austin Aerts, Chief Financial Officer	Adoption	5/22/2024	6/11/2025 [2]	Indeterminable [3]
John J. Boniface, Ph.D., Chief Scientific Officer	Adoption	5/15/2024	7/31/2025	Indeterminable [4]
Paul Kearney, Ph.D., Chief Data Officer	Adoption	5/14/2024	7/31/2025	Indeterminable [5]
Robert G. Harrison, Chief Information Officer	Adoption	5/14/2024	7/31/2025	Indeterminable [6]
Benjamin G. Jackson, General Counsel	Adoption	5/20/2024	7/31/2025 [2]	Indeterminable [7]
Gregory C. Critchfield, M.D., M.S., Director	Adoption	5/11/2024	7/31/2025	Up to 175,564
Joshua Phillips, Director	Adoption	6/14/2024	4/4/2025	Up to 12,500
Jane F. Barlow, M.D., Director	Adoption	5/10/2024	7/31/2025	Up to 102,000
Sandra A.J. Lawrence, Director	Adoption	6/3/2024	7/31/2025	Up to 13,000
Ryan Trimble, Director [8]	Adoption	5/22/2024	7/31/2025	Up to 250,229
Catalyst Health Ventures, L.P., Catalyst Health Ventures (PF), L.P., CHV Investments LLC, and Catalyst Health Ventures Follow-on Fund, L.P. [9]	Adoption	6/10/2024	4/4/2025	Up to 34,211 [10]

(1) Sales under the trading arrangement will not commence until the selling start date. Subject to compliance with Rule 10b5-1, duration could cease earlier than the final date shown above pursuant to the terms of the trading arrangement.

(2) Sales under the trading arrangement exclude specified “No Sale” periods.

(3) The 10b5-1 trading arrangement provides for the sale of up to (i) 47,164 shares of our Class A common stock plus (ii) the net number of shares of our Class A common stock underlying certain restricted stock unit (“RSU”) awards. The number of shares to be sold pursuant to the Rule 10b5-1 trading arrangement is indeterminable with respect to the RSU awards, as such number is subject to the number of shares that will be automatically sold to satisfy applicable tax withholding obligations upon vesting of the RSU awards, which will vary based on the market price of our Class A common stock at the time of vesting.

(4) The 10b5-1 trading arrangement provides for the sale of up to (i) 114,819 shares of our Class A common stock plus (ii) the net number of shares of our Class A common stock underlying certain RSU awards. The number of shares to be sold pursuant to the Rule 10b5-1 trading arrangement is indeterminable with respect to the RSU awards, as such number is subject to the number of shares that will be automatically sold to satisfy applicable tax withholding obligations upon vesting of the RSU awards, which will vary based on the market price of our Class A common stock at the time of vesting.

(5) The 10b5-1 trading arrangement provides for the sale of up to (i) 173,506 shares of our Class A common stock plus (ii) the net number of shares of our Class A common stock underlying certain RSU awards. The number of shares to be sold pursuant to the Rule 10b5-1 trading arrangement is indeterminable with respect to the RSU awards, as such number is subject to the number of shares that will be automatically sold to satisfy applicable tax withholding obligations upon vesting of the RSU awards, which will vary based on the market price of our Class A common stock at the time of vesting.

(6) The 10b5-1 trading arrangement provides for the sale of up to (i) 25,670 shares of our Class A common stock plus (ii) the net number of shares of our Class A common stock underlying certain RSU awards. The number of shares to be sold pursuant to the Rule 10b5-1 trading arrangement is indeterminable with respect to the RSU awards, as such number is subject to the number of shares that will be automatically sold to satisfy applicable tax withholding obligations upon vesting of the RSU awards, which will vary based on the market price of our Class A common stock at the time of vesting.

(7) The 10b5-1 trading arrangement provides for the sale of up to (i) 96,718 shares of our Class A common stock plus (ii) the net number of shares of our Class A common stock underlying certain RSU awards and (iii) the number of shares of our Class A common stock resulting from purchases under the 2021 ESPP. The number of shares to be sold pursuant to the Rule 10b5-1 trading arrangement is indeterminable (a) with respect to the RSU awards, as such number is subject to the number of shares that will be automatically sold to satisfy applicable tax withholding obligations upon vesting of the RSU awards, which will vary based on the market price of our Class A common stock at the time of vesting and (b) with respect to the 2021 ESPP, as such number will vary based on the market price of our Class A common stock at the time of the acquisition of shares under the 2021 ESPP.

(8) Including transactions by trust in which Mr. Trimble has either a direct or indirect pecuniary interest.

(9) CHV GP LLC is the general partner of Catalyst Health Ventures, L.P. ("CHV LP") and Catalyst Health Ventures (PF), L.P. ("CHV PF"). CHV III GP LLC is the general partner of CHV Investments, LLC ("CHV Investments") and Catalyst Health Ventures Follow-on Fund, L.P. ("CHV FO") (together with CHV LP, CHV PF and CHV Investments, the "CHV Funds"). Joshua Phillips, a member of our board of directors, is a managing member of CHV GP LLC and CHV III GP LLC, and a limited partner of CHV PF, CHV Investments, CHV GP LLC and CHV III GP LLC. The securities held by the CHV Funds may be deemed to be beneficially owned by Joshua Phillips. Joshua Phillips disclaims beneficial ownership of these securities except to the extent of his pecuniary benefit therein.

(10) Sales under the trading arrangement for CHV LP is up to 6,793 shares of our Class A common stock, sales under the trading arrangement for CHV PF is up to 9,726 shares of our Class A common stock, sales under the trading arrangement for CHV Investments is up to 17,684 shares of our Class A common stock, and sales under the trading arrangement for CHV FO is up to 8 shares of our Class A common stock.

TD Cowen Sales Agreement

On August 7, 2024, we entered into an at-the-market sales agreement (the "Sales Agreement") with TD Securities (USA) LLC ("TD Cowen"), under which we may offer and sell, from time to time at our sole discretion, shares of our Class A common stock, par value $0.0001 per share (the "Class A Common Stock"), having an aggregate offering price of up to $50.0 million through TD Cowen, as sales agent (the "ATM Offering").

TD Cowen may sell the Class A Common Stock by any method that is deemed to be an "at the market offering" as defined in Rule 415 of the Securities Act of 1933, as amended, including sales made directly on the Nasdaq Global Market ("Nasdaq") or any other existing trading market for the Class A Common Stock. TD Cowen will use commercially reasonable efforts, consistent with its normal sales and trading practices and applicable state and federal laws, rules and regulations and the rules of Nasdaq, to sell the Class A Common Stock from time to time, based upon instructions from us (including any price, time or size limits or other customary parameters or conditions we may impose). We will pay TD Cowen a commission equal to an aggregate of 3.0% of the gross proceeds of any shares of Class A Common Stock sold through TD Cowen under the ATM Offering and have provided TD Cowen with customary indemnification rights.

We are not obligated to make any sales of Class A Common Stock under the Sales Agreement. The offering of shares of Class A Common Stock pursuant to the Sales Agreement will terminate upon the termination of the Sales Agreement as permitted therein.

The foregoing description of the Sales Agreement is qualified in its entirety by reference to the Sales Agreement, a copy of which will be filed as an exhibit to the 2024 Registration Statement (as defined below).

The shares of Class A Common Stock being offered pursuant to the Sales Agreement will be offered and sold pursuant to a shelf registration statement on Form S-3 (the "2024 Registration Statement") that we intend to file with the SEC following the filing of this Quarterly Report on Form 10-Q and a prospectus relating to the ATM Offering which will be included in the 2024 Registration Statement. None of our securities, including any shares of Class A Common Stock, may be sold under the Sales Agreement, and no offers to buy such securities may be accepted, prior to the time the 2024 Registration Statement is declared effective by the SEC.

The legal opinion of Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C. relating to the shares of Class A Common Stock being offered pursuant to the Sales Agreement will be filed as Exhibit 5.1 to the 2024 Registration Statement.

This report shall not constitute an offer to sell or the solicitation of an offer to buy the securities discussed herein, nor shall there be any offer, solicitation, or sale of the securities in any state in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state.

Item 6. Exhibits.

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of Sera Prognostics, Inc., as amended (incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K (File No. 001-40606) filed with the SEC on July 20, 2021).
3.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation of Sera Prognostics, Inc., dated June 9, 2023 (incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K (File No. 001-40606) filed with the SEC on June 14, 2023).
3.3	Restated Bylaws of Sera Prognostics, Inc. (incorporated by reference to Exhibit 3.2 of the Registrant's Current Report on Form 8-K (File No. 001-40606) filed with the SEC on July 20, 2021).
4.1	Specimen Class A Common Stock Certificate (incorporated by reference to Exhibit 4.1 of the Registrant's Registration Statement on Form S-1/A (File No. 333-257038) filed on July 8, 2021).
4.2	Form of Common Stock Purchase Warrant – I (incorporated by reference to Exhibit 4.2 of the Registrant's Registration Statement on Form S-1 (File No. 333-257038) filed on June 11, 2021).
4.3	Form of Common Stock Purchase Warrant – II (incorporated by reference to Exhibit 4.3 of the Registrant's Registration Statement on Form S-1 (File No. 333-257038) filed on June 11, 2021).
4.4	Form of Series E Warrant (incorporated by reference to Exhibit 4.4 of the Registrant's Registration Statement on Form S-1 (File No. 333-257038) filed on June 11, 2021).
4.5	Fourth Amended and Restated Investors' Rights Agreement, dated as of February 23, 2021 (incorporated by reference to Exhibit 4.5 of the Registrant's Registration Statement on Form S-1 (File No. 333-257038) filed on June 11, 2021).
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer and Principal Financial Officer and Principal Accounting Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* The Certification attached as Exhibit 32.1 that accompanies this Quarterly Report on Form 10-Q is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Sera Prognostics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Form 10-Q, irrespective of any general incorporation language contained in such filing.

SIGNATURES

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

SERA PROGNOSTICS, INC.

Date: August 7, 2024

/s/ Zhenya Lindgardt

Zhenya Lindgardt

President and Chief Executive Officer

(Principal Executive Officer)

Date: August 7, 2024

/s/ Austin Aerts

Austin Aerts

Chief Financial Officer

(Principal Accounting Officer and Principal Financial Officer)

Exhibit 31.1

SARBANES-OXLEY SECTION 302(a) CERTIFICATION

I, Zhenya Lindgardt, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Sera Prognostics, Inc.;

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

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

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

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

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

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

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (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(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

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

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

Date: August 7, 2024

By: /s/ Zhenya Lindgardt

Zhenya Lindgardt

President and Chief Executive Officer

(Principal Executive Officer)

Exhibit 31.2

SARBANES-OXLEY SECTION 302(a) CERTIFICATION

I, Austin Aerts, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Sera Prognostics, Inc.;

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

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

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

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

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

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

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (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(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

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

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

Date: August 7, 2024

By: /s/ Austin Aerts

Austin Aerts

Chief Financial Officer

(Principal Accounting Officer and Principal Financial Officer)

Exhibit 32.1

Certification
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), each of the undersigned officers of Sera Prognostics, Inc., a Delaware corporation (the "Company"), does hereby certify, to such officer's knowledge, that:

The Quarterly Report on Form 10-Q for the quarter ended June 30, 2024 (the "Form 10-Q") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 7, 2024

By: /s/ Zhenya Lindgardt

Zhenya Lindgardt

President and Chief Executive Officer

Principal Executive Officer

Date: August 7, 2024

By: /s/ Austin Aerts

Austin Aerts

Chief Financial Officer

Principal Accounting Officer and Principal Financial Officer