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

FORM 10-Q

(Mark One)

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

For the quarterly period ended **September 30, 2025**

OR

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

For the transition period from _____ to _____

Commission file number **001-42934**

BillionToOne, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

81-1082020

(I.R.S. Employer Identification No.)

1035 O'Brien Drive

Menlo Park, CA

(Address of Principal Executive Offices)

94025

(Zip Code)

(650) 460-2551

Registrant's telephone number, including area code

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

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|---|-------------------|---|
| Class A common stock, par value \$0.00001 per share | BLLN | 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 No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 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 No

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

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act).

As of December 5, 2025, the registrant had 41,216,110 shares of Class A common stock, par value \$0.00001 per share, and 4,552,650 shares of Class B common stock, par value \$0.00001 per share outstanding.

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Special Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q (this “Quarterly Report”) contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical facts contained in this Quarterly Report, including statements regarding our future operating results and financial position, our business strategy and plans, our market growth, and our objectives for future operations, are forward-looking statements.

The words “believe,” “may,” “will,” “estimate,” “continue,” “anticipate,” “design,” “intend,” “expect,” “forecast,” “could,” “plan,” “potential,” “predict,” “seek,” “target,” “should,” “would,” or the negative version of these words and similar expressions are intended to identify forward-looking statements. We have based these forward-looking statements on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, strategy, short- and long-term business operations and objectives, and financial needs. Forward-looking statements contained in this Quarterly Report include, but are not limited to, statements about:

- the level of demand for any of our products, which may vary significantly;
- our ability to increase the adoption of our products in the prenatal and oncology markets and in large healthcare systems;
- our ability to generate persuasive clinical validity and utility evidence;
- our ability to expand our portfolio of molecular diagnostic tests;
- our ability to use AI effectively and efficiently;
- our ability to execute our reimbursement strategy and expand coverage of our tests;
- our ability to replicate positive results from trials or studies conducted by us or third parties in current or future trials or studies;
- the potential for our UNITY Fetal Antigen CTA to become the first NIPT to have a companion diagnostics indication pending;
- the successful completion of Johnson & Johnson’s AZALEA Phase 3 clinical trial;
- the implementation of our business model and strategic plans;
- the size and growth potential of the total addressable markets for our current and future products and our ability to serve those markets;
- our ability to realize the benefits of current and future collaborations for the development of our products;
- our ability to maintain, expand and protect our intellectual property;
- developments relating to our competitors and our industry, including with respect to the possibility of competitors initiating legal proceedings against us;
- existing regulations and regulatory developments in the United States and other jurisdictions;
- general economic, industry, and market conditions, including tariffs and inflation;
- our ability to attract, hire, and retain our key personnel and additional qualified personnel;
- our ability to remediate our material weaknesses in our internal control over financial reporting;
- our anticipated use of our existing cash and cash equivalents;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing; and
- other risks and uncertainties, including those listed in the section titled “Risk Factors.”

We caution you that the foregoing list may not contain all of the forward-looking statements made in this Quarterly Report.

These forward-looking statements are subject to a number of risks, uncertainties, and assumptions, including those described in the section titled “Risk Factors.” Moreover, we operate in a very competitive and rapidly changing environment. 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 Quarterly 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, we cannot guarantee future results, performance or achievements. The forward-looking statements made in this Quarterly Report are given only as of the date on which the statements are made. We undertake no obligation to update any of these forward-looking statements for any reason after the date of this Quarterly Report or to conform these statements to actual results or to changes in our expectations, except as required by law.

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Quarterly Report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into or review of all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

Part I - Financial Information

Item 1. Financial Statements (Unaudited)

BillionToOne, Inc
Balance Sheets
(in thousands, except share amounts, unaudited)

| | September 30, 2025 | December 31, 2024 |
|---|--------------------|-------------------|
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 195,152 | \$ 191,477 |
| Accounts receivable | 34,646 | 24,709 |
| Inventories | 17,389 | 8,733 |
| Prepaid expenses and other current assets | 4,529 | 2,898 |
| Total current assets | 251,716 | 227,817 |
| Property and equipment, net | 18,667 | 17,111 |
| Operating lease right-of-use assets, net | 48,024 | 51,739 |
| Other non-current assets | 9,114 | 5,392 |
| Total assets | \$ 327,521 | \$ 302,059 |
| Liabilities, redeemable convertible preferred stock, and stockholders' deficit | | |
| Current liabilities: | | |
| Accounts payable | \$ 7,806 | \$ 4,304 |
| Accrued expenses and other current liabilities | 8,041 | 3,882 |
| Accrued commissions | 2,922 | 2,756 |
| Accrued compensation and employee benefits | 13,687 | 8,419 |
| Deferred revenue, current | 2,683 | 2,806 |
| Operating lease liabilities, current | 4,902 | 4,393 |
| Financing lease liabilities, current | 744 | 1,826 |
| Total current liabilities | 40,785 | 28,386 |
| Operating lease liabilities, non-current | 47,046 | 50,802 |
| Financing lease liabilities, non-current | 460 | 874 |
| Long-term debt | 54,986 | 51,481 |
| Other non-current liabilities | 4,348 | 2,763 |
| Total liabilities | 147,625 | 134,306 |
| Commitments and contingencies (Note 7) | | |
| Redeemable convertible preferred stock, \$0.00001 par value; 29,544,989 shares authorized as of September 30, 2025 and December 31, 2024; 29,084,235 shares issued and outstanding as of September 30, 2025 and December 31, 2024; aggregate liquidation preference of \$422,458 as of September 30, 2025 and December 31, 2024 | | |
| | 419,409 | 419,409 |
| Stockholders' deficit: | | |
| Common stock, \$0.00001 par value, 51,100,000 shares authorized as of September 30, 2025 and December 31, 2024; 11,178,467 and 10,925,950 shares issued and outstanding as of September 30, 2025 and December 31, 2024, respectively | | |
| | - | - |
| Additional paid-in capital | 41,211 | 30,545 |
| Accumulated deficit | (280,724) | (282,201) |
| Total stockholders' deficit | (239,513) | (251,656) |
| Total liabilities, redeemable convertible preferred stock, and stockholders' deficit | \$ 327,521 | \$ 302,059 |

The accompanying notes are an integral part of these interim financial statements.

BillionToOne, Inc.
Statements of Operations and Comprehensive Income (Loss)
(in thousands, except per share amounts, unaudited)

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|-------------------------------------|-------------|------------------------------------|-------------|
| | 2025 | 2024 | 2025 | 2024 |
| Revenue | \$ 83,523 | \$ 38,419 | \$ 209,059 | \$ 107,505 |
| Cost of revenue | 25,107 | 18,204 | 69,205 | 52,309 |
| Gross profit | 58,416 | 20,215 | 139,854 | 55,196 |
| Operating expenses: | | | | |
| Research and development | 12,953 | 9,550 | 35,134 | 25,600 |
| Selling, general and administrative | 35,830 | 23,299 | 99,029 | 65,050 |
| Total operating expenses | 48,783 | 32,849 | 134,163 | 90,650 |
| Income (loss) from operations | 9,633 | (12,634) | 5,691 | (35,454) |
| Other income (expense): | | | | |
| Interest income | 1,535 | 1,952 | 4,492 | 4,148 |
| Interest expense | (20) | (422) | (92) | (2,339) |
| Net (loss) gain on extinguishment of debt | - | (1,346) | - | 7,289 |
| Change in fair value of term loan | (3,936) | (2,283) | (7,038) | (2,283) |
| Change in fair value of convertible notes | - | - | - | (835) |
| Other expense, net | (1,630) | (171) | (1,591) | (614) |
| Total other (expense) income | (4,051) | (2,270) | (4,229) | 5,366 |
| Income (loss) before provision for income taxes | 5,582 | (14,904) | 1,462 | (30,088) |
| Provision for income taxes | (129) | - | (15) | 5 |
| Net income (loss) and comprehensive income (loss) | \$ 5,711 | \$ (14,904) | \$ 1,477 | \$ (30,093) |
| Less: Net income attributable to participating securities | (4,204) | - | (1,089) | - |
| Net income (loss) attributable to common stockholders | 1,507 | (14,904) | 388 | (30,093) |
| Net income (loss) per share, basic and diluted: | | | | |
| Net income (loss) per share, basic | \$ 0.14 | \$ (1.47) | \$ 0.04 | \$ (2.99) |
| Net income (loss) per share, diluted | \$ 0.10 | \$ (1.47) | \$ 0.03 | \$ (2.99) |
| Weighted-average shares used in calculating net income (loss) per share, basic and diluted: | | | | |
| Weighted-average shares used in calculating net income (loss) per share, basic | 10,429,583 | 10,107,487 | 10,376,253 | 10,049,097 |
| Weighted-average shares used in calculating net income (loss) per share, diluted | 15,571,949 | 10,107,487 | 15,117,365 | 10,049,097 |

The accompanying notes are an integral part of these interim financial statements.

BillionToOne, Inc
Statements of Redeemable Convertible Preferred Stock and Stockholders' Deficit
(in thousands, except share data, unaudited)

| | | Three Months Ended September 30, 2025 | | | | | |
|---|-------------------|---------------------------------------|-------------------|----------------------------|---------------------|-----------------------------|---------------------|
| Redeemable Convertible Preferred Stock | | Common Stock | | Additional Paid-In Capital | Accumulated Deficit | Total Stockholders' Deficit | |
| Shares | Amount | Shares | Amount | | | | |
| Balance at June 30, 2025 | 29,084,235 | \$ 419,409 | 11,085,044 | \$ - | \$ 36,182 | \$ (286,435) | \$ (250,253) |
| Issuance of common stock upon exercise of stock options | - | - | 93,423 | - | 554 | - | 554 |
| Stock-based compensation | - | - | - | - | 4,475 | - | 4,475 |
| Net income | - | - | - | - | - | 5,711 | 5,711 |
| Balance at September 30, 2025 | 29,084,235 | \$ 419,409 | 11,178,467 | \$ - | \$ 41,211 | \$ (280,724) | \$ (239,513) |
| | | Three Months Ended September 30, 2024 | | | | | |
| Redeemable Convertible Preferred Stock | | Common Stock | | Additional Paid-In Capital | Accumulated Deficit | Total Stockholders' Deficit | |
| Shares | Amount | Shares | Amount | | | | |
| Balance at June 30, 2024 | 29,084,235 | \$ 419,435 | 10,778,769 | \$ - | \$ 25,578 | \$ (255,820) | \$ (230,242) |
| Issuance of Series D redeemable convertible preferred stock, net of issuance costs of \$474 | - | (26) | - | - | - | - | - |
| Issuance of common stock upon exercise of stock options | - | - | 29,804 | - | 142 | - | 142 |
| Stock-based compensation | - | - | - | - | 2,150 | - | 2,150 |
| Net loss | - | - | - | - | - | (14,904) | (14,904) |
| Balance at September 30, 2024 | 29,084,235 | \$ 419,409 | 10,808,573 | \$ - | \$ 27,870 | \$ (270,724) | \$ (242,854) |
| | | Nine Months Ended September 30, 2025 | | | | | |
| Redeemable Convertible Preferred Stock | | Common Stock | | Additional Paid-In Capital | Accumulated Deficit | Total Stockholders' Deficit | |
| Shares | Amount | Shares | Amount | | | | |
| Balance at December 31, 2024 | 29,084,235 | \$ 419,409 | 10,925,950 | \$ - | \$ 30,545 | \$ (282,201) | \$ (251,656) |
| Issuance of common stock upon exercise of stock options | - | - | 252,517 | - | 1,085 | - | 1,085 |
| Stock-based compensation | - | - | - | - | 9,581 | - | 9,581 |
| Net income | - | - | - | - | - | 1,477 | 1,477 |
| Balance at September 30, 2025 | 29,084,235 | \$ 419,409 | 11,178,467 | \$ - | \$ 41,211 | \$ (280,724) | \$ (239,513) |

BillionToOne, Inc.
Statements of Redeemable Convertible Preferred Stock and Stockholders' Deficit
(in thousands, except share data, unaudited)

| | Nine Months Ended September 30, 2024 | | | | | | | |
|--|--|-------------------|-------------------|-------------|----------------------------|---------------------|-----------------------------|--|
| | Redeemable Convertible Preferred Stock | | Common Stock | | Additional Paid-In Capital | Accumulated Deficit | Total Stockholders' Deficit | |
| | Shares | Amount | Shares | Amount | | | | |
| Balance at December 31, 2023 | 22,701,179 | \$ 249,527 | 10,572,061 | \$ - | \$ 21,578 | \$ (240,631) | \$ (219,053) | |
| Issuance of Series C-1 redeemable convertible preferred stock upon conversion of Convertible Notes | 1,726,823 | 39,886 | - | - | - | - | - | |
| Issuance of Series D redeemable convertible preferred stock, net of issuance costs of \$474 | 4,656,233 | 129,996 | - | - | - | - | - | |
| Issuance of common stock upon exercise of stock options | - | - | 263,262 | - | 778 | - | 778 | |
| Stock-based compensation | - | - | - | - | 6,055 | - | 6,055 | |
| Repurchase of common stock | - | - | (26,750) | - | (546) | - | (546) | |
| Vesting of early exercises | - | - | - | - | 5 | - | 5 | |
| Net loss | - | - | - | - | - | (30,093) | (30,093) | |
| Balance at September 30, 2024 | <u>29,084,235</u> | <u>\$ 419,409</u> | <u>10,808,573</u> | <u>\$ -</u> | <u>\$ 27,870</u> | <u>\$ (270,724)</u> | <u>\$ (242,854)</u> | |

The accompanying notes are an integral part of these interim financial statements.

BillionToOne, Inc
Statements of Cash Flows
(in thousands, unaudited)

| | Nine Months Ended September 30, | |
|--|--|-------------|
| | 2025 | 2024 |
| Cash flows from operating activities: | | |
| Net income (loss) | \$ 1,477 | \$ (30,093) |
| Adjustments to reconcile net income (loss) to net cash used in operating activities: | | |
| Stock-based compensation | 9,581 | 6,055 |
| Depreciation and amortization | 5,232 | 5,241 |
| Amortization of debt issuance costs and accretion of exit fees | - | 341 |
| Debt issuance costs on term loan expensed upon election of fair value option | - | 453 |
| Amortization of operating right-of-use assets | 3,715 | 3,452 |
| Loss on disposal of fixed assets | 7 | 11 |
| Change in fair value of common stock warrant liability | 1,409 | 500 |
| Change in fair value of redeemable convertible preferred stock warrant liability | 176 | 49 |
| Net gain on extinguishment of debt | - | (7,289) |
| Change in fair value of convertible notes | - | 835 |
| Change in fair value of term loan | 3,505 | 1,650 |
| <i>Changes in operating assets and liabilities:</i> | | |
| Accounts receivable | (9,937) | (13,741) |
| Inventories | (8,656) | (644) |
| Prepaid expenses and other current assets | (1,727) | (879) |
| Other non-current assets | (62) | (3,110) |
| Accounts payable | 3,047 | 2,223 |
| Accrued expenses and other current liabilities | 3,972 | 882 |
| Accrued commissions | 166 | 642 |
| Accrued compensation and employee benefits | 5,268 | 3,306 |
| Deferred revenue | (123) | (49) |
| Operating lease liabilities | (3,247) | (2,787) |
| Net cash provided by (used in) operating activities | 13,803 | (32,952) |
| Cash flows from investing activities: | | |
| Purchases of property and equipment | (7,344) | (3,328) |
| Net cash used in investing activities | (7,344) | (3,328) |

BillionToOne, Inc
Statements of Cash Flows
(in thousands, unaudited)

| | Nine Months Ended September 30, | |
|--|---------------------------------|------------|
| | 2025 | 2024 |
| Cash flows from financing activities: | | |
| Proceeds from issuance of debt, net | - | 49,775 |
| Repayment of debt upon extinguishment | - | (35,000) |
| Payment of exit fee and prepayment payable upon debt extinguishment | - | (1,688) |
| Principal payments on finance lease liabilities | (1,449) | (1,785) |
| Repurchase of common stock outstanding | - | (546) |
| Payment of debt issuance costs on term loan | - | (228) |
| Payment of deferred offering costs | (2,516) | - |
| Proceeds from exercise of stock options, net of repurchases | 1,181 | 781 |
| Proceeds from issuance of Series D redeemable convertible preferred stock, net of issuance costs | - | 129,996 |
| Net cash (used in) provided by financing activities | (2,784) | 141,305 |
| Net increase in cash and cash equivalents | 3,675 | 105,025 |
| Cash and cash equivalents at beginning of period | 191,477 | 97,268 |
| Cash and cash equivalents at end of period | \$ 195,152 | \$ 202,293 |
| Supplemental cash flow disclosure: | | |
| Cash payments for interest | \$ 3,626 | \$ 2,845 |
| Cash paid for income taxes | \$ 460 | \$ 9 |
| Supplemental non-cash investing and financing activities: | | |
| Purchases of property and equipment in accounts payable and accrued expenses and other current liabilities | \$ 500 | \$ 214 |
| Issuance of Series C-1 redeemable convertible preferred stock upon settlement of convertible notes | \$ - | \$ 39,886 |
| Deferred offering costs in accounts payable and accrued expenses and other current liabilities | \$ 1,144 | \$ - |
| Cash paid for amounts included in the measurement of operating lease liabilities | \$ 6,594 | \$ 6,374 |
| Right-of-use assets obtained in exchange for new finance lease liabilities | \$ - | \$ 214 |
| Operating cash flows from financing leases (interest paid) | \$ 89 | \$ 196 |

The accompanying notes are an integral part of these interim financial statements.

BillionToOne, Inc
Notes to Unaudited Interim Financial Statements

(1) Description of Business

BillionToOne, Inc. (the “Company”, “we”, or “our”) was formed in 2016, and is headquartered in Menlo Park, California. The Company is a precision diagnostics company that quantifies biology to create molecular diagnostics. The Company’s proprietary molecular counting platform is designed to detect and measure DNA molecules at the single-count level to help improve disease detection. The Company currently applies the proprietary technology to non-invasive prenatal screening (“Prenatal”) and liquid biopsy (“Oncology”).

(2) Summary of Significant Accounting Policies***Basis of Presentation***

The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (“U.S. GAAP”). Prior to April 2024, the financial statements also included the Company’s wholly owned subsidiary SeqIndia Labs Private Limited which had immaterial activities and was not material to these financial statements and was divested in April 2024. All intercompany transactions and balances have been eliminated upon consolidation.

The unaudited interim financial statements should be read in conjunction with the audited financial statements and the related notes thereto as of and for the year ended December 31, 2024, included in the Company’s prospectus filed with the SEC pursuant to Rule 424(b) under the Securities Act of 1933, as amended, on November 6, 2025 (the “Final Prospectus”).

For a summary of the Company’s significant accounting policies refer to “Note 2. Summary of Significant Accounting Policies” in the notes to the financial statements as of and for the year ended December 31, 2024 included in the Final Prospectus. There have been no significant changes to these policies during the nine months ended September 30, 2025.

Unaudited interim financial information

The unaudited financial statements do not include all disclosures, including certain notes required by GAAP on an annual reporting basis. The unaudited interim financial statements have been prepared on the same basis as the annual financial statements. In management’s opinion, the unaudited financial statements reflect all normal recurring adjustments necessary to state fairly the balance sheets, statements of operations and comprehensive income (loss), of redeemable convertible preferred stock and stockholders’ deficit, and of cash flows for the interim periods, but are not necessarily indicative of the results of operations to be anticipated for the full fiscal year or any future period.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. On a regular basis, management evaluates estimates, including, but not limited to: the fair value of common stock, stock-based compensation, deferred tax assets and liabilities, useful lives of long-lived assets, the incremental borrowing rate applied to operating and finance leases, determination of revenue recognition and accounts receivable, the valuation of warrants for common stock and warrants for redeemable convertible preferred stock, and valuation of debt and convertible notes. These estimates are inherently subject to judgment and actual results could differ from those estimates.

Risks and Uncertainties

Certain of the Company’s product candidates are in development. If the Company is unable to advance its product candidates through development, clinical validation and ultimately commercialize its product candidates, or experiences significant delays in doing so, the Company’s business will be materially harmed. Even if the Company completes the necessary validation studies and product development, the process to meet

BillionToOne, Inc
Notes to Unaudited Interim Financial Statements

any applicable regulatory requirements can be expensive. As a result, the Company cannot predict when, or if, it will be able to commercialize a product candidate.

The Company is subject to certain risks and uncertainties that the Company believes could have a material adverse effect on its future financial position or results of operations. As of the date of issuance of the financial statements, the Company is not aware of any specific event or circumstance that would require it to update its estimates, judgments, or the carrying value of its assets or liabilities. These estimates may change as new events occur and additional information is obtained and are recognized in the financial statements as soon as they become known. Actual results could differ from those estimates, and any such differences may be material to the Company's financial statements.

The Company is subject to regulation and enforcement by the federal government and by authorities in state and foreign jurisdictions in which the Company conducts business. Such laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, privacy and security laws and regulations. If the Company's operations are found to be in violation of any such laws or government regulations that apply to use, the Company may be subject to penalties, including, without limitation, civil and criminal penalties, damages, fines, the curtailment or restructuring of operations and exclusion from participation in federal and state healthcare programs.

Revenue

The Company recognizes revenue upon transfer of control of promised goods and services in an amount that reflects the consideration it expects to be entitled to receive in exchange for those goods and services. Under ASC 606—Revenue from Contracts with Customers (ASC 606), the Company applies the following five-step approach:

- Identify the contract with a customer
- Identify the performance obligations in the contract
- Determine the transaction price
- Allocate the transaction price to the performance obligations in the contract
- Recognize revenue when, or as, a performance obligation is satisfied

The Company generates revenue primarily from prenatal and oncology testing services, which are referred to as testing services or test results. The Company considers the patient as its customer, that requests a test service through their physician. Test results are the single performance obligation being provided to customers. Testing service revenue is recognized at a point in time when test results are delivered to the ordering physician. The Company generally bills an insurance carrier, Medicaid, Medicare, or a patient or a combination of both upon delivery of test results.

The Company enters into contracts with third-party payors, including insurance carriers and Medicaid, to set the pricing for tests provided to patients. Due to the nature of these third-party payor contract arrangements, the total consideration the Company expects to collect for test results is variable as they are dependent on the terms negotiated with the third-party payor. The predominance of the Company's revenue is derived from payments by third-party insurance carriers.

The Company uses the expected value method of estimating variable consideration. The total consideration the Company expects to collect in exchange for the Company's products is an estimate and is largely variable in nature. Consideration includes reimbursement from both patients and third-party payors. The Company establishes variable consideration by considering historical payment trends for tests delivered, test reimbursement disallowances, and contractual arrangements in place, among other factors, which is adjusted for current expectations. Current expectations of cash collections factor in changes in reimbursement rate trends, historical events not expected to recur, and future known changes such as anticipated contractual pricing changes or changes to insurance coverage. The Company also considers hindsight, where applicable, in estimates established for variable consideration and updates those estimates when actual experience supports doing so. In establishing variable consideration, the Company considers payors with similar reimbursement

BillionToOne, Inc
Notes to Unaudited Interim Financial Statements

characteristics together. The Company monitors the cash collections against the estimated variable consideration over the expected cash collection period and any difference is recognized as an adjustment to estimated revenues after such estimated cash collection period has closed.

In January 2023, the Company entered a partnership with Johnson & Johnson under which the Company is licensing the Company's proprietary knowledge, performing clinical trial support services including developing a clinical study assay, and other testing services to support a clinical trial for the counterparty. The Company concluded that the agreement with Johnson & Johnson was within the scope of ASC 606 because the counterparty in the agreement meets the definition of a customer. The Company evaluated the terms of the agreement for revenue recognition, including whether the services are capable of being distinct and considered distinct within the context of the contract. The Company concluded that the licensing of the know how is not distinct from the other promises within the agreement and, as a result, was treated as a single performance obligation. Under this contract the Company receives payments upon the achievement of milestones, including (i) receipt of approval of the trial, which was achieved in 2023, (ii) various patient enrollment milestones, and (iii) subsequent full trial completion, as well as reimbursement for testing services. In making assessment of whether variable consideration should be included in the transaction price, the Company considers the degree of complexity and uncertainty associated with each milestone and related testing services, and whether achievement of the milestones and testing services are dependent on parties other than the Company.

In July 2025, the Company entered into a partnership with Johnson & Johnson for the development and commercialization of a companion diagnostic (CDx), intended for use with a new drug candidate of Johnson & Johnson. The Company is providing services related to regulatory filings to support companion diagnostic submissions for the Company's assay. The development and regulatory support services represent a single performance obligation as the Company performs a significant integration service, such as analytical validation and regulatory submissions. The individual promises are not separately identifiable from other promises in the contract, and therefore, not distinct. The Company generates revenue from achievement of milestones, including (i) various CDx development milestones, (ii) FDA regulatory submission and pre-approval, and (iii) CDx approval by FDA. For the companion diagnostic development and regulatory approval performed, the Company is compensated through a combination of an upfront fee and performance-based, non-refundable regulatory and development milestones. The transaction price represents variable consideration and the Company uses the most likely amount to estimate variable consideration. Application of the constraint for variable consideration to milestone payments is an area that requires significant judgment. The Company evaluates factors such as the scientific, clinical, regulatory, and other risks that must be managed to achieve the respective milestone and the level of effort and investment required to achieve the respective milestone. In making this assessment, the Company considers its historical experience with similar milestones, the degree of complexity and uncertainty associated with each milestone, and whether the achievement of the milestone is dependent on parties other than the Company. The constraint for variable consideration is applied to the contract price such that it is probable a significant cumulative reversal of revenue will not occur when the uncertainty associated with the contingency is resolved. Application of the constraint for variable consideration is assessed and updated at each reporting period as a revision to the estimated transaction price.

The Company recognizes revenue for the single performance obligation for the J&J partnership agreements over the period the services are provided. Specifically, the Company recognizes revenue using an input method to measure progress, utilizing costs incurred to-date relative to the total expected costs as a measure of progress. The Company assesses the changes to the total expected cost estimates in determining the revenue recognition for each reporting period.

The Company applies the practical expedient not to disclose the value of unsatisfied performance obligations for contracts with an original expected length of one year or less. As of September 30, 2025, the Company's remaining performance obligations beyond one year were approximately \$4.7 million.

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Disaggregation of revenue

The following table presents disaggregation of revenue by Prenatal, Oncology and Clinical trial support and other services for the three and nine months ended September 30, 2025 and 2024 (in thousands):

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|-------------------------------------|------------------|------------------------------------|-------------------|
| | 2025 | 2024 | 2025 | 2024 |
| Prenatal | \$ 74,071 | \$ 36,601 | \$ 191,001 | \$ 102,680 |
| Oncology | 8,691 | 1,138 | 15,814 | 1,851 |
| Clinical trial support and other services | 761 | 680 | 2,244 | 2,974 |
| Total revenues | <u>\$ 83,523</u> | <u>\$ 38,419</u> | <u>\$ 209,059</u> | <u>\$ 107,505</u> |

Substantially all revenues recognized for the three and nine months ended September 30, 2025 and 2024 were generated in the United States.

Deferred revenue

Deferred revenue, which is a contract liability, consists of billings or cash received for services in advance of revenue recognition and is recognized as revenue when all the Company's revenue recognition criteria are met. As of September 30, 2025 and December 31, 2024, the deferred revenue balance was \$2.7 million and \$2.8 million, respectively, all of which is considered short-term. For the three months ended September 30, 2025 and 2024 and nine months ended September 30, 2025 and 2024, revenue recognized from deferred revenue at the beginning of the period was \$0.6 million, \$0.7 million, \$2.1 million, and \$3.0 million, respectively.

Comprehensive Income (Loss)

During the three months ended September 30, 2025 and 2024 and nine months ended September 30, 2025 and 2024, the Company did not have any other comprehensive income (loss) and, therefore, the net income (loss) and comprehensive income (loss) was the same.

Deferred Offering Costs

Deferred offering costs, consisting of legal, accounting, and other fees and costs relating to the Company's initial public offering (IPO) are capitalized within other non-current assets on the balance sheets. The deferred offering costs will be offset against the proceeds received by the Company upon the closing of the IPO. As of September 30, 2025, the Company had \$3.7 million of deferred offering costs. As of December 31, 2024, the Company had no deferred offering costs.

Segment information

Operating segments are defined as components of an entity for which separate financial information is available and that is regularly reviewed by the Chief Operating Decision Maker ("CODM") in deciding how to allocate resources and assess performance. The Company's Chief Executive Officer is the Company's CODM. The CODM reviews financial information presented on a company-wide basis to make operating decisions, allocating resources, and evaluating financial performance. As such, the Company has determined that it is managed as one operating segment and one reportable segment.

Key areas of focus for the CODM when making decisions on the allocations of resources is cash used in operations as well as revenue, gross margin and net income (loss); this information is used by the CODM and compared to budgeted amounts in order for the CODM to make decisions on how resources should be allocated across the organization. The Company's segment measure of profitability is net income (loss).

Segment revenues are derived from prenatal and oncology testing results, leveraging the Company's diagnostic technology platform, which are delivered to patients, who are the Company's customer. The Company's

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customers are predominantly located in the United States. Substantially all of the Company's long-lived assets are located in the United States. The Company's technology platform is applied similarly in both the prenatal and oncology settings.

The financial statements provide the CODM with a view of the Company's financial condition as it pertains to the Company's assets, liabilities and expenses. Significant expense categories align with the expense categories and amounts presented on the statements of operations.

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 ("ASU 2023-09"), which expands income tax disclosure requirements to include additional information related to the rate reconciliation of effective tax rates to statutory rates, as well as additional disaggregation of taxes paid. This ASU also removed disclosure related to certain unrecognized tax benefits and deferred taxes. ASU 2023-09 is effective for fiscal years beginning after December 15, 2024. This ASU may be applied prospectively or retrospectively, and early adoption is permitted. The Company is currently evaluating this ASU to determine the impact it may have on its financial statements and related disclosures.

In November 2024, the FASB issued ASU 2024-04, Debt – Debt with Conversion and Other Options (Subtopic 470-20): Induced Conversions of Convertible Debt Instruments. This ASU clarifies guidance on the requirements for determining whether certain settlements of convertible debt instruments should be accounted for as an induced conversion or extinguishment. This guidance is effective for the Company beginning on January 1, 2026, and early adoption is permitted, although the Company does not plan to early adopt. The Company is currently evaluating the impact of the adoption of this standard on the Company's financial statement disclosures.

In November 2024 and January 2025, the FASB issued ASU 2024-03 and ASU 2025-01, respectively, Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses, which requires disclosure in the notes to the financial statements of specified information about an entity's certain costs and expenses. The amendments to the standards are effective for the Company's fiscal year beginning January 1, 2027 and interim periods beginning January 1, 2028. Early adoption is permitted. The amendments should be applied either prospectively to the financial statements issued for reporting periods after the effective date of this ASU or retrospectively to any or all prior periods presented in the financial statements. The Company is currently evaluating this ASU to determine the impact it may have on its financial statements and related disclosures.

In July 2025, the FASB issued ASU 2025-05, Measurement of Credit Losses for Accounts Receivable and Contract Assets, which provides for a practical expedient to estimate credit losses related to accounts receivable and contract assets from revenue contracts accounted for in accordance with ASC 606 using information as of the balance sheet date. This ASU is effective for the Company's fiscal year beginning January 1, 2026 and early adoption is permitted. The Company is currently evaluating this ASU to determine the impact it may have on its financial statements and related disclosures.

In September 2025, the FASB issued ASU 2025-06, Intangibles-Goodwill and Other-Internal-Use Software (Subtopic 350-40): Targeted Improvements to the Accounting for Internal-Use Software, which clarifies and expands the existing guidance on capitalizing implementation costs for cloud computing arrangements that are service contracts. The new guidance is effective for public business entities for fiscal years beginning after December 15, 2027, and interim periods within those fiscal years. Early adoption is permitted. The Company is currently evaluating this ASU to determine the impact it may have on its financial statements and related disclosures.

In September 2025, the FASB issued ASU 2025-07, Derivatives Scope Refinements and Scope Clarification for Share-Based Noncash Consideration from a Customer in a Revenue Contract, which amends the guidance under ASC Topic 815 (Derivatives and Hedging) and ASC Topic 606 (Revenue from Contracts with Customers). The ASU (i) refines the scope for derivative accounting to exclude certain non-exchange-traded contracts whose underlyings are based on the operations or activities specific to one of the parties to the contract, and (ii) provides clarification on how to account for share-based noncash consideration from customers (such as equity

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instruments, warrants, or shares) received in exchange for the transfer of goods or services under a revenue contract. The new guidance is effective for public business entities for fiscal years beginning after December 15, 2026, and interim periods within those fiscal years. Early adoption is permitted. The Company is currently evaluating this ASU to determine the impact it may have on its financial statements and related disclosures.

(3) Fair Value Measurements

The fair value measurements of assets and liabilities that are measured at fair value on a recurring basis consisted of the following as of September 30, 2025 (in thousands):

| | As of September 30, 2025 | | | |
|---|---------------------------------|----------------|------------------|------------------|
| | Level 1 | Level 2 | Level 3 | Total |
| Current assets: | | | | |
| Money market funds | \$ 7,770 | \$ - | \$ - | \$ 7,770 |
| Total assets | \$ 7,770 | \$ - | \$ - | \$ 7,770 |
| Liabilities: | | | | |
| Redeemable convertible preferred stock warrants | \$ - | \$ - | \$ 406 | \$ 406 |
| Common stock warrants | - | - | 3,942 | 3,942 |
| Term loan | - | - | 54,986 | 54,986 |
| Total liabilities | \$ - | \$ - | \$ 59,334 | \$ 59,334 |

The fair value measurements of assets and liabilities that are measured at fair value on a recurring basis consisted of the following as of December 31, 2024 (in thousands):

| | As of December 31, 2024 | | | |
|---|--------------------------------|----------------|------------------|------------------|
| | Level 1 | Level 2 | Level 3 | Total |
| Current assets: | | | | |
| Money market funds | \$ 7,538 | \$ - | \$ - | \$ 7,538 |
| Total assets | \$ 7,538 | \$ - | \$ - | \$ 7,538 |
| Liabilities: | | | | |
| Redeemable convertible preferred stock warrants | \$ - | \$ - | \$ 230 | \$ 230 |
| Common stock warrants | - | - | 2,533 | 2,533 |
| Term loan | - | - | 51,481 | 51,481 |
| Total liabilities | \$ - | \$ - | \$ 54,244 | \$ 54,244 |

Level 3 instruments consist of the Company's Series A-6 redeemable convertible preferred stock warrant liabilities, common stock warrant liabilities, a term loan and convertible notes.

The fair values of the Series A-6 redeemable convertible preferred stock warrant and common stock warrant are measured using a probability weighted option pricing model.

The significant assumptions used in preparing the option pricing model for valuing the common stock warrant liability as of September 30, 2025 and December 31, 2024, are as follows:

| | September 30, 2025 | December 31, 2024 |
|----------------|-------------------------------|------------------------------|
| Stock price | \$ 40.77 | \$ 20.32 |
| Exercise price | \$2.80 – \$10.92 | \$2.80 – \$10.92 |
| Volatility | 76.1 % | 84.0 % |

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| | | |
|-----------------------|--------|--------|
| Expected term (years) | 1.50 | 2.30 |
| Risk-free rate | 3.50 % | 4.14 % |
| Dividend yield | - % | - % |

The significant assumptions used in preparing the option pricing model for valuing the redeemable convertible preferred stock warrant liability as of September 30, 2025 and December 31, 2024, are as follows:

| | September 30, 2025 | December 31, 2024 |
|-----------------------|-------------------------------|------------------------------|
| Stock price | \$ 42.08 | \$ 25.83 |
| Exercise price | \$ 2.59 | \$ 2.59 |
| Volatility | 76.1 % | 84.0 % |
| Expected term (years) | 1.50 | 2.30 |
| Risk-free rate | 3.50 % | 4.14 % |
| Dividend yield | - % | - % |

The fair value of the convertible notes is measured based on the present value of the notes based on the fair market yield to maturity and an estimate of the probability of the notes' conversion features. The fair market yield was estimated based on publicly traded debt securities with similar maturities and risk. During the nine months ended September 30, 2024, the Company settled the convertible notes through the issuance of Series C-1 redeemable convertible preferred stock to the noteholders (See Note 7).

The significant assumptions used in preparing discounted cash flow for valuing the convertible notes as of right before the conversion date of May 15, 2024, are as follows:

| | May 15, 2024 |
|------------------------------------|-------------------------|
| Principal outstanding (in \$'000s) | 30,000 |
| Expected term (years) | - |
| Risk-free rate | 5.46 % |
| Interest rate | 8.00 % |

In August 2024, the Company entered into a new term loan agreement for which the Company elected to account for using the fair value option. As such, the fair value of the debt is calculated by using the probability weighting of the present value of settlement scenarios (See Note 8).

The significant assumptions used in preparing the income approach model for valuing the new term loan as of September 30, 2025 and December 31, 2024, are as follows:

| | September 30, 2025 | December 31, 2024 |
|------------------------------------|-------------------------------|------------------------------|
| Discount rate | 8.02 % | 9.37 % |
| Annual interest rate | 8.00 % | 8.00 % |
| Expected term (years) – Scenario 1 | 4.50 | 5.32 |
| Expected term (years) – Scenario 2 | 5.85 | 6.69 |

The common stock warrants, redeemable convertible preferred stock warrants, convertible notes and term loan are all classified as Level 3 fair value measurements due to the lack of relevant observable market data for the respective fair value inputs for each instrument.

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The following tables present a summary of the changes in the fair value of the Company's Level 3 financial instruments (in thousands):

| | Common Stock Warrants | Redeemable Convertible Preferred Stock Warrants | Term Loan |
|-------------------------------|--------------------------|--|------------------|
| Balance at December 31, 2024 | \$ 2,533 | \$ 230 | \$ 51,481 |
| Adjustments to fair value | (58) | 2 | 1,797 |
| Balance at March 31, 2025 | 2,475 | 232 | 53,278 |
| Adjustments to fair value | (5) | 19 | (1,206) |
| Balance at June 30, 2025 | 2,470 | 251 | 52,072 |
| Adjustments to fair value | 1,472 | 155 | 2,914 |
| Balance at September 30, 2025 | <u>\$ 3,942</u> | <u>\$ 406</u> | <u>\$ 54,986</u> |

| | Common Stock Warrants | Redeemable Convertible Preferred Stock Warrants | Convertible Notes | Term Loan |
|-------------------------------|--------------------------|--|-------------------|------------------|
| Balance at December 31, 2023 | \$ 1,653 | \$ 146 | \$ 47,686 | \$ — |
| Adjustments to fair value | 167 | 16 | 337 | — |
| Balance at March 31, 2024 | 1,820 | 162 | 48,023 | — |
| Adjustments to fair value | 190 | 17 | 498 | — |
| Gain on extinguishment | — | — | (8,635) | — |
| Settlements | — | — | (39,886) | — |
| Balance at June 30, 2024 | 2,010 | 179 | — | — |
| Additions | — | — | — | 50,000 |
| Adjustments to fair value | 143 | 16 | — | 1,650 |
| Balance at September 30, 2024 | <u>\$ 2,153</u> | <u>\$ 195</u> | <u>\$ —</u> | <u>\$ 51,650</u> |

For the three months ended and nine months ended September 30, 2025 and 2024, the Company recognized losses related to the change in the fair value of the common stock warrant liability and redeemable convertible preferred stock warrant liability in other expense, net in the statements of operations and comprehensive income (loss). The Company will continue to recognize changes in the fair value of the common stock warrant liability and redeemable convertible preferred stock warrant liability until the warrants are exercised, expire, or qualify for equity classification.

For the nine months ended September 30, 2024, the Company recognized losses related to the change in the fair value of convertible notes in change in fair value of convertible notes in the statements of operations and comprehensive income (loss). During the nine months ended September 30, 2024, the convertible notes were settled in Series C-1 Redeemable Convertible Preferred Stock which was accounted for as a debt extinguishment as the settlement was not pursuant to the original conversion terms. The Company recorded a gain on extinguishment in net gain on extinguishment of debt in the statements of operations and comprehensive income (loss) upon the conversion date (See Note 7).

For the three months ended September 30, 2025 and 2024 and the nine months ended September 30, 2025 and 2024, the Company recognized a loss related to the change in fair value of the term loan in change in fair value of term loan in the statements of operations and comprehensive income (loss).

The common stock warrant liability and redeemable convertible preferred stock warrant liabilities are recorded within other non-current liabilities on the balance sheets as of September 30, 2025 and December 31, 2024. The term loan is recorded within long-term debt on the balance sheet as of September 30, 2025 and December 31, 2024.

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The Company recognizes transfers among Level 1, Level 2 and Level 3 classifications as of the actual date of the events or change in circumstances that caused the transfers. During the three and nine months ended September 30, 2025 and 2024, the Company had no transfers of financial assets or liabilities between different levels of the fair value hierarchy.

(4) Accrued Expenses and Other Current Liabilities

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

| | September 30, 2025 | December 31, 2024 |
|--|-----------------------|----------------------|
| Accrued professional services | \$ 1,819 | \$ 898 |
| Accrued inventory purchases | 2,303 | 443 |
| Accrued fixed asset purchases | 57 | 798 |
| Insurance payor liability | 1,487 | — |
| Accrued property and other taxes | 161 | 443 |
| Accrued information technology purchases | 413 | 250 |
| Accrued legal expense | 836 | 191 |
| Accrued phlebotomy expense | 160 | 171 |
| Accrued insurance expense | 75 | 159 |
| Accrued rent | 122 | 160 |
| Accrued clinical expenses | 242 | 98 |
| Other | 366 | 271 |
| Accrued expenses and other current liabilities | <u>\$ 8,041</u> | <u>\$ 3,882</u> |

(5) Redeemable Convertible Preferred Stock

As of September 30, 2025 and December 31, 2024, redeemable convertible preferred stock consisted of the following (in thousands, except for share data):

| | Shares Authorized | Shares Issued and Outstanding | Net Carrying Value | Aggregate Liquidation Preference |
|------------|----------------------|-------------------------------------|-----------------------|--|
| Series A-1 | 1,349,650 | 1,349,650 | \$ 3,493 | \$ 540 |
| Series A-2 | 1,137,210 | 1,137,210 | 2,943 | 910 |
| Series A-3 | 899,730 | 899,730 | 2,328 | 900 |
| Series A-4 | 25,761 | 25,761 | 67 | 50 |
| Series A-5 | 114,613 | 114,613 | 297 | 100 |
| Series A-6 | 5,805,861 | 5,796,201 | 14,999 | 15,000 |
| Series B-1 | 5,182,287 | 5,182,287 | 54,889 | 55,000 |
| Series B-2 | 2,566,902 | 2,566,902 | 27,243 | 16,025 |
| Series C | 6,079,919 | 5,628,825 | 143,268 | 143,500 |
| Series C-1 | 1,726,823 | 1,726,823 | 39,886 | 33,870 |
| Series D | 4,656,233 | 4,656,233 | 129,996 | 156,563 |
| Total | <u>29,544,989</u> | <u>29,084,235</u> | <u>\$ 419,409</u> | <u>\$ 422,458</u> |

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(6) Commitments and Contingencies***Legal Proceedings***

From time to time, the Company is party to certain claims in the ordinary course of business. The Company, in conjunction with its legal counsel, assesses the need to record a liability for litigation or contingencies. A liability is recorded when and if it is determined that such a liability for litigation or contingencies is both probable and the amount can be reasonably estimated. The Company believes that it is not presently a party to any litigation of which the outcome, if determined adversely, would individually or in the aggregate be expected to have a material and adverse effect on the business, operating results, cash flows, or financial position. Legal fees are expensed in the period in which they are incurred.

Indemnification Agreements

The Company has entered into indemnification agreements with its directors and officers against any liabilities that may arise by reason of their status or service as directors or officers, other than liabilities arising from willful misconduct of the individual.

Additionally, in the ordinary course of business, the Company enters into agreements of varying scope and terms pursuant to which it agrees to indemnify customers, vendors, lessors, business partners, and other parties with respect to certain matters, including, but not limited to, losses arising out of the breach of such agreements, services to be provided by the Company, or from intellectual property infringement claims made by third parties. As of September 30, 2025 and December 31, 2024, no demands have been made upon the Company to provide indemnification under such agreements, and there are no claims that the Company is aware of that could have a material adverse effect on its financial position, results of operations, or cash flows. Accordingly, the Company has no liabilities recorded for these agreements as of September 30, 2025 and December 31, 2024.

(7) Convertible Notes

In September 2022, the Company entered into a Note Purchase Agreement for unsecured Convertible Promissory Notes (the "Notes") to several note holders (the "Note Holders") with a principal sum of \$30.0 million together with interest thereon from the date of the Notes. The Notes accrue interest at a rate of 8.0% per annum, simple interest. The Notes were scheduled to mature on September 20, 2024, and the Company may not make prepayments without written consent of the majority Note holders.

During May 2024, concurrent with the issuance of Series D redeemable convertible preferred stock, and pursuant to negotiation with the Note Holders, the Company and Note Holders agreed to settle the Notes through the issuance of Series C-1 redeemable convertible preferred stock to the Note Holders instead of Series D redeemable convertible preferred stock. The Notes converted into an aggregate of 1,726,823 shares of Series C-1 redeemable convertible preferred stock at a conversion price of approximately \$19.6143 per share. The change in terms of the Notes was accounted for as a debt extinguishment as the settlement was not pursuant to the original conversion terms. Immediately prior to the extinguishment, the Company recorded a mark-to-market adjustment for the Notes resulting in a loss of \$0.8 million for the nine months ended September 30, 2024 which was recorded to change in fair value of convertible notes in the Company's statements of operations and comprehensive income (loss). Upon extinguishment, the Company derecognized the Notes on the balance sheets at their fair value immediately prior to the extinguishment of \$48.5 million. The difference of \$8.6 million between the fair market value of the Series C-1 redeemable convertible preferred shares received by the Note Holders of \$39.9 million and the fair value of the Notes immediately prior to the extinguishment was recorded as a gain on debt extinguishment in the Company's statements of operations and comprehensive income (loss) for the nine months ended September 30, 2024.

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(8) Long-term Debt**Oberland Note Purchase Agreement**

In August 2024, the Company entered into a note purchase agreement (the “2024 Notes”) with BWCB SA LLC, an entity affiliated with Oberland Capital Management, LLC (“Oberland Capital”), which provided the Company with up to four tranches of capital advances totaling up to \$140.0 million. The advanced principal accrues interest at a rate of 8.0% per annum. The first tranche of \$50.0 million was advanced on August 5, 2024, with a Maturity Date on the seventh anniversary of the first purchase date (August 5, 2031). The first tranche requires interest-only payments through August 5, 2031 and a lump sum payment due on August 5, 2031.

The second tranche of up to \$35.0 million in principal was available at the Company’s option at any time prior to September 30, 2025 provided that the trailing six-month worldwide net revenue of the Company is at least \$80.0 million. The Company did not elect the option to draw on the second tranche.

The Company is required to sell the third tranche of notes in the amount of \$30.0 million prior to March 31, 2026 as the Company achieved the revenue and gross margin thresholds triggering this obligation during the first half of fiscal 2025. The thresholds triggering this tranche are trailing six-month revenue of at least \$112.5 million and a trailing six-month gross margin of at least 45%. Gross Margin is defined as (I) net revenue minus cost of goods sold divided by (II) net revenue, expressed as a percentage. The terms of the third tranche are identical to those of the first \$50 million tranche. Lastly, the fourth tranche of up to \$25.0 million in principal will be made available to the Company at the mutual agreement of the parties at any time prior to March 31, 2026.

The Company has the option at any time to prepay all of the then-outstanding notes, and Oberland Capital has the option to redeem the notes upon (i) a change in control of the Company, (ii) an event of default, or (iii) the maturity date. The redemption price of the note shall equal to the following: (1) 130% of principal amounts of notes if the payment is made within 24 months of issuance; (2) 145% of principal amounts of notes if the payment is made within 36 months of issuance; (3) If the payment is made within 48 months, an amount that would generate an internal rate of return (“IRR”) of 12.25%; (4) if the payment is made within 60 months of the issuance, an amount that would generate an IRR of 11.75%; (5) if the payment is made thereafter but before maturity, an amount that would generate an IRR of 11.25%; and (6) if the payment is made at maturity, an amount that would generate an IRR of 10.0%.

The Company is required to maintain trailing six-month net revenue based on a schedule that gradually increases up to \$120.0 million after the year ending December 31, 2026.

| Period | Minimum Trailing Six-Month Net Revenue Threshold (in millions) |
|---------------|---|
| Q1 2025 | \$ 56.1 |
| Q2 2025 | \$ 65.6 |
| Q3 2025 | \$ 75.8 |
| Q4 2025 | \$ 82.8 |
| Q1 2026 | \$ 87.2 |
| Q2 2026 | \$ 101.8 |
| Q3 2026 | \$ 117.2 |
| Q4 2026 | \$ 120.0 |
| Thereafter | \$ 120.0 |

In addition, the Company is required to maintain a trailing six-month Gross Margin of not less than 30%. The agreement also contains a revenue participation agreement, under which, for any fiscal quarter, 0.01% of net revenue for such fiscal quarter (up to \$100.0 million of net revenue for each fiscal year) per each \$1.0 million principal amount of the notes will be payable to Oberland Capital. Amounts paid under the revenue participation agreement during the three and nine months ended September 30, 2025 and 2024 were interest payments on

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the debt. The revenue participation payments are additional financing costs of the loan and are included in the computation of the internal rate of return measures described above and do not reduce principal on the debt. As of September 30, 2025, we have made revenue participation payments of \$0.5 million.

The Company elected to account for the 2024 Notes using the fair value option and changes in fair value related to the 2024 Notes are recorded in change in fair value of term loan on the Company's statements of operations and comprehensive income (loss). The Company also elected to present interest incurred on the 2024 Notes in the change in fair value of the term loan; interest expense under the Oberland Capital arrangement was \$1.0 million, \$0.6 million, \$3.0 million and \$0.6 million for the three months ended September 30, 2025 and 2024 and nine months ended September 30, 2025 and 2024, respectively. Total debt outstanding as of September 30, 2025 and December 31, 2024 was \$55.0 million and \$51.5 million, respectively, and included within long-term debt on the Company's balance sheets. Future principal payments of the Company's long-term debt as of September 30, 2025 and December 31, 2024 are \$50.0 million, and are due during the year ending December 31, 2031. The term loan advances are secured by a lien on the Company's assets.

Redeemable Convertible Preferred Stock Warrants

The Company has issued Comerica Bank a warrant to purchase 9,660 Series A-6 redeemable convertible preferred shares at an exercise price of \$2.59 per share in connection with a former loan and security agreement entered into in March 2020. The warrants are exercisable until March 15, 2030. The warrants are classified as liabilities on the Company's balance sheet.

Western Alliance Bank Debt

In October 2021, the Company entered into a loan and security agreement (the "2021 LSA") with Western Alliance Bank ("WAB"), which provided the Company with three tranches of capital advances totaling \$15.0 million. In July 2022, the Company amended the 2021 LSA, such that WAB made four tranches of capital advances available to the Company for an aggregate amount up to \$35.0 million. During August 2024, the Company elected to prepay the outstanding amount of the term loans of \$35.0 million in principal and the \$1.5 million exit fee that became payable upon early loan payoff. The Company recognized a loss on the extinguishment of debt of \$1.3 million in the statements of operations and comprehensive income (loss). The loss on extinguishment consisted of incremental expense of \$0.8 million unaccreted exit fee liability, \$0.3 million unamortized debt issuance costs and a \$0.2 million prepayment fee assessed by the bank.

Common Stock Warrants

In connection with the 2021 LSA, the Company issued to Western Alliance Bank ("WAB") warrants to purchase shares of the Company's common stock at an exercise price of \$2.80 per share. The number of underlying shares of the warrants was initially 53,571 and was increased to 80,357 upon the funding of the loans in January 2022. The warrants will expire if unexercised on October 12, 2031. Upon the occurrence of an acquisition of the Company, if the acquiror shall not have assumed the warrants, WAB shall have the right to put the warrants back to the Company for cash equal to the greater of (x) \$450,000 or (y) the value of the aggregate consideration payable to WAB had WAB exercised the warrants immediately prior to exercise such put right.

In connection with the 2022 LSA Amendment, the Company issued up to 41,209 warrants for common stock at an exercise price of \$10.92 per share to WAB. 30,907 warrants were exercisable upon execution of the agreement; the remaining warrants become exercisable as the Company makes additional draws on the 2022 LSA Amendment. As of December 31, 2023 all of the warrants were exercisable. The warrants will expire if unexercised on July 22, 2032. Upon the occurrence of an acquisition of the Company, if the acquiror shall not have assumed the warrants, WAB shall have the right to put the warrants back to the Company for cash equal to the greater of (x) \$450,000 or (y) the value of the aggregate consideration payable to WAB had WAB exercised the warrants immediately prior to exercise such put right.

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All the warrants issued to WAB are puttable warrants and thus are liability classified. The warrants were initially recognized at fair value with any subsequent changes in fair value to be recorded in other income (expense) in the statements of operations and comprehensive income (loss) (See Note 3).

The fair value of the warrants as of their respective issuance dates were recorded as a debt discount that is being amortized to interest expense over the term of the loan.

(9) Common Stock

As of September 30, 2025 and December 31, 2024, the Company's Certificate of Incorporation, as amended, authorized the Company to issue 51,100,000 shares of common stock with a par value of \$0.00001. Total common stock outstanding as of September 30, 2025 and December 31, 2024 was 11,178,467 and 10,925,950, respectively. Each share of common stock is entitled to one vote. The holders of common stock are also entitled to receive dividends whenever funds are legally available and when and if declared by the Board of Directors, subject to the prior rights of holders of all series of stock outstanding. No dividends have been declared or paid by the Company since inception.

The Company is required to reserve and keep available out of its authorized but unissued shares of common stock such a number of shares sufficient to affect the conversion of all outstanding shares of redeemable convertible preferred stocks, preferred stock and common stock warrants, and options granted and available for grant under the Company's stock option plan.

The amount of such shares of the Company's common stock reserved for these purposes at September 30, 2025 is as follows:

| | |
|---|-------------------|
| Series A-1 Redeemable Convertible Preferred Stock | 1,349,650 |
| Series A-2 Redeemable Convertible Preferred Stock | 1,137,210 |
| Series A-3 Redeemable Convertible Preferred Stock | 899,730 |
| Series A-4 Redeemable Convertible Preferred Stock | 25,761 |
| Series A-5 Redeemable Convertible Preferred Stock | 114,613 |
| Series A-6 Redeemable Convertible Preferred Stock | 5,796,201 |
| Series B-1 Redeemable Convertible Preferred Stock | 5,182,287 |
| Series B-2 Redeemable Convertible Preferred Stock | 2,566,902 |
| Series C Redeemable Convertible Preferred Stock | 5,628,825 |
| Series C-1 Redeemable Convertible Preferred Stock | 1,726,823 |
| Series D Redeemable Convertible Preferred Stock | 4,656,233 |
| Redeemable Convertible Preferred stock warrants | 9,660 |
| Common stock warrants | 121,566 |
| Options to purchase common stock | 9,041,854 |
| Stock options available for future grants | 719,328 |
| Total common stock reserved | <u>38,976,643</u> |

Stock Plan

In December 2018, the Company adopted the 2018 Stock Plan (the "2018 Plan"). The 2018 Plan authorizes the granting of stock options upon the approval of the Company's Board of Directors, to employees and consultants providing services to the Company. Stock options granted under the 2018 Plan generally expire within 10 years from the date of grant and are generally issued at the fair value of the underlying shares of common stock on the date of grant as determined by the Company's Board of Directors. The shares subject to each option typically allow for 25% of the shares to vest and become exercisable on the first anniversary of the vesting commencement date and thereafter, the remaining 75% will vest and become exercisable in 36 equal monthly installments. The Company may include other vesting terms from time to time.

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Incentive and non-statutory stock options may be granted with exercise prices not less than 100% of the estimated fair value of the common stock on the date of grant, as determined by the Board of Directors.

Subject to Board approval at the grant date, if an option includes an “early exercise” feature, then such option shall be exercisable at any time but any unvested option shares shall be subject to the Company’s right to repurchase them at the original exercise price in the event that the optionee’s service is terminated for any reason. If an option does not permit early exercise, then such option shall not be exercisable with respect to unvested shares. As of September 30, 2025 and December 31, 2024, the Company had authorized 12,409,025 and 10,904,372 shares of common stock reserved for issuance under the 2018 Plan, respectively.

Stock-based Compensation

The weighted average assumptions used to calculate the fair value of option grants issued under the 2018 Plan during the three and nine months ended September 30, 2025 and 2024 were as follows:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|----------------------------|-------------------------------------|----------|------------------------------------|----------|
| | 2025 | 2024 | 2025 | 2024 |
| Fair value of common stock | \$ 31.74 | \$ 16.89 | \$ 25.68 | \$ 15.68 |
| Dividend yield | - | - | - | - |
| Risk-free interest rate | 3.9 % | 4.1 % | 4.2 % | 4.2 % |
| Expected volatility | 74 % | 68 % | 73 % | 68 % |
| Expected term (in years) | 6.02 | 6.05 | 6.28 | 6.01 |

A summary of the Company’s stock option activity and related information is as follows:

| | Number of Options Outstanding | Weighted Average Exercise Price Per Share | Aggregate Intrinsic Value (in thousands) |
|--|-------------------------------------|--|--|
| Balance as of December 31, 2024 | 6,849,412 | \$ 7.28 | \$ 73,992 |
| Granted | 2,721,201 | \$ 20.17 | |
| Exercised | (252,517) | \$ 4.30 | |
| Forfeited or expired | (276,242) | \$ 14.24 | |
| Balance as of September 30, 2025 | 9,041,854 | \$ 11.03 | \$ 268,925 |
| Vested and exercisable as of September 30, 2025 | 4,876,287 | \$ 5.60 | \$ 171,507 |
| Vested and expected to vest as of September 30, 2025 | 9,041,854 | \$ 11.03 | \$ 268,925 |

As of September 30, 2025, there was approximately \$60.7 million of total unrecognized compensation cost related to unvested options, which is expected to be recognized over the weighted average period of 3.8 years. Also, in June 2025, the Board of Directors granted stock options of 1,003,102 shares to the Company’s Chief Executive Officer and Co-Founder and 501,551 shares to the Chief Technology Officer and Co-Founder at an exercise price of \$20.04 per share. The vesting commencement date of the stock option is June 11, 2025 and the stock options vests monthly over six years.

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Stock-Based Compensation Expense

The table below shows stock-based compensation expense included in the statements of operations and comprehensive income (loss) for the three months ended and nine months ended September 30, 2025 and 2024 (in thousands):

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|-------------------------------------|-------------------------------------|-----------------|------------------------------------|-----------------|
| | 2025 | 2024 | 2025 | 2024 |
| Cost of revenue | \$ 401 | \$ 284 | \$ 1,139 | \$ 848 |
| Research and development | 971 | 554 | 2,542 | 1,719 |
| Selling, general and administrative | 3,103 | 1,312 | 5,900 | 3,488 |
| Total stock-based compensation | <u>\$ 4,475</u> | <u>\$ 2,150</u> | <u>\$ 9,581</u> | <u>\$ 6,055</u> |

Secondary Sales of Common Stock

During June 2024, investors of the Company acquired 52,750 shares of common stock at a price per share equal to \$22.42 per share from employee stockholders. During July 2024, investors of the Company acquired an additional 22,302 shares of common stock at a price per share equal to \$22.42 per share from a stockholder who was a former employee of the Company. As a result, the Company recorded a total of \$0.1 million and \$0.4 million for the three months ended and nine months ended September 30, 2024, respectively, in stock-based compensation expense for the difference between the price paid by these investors and the estimated fair value of the acquired common stock from stockholders on the date of the transactions. No secondary sales occurred during the three and nine months ended September 30, 2025.

Repurchase of Common Stock

In February 2024, the Company's Board of Directors agreed to repurchase a total of 26,750 shares of common stock that were held by a former employee of the Company. The repurchase price paid by the Company was \$20.3950 per share, resulting in a total repurchase cost of \$0.5 million. As the repurchase price paid by the Company to the former employee represented an excess over the common stock's estimated fair market value at the time, the Company accounted for this premium as stock-based compensation expense of \$0.2 million during the nine months ended September 30, 2024.

(10) Income Taxes

The Company has an effective tax rate of (2.31)%, 0.15%, (1.03)% and (0.05)% for the three and nine months ended September 30, 2025 and 2024, respectively. The Company has historically incurred U.S. operating losses prior to the nine months ended September 30, 2025 and has minimal profits in its foreign jurisdictions.

The Company updates its estimate of the annual effective tax rate each quarter and makes a cumulative adjustment in such period. The Company recorded immaterial amounts for the three and nine months ended September 30, 2025 and 2024, respectively. Income tax expense (benefit) consists primarily of income taxes for U.S. federal and the states in which the Company conducts business. Due to the Company's history of losses in the United States, a full valuation allowance on substantially all of the Company's deferred tax assets, including net operating loss carryforwards, research and development tax credits, and other book versus tax differences, was maintained.

On July 4, 2025, the One Big Beautiful Bill Act ("OBBBA") was enacted in the U.S. The OBBBA includes significant provisions, such as the permanent extension of certain expiring provisions of the Tax Cuts and Jobs Act, modifications to the international tax framework and the restoration of favorable tax treatment for certain business provisions. The legislation has multiple effective dates, with certain provisions effective in 2025 and others implemented through 2027. The enactment of the OBBBA did not result in a material impact to our provision for income taxes for the three months ended September 30, 2025 given we maintain a full valuation allowance on our federal deferred tax assets. We are currently assessing the long term impact the OBBBA may have on our financial condition, results of operations, cash flows, and effective tax rate.

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(11) Employee Benefit Plan

The Company sponsors a qualified 401(k) defined contribution plan covering eligible employees. Participants may contribute a portion of their annual compensation limited to a maximum annual amount set by the Internal Revenue Service. Employer contributions to the plan are discretionary. During the three and nine months ended September 30, 2025 and 2024, the Company contributed \$0.9 million, \$0.6 million, \$2.6 million and \$1.7 million to this plan, respectively.

(12) Related Party Transactions

In February 2024, the Company repurchased 26,750 shares of common stock that were held by the former CFO. Please refer to Note 9 for additional information on this transaction. There were no other material related party transactions during the three months ended and nine months ended September 30, 2025 and 2024.

(13) Net Income (Loss) Per Share Attributable to Shareholders

For the three months ended and nine months ended September 30, 2024, basic net income (loss) per share is the same as diluted net income (loss) per share as the inclusion of any potential common shares outstanding would have been anti-dilutive. For the three months ended and nine months ended September 30, 2025, diluted net income (loss) per share is computed by applying the two-class method and then by dividing net income attributable to common stockholders by the weighted-average number of diluted common shares outstanding. The dilutive effect of potentially dilutive common shares is reflected in diluted earnings per share by application of the if-converted method for the Company's outstanding preferred stock, the treasury stock method for the Company's other potentially dilutive securities, and is ultimately applied by sequencing instruments beginning with those that are more dilutive.

The following table sets forth the computation of basic and dilutive net income (loss) per share attributable to common stockholders for the three and nine months ended September 30, 2025 and 2024 (in thousands, except per share amounts):

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| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|--|-------------------------------------|-------------|------------------------------------|-------------|
| | 2025 | 2024 | 2025 | 2024 |
| Basic net income (loss) per share: | | | | |
| Numerator: | | | | |
| Net income (loss) | \$ 5,711 | \$ (14,904) | \$ 1,477 | \$ (30,093) |
| Less: Net income attributable to participating securities | (4,204) | — | (1,089) | — |
| Net income (loss) attributable to common stockholders | 1,507 | (14,904) | 388 | (30,093) |
| Denominator: | | | | |
| Weighted-average shares used in calculating net income (loss) per share, basic | 10,429,583 | 10,107,487 | 10,376,253 | 10,049,097 |
| Net income (loss) per share, basic | \$ 0.14 | \$ (1.47) | \$ 0.04 | \$ (2.99) |
| Diluted net income (loss) per share: | | | | |
| Numerator: | | | | |
| Net income (loss) attributable to common stockholders | \$ 1,507 | \$ (14,904) | \$ 388 | \$ (30,093) |
| Denominator: | | | | |
| Weighted-average shares used in calculating net income (loss) per share, basic | 10,429,583 | 10,107,487 | 10,376,253 | 10,049,097 |
| Effect of dilutive securities: | | | | |
| Outstanding stock options | 4,336,722 | — | 3,940,885 | — |
| Warrants to purchase redeemable convertible preferred stock | 8,798 | — | 8,616 | — |
| Warrants to purchase common stock | 98,294 | — | 93,366 | — |
| Restricted stock awards in exchange for non-recourse note | 698,552 | — | 698,245 | — |
| Weighted-average shares used in calculating net income (loss) per share, diluted | 15,571,949 | 10,107,487 | 15,117,365 | 10,049,097 |
| Net income (loss) per share, diluted | \$ 0.10 | \$ (1.47) | \$ 0.03 | \$ (2.99) |

Potentially dilutive securities that were not included in the diluted per share calculations because they would be anti-dilutive were as follows for the three and nine months ended September 30, 2025 and 2024:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|-------------------------------------|------------|------------------------------------|------------|
| | 2025 | 2024 | 2025 | 2024 |
| Redeemable convertible preferred stock | 29,084,235 | 29,084,235 | 29,084,235 | 29,084,235 |
| Outstanding stock options | - | 6,565,802 | - | 6,565,802 |
| Restricted stock awards in exchange for non-recourse note | - | 700,000 | - | 700,000 |
| Warrants to purchase common stock | - | 121,566 | - | 121,566 |
| Warrants to purchase redeemable convertible preferred stock | - | 9,660 | - | 9,660 |
| Unvested early-exercised options | - | 500 | - | 500 |

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(14) Subsequent Events

On November 7, 2025, the Company closed its initial public offering (the "IPO") of 5,233,765 shares of its Class A common stock, which includes the exercise in full by the underwriters of their option to purchase from the Company 682,665 shares of the Company's Class A common stock, at a price to the public of \$60.00 per share. The gross proceeds to the Company from the IPO were \$314.0 million and the net proceeds amounted to \$286.4 million, after deducting underwriting discounts and commissions and offering expenses payable by the Company. Immediately prior to the closing of the IPO, each outstanding share of the Company's Series A-1, Series A-2, Series A-3, Series A-4, Series A-5, Series A-6, Series B-1, Series B-2, Series C, Series C-1 and Series D redeemable convertible preferred stock converted, on a one-for-one basis, into 29,084,235 shares of the Company's Class A common stock (the conversion, the "Reclassification"). Following the Reclassification, and immediately prior to the closing of the IPO, 2,325,108 shares of Class A common stock held by Oguzhan Atay, our Chief Executive Officer and Co-Founder, and 2,227,542 shares of Class A common stock held by David Tsao, our Chief Technology Officer and Co-Founder, were exchanged at a 1:1 ratio for shares of Class B common stock.

In connection with the IPO, the Company's Board of Directors adopted, and its stockholders approved, the 2025 Equity Incentive Plan (the "2025 Plan"), which became effective on November 5, 2025. The 2018 Plan was terminated upon the completion of the IPO, however awards outstanding under the 2018 Plan will remain outstanding and will continue to be governed by their existing terms. The number of shares of Class A common stock available for issuance under the 2025 Plan is 3,297,972 shares of Class A common stock, plus up to 10,034,626 shares remaining available for issuance under the 2018 Plan, subject to annual adjustment on the first day of each fiscal year through January 1, 2035. The 2025 Plan allows for the issuance of a variety of stock-based compensation awards at the discretion of the Board of Directors, including stock options, stock appreciation rights, restricted stock awards, restricted stock unit ("RSU") awards, and other stock-based awards.

In further connection with the IPO, the Company's Board of Directors adopted, and its stockholders approved, the 2025 Employee Stock Purchase Plan (the "2025 ESPP"), which became effective on November 5, 2025. The number of shares of Class A common stock available for issuance under the 2025 ESPP is 548,880 shares of Class A common stock, subject to annual adjustment on the first day of each fiscal year through January 1, 2035. No more than 8,400,000 shares of Class A common stock may be issued under the 2025 ESPP. Each participant may purchase up to the number of shares determined by the Board of Directors on any purchase date, not to exceed 7,500 shares. The price of each share of Class A common stock purchased under the 2025 ESPP will not be less than 85% of the lower of the fair market value per share of Class A common stock on the first day of the applicable offering period or the fair market value per share of Class A common stock on the purchase date.

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

The following discussion and analysis of our financial condition and results of operations should be read together with our unaudited financial statements and the related notes included in Item 1 of this Quarterly Report. This discussion and analysis as well as other parts of this Quarterly Report contain forward-looking statements that involve risks and uncertainties, including information with respect to our plans and strategy for our business. You should carefully read the sections titled “Special note regarding forward-looking statements” and “Risk Factors” to gain an understanding of the factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. Our historical results are not necessarily indicative of the results that may be expected for any period in the future. Unless context requires otherwise, references to “we,” “us,” “our,” “BillionToOne,” or “the Company” here refer to BillionToOne, Inc.

Overview

BillionToOne is transforming healthcare by redefining molecular diagnostics. Our revolutionary single-molecule next-generation sequencing (smNGS) platform achieves what was once thought impossible—detecting and precisely quantifying genetic targets with single-molecule sensitivity. At the heart of this technological breakthrough lies our patented quantitative counting templates (QCTs), enabling measurements at the physical limit of detection—the single DNA molecule. This leap forward addresses a fundamental limitation in healthcare—the inability to detect sparse but clinically crucial disease signals in cell-free DNA (cfDNA).

Founded with the mission to remove the fear of the unknown through powerful and accessible smNGS-based diagnostics, we have swiftly transitioned from an R&D-focused company to a proven commercial organization. Since launching UNITY, our first prenatal product in 2019, we have expanded our offerings first within prenatal genetics, and then to oncology diagnostics. To date, we have processed more than one million smNGS-based tests. Today, we test approximately 1 in 11 babies during pregnancy in the United States, a metric that is continuing to increase rapidly every year. UNITY is the first single-gene non-invasive prenatal test (sgNIPT) that uses cfDNA to provide fetal risk assessment for recessive conditions such as sickle cell disease (SCD) and cystic fibrosis (CF) without requiring a paternal sample or invasive procedures such as amniocentesis. Since then, we have expanded our UNITY offering to cover comprehensive prenatal genetic needs from a single maternal blood draw. In 2024, our unique fetal antigen tests resulted in national medical guideline changes, enabling us to position our tests as “the new standard in prenatal care,” further contributing to both test volume and average selling price (ASP) growth, as we leveraged the guideline changes to contract with more insurance companies. By detecting and identifying an extensive array of severe but actionable genetic disorders during pregnancy, we enable substantially better outcomes for newborns via earlier therapeutic and other clinical interventions.

In the oncology setting, ultrasensitive tests with real-time insights are required to effectively detect, diagnose, and treat patients with a diverse range of mutations and solid tumor types across the cancer care continuum. In 2023, we successfully leveraged our smNGS platform to launch two complementary pan-cancer liquid biopsy tests – Northstar Select[®] and Northstar Response[®]. Our Northstar Select test is used to guide therapy selection and has been shown to detect over 50% more actionable solid tumor mutations than conventional liquid biopsies.

^{1,2} Based on our knowledge of all widely available tests, Northstar Response is the only methylation-based assay that quantifies the amount of cancer (tumor burden) at the single molecule level without requiring a tissue biopsy, enabling real-time monitoring of patient response to therapy with unprecedented precision. Our Northstar tests give physicians extraordinary visibility into cancer profile and treatment response, enabling more informed and earlier treatment decisions that can fundamentally alter patient outcomes. Our business momentum is evidenced by our rapidly scaling commercial success and improving operational efficiency. Of approximately one million smNGS-based tests that we have processed since our initial launch, over 50% of them, or approximately 562,900 tests, were processed within the last 12 months ended September 30, 2025. For the year ended December 31, 2024, we generated revenue of \$152.6 million, representing 113% year-over-year growth, with a gross margin of 53% and net loss of \$41.6 million. While we have generally incurred losses

¹ Bower, X., Wignall, J., Varga, M. G., Zhu, J., O’Sullivan, M., Searle, N. E., Hong, L. K., Dogruluk, T., Li, Z., Farmer, T. E., Rosas-Linhard, E., Luong, J., Lin, E., Simon, M. E., Tsao, D. S., Bosch, J. R. T., Palmer, G., Gajra, A., Huynh, C., & Zhou, W. (2025). Validation of a liquid biopsy assay with increased sensitivity for clinical comprehensive genomic profiling. *The Journal of Liquid Biopsy*, 100322.

² More than 50% more actionable/reportable mutations when compared to the comparator products in the aggregate. Actual percentages may vary depending on the individual comparator test.

since inception, and had an accumulated deficit of \$280.7 million as of September 30, 2025, we had net income of \$1.5 million for the nine months ended September 30, 2025 compared to a net loss of \$30.1 million for the nine months ended September 30, 2024. During the nine months ended September 30, 2025, we generated revenue of \$209.1 million, representing 95% year-over-year revenue growth as compared to the nine months ended September 30, 2024 with a gross margin of 67%. This translated to a non-GAAP income from operations of \$15.3 million for the nine months ended September 30, 2025 compared to a non-GAAP loss from operations of \$29.4 million for the nine months ended September 30, 2024, which represented an improvement of approximately \$44.7 million.

On November 7, 2025, we closed our initial public offering (“IPO”) of our Class A common stock, in which the Company issued and sold 5,233,765 shares of its Class A common stock, which includes the exercise in full of the underwriters’ option to purchase an additional 682,665 shares of Class A common stock, at a public offering price of \$60.00 per share. The IPO resulted in net proceeds of \$286.4 million after underwriting discounts, commissions and offering expenses payable by us. In connection with the IPO, 4,552,650 shares of our Class A common stock owned by Oguzhan Atay, our Chief Executive Officer and Co-Founder, and David Tsao, our Chief Technology Officer and Co-Founder were exchanged for an equivalent number of shares of Class B common stock.

Our key performance metrics

Our revenue is driven by selling and performing molecular diagnostic tests ordered by physicians and other providers. We generally bill the patients’ insurance carrier, the patient, or a combination of both upon delivery of the test results.

Our revenue is the function of two inputs: the number of tests ordered and the ASP that we can achieve through reimbursement. There is a flywheel effect between these two factors. The more tests that we process, the easier it becomes for us to contract with third-party payors and become an in-network provider. This increases our ASP for our tests, as the denial rate of our tests significantly decreases once we become an in-network provider. As we become an in-network provider, it becomes easier for our sales representatives to convince ordering providers to use our tests. We believe that the combined effect of ASP increases, cost of goods sold (COGS) decreases, and improved operational efficiency has been the main driver in decreases in our net losses.

Our total test volume, which represents the number of billable tests that we receive for processing during each period and which we also refer to as tests accessioned, grew to approximately 162,900 tests for the three months ended September 30, 2025, compared to 107,900 for the three months ended September 30, 2024. In addition, our total delivered and billable test volume, which represents the number of billable tests for which we deliver a result to the ordering provider each period, grew to approximately 165,000 tests in the three months ended September 30, 2025, compared to 108,500 delivered and billable tests in the three months ended September 30, 2024.

Key factors affecting our results of operations and performance

We believe certain factors have influenced, and will continue to influence, our operating performance and results of operations. While each of these factors presents significant opportunities for our business, they also pose important risks and challenges that we must successfully address to sustain and grow our business and improve our results of operations. Our ability to successfully address the factors below is subject to various risks and uncertainties, including those described under the section titled “Risk Factors.”

Market adoption and commercial success

Our success and future growth depend on maintaining and expanding market acceptance and achieving commercial success in our prenatal and oncology product lines. This requires our sales teams to develop and maintain relationships with obstetricians, maternal-fetal medicine specialists, oncologists, and other providers. In addition, our sales teams must be able to convincingly communicate the clinical utility and value of our tests in enabling personalized patient care. The commercial success of our existing tests and any new tests we develop will depend upon factors such as clinical evidence supporting their effectiveness, inclusion in clinical practice guidelines, adoption by the medical community, favorable coverage by third-party payors, and our ability to differentiate our offerings in competitive markets. In addition, our ability to maintain and expand our

sales and marketing capabilities to support increased adoption of our molecular diagnostic solutions will be another key factor to our success.

Payor coverage, contracting, and more effective reimbursement operations

Our ASPs and revenue depend heavily on our success in achieving and maintaining broad coverage and adequate reimbursement for our molecular diagnostic tests from third-party payors. Third-party reimbursement for our tests represented more than 90% of our revenue for the nine months ended September 30, 2025 and the year ended December 31, 2024, and we expect government and commercial third-party payors to continue to be our primary source of payments. Coverage and reimbursement by third-party payors, including commercial health insurers, managed care organizations, and government healthcare programs such as Medicare and Medicaid, can be limited and uncertain for the types of specialized molecular diagnostic tests we offer. Each payor makes its own determination as to whether to establish a policy to cover our tests as well as the amount it will reimburse for such tests. Payors make these determinations based on factors that include medical necessity, clinical utility, and cost-effectiveness. Reimbursement rates vary significantly by test-type, payor, and coverage determination. Historically, our market access and reimbursement teams have pursued strategies to increasing our ASPs by expanding our payor coverage and reimbursement. We believe these strategies will continue to grow our ASPs over time.

Internalizing and strengthening our reimbursement capabilities and incorporating automation and AI to reimbursement operations

We have invested in building a high-performing, specialized team dedicated to all aspects of reimbursement, including claims management, appeals, and payor relations. In July 2023, we transitioned from relying on third-party vendors to managing our reimbursement function in-house. This team's expertise and commitment have enabled a more consistent, and accurate billing and appeal process, along with the rapid identification and resolution of reimbursement issues.

In addition, we have integrated our internal systems end-to-end, automated many of the repetitive reimbursement procedures, and incorporated AI for significant efficiency improvements (e.g., using large language models ("LLMs") to read, categorize, and react to thousands of correspondence from insurance companies that we receive every day), allowing our team to significantly increase their productivity. This strategic move not only streamlines our operations and improves cash flow but also allows us to better advocate for the value of our diagnostic tests with payors by providing rapid feedback and responding proactively to evolving reimbursement trends.

Relentless focus on reducing costs and increasing operational efficiency

Our financial results depend upon our ability to support current and future levels of demand for our prenatal screening and oncology diagnostic tests while maintaining discipline around our cost structure. Historically, we have been able to grow the size of our operational team much more slowly than our test volume increases. This has led to significantly increased operational leverage and efficiencies on a per-test basis and has been a driver in improving our net income (loss) margin.

We actively seek ways to continuously reduce our costs-per-test and improve our gross profit margin, long-term profitability, and return on investment. For example, we have reduced COGS per test through automation and optimization of laboratory workflows, successful negotiations with suppliers, and re-design and re-validation of assays with more optimized chemistry or higher-throughput sequencing. Nevertheless, as our test volumes grow, we have made and will continue to make significant investments in state-of-the-art infrastructure to support our growth. In 2023 we successfully expanded our laboratory operations from a single facility with 36,000 square feet in Menlo Park, CA by adding a second laboratory facility in Union City, CA with 90,000 square feet. To further support our growth beyond our current facilities, we have also entered a lease for the construction of 220,000 square feet of laboratory space in Austin, Texas with favorable terms and tenant improvement package. We expect to occupy this facility in 2027, and open in 2028. Once the facility is fully utilized, we expect our potential testing capacity to be nearly triple our current capabilities.

In addition, we must simultaneously enhance our customer service capabilities, improve our billing and administrative processes, expand our quality assurance programs, incorporate new laboratory equipment and automation, and implement new technology systems, all while maintaining competitive turnaround times. As such, our expenses may increase. In order to maintain cost discipline, we will continue to re-design and optimize our processes, integrate AI into our workflows, and increasingly automate both our laboratory and non-

laboratory operations. We believe that our continued focus in optimization, automation, and AI for higher operational efficiencies will drive further productivity gains.

Continued research and development and new product innovation

We expect to maintain significant levels of investment in research and development as we continue to develop new molecular diagnostic assays, enhance existing tests, and expand our testing capabilities into new clinical applications within our prenatal screening and oncology diagnostics product lines. These investments include costs for new test development, costs to validate new assays or to improve current assays, clinical studies to demonstrate utility and support reimbursement efforts, and development costs for new testing methodologies and platforms. Our ability to develop new products, obtain regulatory approvals for such products when required, successfully launch new products into the market, and drive adoption by healthcare providers will continue to play a key role in our competitive position and financial results. We believe these investments are critical to maintaining our technological leadership, supporting physician adoption, and driving favorable coverage decisions by payors across both our prenatal and oncology product lines.

Components of Results of Operations

Revenue

The majority of our revenue is derived from sales of our prenatal test, UNITY, and a smaller portion is derived from sales of our liquid biopsy oncology tests, Northstar. Specifically, in 2024, 96% of our revenue was from our prenatal tests, 2% of our revenue was from our oncology tests, and 2% of our revenue was from our clinical trial support and other services. Additionally, during the nine months ended September 30, 2025, approximately 91% of our revenue was from our prenatal tests, 8% of our revenue was from our oncology tests, and 1% of our revenue was from our clinical trial support and other services. We market our products to health clinics and physicians or a combination of the insurance carrier and patient for fees. Revenue for tests is recognized when test results are delivered to the ordering physician.

For many health clinics and physicians, the payment we ultimately receive depends upon the rate of reimbursement from insurance carriers. We may also negotiate rates with patients if the patient is responsible for payment. Our efforts in obtaining reimbursement based on individual claims, including pursuing appeals or reconsiderations of claim denials, may take a substantial amount of time, and bills may not be paid for many months or, in some cases, ultimately may not receive payment.

We expect our revenue to increase over time as we expand our sales efforts, introduce new products, and contract with more payors. In addition, positive reimbursement decisions from insurance carriers would eliminate much of the uncertainty around payment and increase our overall revenue growth from ordering physicians.

Our clinical trial support and other services includes revenue from a strategic partnership with Johnson & Johnson that utilizes our testing capabilities as part of a project to perform clinical trials. Revenue from this strategic partnership agreement is recognized as services are performed and tests are delivered, as well as upon the achievement of certain milestones including (i) receipt of approval of the trial, which was achieved in 2023, (ii) various patient enrollment milestones, and (iii) subsequent full trial completion. Our revenue derived from this agreement has not been material to our results of operations.

For the three and nine months ended September 30, 2025, the Company recorded revenue of \$3.7 million (or 4% of total revenues) and \$8.7 million (or 4% of total revenues), respectively, as a result of changes in estimate resulting from higher than expected cash collections, due to higher than expected reimbursement rates and lower than expected disallowed claims, and the corresponding impact on our average selling price for tests delivered in prior periods. For the three and nine months ended September 30, 2024, the Company recorded revenue of \$1.4 million (or 4% of total revenues) and \$10.2 million (or 9% of total revenues), respectively, as a result of changes in estimate resulting from higher than expected cash collections, due to higher than expected reimbursement rates and lower than expected disallowed claims, and the corresponding impact on average selling price for tests delivered in prior periods.

Cost of revenue

Our cost of revenue consists primarily of expenses related to materials and consumables, test kits, personnel-related expenses such as salaries, stock-based compensation and related benefits for its operations and

support personnel, shipping costs, overhead allocations, depreciation expense, facilities-related expenses and other services used in connection delivering the Company's services.

Gross profit and gross margin

Gross profit represents revenue less cost of revenue. Gross margin is gross profit expressed as a percentage of revenue. Our gross profit has been, and may in the future be, influenced by several factors, including test volumes and prices paid for our tests, changes in materials and consumables costs, laboratory processing costs, personnel costs, shipping, and logistics costs.

Operating expenses

Research and development expenses

Research and development expenses include costs incurred to develop our technology, clinical samples and conduct clinical studies to develop and support our products. These costs consist primarily of personnel-related expenses such as salaries and related benefits for our product development employees. Research and development expenses also include non-personnel costs such as materials and consumables used for research, clinical third-party services and consulting expenses, and an allocation of our general overhead expenses. These costs are expensed in the period as incurred.

We believe that continued investment in our products is important to our future growth and, as a result, we expect our research and development costs to increase in absolute dollars and moderately decline as a percentage of revenue over time if our revenue increases.

Selling, general and administrative expenses

Selling, general and administrative expenses consist primarily of personnel-related expenses such as salaries and related benefits for our sales, marketing, and general and administrative employees. Selling, general and administrative expenses also include commission payments, marketing related expenses in promoting our brand and tests, and training costs for the sales employees.

We expect selling, general and administrative expenses to increase in absolute dollars as we increase our sales and marketing personnel, increase product offerings, grow our operations and incur additional expenses associated with operating as a public company. These expenses as a result of operating as a public company include expenses necessary to comply with the rules and regulations applicable to companies listed on Nasdaq and related compliance and reporting obligations pursuant to the rules and regulations of the SEC, as well as higher expenses for general and director and officer insurance, investor relations and other professional services.

Interest income

Interest income consists of income earned on our short-term cash and cash equivalents and marketable securities.

Interest expense

Interest expense was mostly attributable to our borrowing with Western Alliance Bank, including the amortization of the debt discount up until August 2024 when we repaid the debt in full. In August 2024 we entered into a term loan agreement with Oberland Capital, and most of our interest expense has been attributable to Oberland since that time. Interest on our finance leases is also recorded in interest expense.

Net (loss) gain on extinguishment of debt

Net (loss) gain on extinguishment of debt relates to the extinguishment of the Western Alliance Bank debt and 2022 Convertible Notes.

We elected to prepay the outstanding amount of the Western Alliance Bank debt in August 2024 and wrote-off the unamortized debt issuance costs incurred before prepayment fees in connection with the extinguishment.

The 2022 Convertible Notes were amended such that the 2022 Convertible Notes converted into a round of preferred equity not originally contemplated in the agreement which we concluded was accounted for as a debt extinguishment. The gain on extinguishment consisted of the difference between the fair value of preferred equity received and the carrying amount of the 2022 Convertible Notes.

Change in fair value of term loan

Change in fair value of term loan relates to the Oberland Capital debt where we elected the fair value option under ASC 825 and is accounted for at fair value on a recurring basis. We also elected to record interest expense related to the Oberland Capital debt as change in fair value of term loan.

Change in fair value of convertible notes

Change in fair value of convertible notes relates to convertible debt where we elected the fair value option under ASC 825 and is accounted for at fair value on a recurring basis. We also elected to record interest expense related to the convertible debt as change in fair value of convertible notes.

Other expense, net

Other expense, net is comprised of the change in fair value of our liabilities related to warrants for common stock and redeemable convertible preferred stock and various income or expense items of a non-recurring nature.

Provision for income taxes

Provision for income taxes consists of U.S. federal, state, and foreign income taxes. We maintain a full valuation allowance on our federal and state deferred tax assets as we have concluded that it is not more likely than not that the deferred tax assets will be realized.

We account for uncertain tax positions in accordance with ASC 740-10, Accounting for Uncertainty in Income Taxes. We recognize the tax effects of an uncertain tax position only if it is more likely than not to be sustained based solely on its technical merits as of the reporting date and only in an amount more likely than not to be sustained upon review by the tax authorities. Interest and penalties related to uncertain tax position are classified in the financial statements as income tax expense.

Results of Operations

Comparison of the three months ended September 30, 2025 and 2024

| | Three Months Ended September 30, | | Change | |
|---|---------------------------------------|-------------|-----------|---------|
| | 2025 | 2024 | Amount | Percent |
| | <i>(in thousands, except percent)</i> | | | |
| Revenue | \$ 83,523 | \$ 38,419 | \$ 45,104 | 117.4 % |
| Cost of revenue | 25,107 | 18,204 | 6,903 | 37.9 |
| Gross profit | 58,416 | 20,215 | 38,201 | 189.0 |
| Operating expenses: | | | | |
| Research and development | 12,953 | 9,550 | 3,403 | 35.6 |
| Selling, general and administrative | 35,830 | 23,299 | 12,531 | 53.8 |
| Total operating expenses | 48,783 | 32,849 | 15,934 | 48.5 |
| Income (loss) from operations | 9,633 | (12,634) | 22,267 | 176.2 |
| Other income (expense): | | | | |
| Interest income | 1,535 | 1,952 | (417) | (21.4) |
| Interest expense | (20) | (422) | 402 | (95.3) |
| Net (loss) gain on extinguishment of debt | - | (1,346) | 1,346 | (100.0) |
| Change in fair value of term loan | (3,936) | (2,283) | (1,653) | 72.4 |
| Other expense, net | (1,630) | (171) | (1,459) | 853.2 |
| Total other (expense) income | (4,051) | (2,270) | (1,781) | (78.5) |
| Income (loss) before provision for income taxes | 5,582 | (14,904) | 20,486 | 137.5 |
| Provision for income taxes | (129) | - | (129) | — |
| Net income (loss) and comprehensive income (loss) | \$ 5,711 | \$ (14,904) | \$ 20,615 | 138.3 % |

Revenues

Revenue increased \$45.1 million, or 117%, for the three months ended September 30, 2025 compared to the three months ended September 30, 2024. This increase was driven primarily by a 52% increase in the total volume of delivered and billable tests to approximately 165,000 for the three months ended September 30, 2025 from approximately 108,500 for the three months ended September 30, 2024. The increase in revenue was also attributable to an increase in our Overall ASP³ of 44%.

We derive our revenue primarily from the number of tests processed and results delivered to the ordering physician. All tests processed are accessioned in our laboratories.

The increase in test volume was driven by higher volumes of our prenatal tests primarily as a result of expansion of our sales force for our prenatal products. In addition, volumes for both our Northstar Select and Northstar Response oncology tests increased as a result of expansion of our oncology sales force. The increase in our ASP per test was driven by several factors. For example, we increased the number of contracts compared to last year that we have with payors for our prenatal tests and we continued to benefit from our proprietary PLA code, both of which drove increases in ASP for the three months ended September 30, 2025 compared to the same period in the prior year. We also benefited from an increased attachment and ordering rate of 22q11.2 micro deletion testing (our 22q test) along with our aneuploidy test and the resulting incremental reimbursement, and coverage of our RhD test from more payors. Furthermore, our ASPs for our Northstar Select oncology test increased as Medicare began to reimburse for this test during the first quarter of 2025, and we began to bill for our Northstar Response oncology test for the first time at the beginning of 2025.

³ Overall ASP is the weighted average Average Selling Price ("ASP") across all of our prenatal and oncology products. It is computed by dividing revenue for our prenatal and oncology tests by the number of tests that are delivered and billable.

Cost of revenue

Cost of revenue increased \$6.9 million, or 38%, for the three months ended September 30, 2025 compared to the three months ended September 30, 2024. The increase was primarily due to an increase of \$4.6 million in expenses associated with testing samples and supplies used in processing tests, phlebotomy, and related shipping costs, driven by a higher volume of tests processed; and an increase of \$1.5 million in labor and consulting related expenses, including stock-based compensation, which were driven by higher test volumes and an increase in product support.

Gross profit and gross margin

Gross profit increased \$38.2 million, or 189%, for the three months ended September 30, 2025 compared to the three months ended September 30, 2024. The increase was primarily due to an increase in tests processed and a higher Overall ASP in conjunction with a lower cost per test as we continued to actively reduce variable expenses and increase efficiency from our fixed costs.

Gross margin increased to 70% for the three months ended September 30, 2025 from 53% for the three months ended September 30, 2024 for the reasons described above.

The increase in our Overall ASP contributed to approximately 88% of the improvement of our gross margin for the three months ended September 30, 2025 as compared to the three months ended September 30, 2024. Decreases in Overall Cost Per Test⁴ contributed to approximately 12% of the improvement in gross margin for the three months ended September 30, 2025.

For the three months ended September 30, 2025, our cost of goods sold consisted of 59% of variable costs and 41% of fixed costs and for the three months ended September 30, 2024 our cost of goods sold consisted of 55% of variable costs and 45% of fixed costs. The increase in variable costs during the period is attributable primarily to an increase in test volume from prenatal testing, partially offset by efficiencies gained in our lab from the increased test volume in both prenatal and oncology testing.

Operating expenses

Research and Development expenses

Research and development expenses increased \$3.4 million, or 36%, for the three months ended September 30, 2025 compared to the three months ended September 30, 2024. The increase was primarily due to a \$2.3 million increase in personnel costs which includes \$0.4 million in stock-based compensation expense, a \$0.9 million increase in materials, equipment expenses and overhead allocations, and a \$0.2 million increase in clinical studies expense. The increase in research and development expenses was primarily driven by an increase in average research and development headcount of 34 employees during the periods presented to support our product development and innovation efforts.

Selling, general and administrative expenses

Selling, general and administrative expenses increased \$12.5 million, or 54%, for the three months ended September 30, 2025 compared to the three months ended September 30, 2024. The increase was primarily due to a \$10.3 million increase in salaries, commissions and related expenditure which includes \$1.8 million in stock-based compensation expense, a \$1.3 million increase in facilities and other costs, and a \$0.9 million increase in professional and consulting fees. The increase in selling, general and administrative expenses was driven by an increase in average selling, general and administrative headcount of 118 employees during the periods presented to support our sales, marketing and other corporate strategies.

Interest income

Interest income decreased by \$0.4 million, or 21%, for the three months ended September 30, 2025 compared to the three months ended September 30, 2024. The decrease was primarily driven by lower interest rates.

⁴ Overall Cost Per Test is the weighted average cost per test across all of our prenatal and oncology products. It is computed by dividing cost of goods sold for our prenatal and oncology tests by the number of tests that are accessioned.

Interest expense

Interest expense decreased \$0.4 million, or 95%, for the three months ended September 30, 2025 compared to the three months ended September 30, 2024. The decrease is attributable to the payoff of the Western Alliance Bank debt; the principal on this debt was no longer outstanding during 2025.

Net (loss) gain on extinguishment of debt

Net (loss) gain on extinguishment of debt was \$1.3 million for the three months ended September 30, 2024. This was due to a \$1.3 million loss on extinguishment of the Western Alliance Bank debt in August 2024. We did not record an extinguishment of debt during the three months ended September 30, 2025.

Change in fair value of term loan

Change in fair value of term loan increased \$1.7 million, or 72% for the three months ended September 30, 2025 compared to the three months ended September 30, 2024. The increase was due to a change in fair value of the Oberland Capital debt of \$1.3 million and interest expense of \$0.4 million.

Other expense, net

Other expense, net increased \$1.5 million, or 853%, for the three months ended September 30, 2025 compared to the three months ended September 30, 2024, which was due to the following events, each of which increased the value of our common stock warrants: a higher probability that an IPO would occur, a reduced timeline until the IPO, and increase in valuation of our public peer companies during the nine months ending September 30, 2025.

Comparison of the nine months ended September 30, 2025 and 2024

| | Nine Months Ended September 30, | | Change | |
|---|---------------------------------------|-------------|------------|---------|
| | 2025 | 2024 | Amount | Percent |
| | <i>(in thousands, except percent)</i> | | | |
| Revenue | \$ 209,059 | \$ 107,505 | \$ 101,554 | 94.5 % |
| Cost of revenue | 69,205 | 52,309 | 16,896 | 32.3 |
| Gross profit | 139,854 | 55,196 | 84,658 | 153.4 |
| Operating expenses: | | | | |
| Research and development | 35,134 | 25,600 | 9,534 | 37.2 |
| Selling, general and administrative | 99,029 | 65,050 | 33,979 | 52.2 |
| Total operating expenses | 134,163 | 90,650 | 43,513 | 48.0 |
| Income (loss) from operations | 5,691 | (35,454) | 41,145 | 116.1 |
| Other income (expense): | | | | |
| Interest income | 4,492 | 4,148 | 344 | 8.3 |
| Interest expense | (92) | (2,339) | 2,247 | (96.1) |
| Net (loss) gain on extinguishment of debt | - | 7,289 | (7,289) | (100.0) |
| Change in fair value of term loan | (7,038) | (2,283) | (4,755) | 208.3 |
| Change in fair value of convertible notes | - | (835) | 835 | (100.0) |
| Other expense, net | (1,591) | (614) | (977) | 159.1 |
| Total other (expense) income | (4,229) | 5,366 | (9,595) | (178.8) |
| Income (loss) before provision for income taxes | 1,462 | (30,088) | 31,550 | 104.9 |
| Provision for income taxes | (15) | 5 | (20) | (400.0) |
| Net income (loss) and comprehensive income (loss) | \$ 1,477 | \$ (30,093) | \$ 31,570 | 104.9 % |

Revenues

Revenue increased \$101.6 million, or 95%, for the nine months ended September 30, 2025 compared to the nine months ended September 30, 2024. This increase was driven primarily by a 52% increase in the total volume of delivered and billable tests to approximately 440,500 for the nine months ended September 30, 2025 from approximately 289,900 for the nine months ended September 30, 2024. The increase in revenue was also attributable to an increase in our Overall ASP of 30%.

We derive our revenue primarily from the number of tests processed and results delivered to the ordering physician. All tests processed are accessioned in our laboratories.

The increase in test volume was driven by higher volumes of our prenatal tests primarily as a result of expansion of our sales force for our prenatal products. In addition, volumes for both our Northstar Select and Northstar Response oncology tests increased as a result of expansion of our oncology sales force. The increase in our ASP per test was driven by several factors. Over the last 12 months we increased the number of contracts we have with payors for our prenatal tests which drove increases in ASP in the first nine months of 2025 compared to the same period in the prior year. In addition, during the second half of 2024 we began to benefit from a new proprietary PLA code for our prenatal tests, as when utilized the new PLA code is typically reimbursed at a higher rate than the codes for which we previously billed; this contributed to an increase in ASPs during the first nine months of 2025. We also benefited from an increased attachment and ordering rate of 22q11.2 micro deletion testing (our 22q test) along with our aneuploidy test and the resulting incremental reimbursement, and coverage of our RhD test from more payors. Furthermore, our ASPs for our Northstar

Select oncology test increased as Medicare began to reimburse for this test during the first quarter of 2025, and we began to bill for our Northstar Response oncology test for the first time at the beginning of 2025.

Cost of revenue

Cost of revenue increased \$16.9 million, or 32%, for the nine months ended September 30, 2025 compared to the nine months ended September 30, 2024. The increase was primarily due to an increase of \$8.8 million in expenses associated with testing samples and supplies used in processing tests, phlebotomy, and related shipping costs, driven by a higher volume of tests processed; and an increase of \$7.8 million in labor and consulting related expenses, including stock-based compensation, which were driven by higher test volumes and an increase in product support.

Gross profit and gross margin

Gross profit increased \$84.7 million, or 153%, for the nine months ended September 30, 2025 compared to the nine months ended September 30, 2024. The increase was primarily due to an increase in tests processed and a higher ASP in conjunction with a lower cost per test as we continued to actively reduce variable expenses and increase efficiency from our fixed costs.

Gross margin increased from 51% for the nine months ended September 30, 2024 to 67% for the nine months ended September 30, 2025 for the reasons described above.

The increase in our Overall ASP contributed to approximately 80% of the improvement of our gross margin for the nine months ended September 30, 2025 as compared to the nine months ended September 30, 2024. Decreases in Overall Cost Per Test contributed to approximately 20% of the improvement in gross margin for the nine months ended September 30, 2025.

For the nine months ended September 30, 2025, our cost of goods sold consisted of 56% of variable costs and 44% of fixed costs and for the nine months ended September 30, 2024 our cost of goods sold consisted of 55% of variable costs and 45% of fixed costs. The increase in variable costs during the period is attributable primarily to an increase in test volume from prenatal testing, partially offset by efficiencies gained in our lab from the increased test volume in both prenatal and oncology testing.

Operating expenses

Research and development expenses

Research and development expenses increased \$9.5 million, or 37%, for the nine months ended September 30, 2025 compared to the nine months ended September 30, 2024. The increase was primarily due to a \$7.3 million increase in personnel costs which includes \$0.8 million in stock-based compensation expense and a \$2.7 million increase in materials, equipment expenses and overhead allocations. These amounts were partially offset by a \$0.5 million decrease in clinical studies expense. The increase in research and development expenses was primarily driven by an increase in average research and development headcount of 31 employees during the periods presented to support our product development and innovation efforts.

Selling, general and administrative expenses

Selling, general and administrative expenses increased \$34.0 million, or 52%, for the nine months ended September 30, 2025 compared to the nine months ended September 30, 2024. The increase was primarily due to a \$26.7 million increase in salaries, commissions and related expenditure which includes \$2.3 million in stock-based compensation expense, a \$4.0 million increase in facilities and other costs, and a \$3.1 million increase in professional and consulting fees. The increase in selling, general and administrative expenses was driven by an increase in average selling, general and administrative headcount of 101 employees during the periods presented to support our sales, marketing and other corporate strategies.

Interest income

Interest income increased by \$0.3 million, or 8%, for the nine months ended September 30, 2025 compared to the nine months ended September 30, 2024. The increase was due to higher average balances of cash and cash equivalents.

Interest expense

Interest expense decreased \$2.2 million, or 96%, for the nine months ended September 30, 2025 compared to the nine months ended September 30, 2024. The decrease is attributable to the payoff of the Western Alliance Bank debt; the principal on this debt was no longer outstanding during 2025.

Net (loss) gain on extinguishment of debt

Net (loss) gain on extinguishment of debt was \$7.3 million for the nine months ended September 30, 2024. This was due to an \$8.6 million gain on extinguishment of the 2022 Convertible Notes due to a modification of the class of preferred stock into which the 2022 Convertible Notes ultimately converted in May 2024. This amount was partially offset by a \$1.3 million loss on extinguishment of the Western Alliance Bank debt in August 2024. We did not record an extinguishment of debt during the nine months ended September 30, 2025.

Change in fair value of term loan

Change in fair value of term loan increased \$4.8 million, or 208% for the nine months ended September 30, 2025 compared to the nine months ended September 30, 2024. The increase was due to interest expense of \$2.9 million, which includes revenue participation and a change in fair value of the Oberland Capital debt of \$1.9 million.

Change in fair value of convertible notes

Change in fair value of convertible notes decreased \$0.8 million for the nine months ended September 30, 2025 compared to the nine months ended September 30, 2024. The decrease was due to a change in fair value of the 2022 Convertible Notes that were extinguished in 2024.

Other expense, net

Other expense, net increased \$1.0 million, or 159%, for the nine months ended September 30, 2025 compared to the nine months ended September 30, 2024 which was due to the following events, each of which increased the value of our common stock warrants: a higher probability that an IPO would occur, a reduced timeline until the IPO, and increase in valuation of our public peer companies during the nine months ending September 30, 2025.

Non-GAAP financial measures

We use certain non-GAAP financial measures to supplement our financial statements, which are presented in accordance with GAAP. These non-GAAP financial measures include EBITDA, Adjusted EBITDA, non-GAAP operating income (loss), and non-GAAP net income (loss). We use these non-GAAP financial measures for financial and operational decision-making and as a means to assist us in evaluating period-to-period comparisons. By excluding the impact of certain items that we believe do not directly reflect our underlying operations, we are of the opinion that EBITDA, Adjusted EBITDA, non-GAAP operating income (loss) and non-GAAP net income (loss) provide meaningful supplemental information regarding our performance. Accordingly, we believe these non-GAAP financial measures are useful to investors and others because they allow for additional information with respect to financial measures used by management in its financial and operational decision-making and forecasting. These metrics also provide investors and other users of our financial information with additional tools to compare business performance across companies and periods, while eliminating the effects of items that may vary for different companies for reasons unrelated to core operating performance. However, there are a number of limitations related to the use of non-GAAP financial measures, and these non-GAAP measures should be considered in addition to, not as a substitute for or in isolation from, our financial results prepared in accordance with GAAP. Other companies, including companies in our industry, may calculate these non-GAAP financial measures differently or not at all, which reduces their usefulness as comparative measures.

EBITDA

We define EBITDA as net income (loss) adjusted for income taxes, interest income, interest expense, and depreciation and amortization expense. A reconciliation of net income (loss), the most directly comparable GAAP financial measure, to EBITDA is presented below (in thousands):

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|--------------------------------|-------------------------------------|-------------|------------------------------------|-------------|
| | 2025 | 2024 | 2025 | 2024 |
| Net income (loss) | \$ 5,711 | \$ (14,904) | \$ 1,477 | \$ (30,093) |
| Income tax (benefit) / expense | (129) | - | (15) | 5 |
| Interest (income) | (1,535) | (1,952) | (4,492) | (4,148) |
| Interest expense | 20 | 422 | 92 | 2,339 |
| Depreciation and amortization | 1,692 | 1,809 | 5,232 | 5,241 |
| EBITDA | \$ 5,759 | \$ (14,625) | \$ 2,294 | \$ (26,656) |

Adjusted EBITDA

We define Adjusted EBITDA as net income (loss) adjusted for income taxes, interest income, interest expense, depreciation and amortization expense, and certain other items which include significant non-cash items events that are highly variable, significant in size, and that we do not believe are indicative of ongoing or future business operations, which include: stock-based compensation expense; net gain on extinguishment of debt; change in fair value of term loan; and change in value of convertible notes. A reconciliation of net income (loss), the most directly comparable GAAP financial measure, to Adjusted EBITDA is presented below (in thousands):

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|-------------------------------------|-------------|------------------------------------|-------------|
| | 2025 | 2024 | 2025 | 2024 |
| Net income (loss) | \$ 5,711 | \$ (14,904) | \$ 1,477 | \$ (30,093) |
| Income tax (benefit) / expense | (129) | - | (15) | 5 |
| Interest (income) | (1,535) | (1,952) | (4,492) | (4,148) |
| Interest expense | 20 | 422 | 92 | 2,339 |
| Depreciation and amortization | 1,692 | 1,809 | 5,232 | 5,241 |
| Stock-based compensation expense | 4,475 | 2,150 | 9,581 | 6,055 |
| Net (gain) loss on extinguishment of debt | - | 1,346 | - | (7,289) |
| Decrease in fair value of term loan | 3,936 | 2,283 | 7,038 | 2,283 |
| Decrease in fair value of convertible notes | - | - | - | 835 |
| Adjusted EBITDA | \$ 14,170 | \$ (8,846) | \$ 18,913 | \$ (24,772) |

Non-GAAP income (loss) from operations

We define non-GAAP operating income (loss) as operating income (loss) presented in accordance with GAAP, adjusted to exclude stock-based compensation expenses.

A reconciliation of income (loss) from operations, the most directly comparable GAAP financial measure, to non-GAAP income (loss) from operations is presented below (in thousands):

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|--|-------------------------------------|-------------|------------------------------------|-------------|
| | 2025 | 2024 | 2025 | 2024 |
| Income (loss) from operations | \$ 9,633 | \$ (12,634) | \$ 5,691 | \$ (35,454) |
| Stock-based compensation expense | 4,475 | 2,150 | 9,581 | 6,055 |
| Non-GAAP income (loss) from operations | \$ 14,108 | \$ (10,484) | \$ 15,272 | \$ (29,399) |

Non-GAAP net income (loss)

We monitor non-GAAP net income (loss) for planning and performance measurement purposes. We define non-GAAP net income (loss) as net income (loss) reported on our statements of operations, excluding the impact of stock-based compensation expenses, net gain or loss on extinguishment of debt, change in fair value of the term loan, and change in fair value of convertible notes. We exclude fair value adjustments related to debt, which can fluctuate significantly and do not directly reflect our underlying operations. Our calculation of non-GAAP net income (loss) does not currently include the tax effects of the stock-based compensation expense adjustment because such tax effects have not been material to date.

A reconciliation of net income (loss), the most directly comparable GAAP financial measure, to non-GAAP net income (loss) is presented below (in thousands):

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|-------------------------------------|-------------|------------------------------------|-------------|
| | 2025 | 2024 | 2025 | 2024 |
| Net income (loss) | \$ 5,711 | \$ (14,904) | \$ 1,477 | \$ (30,093) |
| Stock-based compensation expense | 4,475 | 2,150 | 9,581 | 6,055 |
| Net (gain) loss on extinguishment of debt | - | 1,346 | - | (7,289) |
| Decrease in fair value of term loan | 3,936 | 2,283 | 7,038 | 2,283 |
| Decrease in fair value of convertible notes | - | - | - | 835 |
| Non-GAAP net income (loss) | \$ 14,122 | \$ (9,125) | \$ 18,096 | \$ (28,209) |

Liquidity and capital resources

Since our inception, prior to our IPO, we have financed our operations primarily through the issuance of convertible notes, redeemable convertible preferred stock, debt, and cash generated from the sale of our products. As of September 30, 2025, our principal sources of liquidity were cash and cash equivalents of \$195.2 million and working capital of \$210.9 million. On November 7, 2025, we closed our IPO of our Class A common stock. The total net proceeds received were approximately \$286.4 million after deducting underwriting discounts, commissions and offering expenses payable by us. Cash and cash equivalents are comprised of cash held in sweep accounts, checking accounts, lock-box accounts and money market funds. Our principal use of cash is to fund operations and invest in research and development to support our growth.

We have generated significant losses from operations and negative cash flows from operating activities in the past as reflected in our accumulated deficit of \$280.7 million as of September 30, 2025, though we did have positive operating income and positive cashflow in the nine months ended September 30, 2025. We believe our current cash and cash equivalents will be sufficient to fund our operations for at least the next 12 months. Our future capital requirements, however, will depend on many factors, including our growth rate, the timing and extent of our sales and marketing and research and development expenditures, the continuing market acceptance of our products, and the use of cash to fund potential mergers or acquisitions. In the event that additional financing is required from outside sources, we may seek to raise additional funds through equity, equity-linked arrangements, and debt. If we are unable to raise additional capital when desired and at reasonable rates, our business, results of operations, and financial condition could be adversely affected.

Oberland Capital note purchase agreement

We have a debt facility with availability of up to \$140.0 million, issuable in four separate tranches, pursuant to a Note Purchase Agreement, dated as of August 2, 2024, by and among us, the purchasers party thereto, and BWCB SA LLC (an entity affiliated with Oberland Capital), as purchaser's agent. The advanced principal accrues interest at a rate of 8.0% per annum. The first tranche of \$50.0 million was advanced on August 5, 2024, with a maturity date of August 5, 2031, interest-only payments through August 5, 2031 and a lump sum payment due on August 5, 2031. The lump sum payment includes all of the outstanding principal plus a payment that would generate an IRR for the purchasers of 10.0%. The term loan advances are secured by a lien on our assets.

We are required to sell a tranche of notes in the amount of \$30.0 million prior to March 31, 2026 as we achieved the revenue and gross margin thresholds triggering this obligation on June 30, 2025 based on our results for the first half of 2025. The thresholds triggering this tranche are trailing six-month revenue of at least \$112.5 million and a trailing six-month gross margin of at least 45%. The terms of this tranche are identical to those of the first \$50.0 million tranche.

We have the option at any time to prepay all of the then-outstanding notes, and Oberland Capital has the option to redeem the notes upon a change in control of the Company, an event of default, or maturity. The repayment amount of the note shall equal: (1) 130% of the principal amount if the payment is made within 24 months of issuance; (2) 145% of the principal amount if the payment is made within 36 months of issuance; (3) if the payment is made within 48 months, an amount that would generate an internal rate of return ("IRR") for the purchasers of 12.25%; (4) if the payment is made within 60 months of the issuance, an amount that would generate an IRR for the purchasers of 11.75%; (5) if the payment is made thereafter but prior to maturity, an amount that would generate an IRR for the purchasers of 11.25%; and (6) if the payment is made at maturity, an amount that would generate an IRR for the purchasers of 10.0%.

Beginning with the fiscal quarter ended March 31, 2025, excluding any fiscal quarter in which our aggregate cash and cash equivalents is greater than 1.1 times the aggregate principal amount of the notes issued under the Note Purchase Agreement, we are required to maintain trailing six-month net revenue based on a schedule that gradually increases up to \$120.0 million after the year ending December 31, 2026, and a trailing six-month gross margin (as defined in the Note Purchase Agreement) of not less than 30%. As of September 30, 2025, we were in compliance with all financial covenants in the agreement. The Note Purchase Agreement also contains a revenue participation provision, under which, for any fiscal quarter, 0.01% of net revenue for such fiscal quarter (up to \$100.0 million of net revenue for each fiscal year) per each \$1.0 million principal amount of the notes will be payable to Oberland Capital. The revenue participation payments are additional financing costs of the loan and are included in the computation of the internal rate of return measures described in the preceding paragraph. Beginning with the fiscal year beginning January 1, 2025, we are required to make revenue participation payments under the Note Purchase Agreement.

Cash flows

The following table summarizes our cash flows for the periods presented (in thousands):

| | Nine Months Ended September 30, | |
|--|------------------------------------|-------------|
| | 2025 | 2024 |
| Cash provided by (used in) operating activities | \$ 13,803 | \$ (32,952) |
| Cash used in investing activities | (7,344) | (3,328) |
| Cash (used in) provided by financing activities | (2,784) | 141,305 |
| Net increase in cash and cash equivalents | 3,675 | 105,025 |
| Cash and cash equivalents at beginning of period | 191,477 | 97,268 |
| Cash and cash equivalents at end of period | \$ 195,152 | \$ 202,293 |

Operating activities

Cash provided by operating activities during the nine months ended September 30, 2025 was \$13.8 million. Net income of \$1.5 million includes \$23.6 million in non-cash charges primarily resulting from \$9.6 million of stock-

based compensation, \$5.2 million of depreciation and amortization, \$3.7 million of amortization of right-of-use assets, and \$4.9 million change in fair value of the common stock warrant liability and term loan. Operating assets had outflows of \$20.4 million primarily resulting from a \$9.9 million increase in accounts receivable, \$8.7 million increase in inventory, \$1.7 million increase in prepaid expenses and other current assets, and \$0.1 million increase in other non-current assets. Operating liabilities had inflows of \$9.1 million primarily resulting from a \$12.5 million increase in accounts payable and accrued expense balances, offset by a \$3.2 million decrease in operating lease liabilities.

Cash used in operating activities during the nine months ended September 30, 2024 was \$33.0 million. Net loss of \$30.1 million includes \$11.3 million in non-cash charges primarily resulting from \$6.1 million of stock-based compensation, \$5.2 million of depreciation and amortization, \$3.5 million of amortization of right-of-use assets, and \$3.0 million change in fair value of the common stock warrant liability, term loan and convertible notes, offset by a \$7.3 million gain on extinguishment of debt. Operating assets had outflows of \$18.4 million primarily resulting from a \$13.7 million increase in accounts receivable, \$3.1 million increase in other non-current assets, \$0.9 million increase in prepaid and other current assets, and \$0.6 million increase in inventory. Operating liabilities had inflows of \$4.2 million primarily resulting from a \$7.1 million increase in accounts payable and accrued expense balances, offset by a \$2.8 million decrease in operating lease liabilities.

Investing activities

Cash used in investing activities during the nine months ended September 30, 2025 totaled \$7.3 million due to purchases of property and equipment.

Cash used in investing activities during the nine months ended September 30, 2024 totaled \$3.3 million due to purchases of property and equipment.

Financing activities

Cash used in financing activities during the nine months ended September 30, 2025 totaled \$2.8 million which was comprised of \$2.5 million of payments of deferred offering costs, principal payments on finance lease liabilities of \$1.4 million, offset by \$1.2 million in proceeds from the exercise of stock options, net of repurchases.

Cash provided by financing activities during the nine months ended September 30, 2024 totaled \$141.3 million which was comprised of \$130.0 million of proceeds from issuance of Series D redeemable convertible preferred stock, net of issuance costs, \$49.8 million in proceeds from the issuance of debt, net, offset by \$36.7 million repayment of debt, exit fee and prepayment payable upon debt upon extinguishment, and \$1.8 million principal payments on finance lease liabilities.

Contractual obligations and commitments

Operating lease commitments. Our operating lease commitments primarily include our labs and corporate offices. As of September 30, 2025, we had fixed lease payment obligations of \$70.1 million, with \$9.1 million to be paid within 12 months and the remainder thereafter.

Finance lease commitments. Our finance lease commitments primarily relate to equipment used in our labs. As of September 30, 2025, we had fixed lease payment obligations of \$1.2 million, with \$0.7 million to be paid within 12 months and the remainder thereafter.

Off-balance sheet arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet financing arrangements or any relationships with unconsolidated entities or financial partnerships, including entities sometimes referred to as structured finance or special purpose entities, that were established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes.

Critical accounting estimates

We prepare our financial statements in conformity with GAAP. The preparation of financial statements in conformity with GAAP required certain estimates and assumptions to be made that may affect our financial statements. Accounting policies that have a significant impact on our results are described in Note 2 to our financial statements included in Item 1 in this Quarterly Report. The accounting policies discussed in this

section are those that we consider to be the most critical. We consider an accounting policy to be critical if the policy is subject to a material level of judgment and if changes in those judgments are reasonably likely to materially impact our results.

We base our estimates and judgments on reasonably available information. Our estimates and assumptions may affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results may differ from those estimates and such differences may be material to the financial statements.

We continue to monitor and assess our critical estimates in light of developments, and as new events occur and additional information is obtained, our estimates may change materially in future periods.

Revenue

We generate revenue primarily from our prenatal and oncology testing services, which are referred to as testing services or test results. We consider the patient as our customer, that requests our test service through their physician. Test results are the single performance obligation being provided to customers. Testing service revenue is recognized at a point in time when test results are delivered to the ordering physician. We generally bill an insurance carrier, Medicaid or a patient or a combination of both upon delivery of test results. The amount of revenue recognized reflects the consideration we expect to be entitled to receive in exchange for the test results.

We recognize revenue upon transfer of control of promised goods and services in an amount that reflects the consideration we expect to be entitled to receive in exchange for those goods and services. Under ASC 606, Revenue from Contracts with Customers (ASC 606), we apply the following five-step approach: (1) identify the contract with a customer, (2) identify the performance obligations in the contract, (3) determine the transaction price, (4) allocate the transaction price to the performance obligations in the contract, and (5) recognize revenue when, or as, a performance obligation is satisfied.

We recognize revenue applying estimated consideration to be received for the performance obligations delivered to customers and their representatives. In accordance with ASC 606, we apply the constraint on variable consideration and include such amounts in the transaction price only to the extent that it is probable that a significant reversal of cumulative revenue will not occur when the associated uncertainty is resolved.

We apply the expected value method of estimating variable consideration. The total consideration we expect to collect in exchange for our products is an estimate and is largely variable in nature. Consideration includes reimbursement from both patients and insurance carriers. We establish variable consideration by considering historical payment trends for tests delivered, test reimbursement disallowances, and contractual arrangements in place, among other factors, which is adjusted for current expectations. Current expectations of cash collections factor in changes in reimbursement rate trends, historical events not expected to recur, and future known changes such as anticipated contractual pricing changes or changes to insurance coverage. We also consider hindsight, where applicable, in estimates established for variable consideration and update those estimates when actual experience supports doing so. In establishing variable consideration, we consider payors with similar reimbursement characteristics together. We monitor cash collections against the estimated variable consideration over the expected cash collection period and any difference is recognized as an adjustment to estimated revenues after such estimated cash collection period has closed.

We enter into contracts with third-party payors including insurance carriers and Medicaid to set the pricing for tests provided to patients. Due to the nature of these third-party payor contract arrangements, the total consideration we expect to collect for test results is variable as they are dependent on the terms negotiated with the third-party payor. The predominance of our revenue is derived from payments by third-party insurance carriers. Additionally, we entered into an agreement with Johnson & Johnson in 2023 to utilize our testing capabilities as part of a project to perform a clinical trial. This arrangement involved the performance of testing and related regulatory consulting services. Revenue for this contract is primarily recognized proportionally as services are performed. Revenue derived from this contract is not material to our results of operations.

Stock-based compensation

We measure stock-based compensation expense for all stock-based payment awards based on the estimated fair value of the awards on the date of grant. The fair value of each stock option granted is estimated using the Black-Scholes Model. The model requires us to make assumptions and judgments about the variable inputs used in the Black-Scholes Model, including expected term, the volatility of our common stock, and assumed

risk-free interest rate. Stock-based compensation is recognized net of actual forfeitures on a straight-line basis over the requisite service period of the awards. We account for forfeitures as they occur.

We have granted awards to employees that vest based on continued service (service conditions). Stock-based compensation expense is recognized on a straight-line basis over the service period.

Common stock valuations

The fair value of the common stock underlying our stock-based awards has historically been determined by our Board of Directors, with input from management and contemporaneous third-party valuations. We believe that our Board of Directors has the relevant experience and expertise to determine the fair value of our common stock. Given the absence of a public trading market of our common stock until our IPO in November 2025, and in accordance with the American Institute of Certified Public Accountants Practice Aid, Valuation of Privately-Held Company Equity Securities Issued as Compensation, our Board of Directors exercised reasonable judgment and considered numerous objective and subjective factors to determine the best estimate of the fair value of our common stock at each grant date. These factors include:

- the results of contemporaneous valuations performed at periodic intervals by a third-party valuation firm;
- the prices, rights, preferences, and privileges of our redeemable convertible preferred stock relative to those of our common stock;
- the prices of our redeemable convertible preferred stock and common stock sold to investors in arms-length transactions;
- our actual operating and financial performance and estimated trends and prospects for our future performance;
- our stage of development;
- the likelihood of achieving a liquidity event, such as an initial public offering, direct listing, or sale of our company, given prevailing market conditions;
- the lack of marketability involving securities in a private company;
- the market performance of comparable publicly traded companies; and
- U.S. and global capital market conditions.

In valuing our common stock, the fair value of our business was determined using various valuation methods, including combinations of the income approach and the market approach with input from management. The income approach involves applying an appropriate risk-adjusted discount rate to projected cash flows based on forecasted revenue and costs. The market approach estimates value based on a comparison of the subject company to comparable public companies in a similar line of business. From the comparable companies, a representative market value multiple was determined, which was applied to our operating results to estimate the enterprise value of our company.

Once the enterprise value was determined under the market approach, we derived the equity value of our company and used a hybrid method that considered both an option pricing model (OPM) and the probability weighted expected return method (PWERM) to allocate that value among the various classes of securities to arrive at the fair value of the common stock. The OPM is based on the Black-Scholes-Merton option valuation model, which allows for the identification for a range of possible future outcomes, each with an associated probability. The OPM is appropriate to use when the range of possible future outcomes is difficult to predict and thus creates highly speculative forecasts. PWERM involves a forward-looking analysis of the possible future outcomes of the enterprise including an IPO as well as non-IPO market-based outcomes. After the equity value is determined and allocated to the various classes of shares, a discount for lack of marketability (DLOM) is applied to arrive at the fair value of ordinary shares. A DLOM is applied based on the theory that as an owner of a private company stock, the stockholder has limited opportunities to sell this stock and any such sale would involve significant transaction costs, thereby reducing overall fair market value.

In addition, we also considered any secondary transactions involving our capital stock. In our evaluation of those transactions, we considered the facts and circumstances of each transaction to determine the extent to which they represented a fair value exchange. Factors considered include transaction volume, timing, whether

the transactions occurred among unrelated parties, and whether the transaction involved investors with access to our financial information.

Application of these approaches involves the use of estimates, judgment, and assumptions that are highly complex and subjective, such as those regarding our expected future revenue, expenses, and future cash flows, discount rates, market multiples, the selection of comparable companies, and the probability of possible future events. Changes in any or all of these estimates and assumptions or the relationships between those assumptions impact our valuations as of each valuation date and may have a material impact on the valuation of our common stock.

For valuations after the completion of this offering, our Board of Directors will determine the fair value of each share of underlying common stock based on the closing price of our common stock as reported on the date of grant. Future expense amounts for any particular period could be affected by changes in our assumptions or market conditions.]

Recent accounting pronouncements

See Note 2 of our financial statements for more information regarding recently issued accounting pronouncements.

Emerging growth company status

We are an “emerging growth company” as defined in the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to use this exemption from new or revised accounting standards until the earlier of the date we (i) qualify for treatment as an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided for emerging growth companies. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

Item 3. Quantitative And Qualitative Disclosures About Market Risk

We are exposed to market risks in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates. Our market risk exposure is primarily the result of fluctuations in interest rates, inflation and foreign currency exchange rates.

Interest Rate Risk

We are exposed to market risk related to changes in interest rates. We had cash and cash equivalents of \$97.3 million, \$191.5 million and \$195.2 million as of December 31, 2023 and 2024 and September 30, 2025, respectively. Our cash and cash equivalents consist of cash held in sweep accounts, checking accounts, and lock-box accounts. The cash and cash equivalents are primarily for working capital purposes. Such interest earning instruments carry a degree of interest rate risk. Our financing arrangement with Western Alliance Bank subjected us to variable amount of interest on the principal balance outstanding, the debt was extinguished in 2024. Our debt facility with Oberland Capital is at a fixed rate of interest. The effect of a hypothetical 10% change in interest rates would not have had a material impact on our financial statements for the years ended December 31, 2023 and 2024 or the nine months ended September 30, 2025.

Inflation risk

We do not believe that inflation has had a material effect on our business, financial condition, or results of operations. If our costs were to become subject to significant inflationary pressures, we may not be able to fully offset such higher costs through increases in revenue as increases in inflation rates may also negatively affect demand for our product offerings, and our ability to raise capital and cashflow. Our inability or failure to fully offset any such higher costs could harm our business, financial condition, and results of operations.

Foreign currency exchange rate fluctuations

Our operations are currently conducted almost entirely in the United States as international markets contribute less than 1% of our revenue. If we choose to expand internationally, our results of operations and cash flows may become subject to fluctuations due to changes in foreign currency exchange rates. In periods when the U.S. dollar declines in value as compared to the foreign currencies in which we incur expenses, our foreign currency-based expenses will increase when translated into U.S. dollars. In addition, future fluctuations in the value of U.S. dollar may affect the price at which we sell our tests outside the United States. To date, our foreign currency risk has been minimal.

Item 4. Controls and Procedures

Limitations on Effectiveness of Controls and Procedures

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints, and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")), as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that these disclosure controls and procedures were not effective at the reasonable assurance level as of September 30, 2025 due to the material weaknesses in our internal control over financial reporting as described below.

Notwithstanding the material weakness in our internal controls over financial reporting as of September 30, 2025, management has concluded that the financial statements included in this Form 10-Q present fairly, in all material respects, our financial position, results of operations and cash flows for the periods presented in conformity with accounting principles generally accepted in the United States.

Previously Reported Material Weaknesses in Internal Control over Financial Reporting

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

Our management previously determined that we did not design and maintain an effective control environment commensurate with our financial reporting requirements. Specifically, we lack a sufficient complement of resources with the appropriate knowledge, experience, and training to appropriately analyze, record and disclose accounting matters commensurate with our accounting and reporting requirements. Additionally, the lack of sufficient resources resulted in an inability to consistently establish appropriate segregation of duties in our finance and accounting functions. This material weakness contributed to the following additional material weaknesses:

- We did not design and maintain effective controls to appropriately analyze, account for, and present and disclose amounts related to certain financial instruments. Specifically, we did not design and maintain controls to appropriately analyze, account for, and present and disclose amounts related to outstanding common stock warrants. Additionally, we did not design and maintain controls to appropriately present and disclose amounts related to debt instruments. These material weaknesses resulted in immaterial adjustments to the financial statements. Additionally, these material weaknesses could result in a misstatement of account balances or disclosures that would result in a material misstatement to the annual or interim financial statements that would not be prevented or detected.
- We did not design and maintain user access controls to ensure appropriate segregation of duties and to adequately restrict user and privileged access to appropriate personnel in creating and posting journal entries. This material weakness did not result in a misstatement to the financial statements; however, it

could result in a misstatement of account balances or disclosures that would result in a material misstatement to the annual or interim financial statements that would not be prevented or detected.

Remediation Efforts

During the quarter ended September 30, 2025, we continued our remediation efforts related to the material weaknesses discussed above. The remediation steps we have taken are ongoing and include the following:

- consulted with experts on technical accounting matters, internal controls, and in the preparation of our financial statements;
- engaged a third party to assist in evaluating segregation of duties risks and design and implement controls to address those risks;
- began to design and implement controls related to restricting user and privileged access to appropriate personnel, including as it relates to creating and posting journal entries;
- engaged a third party to assist management in evaluating the accounting for financial instruments; and
- hired additional accounting, finance, operations, and information technology resources with relevant public company experience.

We have made progress towards designing and implementing the plan to remediate the material weaknesses and will continue to review, revise, and improve the design and implementation of our internal controls as appropriate. Although we have made enhancements to our control procedures, these material weaknesses will not be considered remediated until our controls are effectively designed, implemented, and operational for a sufficient period of time, and management concludes, through testing, that these controls are operating effectively. Accordingly, the material weaknesses were not remediated as of September 30, 2025.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting identified (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the period covered by this Quarterly Report on Form 10-Q that has materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Part II - Other Information

Item 1. Legal Proceedings

From time to time, we are involved in legal claims, regulatory investigations, inquiries, proceedings and other legal matters arising from the normal course of business and typical for our industry. Although no formal legal proceeding has been instituted, from time to time, we receive requests from governmental agencies, or third parties working on their behalf, for documents and information related to our products. We do not view any of the legal claims, regulatory investigations, inquiries, proceedings and other legal matters that we are currently subject to as being material to our business; however, it is difficult to assess the outcome of these matters, and we may not prevail in any current or future proceedings or litigation.

Litigation or any other legal, regulatory or administrative proceedings, regardless of the outcome, can result in substantial cost and diversion of our resources, including our management's time and attention, and there can be no assurances that favorable final outcomes will be obtained. For additional information on risks relating to legal proceedings, see the section titled "Risk Factors—Risks Related to Our Business and Strategy—We have been, and in the future may be, involved in legal proceedings, regulatory investigations and inquiries and other legal matters, which may have an adverse effect on our business, financial condition, results of operations and prospects."

Item 1A. Risk Factors

A description of risks and uncertainties facing our business is set forth below. You should carefully consider the risks described below, as well as the other information in this Quarterly Report on Form 10-Q ("Quarterly Report"), including our financial statements and the related notes and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" in this Quarterly Report. Additional risks and uncertainties that we are not currently aware of, or that we currently believe are not material, may also adversely affect our business. This Quarterly Report also contains forward-looking statements that involve risks and uncertainties. See the section titled "Special Note Regarding Forward-Looking Statements." The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations, and growth prospects. In such an event, the price of our securities could decline, and you may lose all or part of your investment.

Risk Factors Summary

The following is a summary of the most significant risks, challenges and uncertainties facing our business. This summary should be read in conjunction with the risk factors described below in this section and should not be considered an exhaustive list or summary of all of the significant or material risks, challenges and uncertainties that we face.

- Our limited operating history and rapid growth make it difficult to evaluate our future prospects and the risks and challenges we may encounter.
- We primarily generate revenue from sales of our molecular diagnostic tests and we are highly dependent on them for our success.
- If the government and other third-party payors fail to provide coverage and adequate payment for our existing and future tests, our revenue and prospects for profitability will be harmed.
- Our revenue may be adversely affected if we are unable to successfully obtain reimbursement from the Medicare program and state Medicaid programs.
- Our billing and claim processing are complex and time-consuming, and any delay in submitting claims or failure to comply with applicable billing requirements could hinder collection and have an adverse effect on our revenue.
- The inherent variability of the insurance coverage and reimbursement landscape makes it difficult to predict amounts we ultimately collect for our tests, and if our estimates of revenue to be recognized materially differs from the revenue recorded for tests, our revenue or operating results may fall below investor or analyst expectations.
- The loss of key members of our senior management team or our inability to attract and retain highly skilled scientists, technicians, clinicians, and sales representatives could adversely affect our business.

- If our existing laboratory facilities become damaged or inoperable or we are required to vacate our existing facilities, our ability to perform our tests and pursue our research and development efforts may be jeopardized.
- Our tests in development may not be clinically effective or may never achieve significant commercial market acceptance and our test offerings that we have recently launched may not be commercially successful.
- If our products do not meet the expectations of patients and our customers, our operating results, reputation and business could suffer.
- International trade policies, including tariffs, sanctions and trade barriers may adversely affect our business, financial condition, results of operations and prospects.
- New product development and commercialization involve a lengthy and complex process and we may be unable to develop or commercialize new products on a timely basis or at all.
- We have been, and in the future may be, involved in legal proceedings, regulatory investigations and inquiries and other legal matters, which may have an adverse effect on our business, financial condition, results of operations and prospects.
- Any inability to effectively protect our proprietary technologies could harm our competitive position.
- We have identified material weaknesses in our internal control over financial reporting. If our remediation of such material weaknesses is not effective, or if we identify additional material weaknesses in the future or otherwise fail to develop and maintain effective internal control over financial reporting, our ability to produce timely and accurate financial statements or comply with applicable laws and regulations could be impaired.

Risks Related to Our Business and Strategy

Our limited operating history and rapid growth make it difficult to evaluate our future prospects and the risks and challenges we may encounter.

We were founded in 2016 and received our first commercial test sample in 2019. We have since experienced rapid growth in revenue, headcount, adoption of our products and testing volume. We operate in a highly competitive market characterized by rapid technological advances. Our business has evolved, and we expect it to continue to evolve, over time to remain competitive. Our limited operating history, evolving business, rapid growth and ambitious goals make it difficult to evaluate our future prospects and the risks and challenges we may encounter, and may increase the risk that we will not continue to grow at or near historical rates. Further, these factors may make it difficult for us to accurately project the future performance of our business.

We intend to continue to expand our overall business, customer base, headcount and operations, and managing our growth will also require significant expenditures and allocation of valuable management resources. Continued growth increases the challenges involved in:

- recruiting, training and retaining sufficient skilled technical, marketing, sales and management personnel;
- preserving our high performing culture, core values and entrepreneurial environment;
- developing and improving our internal administrative infrastructure, particularly our financial, operational, compliance, recordkeeping, communications and other internal systems;
- maintaining high levels of satisfaction with our products among our customers; and
- effectively managing expenses related to any future growth.

We have encountered in the past, and will encounter in the future, risks and uncertainties frequently experienced by growing companies with limited operating histories in rapidly changing industries. Our future financial performance and our ability to commercialize our products, to increase our sales and to compete effectively will depend, in part, on our ability to manage our potential future growth effectively, without compromising quality. If our assumptions regarding these risks and uncertainties, which we use to plan and operate our business, are incorrect or change, or if we do not address these risks successfully, our results of operations could differ materially from our expectations and our business, financial condition and results of operations could be adversely affected.

We primarily generate revenue from sales of our molecular diagnostic tests and we are highly dependent on them for our success.

Our ability to execute our growth strategy and become or remain profitable is highly dependent on the continued adoption and use of our molecular diagnostic tests, which are our primary source of revenue. Continued adoption and use of our tests will depend on several factors, including the prices we charge for our tests, the

scope of coverage and amount of reimbursement available from third-party payors for our tests, the availability of clinical data that supports the value of our tests and the inclusion of our tests in industry treatment guidelines. In addition, many healthcare providers have existing relationships with companies that develop molecular diagnostic tests, including our competitors, and may continue to use their tests instead of ours. If we are unable to achieve or maintain commercial success for our tests, our business, results of operations and financial condition would be materially and adversely affected. We cannot assure that our tests will continue to maintain or gain market acceptance, and any failure to do so would materially harm our business and results of operations.

If the government and other third-party payors fail to provide coverage and adequate payment for our existing and future tests, our revenue and prospects for profitability will be harmed.

Our business depends on our ability to obtain and maintain adequate coverage and reimbursement from third-party payors and patients. Reimbursement from third-party payors for our tests represented more than 90% of our revenue for each of the years ended December 31, 2023 and 2024, and we expect government and commercial third-party payors to continue to be our primary source of payments. If we are unable to obtain or maintain coverage or adequate reimbursement from, or achieve in-network status with, third-party payors for our existing or future tests, our ability to generate revenue will be limited. For example, physicians may be reluctant to order our tests due to the potential of a substantial out-of-pocket cost to the patient if reimbursement coverage is unavailable or insufficient.

The insurance landscape, particularly for molecular diagnostics, is continually changing and our efforts to broaden reimbursement for our tests with third-party payors may not be successful. Third parties, such as commercial health insurers and government programs, from whom we have received reimbursement may withdraw coverage or decrease the amount of reimbursement for our tests at any time and for any reason, or may otherwise adopt requirements, programs or policies that may restrict or adversely affect our business. In addition, in some cases, our tests or their uses within certain populations are considered experimental by third-party payors and, as a result, some payors have decided not to cover or reimburse for such tests. Some payors may not load our Proprietary Laboratory Analyses (PLA) codes into their system, necessitating us to bill multiple codes for multiple conditions analyzed in a single panel test, resulting in varied billing practices and limiting our reimbursement in those situations. Payors may also dispute our billing or coding practices. Based on any of the foregoing, third-party payors 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, and we may be required to refund reimbursements already received or otherwise bring legal action to defend our position. We deal with demands for overpayment recoupment from third-party payors from time to time in the ordinary course of our business, and it is likely that we will continue to do so in the future. If a third-party payor denies payment for testing, the reimbursement revenue for our testing could decline. If a third-party payor successfully proves that payment for prior testing was in breach of contract or otherwise contrary to law, they may recoup payment or bring legal action to do so, which amounts could be significant and would adversely impact our results of operations, and it may decrease reimbursement going forward. We may also decide to negotiate and settle with a third-party payor in order to resolve an allegation of overpayment.

In addition, third-party reimbursement for our tests is based on professional society practice guidelines around the tests performed by our products. These guidelines are issued by medical professional societies in the prenatal and oncology clinical areas, such as ACOG for our prenatal tests and the National Comprehensive Cancer Network (NCCN) for our oncology tests. While ACOG guidelines generally acknowledge that NIPT is the most sensitive screening option for, and/or are generally supportive of NIPT in, average-risk pregnancies in addition to high-risk pregnancies, and NCCN is generally supportive of comprehensive genomic profiling tests, a category that includes Northstar Select, not all of our current tests are covered under practice guidelines, and we cannot predict whether our future tests will be covered by such guidelines. Further, medical professional societies, at times, change their guidelines. In that case, our tests may no longer be covered, which could negatively affect our ability to obtain reimbursement, or the tests offered by our competitors may be more highly preferred by the ordering providers as a result of a change in a medical guideline.

While our primary prenatal tests, such as carrier testing and aneuploidy, have broad guideline support and payor coverage, certain add-ons of our prenatal tests, such as the 22q microdeletion component of UNITY Aneuploidy NIPT or the single-gene NIPT component of our UNITY Fetal Risk Screen, are covered by only a small number of insurance companies, due to more limited, or non-existent, medical guideline support. In oncology, Northstar Select is covered broadly by Medicare, but more narrowly for only certain indications (e.g., lung cancer) by commercial third-party payors. Northstar Response is currently neither covered by Medicare nor by many insurance companies.

In that case, our tests may no longer be covered, which could negatively affect our ability to obtain reimbursement, or the tests offered by our competitors may be more highly preferred by the ordering providers as a result of a change in a medical guideline.

If a third-party payor denies coverage, it may be difficult for us to collect from the patient. In particular, we are often unable to collect the full amount of a patient's responsibility where we are an out-of-network provider and the patient is left with a large balance, despite our efforts to collect. As a result, we cannot always collect the full amount due for our tests when third-party payors deny coverage, cover only a portion of the invoiced amount or the patient has a large cost-sharing obligation. We believe that our billing policies and our patient collection practices are compliant with applicable laws and reimbursement policies. However, from time to time we receive inquiries from third-party payors regarding our billing policies and collection practices. We address these inquiries as and when they arise, but there is no guarantee that we will always be successful in addressing such concerns, which may result in a third-party payor 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 recoupment of previous amounts paid. Any of such occurrences could cause third-party payor revenue for our testing, which represented more than 90% of our revenue for each of the years ended December 31, 2023 and 2024, to decline. Additionally, if we were required to make a repayment, such repayment could be significant, which would adversely impact our results of operations, and we might be required to restate our financials from a prior period, which would likely cause the market price of our Class A common stock to decline. As part of our revenue recognition process, we estimate the expected amount of consideration to be received from our tests using all the information (historical, current and forecasted) that is reasonably available to identify possible consideration amounts. The estimate of revenue is affected by, among other factors, changes in payor mix, payor collections, current customer contractual requirements, experience with collections from third-party payors, and changes in medical policies. We have experienced, and may continue to experience, positive and negative changes in our revenue estimates for previously delivered tests as a result of third-party payors disputing our claims or denying payment for tests that we have performed or from changes in the estimated transaction price due to contractual adjustments, obtaining updated information from payors and patients that was unknown at the time the performance obligation was met and settlements with third-party payors. While we believe our revenue recognition process is reasonable and performed in accordance with applicable accounting standards, we cannot guarantee that our revenue estimates for our tests will be accurate or equal the amount of cash actually collected or that we will not continue to recognize positive or negative changes in our revenue for tests performed in prior periods.

Given the efforts to control and reduce healthcare costs, in the United States and internationally, available levels of reimbursement may change for our current and future products, if authorized for marketing. Third-party reimbursement and coverage may not be available or adequate in either the United States or international markets, which may reduce the demand for our products or our ability to sell our products on a profitable basis. Additionally, the U.S. government may propose and pass legislation designed to reduce the cost of healthcare. We expect that there will continue to be federal and state proposals to implement governmental controls or impose healthcare requirements. In addition, the Medicare and Medicaid programs and increasing emphasis on managed care in the United States will continue to put pressure on product pricing. Cost control initiatives could decrease the price that we would receive for any tests in the future, which would limit our revenue and profitability.

Our revenue may be adversely affected if we are unable to successfully obtain reimbursement from the Medicare program and state Medicaid programs.

The Centers for Medicare & Medicaid Services (CMS) plays a crucial role in determining reimbursement rates for all Current Procedural Terminology (CPT) codes, which are vital for billing and payment for our tests. Annually, CMS publishes these rates in the Clinical Laboratory Fee Schedule (CLFS), providing a comprehensive guideline for laboratories and healthcare providers. If CMS decides to alter the reimbursement rates for the CPT codes associated with the company's tests, it could have an adverse effect on our revenues. Any such changes could impact not only Medicare coverage but also the reimbursement landscape from Medicaid programs and commercial third-party payors because many private insurance companies and state Medicaid plans establish their payment rates as a percentage of the amounts that Medicare allocates for the same CPT codes. Consequently, any modifications in CMS's reimbursement structure could lead to reduced coverage or lower reimbursement rates for our tests.

The Protecting Access to Medicare Act of 2014 (PAMA) introduced a multi-year pricing program and new payment methodology to calculate the rates for tests listed under the CLFS that are reimbursable by Medicare Part B. Under PAMA, services payable by Medicare under the CLFS are adjusted based on negotiated payment rates paid by private payors for the same test reported by an "applicable laboratory" to CMS. However, the

PAMA reporting requirements were suspended in 2021 and have continued to be delayed, most recently until 2026, which in turn has not resulted in rate reductions under the Medicare Part B CLFS. Accordingly, any decrease in the reimbursement we receive under the CLFS due to PAMA in the future may negatively impact our revenue when the PAMA rates are implemented. In addition, federal budgetary limitations and changes in healthcare policy, such as the creation of broad limits for our tests and requirements that beneficiaries of federal health care programs pay for, or pay for higher portions of, clinical laboratory tests or services received, could substantially diminish the utilization of our tests, increase costs and adversely affect our ability to generate revenue and achieve profitability.

It is estimated that nearly half of all births in the United States are to state Medicaid program beneficiaries. Each state's Medicaid program has its own coverage determinations related to our testing, and several state Medicaid programs do not provide coverage for our testing⁵. Even if our testing is covered by a state Medicaid program, we must be recognized as an enrolled Medicaid provider by the state in which the Medicaid beneficiary receiving the services resides in order for us to be reimbursed by a state's Medicaid program, including under a Medicaid managed care plan. Furthermore, in certain states that have implemented managed care organizations (MCOs) that are typically operated by commercial third-party payors, we may also need to contract with one or more MCOs as a participating network provider for us to be reimbursed for testing services that we provide to a Medicaid beneficiary in such state.

Our Union City laboratory, where our prenatal tests are processed, is currently enrolled as a Medicaid provider in over 40 states. However, even if we are recognized as a Medicaid provider in a state, the Medicaid reimbursement amounts are sometimes as low, or lower, than the Medicare reimbursement rate. In addition, from time to time we receive requests from state Medicaid programs seeking information or documents to determine eligibility for and the amount of Medicaid reimbursement. As a result of all of these factors, some state Medicaid programs may only reimburse our testing at a low dollar amount, or not at all. Low or zero-dollar Medicaid reimbursement rates for our tests could have an adverse effect on our business and revenue.

Our billing and claim processing are complex and time-consuming, and any delay in submitting claims or failure to comply with applicable billing requirements could hinder collection and have an adverse effect on our revenue.

Billing for our tests is complex, time-consuming and expensive. Depending on the billing arrangement and applicable law, we bill various payors, such as Medicare, Medicaid, health plans, insurance companies and patients, all of which may have different billing requirements. Several factors make the billing process complex, including:

- differences between the list prices for our tests and the reimbursement rates of payors;
- compliance with complex federal and state regulations related to billing government healthcare programs, including Medicare and Medicaid, to the extent our tests are covered by such programs;
- differences in coverage among payors and the effect of patient co-payments or co-insurance;
- differences in information, pre-authorization and other billing requirements among payors;
- changes to codes and coding instructions governing our tests;
- incorrect or missing billing information; and
- the resources required to manage the billing and claim appeals process.

These billing complexities and the related uncertainty in obtaining payment for our tests could negatively affect our revenue and cash flow, our ability to achieve or maintain profitability and the consistency and comparability of our results of operations. In addition, if claims for our tests are not submitted to payors on a timely basis, or if we fail to comply with applicable billing requirements, it could have an adverse effect on our revenue and our business.

In addition, the coding procedure used by third-party payors to identify various procedures, including our tests, during the billing process is complex, does not adapt well to our tests and may not enable coverage and adequate reimbursement rates. Third-party payors require us to identify the test for which we are seeking reimbursement using a Current Procedural Terminology (CPT) code. CPT coding plays a significant role in how our tests are reimbursed both from commercial and governmental payors. The CPT code set is maintained by the American Medical Association (AMA). In cases where there is not a specific CPT code to describe a test, the test may be billed under an unlisted molecular pathology procedure code or through the use of a combination of single gene CPT codes, depending on the payor. PAMA authorized the adoption of new,

⁵ Our carrier screen test is not covered by Alabama, Michigan, or Nevada, and our aneuploidy test is not covered by Nebraska, Nevada or Utah. State Medicaid coverage for our RhD and fetal antigen tests is currently uncommon. Our oncology test are covered at the federal level by Medicare. Medicaid coverage for our oncology tests is less relevant, as the vast majority of cancer patients do not have Medicaid coverage.

temporary billing codes and unique test identifiers for FDA-cleared or approved tests as well as advanced diagnostic laboratory tests. The AMA has created a new section of CPT codes, Proprietary Laboratory Analyses codes (PLA), to facilitate implementation of this section of PAMA. We received PLA codes for most of our tests in 2024. Because billing third-party payors for our tests is an unpredictable, challenging, time-consuming and costly process, we may face long collection cycles and the risk that we may never collect at all, either of which could adversely affect our business, results of operations and financial condition, and we may have to increase collection efforts and incur additional costs. Additionally, because next generation genomic sequencing is a rapidly evolving area of medicine, and because clinical treatment guidelines continue to develop, any changes to, or interpretations of, applicable billing and coding guidance, rules, policies, and procedures may impact our business. There is no guarantee that our retrospective or prospective billing practices will not be challenged or reversed, such as by a demand for repayment, recoupment, or prospective billing policies. Any such attempts could adversely affect our results and operations.

The inherent variability of the insurance coverage and reimbursement landscape makes it difficult to predict amounts we ultimately collect for our tests, and if our estimates of revenue to be recognized materially differs from the revenue recorded for tests, our revenue or operating results may fall below investor or analyst expectations.

It is difficult to predict the amounts, if any, we are able to collect for our tests from third-party payors. We are a participating in-network provider with some commercial third-party payors from whom we receive reimbursement for our molecular diagnostic tests. We also provide testing services to patients as a non-participating (out of network) provider. While we have contracts as an in network provider with some payors, we do not have contracts with all payors (out of network) and these payors may determine independently the amount that they are willing to reimburse us for our tests.

Even when payors have paid a claim, they may elect at any time (subject to applicable federal or state law restrictions) to review previously paid claims for overpayment against such claims. In the event of an overpayment determination, the payor may offset the amount they determine they overpaid against amounts they owe us on current claims. There is generally a defined process and we have limited leverage to dispute these retroactive adjustments and we cannot predict when, or how often, a payor might engage in these reviews. A significant amount of these offsets by one or more payors in any given quarter could have a material effect on our results of operations and cause them to fall below expectations or guidance we may provide.

Our efforts to become a participating provider of a number of government and commercial third-party payors may not be successful. Even when we have obtained positive coverage decisions for our tests from third party payors and entered into agreements with them, such agreements typically are standard form contracts and may allow payors to terminate coverage on short notice, impose significant obligations on us and create additional regulatory and compliance hurdles for us.

As part of our billing operations, we appeal claim denials from third party payors, and if successful, we receive payments from these appeals. However, due to the inherent variability of the insurance landscape, we cannot guarantee future success of, or any payments from, appeals of claim denials by all payors. Historical success and payments are not indicative of future success of and payments from such appeals. To receive payments from these appeals, we may need to pursue arbitration and/or litigation, either of which would require resources and costs.

Due to the inherent variability and unpredictability of the insurance landscape, including, without limit, the amount that payors reimburse us for any of our tests, we estimate the amount of revenue to be recognized at the time a test is provided and record revenue adjustments if and when the cash subsequently received for a test differs from the revenue recorded for the test. Due to this variability and unpredictability, previously recorded revenue adjustments are not indicative of future revenue adjustments from actual cash collections, which may fluctuate significantly. If this variability and unpredictability results in our revenue or operating results falling below the expectations of analysts or investors or below any guidance we may provide, the market price of our Class A common stock could decline substantially.

The loss of key members of our senior management team or our inability to attract and retain highly skilled scientists, technicians, clinicians, and sales representatives could adversely affect our business.

Our success depends on the skills, experience and performance of key members of our senior management team, including Oguzhan Atay, our Chief Executive Officer and David Tsao, our Chief Technology Officer (our Co-Founders). The individual and collective efforts of our Co-Founders, as well as other key employees, will be important as we continue to develop our platform and additional products, and as we expand our commercial

activities. The loss or incapacity of either of our Co-Founders or other members of our executive management team could adversely affect our operations if we experience difficulties in hiring qualified successors. Our executive officers are at-will employees and we cannot guarantee their retention for any period of time. We do not maintain "key person" insurance on any of our employees, including our Co-Founders.

Our expected future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees. Recruiting and retention difficulties can limit our ability to support our research and development and sales programs. All of our employees are at-will, which means that either we or the employee may terminate their employment at any time. Our research and development programs and laboratory operations depend on our ability to attract and retain highly skilled scientists and technicians. We may not be able to attract or retain qualified scientists and technicians in the future due to the competition for qualified personnel among life science businesses, particularly near our headquarters in Menlo Park, California. We also face competition from universities and public and private research institutions in recruiting and retaining highly qualified scientific personnel.

In addition, we may have difficulties locating, recruiting or retaining qualified sales representatives. We currently sell to clinicians and healthcare providers in the United States through our own sales organization. Each of our target markets is large, distinctive and diverse. As a result, we prefer for our sales representatives to have established prenatal or oncology-focused expertise, as applicable. Competition for such employees within the molecular diagnostics industry is intense and oftentimes such individuals are subject to noncompetition and other employment restrictions by their former employer. We may not be able to attract and retain personnel or be able to build or maintain an efficient and effective sales organization, which could negatively impact sales and market acceptance of our products and limit our revenue growth and potential profitability. In particular, it may be challenging for us to recruit, train and retain sales personnel with oncology testing expertise, as we have relatively limited experience selling our products in this market compared with the prenatal testing market.

If our existing laboratory facilities become damaged or inoperable or we are required to vacate our existing facilities, our ability to perform our tests and pursue our research and development efforts may be jeopardized.

We currently derive nearly all of our revenue from tests performed at our laboratory facility located in Union City, California, with a small percentage of our revenue derived from a second facility in Menlo Park, California. While we expect to open a third laboratory facility in Austin, Texas in 2028, there is no assurance that we will be able to fully operationalize this facility to its capacity in a timely manner or at all. Our facility and equipment could be harmed or rendered inoperable by natural or man-made disasters, including war, fire, earthquake, flood, hurricanes, tornadoes, power loss, communications failure or terrorism, which may render it difficult or impossible for us to perform our tests and may also cause us to lose valuable stored blood samples. The inability to perform our tests or to reduce the backlog that could develop if our facility is inoperable, for even a short period of time, may result in the loss of customers or harm to our reputation, and we may be unable to regain those customers or repair our reputation. It would be difficult, time-consuming and expensive to rebuild our facility, to locate and qualify a new facility or enable a third party to practice our proprietary technology, particularly in light of licensure and accreditation requirements. Even if we are able to find a third party with such qualifications to perform our tests, the parties may be unable to agree on commercially reasonable terms. Our physical laboratory facilities are also subject to regulatory oversight, such as by the federal Occupational Safety and Health Administration (OSHA), and certain state analogs. On occasion, certain safety issues may be required to be reported directly to OSHA. If not remediated, these regulatory bodies could intervene and suspend our operations, which could have a material impact on our business.

We carry insurance for damage to our property and disruption of our business, but this insurance may not cover all of the risks associated with damage or disruption to our facility and business, may not provide coverage in amounts sufficient to cover our potential losses and may not continue to be available to us on acceptable terms, if at all.

Our tests in development may not be clinically effective or may never achieve significant commercial market acceptance and our test offerings that we have recently launched may not be commercially successful.

We may not succeed in achieving significant commercial market acceptance of our test offerings that we have launched in recent years or are currently developing. Our ability to successfully develop and commercialize our current tests, as well as any future tests that we may develop or acquire, may depend on several factors, including:

- our ability to convince the medical community and consumers of our tests of their potential advantages over existing tests or other competing products or services;
- our ability to market current and future products in new and existing markets;
- our ability to collaborate with pharmaceutical companies;
- the agreement by third-party payors to reimburse our tests, the scope and extent of which will affect patients' willingness or ability to pay for our tests and will likely heavily influence physicians' decisions to recommend our tests; and/or
- the willingness of physicians to utilize our molecular diagnostic tests, which can be difficult to interpret as our tests only predict as to a probability, not certainty, that a tested individual will develop the disease, will benefit from a particular therapy or has an aggressive form of the disease that the test is intended to predict.

We may have to spend substantial time and money to overcome obstacles to commercial acceptance of our tests, and our anticipated timeline to launch new test offerings may not occur at the time we expect.

The tests we enhance or develop may not be clinically effective or commercially successful, may not ultimately meet our desired target product profile, or may not be offered at acceptable cost and with the test performance metrics necessary to address the relevant clinical need or commercial opportunity. We also may experience difficulties completing the clinical development of any new or enhanced product, or establishing or maintaining the collaborations that may be essential to our clinical development and commercialization efforts. Clinical development requires large numbers of patient specimens and, for certain products, may require large, prospective, and controlled clinical trials. We may not be able to enroll patients or collect a sufficient number of appropriate specimens in a timely manner, or we may experience delays during clinical development due to slower than anticipated enrollment, or due to changes in study or trial design or other unforeseen circumstances, or we may be unable to afford or manage the large-sized clinical trials that some of our planned future products may require. Our ongoing research and development and clinical study activities are subject to extensive regulation and review by numerous governmental authorities both in the United States and abroad. Clinical testing is difficult to design and implement, can take many years, can be expensive and carries uncertain outcomes. The results of nonclinical studies and clinical studies of our products conducted to date, and ongoing or future studies of our current, planned or future products may not be predictive of the results of later clinical studies, and interim results of a clinical study do not necessarily predict final results. Clinical studies may produce negative or inconclusive results, and we may decide to conduct additional clinical and nonclinical testing in addition to those we have planned before we are able to launch our products. We may experience delays in our nonclinical studies and clinical studies for a number of reasons, which could adversely affect the costs, timing or successful completion of such studies or trials.

In addition, the publication of clinical data in peer-reviewed journals is an important step in commercializing and obtaining reimbursement for our tests, and our inability to control when, if ever, results are published may delay or limit our ability to derive sufficient revenue from any test that is the subject of a study or trial. Peer-reviewed publications regarding our tests may be limited by many factors, including delays in the completion of, poor design of or lack of compelling data from, nonclinical studies and clinical studies, as well as delays in the review, acceptance and publication process. If our tests or the technology underlying our current or future tests do not receive sufficient favorable exposure in peer-reviewed publications, the rate of clinician adoption of our tests and positive reimbursement coverage determinations for our tests could be negatively affected.

We rely on a limited number of suppliers or, in some cases, sole or single-source suppliers, for some of our laboratory instruments and materials and may not be able to find replacements or promptly transition to alternative suppliers.

We rely on a limited number of suppliers, or, in some cases, sole- or single-source suppliers, for certain sequencers, reagents, blood tubes and other equipment, instruments and materials that we use in our laboratory operations. Any disruption in operations of sole or single-source suppliers or termination or suspension of our relationships with them could materially and adversely impact our supply chain and laboratory operations and thus our ability to conduct our business and generate revenue. An interruption in our laboratory operations could occur if we encounter delays or difficulties in securing such laboratory equipment, instruments or materials, and if we cannot then obtain an acceptable substitute. Any such interruption could significantly and adversely affect our business, financial condition, results of operations and reputation.

If we were required to replace a supplier, transitioning to a new supplier would be time-consuming and expensive, may result in interruptions in our laboratory operations, could affect the performance specifications of our laboratory operations or could require that we revalidate our tests. While we have successfully transitioned suppliers in the past and we strive to keep, at least, a three-month inventory of a vast majority of

required materials, transitioning suppliers may not always be possible in the future. We estimate replacing suppliers could take approximately one to nine months. If we were to encounter delays or difficulties in securing, reconfiguring or integrating the equipment and reagents we require for our products or in revalidating our products, our business, financial condition, results of operations and reputation could be materially and adversely affected.

Legislative or regulatory developments such as the BIOSECURE Act, proposed in the 118th Congress but not enacted, or the new iteration of the BIOSECURE Act, known colloquially as BIOSECURE 2.0, that was recently added as an amendment to the National Defense Authorization Act in the 119th Congress, could materially affect our business operations, supply chain, or ability to contract with U.S. government agencies. If a statute akin to the BIOSECURE Act or BIOSECURE 2.0 is enacted, in addition to potential other restrictions on our business, it would prohibit federal agencies from contracting with entities that use biotechnology equipment or services from certain foreign entities deemed to be under the control of foreign adversaries.

While we may currently rely, or in the future may rely, on equipment, reagents, or laboratory services from one or more companies that could be designated as “biotechnology companies of concern” under this or similar legislation, we have undertaken and continue to undertake measures to mitigate the risks associated with utilizing material from biotechnology companies of concern. Further, and as a longstanding policy and practice, we utilize robust screening measures to ensure that any genetic data we obtain is protected to the maximum extent under law. If we are unable to verify or restructure our supply chain in compliance with such laws, we could become ineligible for federal contracts, grants, or funding, may be unable to receive reimbursement from Medicaid and Medicare agencies, which provide a substantial percentage of our total revenue, and could face reputational harm, contractual liabilities, or enforcement action.

Even if legislation akin to the BIOSECURE Act or BIOSECURE 2.0 is not enacted, similar legislative or regulatory initiatives may be adopted, and compliance could require significant operational changes, increased costs, or procurement delays. There can be no assurance that we will not be adversely affected by their implementation.

We rely on commercial courier delivery services to transport samples to our facilities in a timely and cost-efficient manner and if these delivery services are disrupted, our business may be harmed.

Our business depends on our ability to quickly and reliably deliver test results to our customers and their patients. We typically receive blood samples for analysis at our laboratory facilities within days of collection from the patient. Disruptions in delivery service, which have occurred in the past and may occur in the future – whether due to error by the courier service, labor disruptions, bad weather, natural disaster, terrorist acts or threats or for other reasons – could adversely affect specimen integrity, our ability to process or store samples 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 business, financial condition, results of operations may be adversely affected.

If our products do not meet the expectations of patients and our customers, our operating results, reputation and business could suffer.

Our success depends on the market’s confidence that we can provide reliable, high-quality precision prenatal and oncology products that will improve clinical outcomes and lower healthcare costs. We believe that patients, clinicians, healthcare providers and payors are likely to be particularly sensitive to product defects and errors in the use of our products, including if our products fail to detect clinically relevant information with high accuracy from samples or if we fail to list or inaccurately include certain treatment options and available clinical trials in our test reports, and there can be no guarantee that our products will meet their expectations. Furthermore, if our competitors’ products do not perform to expectations, it may result in lower confidence in our tests as well. As a result, the failure of our products to perform as expected could significantly impair our operating results and our reputation. In addition, we may be subject to legal claims arising from any defects or errors in our products. Confidence in us, as well as the strength of our brand and reputation, could also be eroded by perceived failures by us or our competitors, even absent any evidence of failure or wrongdoing.

If our information technology systems or those third parties with whom we work or our data, are or were compromised, we could experience adverse consequences resulting from such compromise, including regulatory investigations or actions, litigation, fines and penalties, disruptions of our business operations, reputational harm, loss of revenue or profits, loss of customers or sales, and other adverse consequences.

In the ordinary course of our business, we and the third parties with whom we work, process, 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 protected health information (PHI) and other personally identifiable information, credit card and other financial information, intellectual property and proprietary business information owned or controlled by us or other parties such as customers and payors. We manage and maintain our applications and data utilizing a combination of on-site systems and cloud-based data centers. We utilize external security and infrastructure vendors to manage parts of our data centers. Our information technology systems store a wide variety of information critical to our business, including research and development information, patient data, commercial information and business and financial information. We face a number of risks related to protecting this critical information, including loss of access, inappropriate use or disclosure, unauthorized access, inappropriate modification and our being unable to adequately monitor, audit or modify our controls over such critical information. This risk extends to the third-party providers, strategic partners and other contractors, subcontractors or consultants we use to manage this sensitive data or otherwise process it on our behalf.

Cyberattacks, security breaches, computer viruses, malicious internet-based activity, online and offline fraud, ransomware attacks, phishing, structured query language injections, social engineering schemes, distributed denial-of-service attacks, supply chain attacks, malware and other incidents, as well as employee theft or misuse, human error, fraud, denial or degradation of service attacks, unauthorized access or use by persons inside our organization or persons with access to systems inside our organization, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive information and information technology systems, and those of the third parties with whom we work. Misappropriation, exposure, loss or other unauthorized disclosure of confidential data, personal information, materials or information, as well as interruptions, delays or cessation of service often result from these events. Increasingly complex methods have been used in cyberattacks, and the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased and come from a variety of sources, including traditional computer “hackers,” threat actors, “hacktivists,” organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors. Because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches.

The costs of attempting to protect against the foregoing risks and responding to a cyberattack are significant. Breaches of our and/or our vendors’ security measures and the unauthorized dissemination of sensitive personal information or proprietary or confidential information about us, our customers or other third-parties, could result in investigations, regulatory enforcement actions, notices to affected individuals, regulators and the media, material fines and penalties, loss of customers, litigation or other actions which could have a material adverse effect on our business, prospects, reputation, results of operations and financial condition. Breaches and incidents also cause operational harm such as by preventing us from performing our laboratory operations, preparing and providing reports to customers, billing payors, processing reimbursement appeals, handling patient or physician inquiries, conducting research and development activities and managing the administrative aspects of our business.

We and certain of our service providers are from time to time subject to cyberattacks and security incidents. Although we have implemented security measures and an enterprise security program to prevent unauthorized access to our systems, information and patient data, there is no assurance that these measures will be effective. As cyber threats evolve, we may be required to expend significant additional resources to continue to modify or enhance our protective measures or to investigate and remediate any information security vulnerabilities, and these efforts may not be successful.

We have contingency plans and insurance coverage for certain potential claims, liabilities and costs relating to security incidents that may arise from our business or operations; however, the coverage may not be sufficient to cover all claims, liabilities and costs arising from the incidents, including fines and penalties. 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. The ultimate resolution of any such incidents or estimating the amounts or ranges of potential loss, if any, that could result therefrom are highly uncertain. If we cannot successfully resolve a security incident or contain any potential loss, it could materially impact our ability to operate our business as well as our results of operations and financial position.

If we experience a significant disruption in our information technology systems, or those of third-parties upon which we rely, our business operations and financial condition could be adversely affected.

Our IT and communications systems support a variety of functions, including sample processing, tracking, quality control, customer service and support, billing, research and development activities, and various general and administrative activities. The availability of our products and services and fulfillment of our customer contracts depends on the continuing operation of these systems. We currently maintain a data center within Amazon Web Services (AWS). In addition, our proprietary QCT technology is a crucial component of our test processing. We host the significant majority of these algorithms on a cloud-based software platform pursuant to an agreement with AWS. Our bioinformatics platform is hosted on third-party data center hosting facilities operated by AWS. We also host our algorithms on AWS platforms directly. Our algorithms are currently used to run many of our tests and certain of our research and development activities. In the event of any technical problems that may arise in connection with our on-site data systems, bioinformatics platform or the AWS servers on which the bioinformatics platform is hosted, or the AWS servers that host our data directly, or difficulties in or termination of our relationship with AWS, we could experience interruptions in our laboratory operations, and we may be unable to access our proprietary algorithms and therefore be unable to process tests or conduct any other activities that require access to such algorithms. Disruptions to the IT and communications systems supporting our laboratory and other operations may be caused by a variety of factors, including infrastructure changes, disruptions or shutdowns due to power outages, human or software errors, natural disasters, hardware failures, computer viruses, security attacks, fraud, spikes in customer usage and denial of service issues. Our IT and communication systems, and those of third-parties upon which we rely, also may experience interruptions, delays or cessations of service or produce errors in connection with system implementation, integration, upgrades or system migration work that takes place from time to time. We do not have any backup platform, server or other means to host our algorithms, and may be unable to find and implement an alternative platform that is satisfactory for our needs on commercially reasonable terms, in a timely manner, or at all. Interruptions in our operations or service may reduce our revenue, cause us to issue refunds, result in the loss of customers, or harm our reputation. We could also be exposed to potential lawsuits and liability claims.

Recent or future macroeconomic pressures resulting from geopolitical uncertainty, public health developments or other matters may have an adverse impact on our business, financial results and prospects.

Recent geopolitical matters have led to significant uncertainty and negative impact on the macroeconomic environment, such as the imposition of tariffs, inflation, rising interest rates, market volatility and supply chain issues. Parts of our direct and indirect supply chain are located overseas and both international and domestic components have been, and may in the future be, subject to disruption by these developments. Global economic and business activities continue to face widespread uncertainties, and global credit and financial markets have experienced extreme volatility and disruptions in the past, including severely diminished liquidity and credit availability, rising inflation and monetary supply shifts, rising interest rates, labor shortages, supply chain issues, declines in consumer confidence, declines in economic growth, increases in unemployment rates, recession risks, and uncertainty about economic and geopolitical stability. A severe or prolonged economic downturn, or additional global financial or political crises, could adversely impact our business, financial results, and prospects. In addition, such macroeconomic conditions could impact our ability to access the public markets as and when appropriate or necessary to carry out our operations or our strategic goals. We cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

In the event of public health developments, health epidemics or outbreaks in the future, our operations could be disrupted and our business adversely impacted. Such disruptions or impacts may be similar to those faced during the COVID-19 pandemic, such as mandated business closures in impacted areas, limitations with employee resources due to stay at home orders or sickness of employees or their families, diversion or prioritization of health care resources away from the conduct of testing, limitations on patients' access to our products, disruptions or restrictions affecting the ability of our laboratory facility to process our tests, reduced demand for certain of our products, or supply chain constraints.

International trade policies, including tariffs, sanctions and trade barriers may adversely affect our business, financial condition, results of operations and prospects.

Current or future tariffs or other restrictive trade measures may raise the costs of raw materials, components or finished goods, which may adversely impact both our product offerings and our operational expenses. Such

cost increases may reduce our margins, which could negatively impact our revenue. Our manufacturers, suppliers and distribution channels are also affected by the current trade environment, and we may experience supply chain disruptions as a result of increased costs and uncertainty, as well as risks to the long-term viability of key vendors, which may impact our ability to meet customer demand or manage inventory efficiently. Tariff and other trade-related cost pressures and supply chain disruptions may lead to reputational harm if we are unable to deliver test services on expected timelines.

Trade disputes, trade restrictions, tariffs and other political tensions between the U.S. and other countries may also exacerbate unfavorable macroeconomic conditions including inflationary pressures, foreign exchange volatility, financial market instability, and economic recessions or downturns, which may negatively impact our business and operations and contribute to volatility in the price of our common stock.

While we continue to monitor trade developments, the ultimate impact of these risks remains uncertain and any prolonged economic downturn, escalation in trade tensions, or deterioration in international perception of U.S.-based companies could materially and adversely affect our business, results of operations, financial condition and prospects.

If we were to be sued for product liability or professional liability, we could face substantial liabilities that exceed our resources.

The marketing, sale and use of our products has in the past and could in the future lead to the filing of product liability or similar claims were someone to allege that our tests failed to perform as designed or as claimed in our promotional materials, performed pursuant to incorrect or inadequate laboratory procedures, if we delivered incorrect or incomplete test results or our tests failed to produce a result, or if someone were to misinterpret test results. We may also be subject to professional liability for errors in, a misunderstanding of, or inappropriate reliance upon, the information we provide in the ordinary course of our business activities. A product liability or professional liability claim could result in substantial damages and be costly and time-consuming for us to defend. Even though our tests are highly accurate, they are not 100% accurate and we may report false negative or false positive results, which may subject us to lawsuits claiming product or professional liability or other claims, as has happened in the past and may happen in the future. 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, this insurance may not fully protect us from the financial impact of defending against product liability or professional liability claims. Any product liability or professional liability claim brought against us, with or without merit, could increase our insurance rates or prevent us from securing insurance coverage in the future. Additionally, any product liability or professional liability lawsuit could damage our reputation or cause current customers to terminate existing agreements with us and potential customers to seek other partners, any of which could adversely impact our results of operations.

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 similar rates.

Our total addressable market opportunity estimates and growth forecasts are subject to significant uncertainty and are based on internal and third-party assumptions and estimates that may not prove to be accurate. While we believe our assumptions and the data underlying our estimates are reasonable, these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time, thereby reducing the predictive accuracy of these underlying factors. As a result, our estimates of the annual total addressable market for our current or future products may prove to be incorrect. If the actual number of patients who would benefit from our products, the price at which we can sell our products, the number of tests we are able to successfully develop and commercialize, or the annual total addressable market for our products is smaller than we have estimated, it may impair our sales growth and have an adverse impact on our business, financial condition and results of operations. Additionally, half of our estimated total addressable market includes early detection, an area in which we have not yet begun specific product development or commercial sales. There can be no assurance that we will launch future products on the timeline we expect or at all. Even if a market in which we compete, or expect to compete, meets our size estimates and forecasted growth for such market, we may not be able to penetrate the existing market to capture additional market share and our business could fail to grow at similar rates.

We may acquire businesses, form joint ventures or make investments in companies or technologies that could negatively affect our operating results, distract management's attention from other business concerns, dilute our stockholders' ownership, and significantly increase our debt, costs, expenses, liabilities and risks.

In the future we may seek to acquire or invest in businesses, technologies, services, products, or other assets that we believe could complement or expand our products, enhance our technical capabilities, or otherwise offer opportunities for our business. Other than our partnerships with Johnson & Johnson, we have limited experience with acquisitions and forming strategic partnerships. We may compete for those opportunities with others including our competitors, some of which may have greater financial or operational resources than we do. We may not be able to identify suitable acquisition candidates or strategic partners, we may have inadequate access to information or insufficient time to complete due diligence, and we may not be able to complete such transactions on favorable terms, if at all. If we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. Integration of an acquired business may disrupt our ongoing operations and require management resources that we would otherwise focus on developing our existing business. In addition, any acquisition could result in the incurrence of debt, contingent liabilities or future write-offs of intangible assets or goodwill, any of which could have a material adverse effect on our financial condition, results of operations and cash flows. We may also experience losses related to investments in other companies, which could have a material negative effect on our results of operations and financial condition.

We may not realize the anticipated benefits of any acquisition, technology license, strategic investments or partnerships, or joint venture. To finance any acquisitions, joint ventures or investments, we may choose to issue shares of our Class A common stock as consideration, which would dilute the ownership of our stockholders. If the market price of our Class A common stock is low or volatile, we may not be able to acquire other companies or fund a joint venture project using our stock as consideration.

Also, the anticipated benefit of any strategic alliance, joint venture or acquisition may not materialize or such strategic alliance, joint venture or acquisition may be prohibited. For example, our debt facility with Oberland Capital Management LLC (Oberland Capital) restricts our ability to pursue certain mergers, acquisitions, or consolidations that we may believe to be in our best interest. Additionally, future acquisitions or dispositions could result in potentially dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities or amortization expenses or write-offs of goodwill, any of which could harm our financial condition. We cannot predict the number, timing or size of future joint ventures or acquisitions, or the effect that any such transactions might have on our operating results.

New product development and commercialization involve a lengthy and complex process and we may be unable to develop or commercialize new products on a timely basis or at all.

Our products have taken time and considerable resources to develop, and we may not be able to complete the development and commercialization of new products on a timely basis, or at all. Before we can commercialize any new products, we may need to expend significant funds to:

- conduct substantial research and development, including validation studies;
- find appropriate third party collaborators to conduct clinical studies;
- further develop and scale our laboratory processes to accommodate different products; and
- further develop and scale our infrastructure to be able to analyze increasingly large amounts of data.

Our product development process involves a high degree of risk, and product development efforts may fail for many reasons, including:

- failure of the product to perform as expected, including defects and errors;
- inability to pass validation required by regulatory requirements;
- inability to find appropriate samples for clinical validity and utility studies;
- failure to demonstrate the clinical validity or utility of the product;
- inability to obtain necessary reimbursement by commercial or government payors;
- unattractive economics due to unexpected higher costs of the final version of the product; or
- high cost of commercialization.

Our development plan involves using data and analytical insights generated from our current products to foster research and development investment in our future products. However, if we are unable to generate additional or compatible data and insights, then we may not be able to advance our products under development as quickly, or at all, or without significant additional investment.

As we develop products, we have made and will have to make significant investments in product development, marketing and selling resources, including investing heavily in clinical studies, which could adversely affect our future cash flows. In addition, in our development and commercialization plans, we may forego other opportunities that may provide greater revenue or be more profitable. As a result, even if our development efforts result in commercially viable products, our business and results of operations could underperform in comparison to our customers and competitors.

The molecular diagnostics industry is subject to rapid change, which could make our current products, and any future products we may develop, obsolete.

Our industry is characterized by rapid changes, including technological and scientific breakthroughs, frequent new product introductions and enhancements and evolving industry standards, all of which could make our current and future products obsolete. Our future success will depend on our ability to keep pace with the evolving needs of our customers on a timely and cost-effective basis and to pursue new market opportunities that develop as a result of scientific and technological advances. In recent years, there have been numerous advances in technologies in the prenatal and oncology fields, as well as advances in the application of machine learning and AI to molecular diagnostics and decision-making. We must continuously enhance our platform and develop new products to keep pace with evolving standards of care. If we do not update our product offerings to reflect new scientific knowledge about disease biology, information about new therapies or relevant clinical studies, or insights regarding the current treatment landscape for applicable indications and advances in computational biology, software development and AI, our products could become obsolete and sales of our current products and any new products we may develop could decline or fail to grow as expected. Further, to the extent that pharmaceutical or biotechnology companies are able to develop therapies or technologies that eradicate or substantially limit the incidence or severity of diseases for which we sell molecular diagnostic tests, the market for our applicable products could disappear entirely.

If we are unable to support demand for our current and future products, including ensuring that we have adequate capacity to meet increased demand, or we are unable to successfully manage our anticipated growth, our business could suffer.

As our volume of test sales grows, we will need to continue to increase our workflow capacity for sample intake, customer service, billing and general process improvements, expand our internal quality assurance program and extend our platform to support comprehensive genomic analysis at a larger scale within expected turnaround times. We will need additional certified laboratory scientists and other scientific and technical personnel to process higher volumes of our molecular diagnostic products. Portions of our process are not automated and may require additional personnel to scale. We will also need to purchase additional equipment, some of which can take several months or more to procure, setup and validate and increase our software and computing capacity to meet increased demand. There is no assurance that any of these increases in scale, expansion of personnel, equipment, software and computing capacities or process enhancements will be successfully implemented, if at all, or that we will have adequate space in our laboratory facility or be able to secure additional facility space to accommodate such required expansion.

As we commercialize additional products, we will need to incorporate new equipment, implement new technology systems and laboratory processes, and hire new personnel with different qualifications. Failure to manage this growth could result in turnaround time delays, higher product costs, declining product quality, deteriorating customer service and slower responses to competitive challenges. A failure in any one of these areas could make it difficult for us to meet market expectations for our products and could damage our reputation and prospects.

Our employees, contractors, consultants and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk of fraud or other misconduct by our employees, contractors, consultants and commercial partners. Misconduct by these parties could include intentional failures to comply with applicable federal, state and local regulations and with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately, or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct could also involve the improper use of information obtained in the course of clinical trials, which

could result in regulatory sanctions and cause serious harm to our reputation. We currently have a code of conduct and compliance program applicable to all of our employees, contractors, consultants and partners, but it is not always possible to identify and deter misconduct, and our code of conduct, compliance program operations and the other precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses, or in protecting us from governmental investigations, lawsuits or other actions stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant civil, criminal and administrative penalties, including, without limitation, damages, monetary fines, individual imprisonment, disgorgement of profits, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs or from network participation with commercial third-party payors, contractual damages, reputational harm, diminished profits and future earnings, additional reporting or oversight obligations if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with the law and curtailment or restructuring of our operations, which could have a significantly adverse impact on our business. Whether or not we are successful in defending against such actions, we could incur substantial costs and expenses, including legal fees and divert the attention of management from the operation of our business.

We have been, and in the future may be, involved in legal proceedings, regulatory investigations and inquiries and other legal matters, which may have an adverse effect on our business, financial condition, results of operations and prospects.

We have been, and may in the future be, subject to threatened or actual legal claims, regulatory surveys or investigations, inquiries, proceedings and other legal matters. For example, from time to time we receive and respond to subpoenas from government authorities for records involving Medicaid patients. We consider our historical experiences with such claims and proceedings to be in the normal course of our business and typical for our industry.

We also operate in a highly competitive industry, and competitors frequently use legal proceedings as a tactic against each other, and our competitors may use legal proceedings, or the threat of legal proceedings, against us. For example, the marketing activities of molecular diagnostic companies are subject to less stringent regulation by the FDA, which can lead to greater variability in marketing and sales practices among industry participants, including in the way that laboratories communicate with physicians and patients about their tests. Lower enforcement risks and variability in the interpretation of permissible communications can sometimes lead to claims of inaccurate or misleading communications by a laboratory company against a competitor. Our decision to become a public company heightened our profile and increased the risk that a competitor may initiate a legal proceeding against us, simply to disrupt our business. Even if we believe any such claims are without merit and not material to our business, financial condition, results of operations, or prospects, any such legal proceedings will require the attention of our management to respond and resources to defend. If we are involved in a dispute with a competitor, we may need to defend our practices or take actions, including pursuing a lawsuit, to enforce compliance by another laboratory, which can be costly, may affect our reputation with customers and patients, and there is no assurance that we would prevail in any such action.

We do not view any of the legal claims, regulatory investigations, inquiries, proceedings and other legal matters that we are currently subject to as being material to our business; however, it is difficult to assess the outcome of these matters, and we may not prevail in any current or future proceedings or litigation. There are many uncertainties associated with these matters. Such matters may cause us to incur costly litigation and/or substantial settlement charges, divert management attention, result in adverse judgments, fines, penalties, injunctions or other relief, and may result in loss of customer or investor confidence regardless of their merit of the proceeding or ultimate outcome. Since litigation is inherently uncertain, there is no guarantee that we will be successful in defending ourselves against such claims or proceedings, or that our assessment of the materiality of these matters, including any reserves taken in connection therewith, will be consistent with the ultimate outcome of such matters. In addition, the resolution of any intellectual property litigation may require us to make royalty payments, which could adversely affect gross margin in future periods. If any of the foregoing were to occur, our business, financial condition, results of operations, cash flows, prospects, or market price of our Class A common stock could be adversely affected.

Ethical, legal and social concerns related to the use of genetic information could reduce demand for our tests.

Genetic testing, like that conducted using our tests, has raised ethical, legal and social issues regarding privacy and the appropriate uses of the resulting information. Governmental authorities could, for social or other purposes, limit or regulate the use of genomic information or genomic testing or prohibit testing for genetic

predisposition to certain conditions, particularly for those that have no known cure. Patients may also refuse to use genetic tests even if permissible, for similar reasons such as religious concerns; they may also refuse genetic testing due to concerns regarding eligibility for life or other insurance. Ethical and social concerns may also influence U.S. and foreign patent offices and courts with regard to patent protection for technology relevant to our business. These and other ethical, legal and social concerns may limit market acceptance of our tests or reduce the potential markets for services and products enabled by our technology platform, either of which could harm our business.

The increasing use of social media platforms presents new risks and challenges.

Social media is increasingly being used to communicate about our products. Social media practices in our industry continue to evolve and regulations and regulatory guidance relating to such use are evolving and not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business, resulting in potential regulatory actions against us, along with the potential for litigation. In addition, there is a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us or our 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 such as reputational damage.

If we cannot compete successfully with our competitors, we may be unable to increase or sustain our revenue or to achieve and then sustain profitability.

Growing understanding of the importance of molecular diagnostic testing is leading to more companies offering services in our industry. This has included new and accelerated development programs by a number of potential competitors and increasing levels of merger and acquisition and investment activity by both existing and new competitors. Currently, in prenatal, our main competitors offering NIPs include Illumina, through its subsidiary Verinata, Laboratory Corporation of America Holdings (Labcorp), Myriad Genetics, Inc. (Myriad), Natera, Inc. (Natera), and Quest Diagnostics Incorporated (Quest). We also compete with companies providing carrier screening tests such as Fulgent Genetics, Labcorp, Myriad, Natera, and Quest. Each of these companies offers comprehensive carrier screening panels. In oncology, our main competitors for our therapy selection and response monitoring tests include Caris Life Sciences, Inc., Foundation Medicine, Inc., which was acquired by Roche Holdings, Guardant Health, Inc., NeoGenomics Laboratories, Inc., and Tempus AI, Inc. As we expand our oncology offerings into applications such as MRD testing, as well as potentially testing for early detection in the future, we anticipate facing competition from a broader universe of companies, including Exact Sciences, Grail, Haystack, which was acquired by Quest, and Natera. Most if not all of our competitors sell molecular diagnostic tests and have or may develop tests that compete with ours. In addition, new competitors, including academic medical centers or healthcare providers, may also develop their own tests and may decide to enter our markets.

Some of our competitors and potential competitors may have advantages such as: longer operating histories; larger customer bases; greater brand recognition and market penetration; substantially greater financial, technological and research and development resources and selling and marketing capabilities; more experience dealing with third-party payors; the ability to secure key inputs from vendors on more favorable terms; and the ability to adopt more aggressive pricing policies and devote substantially more resources to product development. As a result, our competitors may be able to respond more quickly to changes in customer requirements, devote greater resources to the development, promotion and sale of their tests than we do or sell their tests at prices designed to win significant levels of market share. We may not be able to compete effectively against these organizations. Furthermore, certain products offered by our competitors and potential market entrants may have attained FDA approval or Advanced Diagnostic Laboratory Test (ADLT) status. The presence of FDA approval, ADLT status, or both, enables such products to qualify for higher reimbursement rates, under CLFS, thereby affording competitors the opportunity to achieve higher profit margins. Increased competition and cost-saving initiatives on the part of governmental entities and other third-party payors are likely to result in pricing pressures, which could harm our sales, profitability or ability to gain market share. In addition, competitors may be acquired by, receive investments from or enter into other commercial relationships with larger, well-established and well-financed companies. In addition, companies or governments that control access to genetic testing through umbrella contracts or regional preferences could promote our competitors or prevent us from performing certain services. If we are unable to compete successfully against current and future competitors, we may be unable to increase market acceptance and sales of our tests, which could prevent us from increasing our revenue or achieving profitability and could cause our stock price to decline.

In addition, the market is constantly changing, and we are not in control of how our competitors' product development and pricing strategies are established. Our competitors may develop lower-priced, less complex

tests that payors and providers could view as functionally equivalent to our products, which could force us to lower the list price of our tests and impact our operating margins and our ability to achieve and maintain profitability. In addition, technological innovations that result in the creation of enhanced diagnostic tools that are more effective than ours may enable healthcare providers to deliver specialized diagnostic tests similar to ours in a more patient-friendly, efficient or cost-effective manner than is currently possible. If we cannot compete successfully against current or future competitors, we may be unable to increase or create market acceptance and sales of our products, which could prevent us from increasing or sustaining our revenue or achieving or sustaining profitability.

We have incurred significant losses since inception, and we may not be able to generate sufficient revenue to achieve or maintain profitability.

We have incurred significant losses since our inception. For the years ended December 31, 2023 and 2024, and the nine months ended September 30, 2024, we incurred net losses of \$82.7 million, \$41.6 million and \$30.1 million, respectively; however, we had net income of approximately \$1.5 million for the nine months ended September 30, 2025. As of September 30, 2025 we had an accumulated deficit of \$280.7 million. To date, we have financed our operations principally from the sale of preferred stock, convertible securities and debt and revenue generated from our tests. We have devoted substantially all of our resources to the development and commercialization of our smNGS platform and current products, and to sales and marketing and research and development activities. In addition, as a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company.

While we have been able to achieve gross margin of 24% and 53% for the years ended December 31, 2023 and 2024, and 51% and 67% for the nine months ended September 30, 2024 and 2025, respectively, factors including reimbursement rates, insurance coverage policies, supply chain issues or increased personnel costs could cause our gross margin for existing or new products to decrease. We will need to generate substantial revenue and maintain our gross margin profile to achieve and then sustain profitability, and even if we achieve profitability, we cannot be sure that we will remain profitable for any period of time. While we have recently experienced improvements in our operational efficiency that has contributed to revenue growth, in the future we may not be able to continue to improve operational efficiency or manage costs as we expand our business. In addition, though we expect that our test volumes and ASPs will increase in the future, our failure to achieve and sustain profitability in the future will make it more difficult to finance our business and accomplish our strategic objectives, which would have a material adverse effect on our business, financial condition and results of operations and cause the market price of our common stock to decline.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or any guidance we may provide.

Our quarterly and annual operating results may fluctuate significantly, which makes it difficult for us to predict our future operating results. These fluctuations may occur due to a variety of factors, many of which are outside of our control, including:

- the level of demand for any of our products, which may vary significantly;
- the timing and cost of, and level of investment in, research, development, regulatory compliance or commercialization activities relating to our products, which may change from time to time;
- the introduction of new products or product enhancements by us or others in our industry;
- coverage and reimbursement policies with respect to our products and products that compete with our products;
- expenditures that we may incur to develop or commercialize additional products and technologies;
- changes in governmental regulations including with respect to privacy and data security and CLIA (as defined below), and our compliance therewith;
- future accounting pronouncements or changes in our accounting policies; and
- the impact of natural disasters, political and economic instability, including wars, terrorism, and political unrest, epidemics or pandemics, boycotts, high inflation, volatility, tariffs and other trade actions or curtailments, and other business restrictions.

The cumulative effects of factors discussed above could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any guidance we may provide, or if the guidance we

provide is below the expectations of analysts or investors, the market price of our Class A common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated guidance we may provide.

We may need to raise additional capital, and if we cannot do so when needed or on commercially acceptable terms, we will be required to slow or cease our investment in our product development and commercialization plans, which would have an adverse effect on our business.

We have incurred net losses since our inception. While we have introduced products that are generating revenue, this revenue may not be sufficient to fund all of our operations, including our product development and commercialization plans and our sales and marketing efforts. Consequently, we may need to generate additional revenue to achieve or maintain future profitability and may need to raise additional funds through public or private equity or debt financings, corporate collaborations or licensing arrangements to continue to fund or expand our operations. However, subject to limited exceptions, our debt facility with BWCB SA LLC (an entity affiliated with Oberland Capital) prohibits us from incurring additional indebtedness without the prior written consent of Oberland Capital and investors holding at least 50% of the aggregate principal amount of the Note Purchase Agreement (as defined below). If sufficient funds on acceptable terms are not available when needed, or at all, we could be forced to significantly reduce operating expenses and delay, scale back or eliminate one or more of our development programs or our business operations. Furthermore, changing circumstances could result in lower revenues or cause us to consume capital significantly faster than we currently anticipate, and we may need to raise capital sooner or in greater amounts than currently expected because of circumstances beyond our control.

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

- our ability to achieve broader commercial success with our tests;
- the costs and success of our research, development, and commercialization efforts for potential new offerings and additional indications for, and enhancements to, current offerings;
- the cost of expanding our offerings, including our sales and marketing efforts;
- our ability to obtain coverage and reimbursement for our tests, as we continue to invest in expanding our offerings;
- our ability to generate sufficient revenue from our tests;
- our ability to collect on our accounts receivable;
- our need to finance capital expenditures and further expand our laboratory operations;
- our ability to manage our operating costs;
- costs and expenses to protect or enforce our intellectual property rights or to defend against infringement claims brought against us, including any associated litigation settlements or judgments we are required to pay; and
- the timing and results of any regulatory authorizations that we are required to obtain for our tests.

While we currently have in place a debt facility pursuant to which we have an obligation to sell a tranche of notes in the amount of \$30.0 million before March 31, 2026, as described in more detail below, we may need to raise additional capital which may not be available on satisfactory terms or at all. Furthermore, any additional capital raised through the sale of equity or convertible securities, or grant of equity or convertible securities in connection with any debt financing, will dilute stockholders' ownership interests in us and may have an adverse effect on the market 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.

These alternatives for raising additional capital may not be available to us on acceptable or commercially reasonable terms, if at all, or in amounts sufficient to meet our needs. If we are not able to obtain adequate funding when needed, we may be required to delay or slow our investment in the development and commercialization of our products and significantly scale back our business and operations, which would have an adverse effect on our business.

Risks related to our intellectual property

Any inability to effectively protect our proprietary technologies could harm our competitive position.

We rely on patent protection as well as trademark, copyright, trade secret and other intellectual property rights protection and contractual restrictions to protect our proprietary technologies, all of which provide limited

protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. As of September 30, 2025, we held nine U.S. issued patents, 45 foreign patents, 14 pending U.S. patent applications and 32 foreign patent applications. If we fail to obtain, maintain and/or protect our intellectual property rights, third parties may be able to compete more effectively against us. Our success and ability to compete depend to a large extent on our ability to develop proprietary products and technologies and to maintain adequate protection of our intellectual property in the United States and other countries. The laws of some foreign countries do not protect proprietary rights to the same extent as the laws of the United States, and we may encounter difficulties in establishing and enforcing our proprietary rights outside of the United States. In addition, the proprietary positions of companies developing and commercializing tools for molecular diagnostics, including ours, generally are uncertain and involve complex legal and factual questions. This uncertainty may materially affect our ability to defend or obtain patents or to address the patents and patent applications owned or controlled by our collaborators and licensors.

We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies are protected by valid and enforceable patents or are effectively maintained as trade secrets. However, obtaining, maintaining and enforcing biotechnology patents is costly, time-consuming and complex. We may fail to apply for patents on important products, services or technologies in a timely fashion or at all, or we may fail to apply for patents in potentially relevant jurisdictions. We may not be able to file and prosecute all necessary or desirable patent applications, or maintain or enforce patents that may issue from such patent applications, at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. We have worked to procure patents protecting our technologies, but our procurement efforts may not always be successful, and any patents we successfully procure may be challenged in ways that lead to post-procurement scope reduction or invalidity. Any such challenges may impede our ability to protect our proprietary rights from unauthorized use. In addition, any finding that others have claims of inventorship or ownership rights to our patents and applications could require us to obtain certain rights to practice related technologies, which may not be available on favorable terms or at all.

The patent positions of molecular laboratory companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in such companies' patents has emerged to date in the United States or elsewhere. Courts frequently render opinions in the biotechnology field that may affect the patentability of certain inventions or discoveries, including opinions that may affect the patentability of methods for analyzing or comparing DNA sequences.

In particular, the patent positions of companies engaged in the development and commercialization of molecular diagnostic tests, like us, are particularly uncertain. Various courts, including the U.S. Supreme Court, have rendered decisions that affect the scope of patentability of certain inventions or discoveries relating to certain molecular diagnostic tests and related methods. These decisions state, among other things, that a patent claim that recites an abstract idea, natural phenomenon or law of nature (for example, the relationship between particular genetic variants and cancer) are not themselves patentable. Precisely what constitutes a law of nature is uncertain, and it is possible that certain aspects of molecular diagnostics tests would be considered natural laws. Accordingly, the evolving legal and administrative standards around the world, including in the United States may adversely affect our ability to obtain patents and may facilitate third-party challenges to any owned or future licensed patents. The laws of some foreign jurisdictions do not protect intellectual property rights to the same extent as the laws of the United States, and we may encounter difficulties in protecting and defending such rights in foreign jurisdictions. The legal systems of many foreign jurisdictions do not favor the enforcement of patent rights and other intellectual property protection, particularly those relating to biotechnology, which could make it difficult for us to stop the infringement of our patent rights and other intellectual property rights thereunder. Proceedings to enforce our patent rights and other intellectual property protection in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected and our business could be harmed.

In addition to pursuing patents covering our products, services and technology, we take steps to protect our intellectual property and proprietary technology by entering into agreements, including confidentiality and non-disclosure agreements with those that have access to our confidential and proprietary information including employees, independent contractors, academic institutions, corporate partners and advisers, and invention assignment agreements with our employees and independent contractors, and when needed, our advisers. However, we cannot be certain that such agreements have been entered into with all relevant parties, and we

cannot be certain that our trade secrets and other proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Such agreements may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements, and we may not be able to prevent such unauthorized use or disclosure or obtain adequate remedies for breaches.

Monitoring unauthorized use or disclosure is difficult, and we do not know whether the steps we have taken to prevent such use or disclosure are, or will be, adequate. If we were to enforce a claim that a third party had illegally obtained and was using our trade secrets, it would be expensive and time-consuming, and the outcome would be unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets.

We also seek to preserve the integrity and confidentiality of our proprietary information by maintaining physical security of our premises and physical and electronic security of our information technology systems, but it is possible that these security measures could be breached. If any of our confidential proprietary information were to be lawfully obtained or independently developed by a competitor, absent patent protection, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position.

If we are subject to litigation or other proceedings arising from a claim of infringement of the intellectual property of a third party, we might incur significant costs and delays in test introduction or we could be prevented from using technologies incorporated in our tests.

Our success depends in part on our non-infringement of the patents or intellectual property rights of third parties, and our ability to successfully prevent third parties from infringing our intellectual property. We operate in a crowded technology area in which there has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the molecular diagnostics industry. For example, third parties in this industry have brought numerous patent infringement lawsuits against one another in which certain of these parties were found to infringe the others' patents. Third parties have also challenged other parties' patents and successfully invalidated some of those patents in patent infringement lawsuits or post-grant proceedings. Some of these third parties are our competitors and some have broad patent claims. These competitors or other third parties may also target us in patent infringement lawsuits or may also challenge our patents. Our decision to become a public company heightened our profile and increased the risk that a competitor may initiate a patent infringement lawsuit against us to disrupt our business. Even if we believe any such claims are without merit and not material to our business, financial condition, results of operations, or prospects, any such legal proceeding will require the attention of our management to respond and resources to defend.

Third parties have already asserted and may in the future assert that we are infringing their intellectual property rights. We may become subject to and/or initiate future intellectual property litigation as our product portfolio, and the level of competition in our industry, grow. Such proceedings could also include contested post-grant proceedings such as oppositions, *inter partes* review, reexamination, interference, or derivation proceedings before the U.S. Patent and Trademark Office or foreign patent offices.

Should we be unsuccessful defending against patent infringement claims, we may be required to pay substantial royalties, money damages, change our marketing practices, modify our tests, or be enjoined from offering our tests. In addition, we could experience delays in product introductions or sales growth while we attempt to develop non-infringing alternatives. Any of these or other adverse outcomes could delay or prevent us from offering our tests or otherwise have a material adverse effect on our business, financial condition and our results of operations.

If we are found to infringe, misappropriate or otherwise violate a third-party's intellectual property rights, we could be required to obtain a license from such third-party to continue developing, manufacturing, marketing and selling our tests. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us and could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease commercializing the infringing technology, products or product candidates. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent and could be forced to indemnify our customers or collaborators. A finding of infringement could also result in an injunction that forces us to cease some of our business operations, which could materially harm our business. In addition, we may be forced to redesign our tests, seek new regulatory approvals and indemnify third parties pursuant to

contractual agreements. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

We cannot predict whether, or offer any assurance that, any patent infringement claims we may initiate in the future will be successful. We may become subject to counterclaims by patent infringement defendants. Our patents may be declared invalid or unenforceable, or narrowed in scope.

Even if we prevail in an infringement action, we cannot assure you that we would be adequately compensated for the harm to our business. If we are unable to enjoin third-party infringement, our revenue may be adversely impacted and we may lose market share; and such third-party product may continue to exist in the market, but fail to meet our regulatory or safety standards, thereby causing irreparable harm to our reputation as a provider of quality products, which in turn could result in loss of market share and have a material adverse effect on our business, financial condition and our results of operations.

In addition, our agreements with some of our customers, suppliers and other entities with whom we do business require us to defend or indemnify these parties to the extent they become involved in patent infringement claims, including the types of claims described in this risk factor. We have agreed, and may in the future agree, to defend or indemnify third parties if we determine it to be in the best interests of our business relationships. If we are required or agree to defend or indemnify third parties in connection with any infringement claims, we could incur significant costs and expenses that could adversely affect our business, financial condition and results of operations.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions, or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

Changes in patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

Changes in either the patent laws or in interpretations of patent laws in the United States or other countries or regions may diminish the value of our intellectual property rights. We cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents. We may not develop additional proprietary products, services, methods and technologies that are patentable.

Under the Leahy-Smith America Invents Act, assuming that certain requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. Prior to March 16, 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. A third party that files a patent application in the USPTO on or after March 16, 2013, but before us, could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party, requiring us to be cognizant of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we were the first to either (i) file any patent application related to our products or (ii) invent any of the inventions claimed in our patents or patent applications.

The America Invents Act also affects the way patent applications are prosecuted and patent litigation. The Act allows third-party submission of prior art to the USPTO during patent prosecution or post-grant proceedings, including post-grant review, *inter partes* review and derivation proceedings, to attack the validity of a patent. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence might not be sufficient to invalidate the claim if presented in a district court action. Accordingly, third parties may attempt to use the USPTO proceedings to invalidate our patent claims that would not have been invalidated if first challenged by the third party in a district court action, which could increase the uncertainties and costs surrounding our prosecution of patent applications and enforcement or defense of issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Similarly, there is complexity and uncertainty related to European patent laws. In June 2023, a new unitary patent system was introduced, which will significantly impact European patents, including those granted before

the introduction of the system. Under the unitary patent system, after a European patent is granted, the patent proprietor can request unitary effect, thereby getting a European patent with unitary effect (a Unitary Patent). The Unitary Patent will make it possible for a patentee to obtain patent protection in numerous European Union member states in a single patent as an alternative to the current, more expensive system of selecting and paying for validation of a patent in each specific European Union state of interest. Each Unitary Patent is subject to the jurisdiction of the Unitary Patent Court (UPC). As the UPC is a new court system, there is limited precedent for the court, increasing the uncertainty of any litigation. It is not yet known if the UPC will be more or less favorable to patentees than the national courts for each individual European Union state that have historically heard patent litigations in that corresponding state. Patentees having patents granted before the implementation of the UPC will have the option of opting out of the jurisdiction of the UPC and having their patents remain as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC may be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries that are signatories to the UPC. We cannot predict with certainty the long-term effects of the new unitary patent system. Upon each grant of a European patent, we will have to make the decision as to whether to proceed with national patents or a Unitary Patent based. Since the unitary patent system is continuing to develop and we have limited information, we may make a choice that results in some patents being invalidated. In addition, the European Patent Office (the EPO) patent system is relatively stringent in the type of amendments that are allowed during prosecution. These limitations and requirements could adversely affect our ability to obtain new patents in the future that may be important for our business. The EPO also has an opposition procedure in which third parties, such as competitors, can file an opposition against one of our European patents for a period of nine months after grant of the patent. If the opposition is successful, it can result in invalidation of the patent, which could mean that the product covered by that patent is not protected in Europe.

The patent positions of companies engaged in the development and commercialization of molecular laboratory products are particularly uncertain. Court rulings may narrow the scope of patent protection available in certain circumstances and weaken the rights of patent owners in certain situations. We cannot predict how decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patents. Any similar adverse changes in the patent laws of other jurisdictions could also have a material adverse effect on our business, financial condition and results of operations. Depending on future actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future. Any of the foregoing could have a material adverse effect on our business, financial condition and results of operations.

In the United States, the current presidential administration has been making numerous changes that could have unforeseeable short- and long-term effects on intellectual property law and how the patent system operates. These changes may affect patentability of inventions, enforcement of patents, patent scope, patent validity, patent infringement issues and lawsuits, post-grant proceedings within the USPTO, among other areas. In addition, due to reductions in staff within the USPTO, particularly within the Patent Trial and Appeal Board (PTAB), certain processes may take longer or become unavailable to patentees. It may take longer for patents to grant because there are fewer patent examiners or fewer judges within the PTAB to handle patent appeals, which may hinder our ability to protect our products with patents. In addition, the USPTO may reduce or cut certain programs that benefit patentees if the USPTO is understaffed, which may also limit our ability to protect our products with patents. Additionally, patentees may have more limited access to post-grant proceedings at the PTAB within the USPTO since there are fewer judges within the PTAB. This may make it more difficult for us to challenge competitor patents in a cost-effective manner and may instead require us to bring a more costly and lengthy patent litigation to challenge competitor patents.

Issued patents covering our products, services or technology could be found invalid or unenforceable if challenged.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability. Some of our patent rights may be challenged at a future point in time in opposition, derivation, re-examination, *inter partes* review, post-grant review. Any successful third-party challenge to our patent rights in this or any other proceeding could result in the unenforceability or invalidity of such patent rights, which may lead to increased competition to our business. 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, develop, manufacture or commercialize our current or future products, services or technology.

We may not be aware of all third-party intellectual property rights potentially relating to our products 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 our inventions, we may participate in interference proceedings, derivation proceedings or other post-grant proceedings declared by the USPTO that could result in substantial cost to us. 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. If third parties bring actions against our patent rights, we could experience significant costs and management distraction.

In patent litigation in the United States or abroad, defendant counterclaims alleging invalidity or unenforceability of plaintiff's patents are common. 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 patent office or made a misleading statement during prosecution. Similar claims may also be raised before patent offices in the United States or abroad, even outside the context of litigation, through mechanisms including re-examination, post-grant review and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation or amendment to our patent rights in such a way that they no longer cover our products. The outcome of patent litigation or patent office proceedings following assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the relevant patent that protects our products, service or technology. Such a loss of patent protection could have a material adverse impact on our business.

We may in the future initiate or become involved in legal proceedings against a third party to enforce a patent covering one of our products or technology. Defendants in such proceedings could counterclaim that the patents covering our products or technology are invalid or unenforceable and could institute legal proceedings to challenge such patents both in court and before patent offices. Any assertion of invalidity and/or unenforceability against the patents covering our products or technology, even if not successful, could be time-consuming and expensive to defend, damage our reputation in the marketplace and the prospects for our business, and divert our management's attention.

We may be subject to claims challenging the inventorship or ownership of our intellectual property.

We may be subject to claims that former employees, independent contractors, collaborators or other third parties have an interest in or right to our owned or future licensed patents, trade secrets or other intellectual property. For example, we may have inventorship disputes arise from conflicting obligations of employees, independent contractors or others who are involved in developing such intellectual property. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership of our owned patents, trade secrets or other intellectual property. If we fail in defending against any such claims, we may lose exclusive ownership of, or right to use, valuable intellectual property. Even if we are successful in defending against such claims, litigation could result in damage to our reputation and substantial costs and be a distraction to management and other employees. 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 or that our employees have wrongfully used or disclosed trade secrets of their former employers.

We have employed or engaged and expect to employ or engage individuals who were previously employed at or associated with universities or other companies, including our competitors or potential competitors. Although we try to ensure that our employees and independent contractors do not use the proprietary information or know-how of others in their work for us, we have received claims in the past, and may be subject to claims in the future, that our employees or independent contractors have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers or other third parties, or to claims that we have improperly used or obtained such trade secrets. Litigation may be necessary to defend against these claims in the future. If we lose, in addition to paying monetary damages, we may be deprived of valuable

intellectual property and face increased competition. A loss of key personnel or work product could hamper or prevent our ability to develop, manufacture and/or commercialize products, services or technology, which could materially adversely affect our business. Even if we are successful in defending against these claims, litigation could result in damage to our reputation and substantial costs and be a distraction to management and affected individuals.

We may not be able to protect and enforce our trademarks and we could infringe others' trademarks.

We have not yet registered trademarks in all of our potential markets, although we have registered BillionToOne, UNITY Complete, NorthStar Select and NorthStar Response in the United States and certain foreign jurisdictions. If we apply to register additional trademarks in the United States and other countries, our applications may not be allowed for registration in a timely fashion or at all, and our registered trademarks may not be maintained or enforced. In addition, opposition or cancellation proceedings may be filed against our trademark applications and registrations, and our trademarks may not survive such proceedings. If we do not timely register and enforce marks used in connection with our products or technology, we may encounter difficulty in enforcing them against third parties, and if these marks are registered by others, we could infringe such trademarks and may have to defend ourselves to continue the use of our trademarks, which may be time consuming and costly, and we may be unsuccessful.

At times, competitors or other third parties may adopt trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trademark infringement or other violation claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks. Over the long term, if we are unable to establish name recognition based on our trademarks, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks may be ineffective and could result in substantial costs and diversion of resources. Any of the foregoing could have a material adverse effect on our business, financial condition and results of operations.

We may not be able to protect or enforce our intellectual property rights adequately throughout the world.

In addition to nine U.S. issued patents and 14 pending U.S. patent applications, we held 45 foreign patents and 32 foreign patent applications as of September 30, 2025. Filing, prosecuting and defending patents and other intellectual property rights covering our products, services and technology in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some territories outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries and regions do not protect intellectual property rights to the same extent as the laws of the United States, and we may encounter difficulties in protecting and defending such rights in foreign jurisdictions. Consequently, we may not be able to prevent third parties from practicing our inventions in all jurisdictions, or from selling, making or importing products, services or technology by practicing our intellectual property rights. Competitors may practice our intellectual property rights in jurisdictions where we have not obtained patent protection to develop, manufacture, sell or import their own products, services or technology and may also export products, services or technology that infringe upon our intellectual property rights to territories where we have patent protection that do not provide strong intellectual property or enforcement rights as strong as that in the United States. These products, services or technology may compete with our products, services or technology. Our patents or other intellectual property rights existing outside the United States may not be effective or sufficient to prevent third parties from competing with us. Similarly, intellectual property rights may be exhausted in certain situations, and others could import our products sold abroad and compete with us domestically.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of many other countries and regions do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biotechnology, which could make it difficult for us to stop the infringement of our patents and other intellectual property rights in such jurisdictions. Proceedings to enforce our patent rights and other intellectual property rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded to us, if any, may not be commercially meaningful. Accordingly, our efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage.

Failure to comply with the terms of underlying open source software licenses could require us to publicly disclose our proprietary software.

We use open source software to leverage established solutions when those solutions are not central to our unique products. Use and distribution of open source software may entail greater risks than use of third-party commercial software, as open source software licensors generally do not provide warranties or other contractual protections regarding infringement or other violation claims or the quality of the code. Some open source software licenses contain requirements that the licensee make its source code publicly available if the licensee creates modifications or derivative works using the open source software or provide software services at no cost to the user, depending on the type of open source software the licensee uses and how the licensee uses it. If we combine our proprietary software with open source software in a certain manner, we could, under certain open source software licenses, be required to release the source code of our proprietary software to the public for free. This would allow our competitors to create similar products with less development effort and time and ultimately could result in a loss of product sales and revenue. In addition, some companies that use third-party open source software have faced claims challenging their use of such open source software, seeking enforcement of open source license provisions, asserting ownership of open source software incorporated in products and demanding compliance with the terms of the applicable open source license. We may be subject to suits by third parties claiming ownership of what we believe to be open source software, or claiming non-compliance with the applicable open source licensing terms. Use of open source software may also present additional security risks because the public availability of such software may make it easier for hackers and other third parties to compromise or attempt to compromise our systems. If an author or other third party that distributes such open source software were to allege that we had not complied with the conditions of an open source license, we could incur significant legal costs defending ourselves against such allegations. In the event such claims were successful, we could be subject to significant damages or be enjoined from the distribution of our products.

There is little legal precedent and the terms of many open source software licenses have not been interpreted by United States courts, and there is a risk that these licenses could be construed in a way that could impose unanticipated conditions or restrictions on our ability to commercialize our products. Although we have reviewed our use of open source software, we cannot assure investors that our processes for monitoring and controlling our use of open source software in our products will be effective. If we are held to have breached the terms of an open source software license, we could be required to seek licenses from third parties to continue offering our products on terms that are not economically feasible, to re-engineer our product, to discontinue the sale of our products if re-engineering could not be accomplished on a timely basis, or to make generally available, in source code form, our proprietary code, any of which could adversely affect our business, financial condition and results of operations.

Obtaining and maintaining our patent protection depends on compliance with various required procedures, document submissions, fee payments and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States at several stages over the lifetime of the patents and/or applications. We have systems in place to remind us to pay these fees, and we rely on our outside counsel and a third-party service provider to pay these fees due to patent agencies. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar requirements during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance can result in abandonment or forfeiture of the patent or patent application and thus loss of patent rights in the relevant jurisdiction. Such an event would allow our competitors to enter the unprotected market and have a material adverse effect on our business.

Patent terms may be inadequate to protect our competitive position for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our products are obtained, once the patent life has expired, we may be open to competition. Given the amount of time required for the development, testing and regulatory review of our new products or technologies, patents protecting them might expire before or shortly after they are commercialized. As a result, our patent portfolio

may not provide us with a sufficient exclusivity period to exclude others from commercializing products similar or identical to ours.

Further, recent judicial decisions in the U.S. raised questions regarding the award of patent term adjustment (PTA) for patents in families where related patents have issued without PTA. Thus, it cannot be said with certainty how PTA will be viewed in the future and whether patent expiration dates may be impacted.

Risks related to legal and regulatory matters

Our tests are currently marketed as LDTs, and future changes in FDA enforcement of LDTs could subject our operations to much more significant regulatory requirements.

We currently offer a number of genetic tests, each of which is a laboratory developed test (LDT). Our laboratories are currently regulated under Clinical Laboratory Improvement Amendments of 1988 (CLIA) and we have elected to comply with the higher standards and requirements established by the College of American Pathologists (CAP), a CMS-approved accreditation organization, and we are subject to extensive federal and certain state laws and regulations. The Food and Drug Administration (FDA) considers an LDT to be a test that is designed, developed, validated and used within a single laboratory. The FDA had historically taken the position that it had the authority to regulate LDTs as medical devices under the Federal Food, Drug, and Cosmetic Act (FD&C Act) but exercised enforcement discretion until it recently rescinded LDT regulations indicating that it does not have the authority to require clearance, de novo classification, or approval of LDTs prior to market release.

If FDA premarket clearance, approval or de novo classification is required, in the future, for any of our existing or future tests, or for any components or materials we use in tests, and we are not able to obtain such clearance, approval or de novo classification, we may be forced to stop selling our tests or we may be required to modify claims for or make other changes to our tests while we or our suppliers work to obtain FDA clearance, approval or de novo classification. The need for compliance with such FDA regulations would be time-consuming and expensive, potentially diverting resources from other aspects of our business, and we could be subject to legal actions, including fines and penalties, if we fail to comply with these requirements, any of which may adversely impact our business and results of operations. Our business could be adversely affected while such review is ongoing, and if we or our supplier are ultimately unable to obtain premarket clearance, approval or de novo classification. In addition, we may require cooperation in our filings for FDA clearance, approval or de novo classification from third-party manufacturers of the components of our tests. If we are unable to obtain such required cooperation, we may be unable to achieve the desired regulatory clearances, approvals or de novo classifications or may be delayed or be required to expend additional costs and other resources in doing so. Moreover, if FDA premarket clearance, approval or de novo classification is required, our revenue or cash flows may be adversely affected until we obtain such clearance, approval or de novo classification, as most third-party payors, including Medicaid, will not reimburse for use of medical devices which are required to, but which do not, have marketing authorization.

Furthermore, the FDA or the Federal Trade Commission (FTC), as well as state consumer protection agencies, may object to the materials and methods we use to promote the use of our current tests or other LDTs we may develop in the future, and may initiate enforcement actions against us. Enforcement actions by the FDA may include, among others, untitled or warning letters; fines; injunctions; civil or criminal penalties; recall or seizure of current or future tests, products or services; operating restrictions and partial suspension or total shutdown of production. Enforcement actions by the FTC and state consumer protection agencies may include, among others, injunctions, civil penalties and equitable monetary relief, any of which may adversely impact our business, financial position and results of operations.

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 sequencers, 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 labeled as for research use only (RUO). Products utilized in our tests that are intended for research use only and are labeled as RUO are exempt from compliance with FDA requirements, including the approval, clearance or de novo classification and other product quality requirements for medical devices. A product labeled RUO but which is actually intended by the manufacturer for molecular diagnostic use may be viewed by the FDA as adulterated and misbranded under the FDC Act and subject to FDA enforcement action. The FDA has issued guidance stating that when determining the intended use of a product labeled RUO, it will consider the totality of the circumstances surrounding

distribution of the product, including how the product is marketed and to whom. In addition, many of the reagents used to perform our testing are offered for sale as analyte specific reagents (ASRs). ASRs are medical devices and must comply with QSR provisions and other device requirements, but most are exempt from premarket review. The FDA could disagree with a manufacturer's assessment that the manufacturer's products are ASRs, or could conclude that products labeled as RUO are actually intended by the manufacturer for molecular diagnostic use, and could take enforcement action against the manufacturer, including requiring the manufacturer to cease offering the product while it seeks clearance, approval or de novo classification. Manufacturers of 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.

The sequencers and reagents used in processing our tests are generally labeled as RUO in the United States. We are using these sequencers and reagents for molecular diagnostic use. If the FDA were to require clearance, approval or de novo classification for the sale of these sequencers or reagents and if the applicable manufacturer does not obtain such clearance, approval or authorization, we would have to find an alternative sequencing platform. If we were not successful in selecting, acquiring on commercially reasonable terms and implementing an alternative platform on a timely basis, our business, financial condition and results of operations would be adversely affected.

We and the third parties with whom we work are subject to stringent and evolving U.S. and foreign laws, regulations, and rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security, and our actual or perceived failure to comply with those laws and regulations or to adequately secure the information in our possession could result in significant liability or reputational harm.

We are subject to numerous state, federal and foreign laws, requirements and regulations governing the collection, use, disclosure, retention and security of personal information. We collect, process, maintain, retain, evaluate, utilize and distribute large amounts of personal health and financial information and other confidential and sensitive data about customers, patients and others in the ordinary course of our business. Concerns about and claims challenging our practices with regard to the collection, use, retention, disclosure or security of personally identifiable information or other privacy-related matters, even if unfounded, could damage our reputation and harm our business.

As we seek to expand our business, we are, and will increasingly become, subject to various laws, regulations and standards, as well as contractual obligations, relating to the collection, use, retention, security, disclosure, transfer and other processing of sensitive and personal information in the jurisdictions in which we operate. In many cases, these laws, regulations and standards apply not only to third-party transactions, but also to transfers of information between or among us and other parties with which we have commercial relationships. These laws, regulations and standards are interpreted and applied differently over time and from jurisdiction to jurisdiction, and it is possible that they will be interpreted and applied in ways that will materially and adversely affect our business, financial condition and results of operations. The regulatory framework for data privacy, data security and data transfers worldwide is rapidly evolving and, as a result, interpretation and implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future.

Numerous federal, state and foreign laws and regulations govern collection, dissemination, use and confidentiality of PHI, including: the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and regulations promulgated thereunder (collectively, HIPAA); state privacy and confidentiality laws (including state laws requiring disclosure of breaches); federal and state consumer protection and employment laws; and European and other foreign data protection laws. In addition to government regulation, privacy advocates and industry groups have and may in the future propose self-regulatory standards, which may legally or contractually apply to us or which we may elect to comply with such standards. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards or perception of their requirements may have on our business. This evolution often creates uncertainty in our business, affect our ability to operate in certain jurisdictions, 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 laws or regulation, our internal policies and procedures or our contracts governing processing 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.

We are a covered entity under HIPAA, and therefore, must comply with its requirements to protect the privacy and security of PHI and must provide individuals with certain rights with respect to their PHI. We currently, and will in the future, engage business associates to help us carry out healthcare activities and functions. For each such business associate, we must have a written business associate contract or other arrangement with the business associate that requires the business associate to comply with the same standards and safeguards and other requirements under HIPAA. We cannot guarantee that our security safeguards or those of our business associates will not fail or that they will not be deemed inadequate in the future. Determining whether PHI has been handled in compliance with applicable privacy standards and our contractual obligations can be complex and we cannot be sure how these regulations will be interpreted, enforced or applied to our operations.

Entities that are found to be in violation of HIPAA as the result of a breach of unsecured PHI, a complaint about privacy practices or an audit by the U.S. Department of Health and Human Services (HHS) can be subject to significant civil, criminal and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance. While HIPAA does not create a private right of action allowing individuals to sue us in civil court for violations of HIPAA, its standards have been used as the basis for duty of care in state civil suits such as those for negligence or recklessness in the misuse or breach of PHI. A person who knowingly obtains or discloses individually identifiable health information in violation of HIPAA may face additional fines and up to one-year imprisonment. In addition, our responding to government investigations regarding alleged violations of these and other laws and regulations, even if ultimately successful, can consume company resources, impact our business and, if public, harm our reputation.

Further, various states have implemented similar privacy laws and regulations, such as the California Confidentiality of Medical Information Act, that impose restrictive requirements regulating the use and disclosure of health information and other personally identifiable information. In addition, certain state laws may require us under certain circumstances to provide information, upon request, regarding the manner in which we share certain categories of personal information with third parties for marketing or other purposes (e.g. California Shine the Light law). These laws and regulations are not necessarily preempted by HIPAA, and where state laws are more protective, we may have to comply with the stricter provisions. These state data privacy laws are not consistent, and compliance in the event of a widespread data breach is costly. In addition to fines and penalties potentially imposed upon violators, some of these state laws also afford private rights of action to individuals who believe their personal information has been misused. Furthermore, the FTC, and certain state Attorneys General can enforce federal or state consumer protection laws against companies for online collection, use, dissemination and security practices that appear to be unfair or deceptive. The interplay of federal and state laws may be subject to varying interpretations by courts and government agencies.

Our employees and personnel use generative artificial intelligence (AI) and machine learning (ML) technologies (collectively, AI/ML) to perform their work, and the disclosure and use of personal data in AI/ML is subject to various privacy laws and other privacy obligations. We use AI/ML for a variety of internal processes, including to draft sales emails, conduct product research, automate reimbursement processing, and draft code. While we supplement our usage of AI with quality checks and review processes, AI models can produce inaccurate, biased, or incomplete outputs that may affect decision-making or generate erroneous results in critical workflows. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and lawsuits. If we are unable to use AI/ML, it could make our business less efficient and result in competitive disadvantages.

We use AI/ML to assist us in making certain decisions, which is regulated by certain privacy laws. Specifically, we use AI to accelerate the reading of data on test requisition forms that arrive with our tests to our labs during sample accessioning. Based on that data read, the samples are assigned a distinct testing workflow. We manually validate the AI data read after accessioning to confirm the appropriate procedure is followed; however, this validation is subject to human error. Inaccuracies or flaws in the inputs, outputs, or logic of the AI/ML often lead to bias in the models and could lead us to make decisions that adversely impact the rights, employment, and ability of individuals or classes of individuals to obtain certain pricing, products, services, or benefits. We also use AI, including AI/ML in our products and services. The development and use of AI/ML present various privacy and security risks that may impact our business. AI/ML are subject to privacy and data security laws, as well as increasing regulation and scrutiny. While we have implemented robust controls, validations, and human oversight to mitigate the risks of the aforementioned biases and inaccuracies, these measures may not be found sufficient by current or future privacy and data security laws.

Several jurisdictions around the globe, including Europe and certain U.S. states, have proposed enacted, or are considering laws governing the development and use of AI/ML, such as the EU's AI Act. We expect other

jurisdictions will adopt similar laws. Additionally, certain privacy laws extend rights to consumers (such as the right to delete certain personal data) and regulate automated decision making, which may be incompatible with our use of AI/ML. These obligations may make it harder for us to conduct our business using AI/ML, lead to regulatory fines or penalties, require us to change our business practices, retrain our AI/ML, or prevent or limit our use of AI/ML. For example, the FTC has required other companies to turn over (or disgorge) valuable insights or trainings generated through the use of AI/ML where they allege the company has violated privacy and consumer protection laws. If we cannot use AI/ML or that use is restricted, our business may be less efficient, or we may be at a competitive disadvantage.

In addition, the interpretation and application of consumer, health-related and data protection laws, especially with respect to genetic samples and data, in the United States, European Economic Area (EEA) and elsewhere are often uncertain, contradictory and in flux. The General Data Protection Regulation (GDPR) and other privacy laws and regulations related to the use, transfer, and protection of data impose obligations to the extent we test EU citizens or expand internationally. While we believe that our current processes and practices comply with the GDPR, we may need to expend considerable time and resources, including management attention, to revise our practices to ensure ongoing compliance with GDPR.

Some of the above privacy laws and regulations in many cases may be more restrictive than, and may not be preempted by, HIPAA and its implementing rules. In addition, some countries have stricter consumer notice and/or consent requirements relating to personal data collection, use or sharing, more stringent requirements relating to organizations' privacy programs and provide stronger individual rights. Failure to comply with GDPR and other applicable privacy or data security-related laws, rules or regulations in the EEA and elsewhere could have an adverse effect on our business, financial condition and results of operations.

We expect that there will continue to be new proposed laws and regulations in the U.S. and internationally concerning data privacy and security, and we cannot yet determine the impact such future laws, regulations and standards may have on our business. Because the interpretation and application of laws, regulations, standards and other obligations relating to data privacy and security are still uncertain, these laws, regulations, standards and other obligations could be interpreted and applied in a manner that is inconsistent with our data processing practices and policies or the features of our products. In such cases, changes or modifications to our data processing practices and policies to comply with such interpretations in a commercially reasonable manner would be difficult.

We will make public statements about our use and disclosure of personal information through our privacy policy, information provided on our internet platform and press statements. Although we endeavor to comply with our public statements and documentation, we may at times fail to do so or be alleged to have failed to do so. The publication of our privacy policy and other statements that provide promises and assurances about data privacy and security can subject us to potential government or legal action if they are found to be deceptive, unfair or misrepresentative of our actual practices. Any failure, real or perceived, by us to comply with our posted privacy policy or with any legal or regulatory requirements, standards, certifications or orders or other privacy or consumer protection-related laws and regulations applicable to us could cause our customers to reduce their use of our products and could materially and adversely affect our business, financial condition and results of operations. In many jurisdictions, enforcement actions and consequences for non-compliance can be significant and are rising. In addition, from time to time, concerns may be expressed about whether our products or processes compromise the privacy of customers and others. Concerns about our practices with regard to the collection, use, retention, security, disclosure, transfer and other processing of personal information or other privacy-related matters, even if unfounded, could damage our reputation and materially and adversely affect our business, financial condition and results of operations.

We conduct business in a heavily regulated industry, and changes in regulations or violations of regulations may, directly or indirectly, reduce our revenue, adversely affect our results of operations and financial condition, and harm our business.

The molecular diagnostics industry is highly regulated, and there can be no assurance that the regulatory environment in which we operate will not change significantly and adversely to us in the future. Areas of the regulatory environment that may affect our ability to conduct business include, without limitation:

- federal, state and foreign laws applicable to test ordering, documentation of tests ordered, billing practices and claims payment and/or regulatory agencies enforcing those laws and regulations;
- federal, state and foreign health care fraud and abuse laws;
- federal, state and foreign laboratory anti-mark-up laws;

- coverage and reimbursement levels by Medicare, Medicaid, other governmental payors and private insurers;
- restrictions on coverage of and reimbursement for tests;
- federal, state and foreign laws governing laboratory testing, including CLIA, and state licensing laws;
- federal, state and foreign laws and enforcement policies governing the development, use and distribution of diagnostic medical devices;
- laws and regulations governing the marketing of molecular diagnostic tests, including by the FDA pursuant to the medical device provisions of the Federal Food, Drug and Cosmetic Act or FDCA;
- FDA regulation, via the FDCA and its implementing regulations, of the research, design, testing, manufacturing, safety, labeling, storage, recordkeeping, premarket clearance or approval, marketing and promotion and sales and distribution of medical devices in the United States;
- FDA regulation of the import and export of medical devices;
- federal and state laws and enforcement policies governing the use of AI in analyzing data, including data in healthcare-related areas;
- federal, state, local and foreign laws governing the handling and disposal of medical and hazardous waste;
- federal and state Occupational Safety and Health Administration rules and regulations;
- HIPAA, GDPR, CCPA, CPRA and similar state or foreign data privacy and security laws; and
- consumer protection laws.

Changes in the current regulatory framework for algorithmic diagnostic products and services can impose additional regulatory burdens on us. The FDA is currently considering the development of novel regulatory pathways for AI technologies and other software. As the regulatory framework evolves, we may incur substantial costs to ensure compliance with new or amended laws and regulations. Failure to comply with any of these laws and regulations could result in enforcement actions against us or damage to our reputation, any of which could have a material adverse effect on our business, financial condition and results of operations.

Our business could be harmed by the loss, suspension or other restriction on a license, certification, or accreditation, or by the imposition of a fine or penalties, under CLIA, its implementing regulations, or other state, federal and foreign laws and regulations affecting licensure or certification, or by future changes in these laws or regulations.

The laboratory testing industry is subject to extensive laws and regulations, many of which have not been interpreted by the courts. CLIA requires virtually all laboratories to be certified by the federal government and mandates compliance with various operational, personnel, facilities administration, quality and proficiency testing requirements intended to ensure that testing services are accurate, reliable and timely. CLIA certification is also a prerequisite to be eligible to bill state and federal health care programs, as well as many commercial third-party payors, for laboratory testing services. In addition to the CLIA certification, our laboratory is CAP-accredited, which is a voluntary program that many molecular diagnostic labs participate in. CAP is a deemed agency by the CMS for the CLIA program. As a condition of CLIA certification, our laboratory is subject to survey and inspection every two years conducted by CAP, in addition to being subject to additional CMS follow up or complaint inspections. Sanctions for failure to comply with CLIA regulations, including proficiency testing violations, may include suspension, revocation, or limitation of a laboratory's CLIA certificate (and exclude persons or entities from owning, operating or directing a laboratory for two years following such revocation), which is necessary to conduct business, as well as the imposition of significant fines or criminal penalties. In addition, we are subject to regulation under certain state laws and regulations governing laboratory licensure (including California, New York, Maryland, Pennsylvania, Rhode Island and the District of Columbia), some of which have enacted laboratory standards that are more stringent than CLIA. Some states require that we hold licenses or permits to test samples from patients in those states, even if our laboratory facilities are not located in those states, and as a result we are also required to maintain standards related to those states' licensure requirements to conduct testing in our laboratory.

If we are found to be out of compliance with state requirements, the applicable state regulator may suspend, restrict or revoke our license or laboratory permit (and, with respect to California, may exclude persons or entities from owning, operating or directing a laboratory for two years following such license revocation), assess civil monetary penalties, or impose specific corrective action plans, among other sanctions. We cannot assure you that the regulators in any state from which we have obtained a required license or permit will find us to be in compliance with the applicable laws of their respective state at all times, which may result in suspension, limitation, revocation or annulment of our laboratory's license for that state or negative impact to our CLIA certificate, censure or civil monetary penalties, and would result in our inability to test samples from patients in that state. Any such consequences could materially and adversely affect our business by prohibiting or limiting our ability to offer testing.

Any sanction imposed under CLIA, its implementing regulations, or state or foreign laws or regulations governing licensure, or our failure to renew a CLIA certificate, a state or foreign license or accreditation, could have a material adverse effect on our business. If the CLIA certificate of any one of our laboratories is revoked, CMS could seek revocation of the CLIA certificates of our other laboratories based on their common ownership or operation, even though they are separately certified. Changes in state or foreign licensure laws that affect our ability to offer and provide molecular diagnostic services across state or foreign country lines could materially and adversely affect our business. In addition, state and foreign requirements for laboratory certification may be costly or difficult to meet and could affect our ability to receive specimens from certain states or foreign countries.

Companion and complementary diagnostic tests require FDA approval, and we may not be able to secure such approval in a timely manner or at all.

We have entered into a global partnership with Johnson & Johnson to provide our UNITY Fetal Antigen CTA (Clinical Trial Assay) in their AZALEA Phase 3 clinical trial of nivalimab in pregnancies at risk for severe hemolytic disease of fetus and newborn (HDFN), and a related U.S.-specific partnership regarding development of a companion diagnostic product. We may enter into additional partnerships with other pharmaceutical companies. Our companion and complementary diagnostic products, marketing, sales and development activities and manufacturing processes are subject to extensive and rigorous regulation by the FDA pursuant to the federal FDCA, by comparable agencies in foreign countries, and by other regulatory agencies and governing bodies. Under the FDCA, companion diagnostics must receive FDA clearance or approval before they can be commercially marketed in the United States. The process of obtaining marketing approval or clearance from the FDA or by comparable agencies in foreign countries for new products could:

- take a significant period of time;
- require the expenditure of substantial resources;
- involve rigorous pre-clinical testing, as well as increased post-market surveillance;
- require changes to products; and
- result in limitations on the indicated uses of products.

We cannot predict whether or when we will be able to obtain FDA approval for companion diagnostics that we may develop.

Changes in healthcare laws, regulations and policies could increase our costs, decrease our sales and revenue and negatively impact reimbursement for our tests.

There have been in the past, and we anticipate there will continue to be in the future, proposals by legislators at both the federal and state levels and in foreign jurisdictions, regulators and commercial and government payors to reduce healthcare costs while expanding individual healthcare benefits. Certain of these changes could impose additional limitations on the prices we will be able to charge for our tests, the coverage of or the amounts of reimbursement available for our tests from commercial and government payors. For example, the Patient Protection and Affordable Care Act (ACA), adopted in 2010, substantially changed the way healthcare is financed by both commercial third-party payors and government payors, and significantly impacted our industry, required disclosures of financial arrangements with physician customers, required reporting of discovered overpayments, lower thresholds for violations, new government investigative powers, and enhanced penalties for such violations. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, reduced Medicare payments to providers, effective on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2032, unless additional Congressional action is taken.

Government healthcare policy has been and will likely continue to be a topic of extensive legislative and executive activity in the U.S. federal government, particularly given the recent change in administrations, and many U.S. state governments. The current presidential administration is pursuing policies to reduce regulations and expenditures across government including at HHS, the FDA, CMS and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, propose policy changes that create additional uncertainty for our business. These actions, for example, include directives to reduce agency workforce, program cuts, eliminating the Biden administration's executive order that directed HHS to establish an AI task force and developing a strategic plan, and directing certain federal agencies to enforce existing law regarding hospital and plan price transparency and by standardizing prices across hospitals and health plans. Additionally, in its June 2024 decision in *Loper Bright Enterprises v. Raimondo*, or *Loper Bright*, the U.S. Supreme Court overturned the longstanding *Chevron* doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The

Loper Bright decision could result in additional legal challenges to current regulations and guidance issued by federal agencies applicable to our operations, including those issued by the FDA. We cannot predict whether future healthcare 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. healthcare industry, changes to the reimbursement amounts paid by third-party payors for our current and future tests, or limited or inadequate funding for regulatory authorities, may adversely affect our test volumes and adversely affect our business, financial condition, results of operations and cash flows.

We are subject to numerous federal and state healthcare statutes and regulations; complying with such laws pertaining to our business is an expensive and time-consuming process, and any failure to comply could result in substantial penalties and a material adverse effect to our business and results of operations.

Our operations are subject to other extensive federal, state, local and foreign laws and regulations, all of which are subject to change. These laws and regulations may include, among others:

- the federal Anti-Kickback Statute (AKS), which prohibits knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, overtly or covertly, in cash or in kind (e.g. provision of free or discounted goods, services or items), in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal health care programs, such as Medicare, unless a safe harbor applies;
- the federal Eliminating Kickbacks in Recovery Act (EKRA), which prohibits knowingly and willfully soliciting or receiving any remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind, in return for referring a patient or patronage to a laboratory; or paying or offering any remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind, to induce a referral of an individual to a laboratory or in exchange for an individual using the services of that laboratory billed to either commercial third-party payors or government payors;
- the Stark Law and similar state laws, which prohibits a physician from making a referral for certain designated health services covered by the Medicare or Medicaid program, including laboratory and pathology services, if the physician or an immediate family member of the physician has a financial relationship with the entity providing the designated health services and prohibits that entity from billing, presenting or causing to be presented a claim for the designated health services furnished pursuant to the prohibited referral, unless an exception applies;
- the federal Civil Monetary Penalties Law, which prohibits, among other things, the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary 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 healthcare program, unless an exception applies;
- federal and state "Anti-Markup" rules, which, among other things, typically prohibit a physician or supplier billing for molecular diagnostic tests (with certain exceptions) from marking up the price of a purchased test performed by another physician or supplier that does not "share a practice" with the billing physician or supplier;
- the federal government may bring a lawsuit under the False Claims Act (FCA), against any party whom it believes has knowingly or recklessly presented, or caused to be presented, a false or fraudulent request for payment from the federal government, or who has made a false statement or used a false record to get a claim for payment approved. The federal government and a number of courts have taken the position that claims presented in violation of certain other statutes, including the AKS or the Stark Law, can also be considered a violation of the FCA based on the theory that a provider impliedly certifies compliance with all applicable laws, regulations, and other rules when submitting claims for reimbursement;
- the HIPAA fraud and abuse provisions, which created federal criminal statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private insurers, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services;
- federal and state laws related to, among other things, unlawful schemes to defraud, excessive fees for services, unlawful trade practices, insurance fraud, kickbacks, patient inducement and statutory or

common law fraud restrict the provision of products, services or items for free or at reduced charge to government or non-government healthcare program beneficiaries;

- other federal and state fraud and abuse laws, such as state anti-kickback, self-referrals, false claims and anti-markup laws, any of which may extend to services reimbursable by any payor, including private insurers; and
- state laws that prohibit other specified practices, such as: billing physicians for tests that they order; providing tests at no or discounted cost to induce adoption; waiving co-insurance, co-payments, deductibles or other amounts owed by patients; billing a state healthcare program at a price that is higher than what is charged to other payors; or employing, exercising control over or splitting fees with licensed medical professionals.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. Any action brought against us for violation of these laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

Numerous states have enacted laws prohibiting business corporations, such as us, from practicing medicine and from employing or engaging physicians and other medical professionals (generally referred to as the prohibition against the corporate practice of medicine), which could include physician laboratory directors and employees. These laws are designed to prevent interference in the medical decision-making process by anyone who is not a licensed medical professional. For example, California's Medical Board has indicated that determining the appropriate diagnostic tests for a particular condition and taking responsibility for the ultimate overall care of a patient, including making treatment options available to the patient, would constitute the unlicensed practice of medicine if performed by an unlicensed person. Violation of these laws may result in sanctions and civil or criminal penalties. It is possible that governmental authorities may conclude that our business practices, including our consulting and advisory board arrangements with physicians and other healthcare providers, do not comply with current or future corporate practice of medicine or healthcare fraud and abuse statutes, regulations, agency guidance or case law.

The growth of our business, including any international expansion, may increase the potential of violating applicable laws and regulations. Efforts to ensure that our internal operations and business arrangements with third parties comply with applicable laws and regulations will involve substantial costs. Any action brought against us for violation of these or other laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. To the extent our business operations are found to be in violation of any of these laws or regulations, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, monetary fines, individual imprisonment, disgorgement of profits, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting or oversight obligations if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with the law and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and pursue our strategy. If any of the healthcare providers or other parties with whom we interact or may interact in the future, are found not to be in compliance with applicable laws and regulations, they may be subject to criminal, civil or administrative sanctions, including exclusions from participation in various healthcare programs, which could also negatively affect our business or revenue. Additionally, we could be required to refund payments received by us, and we could be required to curtail or cease our operations. Any of the foregoing consequences could seriously harm our business, financial condition, and results of operations. In addition, if any of the physicians or other providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to significant civil, criminal and administrative sanctions, including exclusion from government funded healthcare programs.

We are subject to the U.S. Foreign Corrupt Practices Act and other anti-corruption laws, as well as export control laws, import and customs laws, trade and economic sanctions laws and other laws governing our operations.

Our operations are subject to anti-corruption laws, including the U.S. Foreign Corrupt Practices Act of 1977, as amended (FCPA), the U.S. domestic bribery statute contained in 18 U.S.C. §201, the U.S. Travel Act, and other anti-corruption laws that apply in countries where we do business, collectively referred to as Anti-Bribery/Anti-Corruption laws. The FCPA and these other laws generally prohibit us and our employees and intermediaries from authorizing, promising, offering, or providing, directly or indirectly, improper or prohibited payments, or anything else of value, to government officials or other persons to obtain or retain business or gain some other

business advantage. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted. We are also subject to other laws and regulations governing our international operations, including applicable export control regulations, economic sanctions and embargoes on certain countries and persons, anti-money laundering laws, import and customs requirements and currency exchange regulations, collectively referred to as the Trade Control laws.

While we have adopted policies and practices to meet the requirements of these laws and regulations, there is no assurance that we will be completely effective in ensuring our compliance with all applicable Anti-Bribery/Anti-Corruption laws and Trade Control laws. If we are not in compliance with such laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations and liquidity. Likewise, any investigation of any potential violations of such laws by the United States or other international authorities could also have an adverse impact on our reputation, our business, results of operations and financial condition.

If the validity of an informed consent from a patient intake for any of our tests is challenged, we could be precluded from billing for such testing, forced to stop performing such tests or required to repay amounts previously received, which would adversely affect our business and financial results.

All clinical data and blood samples that we receive for genetic testing are required to have been collected from individuals who have provided appropriate informed consent for us to perform our testing, both commercially and in clinical trials. The collection of data and samples in many different U.S. states results in complex legal questions regarding the adequacy of informed consent and the status of genetic material under different legal systems. The individual's informed consent obtained could be challenged in the future in any particular jurisdiction, and those informed consents could be deemed invalid, unlawful or otherwise inadequate for our purposes. Any findings against us could deny us access to, or force us to stop testing samples in, a particular jurisdiction or could call into question the results of our tests. We could also be precluded from billing third-party payors for tests for which informed consents are challenged, or could be requested to refund amounts previously paid by third-party payors for such tests. We could become involved in legal challenges, which could require significant management and financial resources and adversely affect our revenue and results of operations.

A correction or removal of our products, either voluntarily or at the direction of the FDA or another governmental authority, or the discovery of serious safety issues with our products, could have a significant adverse impact on us.

The FDA has the authority to require the recall of commercialized products that are subject to FDA regulation in the event of material deficiencies or defects in design or manufacture. The authority to require a recall must be based on an FDA finding that there is reasonable probability that the device would cause serious, adverse health consequences or death. The collection kits that are supplied to us by a third party could be subject to a recall. Additionally, our tests may be subject to other types of field actions or corrections, which could impair our ability to produce our products in a cost-effective and timely manner and have an adverse effect on our reputation, results of operations and financial condition. Additionally, we may be subject to liability claims, may be required to bear costs or may take other actions that may have a negative impact on our financial position.

If we initiate a correction or removal for one of our tests, issue a safety alert or undertake a field action or recall to reduce a risk to health imposed by the test, this could lead to increased scrutiny by the FDA and our customers regarding the quality and safety of our tests and to negative publicity, including FDA alerts, press releases or administrative or judicial actions. Furthermore, circulation of any such negative publicity could harm our reputation, be used by competitors against us in competitive situations and cause customers to delay purchase decisions or cancel orders.

Our use of hazardous materials in the development of our tests exposes us to risks related to accidental contamination or injury and requires us to comply with regulations governing hazardous waste materials.

Our operations involve the controlled use of hazardous materials and chemicals. We cannot eliminate the risk of accidental contamination or injury to employees or third parties from the use, storage, handling or disposal of these materials. In the event of contamination or injury, we could be held liable for any resulting damages, and any liability could exceed our resources or any applicable insurance coverage we may have. In addition, we are subject on an ongoing basis to federal, state and local regulations governing the use, storage, handling and

disposal of these materials and specified hazardous waste materials. We could discover that we or our suppliers are not in material compliance with these regulations. Existing laws and regulations may also be revised or reinterpreted, or new laws and regulations may become applicable to us, whether retroactively or prospectively, that may have a negative effect on our business, financial condition and results of operations. An increase in the costs of compliance with such laws and regulations could harm our business and results of operations.

Even if we receive regulatory approval or certification of our products, we will continue to be subject to extensive regulatory oversight.

Medical devices are subject to extensive regulation by the FDA. The FDA had historically taken the position that it had the authority to regulate LDTs as medical devices under the FD&C Act but exercised enforcement discretion until it recently rescinded LDT regulations indicating that it does not have the authority to require clearance, de novo classification, or approval of LDTs prior to market release. However, if any of our molecular diagnostic products become subject to FDA approval requirements, and are subsequently approved by the FDA, we will be required to timely file various reports. If these reports are not filed timely, regulators may impose sanctions and sales of our products may suffer, and we may be subject to product liability or regulatory enforcement actions, all of which could harm our business. In addition, as a condition of approving a PMA, the FDA may also require some form of post-approval study or post-market surveillance, whereby the applicant conducts a follow-up study or follows certain patient groups for a number of years and makes periodic reports to the FDA on the clinical status of those patients when necessary to protect the public health or to provide additional safety and effectiveness data for the device. The product labeling must be updated and submitted in a PMA supplement as results, including any adverse event data from the post-approval study, become available. Failure to conduct or timely complete post-approval studies in compliance with applicable regulations, update the product labeling, or comply with other post-approval requirements could result in withdrawal of approval of the PMA, which would harm our business and revenue.

The FDA and FTC also regulate the advertising and promotion of medical devices to ensure that their promotional claims made are consistent with the applicable marketing authorizations, that there are adequate and reasonable data to substantiate the claims, and that the promotional labeling and advertising is neither false nor misleading in any respect. If the FDA or FTC determines that any of our promotional claims are false, misleading, not substantiated or not permissible, we may be subject to enforcement actions and we may be required to revise our promotional claims and make other corrections or restitutions. Similar requirements apply in foreign jurisdictions.

The FDA, state and foreign authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA, state or foreign regulatory agencies, which may include any of the following sanctions:

- adverse publicity, warning letters, untitled letters, fines, injunctions, consent decrees and civil penalties;
- repair, replacement, refunds, recalls, termination of distribution, administrative detention or seizures of our products;
- operating restrictions, partial suspension or total shutdown of production;
- customer notifications or repair, replacement or refunds;
- refusing our requests for clearances or approvals of new products, new intended uses or modifications to existing products;
- withdrawals of current clearances, approvals or certifications, resulting in prohibitions on sales of our products;
- refusal to issue certificates needed to export products for sale in other countries; and
- criminal prosecution.

Any of these sanctions could also result in higher than anticipated costs or lower than anticipated sales of our products and have a material adverse effect on our reputation, business, results of operations and financial condition. In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions which may prevent or delay approval or clearance of our current or future products under development. For example, on February 23, 2022, the FDA issued a proposed rule to amend the Quality System Regulation (QSR), which establishes current good manufacturing practice requirements for medical device manufacturers, to align more closely with the International Organization for Standardization (ISO) standards. This proposal has not yet been finalized or adopted. Accordingly, it is unclear the extent to which any proposals, if adopted, could impose increased costs of compliance, or otherwise negatively affect our business. Additionally, in September 2019, the FDA issued revised final guidance describing an optional “safety and performance based” premarket review pathway for manufacturers of “certain,

well-understood device types” to demonstrate substantial equivalence under the 510(k) clearance pathway by showing that such device meets objective safety and performance criteria established by the FDA, thereby obviating the need for manufacturers to compare the safety and performance of their medical devices to specific predicate devices in the clearance process. The FDA maintains a list of device types appropriate for the “safety and performance based” pathway and continues to develop product-specific guidance documents that identify the performance criteria for each such device type, as well as recommended testing methods, where feasible. The FDA may establish performance criteria for classes of devices similar to ours, and it is unclear the extent to which such performance standards, if established, could impact our ability to obtain marketing authorization or otherwise create competition that may negatively affect our business.

In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new statutes, regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of any product candidates or make it more difficult to obtain marketing authorizations for, manufacture, market or distribute any product candidate we are developing. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require: additional testing prior to seeking marketing authorization, changes to manufacturing methods recalls, replacement or discontinuance of our products or additional record keeping.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be promulgated that could prevent, limit or delay marketing authorization of any product candidates we develop. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability.

Risks related to financial and accounting matters

We have identified material weaknesses in our internal control over financial reporting. If our remediation of such material weaknesses is not effective, or if we identify additional material weaknesses in the future or otherwise fail to develop and maintain effective internal control over financial reporting, our ability to produce timely and accurate financial statements or comply with applicable laws and regulations could be impaired.

As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, and the rules and regulations of the applicable listing standards of Nasdaq. We expect that the requirements of these rules and regulations will continue to increase our legal, accounting, and financial compliance costs, make some activities more difficult, time-consuming, and costly, and place significant strain on our personnel, systems, and resources.

The Sarbanes-Oxley Act requires, among other things, that we evaluate whether disclosure controls and procedures and internal control over financial reporting were effective. We are continuing to develop and refine our disclosure controls and procedures, internal control over financial reporting, and other procedures that are designed to ensure information required to be disclosed by us in our financial statements and in the reports that we will file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and information required to be disclosed in reports filed or submitted under the Exchange Act is accumulated and communicated to our principal executive and financial officers as appropriate to allow timely decisions regarding required disclosure. In order to maintain and improve the effectiveness of our controls and procedures, we have expended, and anticipate that we will continue to expend, significant resources, including accounting-related costs and significant management oversight.

As a public company, we are required to evaluate and determine the effectiveness of internal control over financial reporting. Beginning with our second annual report following our IPO, we will be required to provide a management report on internal control over financial reporting, and our independent registered public accounting firm may be required to formally attest to the effectiveness of our internal control over financial reporting once we are no longer an “emerging growth company”. Neither we nor our independent registered public accounting firm were required to, and therefore did not, perform an evaluation of the effectiveness of our internal control over financial reporting as of or for any period included in our financial statements, nor any period subsequent in accordance with the provisions of the Sarbanes-Oxley Act. However, in connection with the preparation of our financial statements, we identified material weaknesses in our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

The material weaknesses identified pertained to:

- We did not design and maintain an effective control environment commensurate with our financial reporting requirements. Specifically, we lack a sufficient complement of resources with the appropriate knowledge, experience, and training to appropriately analyze, record and disclose accounting matters commensurate with our accounting and reporting requirements. Additionally, the lack of sufficient resources resulted in an inability to consistently establish appropriate segregation of duties in our finance and accounting functions. This material weakness contributed to the following additional material weaknesses:
 - We did not design and maintain effective controls to appropriately analyze, account for, and present and disclose amounts related to certain financial instruments. Specifically, we did not design and maintain controls to appropriately analyze, account for, and present and disclose amounts related to outstanding common stock warrants. Additionally, we did not design and maintain controls to appropriately present and disclose amounts related to debt instruments. These material weaknesses resulted in immaterial adjustments to the financial statements. Additionally, these material weaknesses could result in a misstatement of account balances or disclosures that would result in a material misstatement to the annual or interim financial statements that would not be prevented or detected.
 - We did not design and maintain user access controls to ensure appropriate segregation of duties and to adequately restrict user and privileged access to appropriate personnel in creating and posting journal entries. This material weakness did not result in a misstatement to the financial statements; however, it could result in a misstatement of account balances or disclosures that would result in a material misstatement to the annual or interim financial statements that would not be prevented or detected.

To date, we have taken the following steps to begin to remediate these material weaknesses:

- consulted with experts on technical accounting matters, internal controls, and in the preparation of our financial statements;
- engaged a third party to assist in evaluating segregation of duties risks and design and implement controls to address those risks;
- began to design and implement controls related to restricting user and privileged access to appropriate personnel, including as it relates to creating and posting journal entries;
- engaged a third party to assist management in evaluating the accounting for financial instruments; and
- hired additional accounting, finance, operations, and information technology resources with relevant public company experience, including a Chief Financial Officer, Controller and a Vice President of Information Systems.

While management has made improvements to our control environment and business processes to support and scale with our growing operations, the identified material weaknesses remain un-remediated. We expect our remediation efforts to continue to take place in 2025 and may extend into 2026, and to include the following:

- continue to consult with experts to complete our assessment of segregation of duties risks and implement processes and controls to address, manage and monitor those risks and our restriction of user access, including enhancing the usage of technology within our systems, applications, and tools;
- continue to engage additional experts, as needed, to consult on future complex accounting matters; and
- continue to expand our resources with the appropriate level of expertise within our accounting, finance, operations, and information technology functions, with the addition of positions such as a director of accounting, a technical accountant, a manager of financial planning and analysis, and additional accounting and information technology personnel.

These material weaknesses will not be considered remediated until management completes the design and implementation of the measures described above and the controls operate for a sufficient period of time and management has concluded, through testing, that these controls are effective. This remediation process, including testing the effectiveness of the remediation efforts, may extend into 2026. Additionally, we cannot ensure that we have identified all, or that we will not in the future identify additional material weaknesses. Material weaknesses may still exist when we report on the effectiveness of our internal control over financial reporting as required under Section 404 of the Sarbanes-Oxley Act, beginning with our second annual report after our IPO.

The process of designing and implementing internal control over financial reporting required to comply with the disclosure and attestation requirements of Section 404 of the Sarbanes-Oxley Act will be time consuming and costly. If during the evaluation and testing process we identify additional material weaknesses in our internal control over financial reporting or determine that existing material weaknesses have not been remediated, our management will be unable to assert that our internal control over financial reporting is effective. If we are unable to assert that our internal control over financial reporting is effective, or when required in the future, if our auditors are unable to express an unqualified opinion as to the effectiveness of our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our Class A common stock could be adversely affected and we could become subject to litigation or investigations by Nasdaq, the SEC, or other regulatory authorities, which could require additional financial and management resources.

Further, as a public company, significant resources and management oversight will be required. As a result, management's attention may be diverted from other business concerns, which could harm our business, operating results, financial condition, and future prospects.

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 (NOL) carryforwards that can be used to offset potential future taxable income and related income taxes. As of December 31, 2024, we had federal and combined state and city NOL carryforwards of \$154.9 million and \$78.6 million, respectively, which, if not utilized, begin to expire in 2036 and 2026, respectively. Federal NOLs incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal NOLs is limited. As of December 31, 2024, we also had federal research and development credit carryforwards of \$4.1 million, which begin to expire in 2041, and state research and development credit carryforwards of \$2.1 million, which do not expire. 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 have experienced ownership changes in the past, and 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" or have experienced an "ownership change" in the past.

Future indebtedness could adversely affect our business and growth prospects.

We have a debt facility with initial availability of up to \$140.0 million, issuable in four separate tranches, pursuant a Note Purchase Agreement, dated as of August 2, 2024, by and among us, the purchasers party thereto, and BWCB SA LLC (an entity affiliated with Oberland Capital), as purchaser's agent, as amended from time to time (the Note Purchase Agreement). As of September 30, 2025, we have drawn the first tranche of \$50 million under the debt facility. The advanced principal accrues interest at a rate of 8.0% per annum. We have the option, but not the obligation, to issue and sell an additional tranche of notes in the amount of \$25.0 million, under the Note Purchase Agreement, as well as an obligation to sell a tranche of notes in the amount of \$30 million before March 31, 2026 as we have achieved the revenue and gross margin thresholds triggering this obligation. We also had the option, but not the obligation, to issue and sell a tranche of notes in the amount of \$35.0 million prior to September 30, 2025, which we did not exercise. The thresholds triggering this tranche are trailing six-month revenue of at least \$112.5 million and a trailing six-month gross margin of at least 45%. These tranches are all subject to the terms and conditions set forth in such Agreement. In the future, any indebtedness we may incur under the Note Purchase Agreement or otherwise could require us to divert funds identified for other purposes for debt service and impair our liquidity. If we cannot generate sufficient cash flow from operations to service our debt, we may need to refinance our debt, dispose of assets or issue equity to obtain necessary funds. We do not know whether we will be able to take any of these actions on a timely basis, on terms satisfactory to us or at all.

Future indebtedness and the cash flow necessary to satisfy such debt have important consequences, including limiting funds otherwise available for financing our capital expenditures by requiring us to dedicate a portion of our cash flows from operations to the repayment of debt and the interest on this debt, and making us more vulnerable to rising interest rates or in the event of a downturn in our business or in the economy generally.

While we believe that our current debt level is low in comparison to our cash balance, if we increase our debt level by exercising our option to issue and sell additional tranches of notes under our debt facility or by entering into additional debt arrangements in the future, our level of indebtedness may place us at a competitive

disadvantage to our competitors that are differently leveraged. Fluctuations in interest rates can increase borrowing costs. Increases in interest rates may directly impact the amount of interest we are required to pay and reduce earnings accordingly. In addition, developments in tax policy, such as the disallowance of tax deductions for interest paid on outstanding indebtedness, could have an adverse effect on our liquidity and our business, financial conditions and results of operations.

We expect to use cash flows from operations to meet our current and future financial obligations for at least the next twelve months, including funding our operations, any debt service requirements and capital expenditures. The ability to make these payments depends on our financial and operating performance, which is subject to prevailing economic, industry and competitive conditions and to certain financial, business, economic and other factors beyond our control.

The terms of our debt facility restrict our current and future operations, particularly our ability to respond to changes or to take certain actions.

The Note Purchase Agreement contains a number of restrictive covenants that impose significant operating and financial restrictions on us and may limit our ability to engage in acts that may be in our long-term best interests. The Note Purchase Agreement includes covenants requiring the Company to maintain certain trailing six-month net revenue levels and trailing six-month gross margin ratios, and includes other covenants that restrict on our ability to:

- sell, transfer or otherwise dispose of our assets;
- change our business or executive office;
- consolidate, merge, liquidate or dissolve;
- incur additional indebtedness or other contingent obligations;
- create liens or encumbrances;
- pay dividends on our equity interests or make other payments in respect of capital stock;
- make investments, acquisitions, loans and advances;
- enter into certain transactions with affiliates;
- make payment on any subordinated debt;
- store inventory or equipment with a third-party bailee;
- fail to apply with applicable law; and
- transfer material assets to subsidiaries.

A breach of the covenants or restrictions under the Note Purchase Agreement could result in an event of default. Such a default may allow the noteholders or our other creditors to accelerate the related debt, which may result in the acceleration of any other debt to which a cross-acceleration or cross-default provision applies. In the event any note holder or any other holders of our indebtedness accelerate repayment, we may not have sufficient assets to repay that indebtedness or be able to borrow sufficient funds to refinance it. Even if we are able to obtain new financing, it may not be on commercially reasonable terms or on terms acceptable to us. As a result of these restrictions, we may be limited in how we conduct our business; unable to raise additional debt or equity financing to operate during general economic or business downturns; or unable to compete effectively or to take advantage of new business opportunities. These restrictions, along with restrictions that may be contained in agreements evidencing or governing other future indebtedness, may affect our ability to execute our growth strategy.

Taxing authorities may successfully assert that we should have collected or in the future should collect sales and use, value added or similar taxes and we could be subject to tax liabilities with respect to past or future sales, which could adversely affect our results of operations.

We do not collect sales and use, value added and similar taxes in all jurisdictions in which we have sales, based on our belief that such taxes are not applicable or that we are not required to collect such taxes with respect to the jurisdiction. Sales and use, value added and similar tax laws and rates vary greatly by jurisdiction and the application of such laws is subject to uncertainty. Certain jurisdictions in which we do not collect such taxes may assert that such taxes are applicable, which could result in tax assessments, penalties and interest, and we may be required to collect such taxes in the future. Such tax assessments, penalties and interest or future requirements may adversely affect our results of operations.

If our estimates or judgments relating to our critical accounting policies are based on assumptions that change or prove to be incorrect, our operating results could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of our common stock.

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America (GAAP), requires management to make estimates and assumptions that affect the amounts reported in our financial statements and accompanying notes. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets, liabilities, equity, revenue and expenses that are not readily apparent from other sources. Actual results could therefore differ materially from these estimates under different assumptions or conditions. It is also possible that interpretation, industry practice and guidance may evolve. If our assumptions change or if actual circumstances differ from our assumptions, our operating results may be adversely affected and could fall below our publicly announced guidance or the expectations of analysts and investors, resulting in a decline in the market price of our Class A common stock.

Risks related to our Class A common stock

The market price for our Class A common stock may be volatile or may decline regardless of our operating performance, and you may lose all or part of your investment.

The market price of our Class A common stock may be highly volatile and may fluctuate or decline substantially as a result of a variety of factors, many of which are beyond our control, including:

- actual or anticipated changes or fluctuations in our results of operations;
- market speculation involving us or other companies in our industry;
- investor perceptions of us and the industry in which we operate or our failure to meet the expectations of investors;
- price and volume fluctuations in the overall stock market from time to time;
- actual or anticipated developments in our business or our competitors' businesses or the competitive landscape generally;
- litigation involving us, other companies in our industry or both, or investigations by regulators into our operations or those of our competitors;
- developments or disputes concerning our or third-party intellectual property or proprietary rights;
- announced or completed acquisitions of businesses or technologies, or other strategic transactions by us or our competitors;
- actual or perceived breaches of, or failures relating to, privacy, data protection or data security;
- new laws or regulations or new interpretations of existing laws or regulations applicable to our business;
- actual or anticipated changes in our senior management or key personnel;
- expiration of contractual lock-up agreements and market stand-off agreements with our executive officers, directors, employees and stockholders;
- changes in the size or growth of our target markets;
- economic and market conditions in general, including those resulting from geopolitical tensions, tariffs and other trade actions, war, pandemics, terrorism or responses to these events; and
- the realization of any risks described under this "Risk Factors" section, or other risks that may materialize in the future.

Furthermore, the stock market has experienced extreme volatility that in some cases has been unrelated or disproportionate to the operating performance of particular companies. These and other factors may cause the market price and demand for our Class A common stock to fluctuate substantially, which may limit or prevent investors from readily selling their shares of Class A common stock and may otherwise negatively affect the liquidity of our Class A common stock.

Our dual-class capital structure has the effect of concentrating voting power with holders of our Class B common stock, who have significant influence over us and, if acting together, will be able to control matters requiring stockholder approval.

Our Class A common stock has one vote per share and our Class B common stock has 15 votes per share. The holders of our outstanding Class B common stock, Drs. Atay and Tsao, together hold 63.5% of the voting power of our outstanding capital stock. As a result, Drs. Atay and Tsao are able to exert significant influence over us and, if acting together, will be able to control matters requiring stockholder approval, including the election of our Board of Directors, the adoption of amendments to our Certificate of Incorporation and Bylaws and the approval of any merger, consolidation, sale of all or substantially all of our assets or other major corporate transactions. In addition, if our Co-Founders continue to beneficially own shares representing in excess of 50% of the voting power of our outstanding capital stock and determine to act together in the future, we could

become eligible to elect the “controlled company” exemption to the corporate governance rules for publicly listed companies. If we were to become a “controlled company” under the corporate governance rules for publicly listed companies, we would not be required to have a majority of our Board of Directors be independent, nor would we be required to have a compensation committee or an independent nominating function. If we use controlled company exemptions in the future, our status as a controlled company could cause our Class A common stock to be less attractive to certain investors or otherwise cause the market price of our Class A common stock to decline. Further, the interests of Drs. Atay and Tsao may not always coincide with, and in some cases may conflict with, our interests and the interests of our other stockholders. For instance, Drs. Atay and Tsao could attempt to delay or prevent a change in control of our company, even if such change in control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock. This concentration of ownership may also affect the prevailing market price of our common stock due to investors’ perceptions that conflicts of interest may exist or arise. As a result, this concentration of ownership may not be in your best interests.

We cannot predict the impact our dual class structure may have on the market price of our Class A common stock.

We cannot predict whether our dual class structure, combined with the concentrated control of Drs. Atay and Tsao, who will beneficially own all of the outstanding shares of our Class B common stock, will result in a lower or more volatile market price of our Class A common stock, adverse publicity or other adverse consequences. Certain stock index providers have in the past excluded companies with multiple classes of shares of common stock from being added to certain stock indices. If our Class A common stock was ineligible for inclusion in indices with such restrictions mutual funds, exchange-traded funds and other investment vehicles that attempt to passively track those indices may not invest in our Class A common stock.

In addition, several stockholder advisory firms and large institutional investors have been critical of the use of multi-class structures. Such advisory firms may publish negative commentary about our corporate governance practices or our capital structure, which may dissuade large institutional investors from purchasing shares of our Class A common stock.

These actions could make our Class A common stock less attractive to other investors and may result in a less active trading market for our Class A common stock.

If securities or industry analysts do not publish research, if they publish inaccurate or unfavorable research about our business, or if our financial results differ from any guidance we provide to the public, the price of our Class A common stock 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, our market, and our competitors. We do not currently have and may never obtain research coverage by securities and industry analysts. We do not have any control over these analysts. If we fail to meet the expectations of these analysts, our stock price could be adversely affected. If no or few securities analysts commence coverage of us, the trading price for our Class A common stock would be negatively affected. In the event we obtain securities or industry analyst coverage, if one or more of the analysts who cover us downgrade our Class A common stock or publish inaccurate or unfavorable research about our business, the market price of our Class A common stock would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our Class A common stock could decrease, which may cause the market price of our Class A common stock and trading volume to decline.

In addition, the stock prices of many companies in the precision diagnostics industry have declined significantly after those companies failed to meet the financial guidance publicly announced by the companies or the expectations of analysts, and stock prices have even declined significantly after such companies exceeded, or even significantly exceeded, such guidance or expectations. If our financial results fail to meet any guidance we announce, or the expectations of analysts or public investors, or even if our financial results exceed, or even significantly exceed, any such guidance or expectations, or if we reduce any such guidance for future periods, the market price of our Class A common stock may decline.

Future sales of substantial amounts of our Class A common stock in the public markets, or the perception that such sales might occur, could reduce the price that our Class A common stock might otherwise attain.

Future sales of a substantial number of shares of our Class A common stock in the public market, particularly sales by our directors, executive officers, and principal stockholders, or the perception that these sales could occur, could adversely affect the market price of our Class A common stock and may make it more difficult for you to sell your Class A common stock at a time and price that you deem appropriate. The resale of the 35,616,629 shares of Class A common stock and all of our Class B common stock outstanding is currently prohibited or otherwise restricted, subject to certain limited exceptions, as a result of securities law provisions, market standoff agreements entered into by certain of our stockholders with us or lock-up agreements entered into by our stockholders with the underwriters in connection with this offering. However, subject to applicable securities law restrictions, these shares will be able to be sold in the public market beginning on the 181st day after the date of the final prospectus for our IPO. Shares issued upon the exercise of stock options outstanding under our equity incentive plans or pursuant to future awards granted under those plans will become available for sale in the public market to the extent permitted by the provisions of applicable vesting schedules, market stand-off agreements and/or lock-up agreements, as well as Rules 144 and 701 under the Securities Act.

In addition, holders of 37,706,613 shares of our Class A common stock (including shares of our Class A common stock issuable upon the conversion of shares of Class B common stock) have certain rights to require us to register the sale of Class A common stock held by such stockholders, including in connection with underwritten offerings. Sales of significant amounts of stock in the public market upon expiration of lock-up agreements and market stand-off provisions, the perception that such sales may occur, or early release of any lock-up agreements or market stand-off provisions, could adversely affect prevailing market prices of our Class A common stock or make it more difficult for you to sell your shares of Class A common stock at a time and price that you deem appropriate.

The market price of our Class A common stock may drop significantly when the restrictions on resale by our existing stockholders lapse, including in the event of a partial release under the lock-up agreement or market stand-off provisions, if we register certain of our stockholders' shares of our Class A common stock for resale, or if there is an expectation that such a lapse of resale restrictions or registration of shares will occur. A decline in the trading price of our Class A common stock might impede our ability to raise capital through the issuance of additional shares of our Class A common stock or other equity securities and may impair your ability to sell shares of our Class A common stock at a price higher than the price you paid for them or at all.

Anti-takeover provisions in our governing documents and under Delaware law could make an acquisition of our company more difficult, limit attempts by our stockholders to replace or remove our current management, and depress the market price of our Class A common stock.

We are a Delaware corporation, and the anti-takeover provisions of Delaware law impose various impediments to the ability of a third party to acquire control of us, even if a change of control would be beneficial to our existing stockholders. In addition, our Certificate of Incorporation and Bylaws contain provisions that could have the effect of rendering more difficult, delaying or preventing an acquisition deemed undesirable by our Board of Directors, including transactions in which stockholders might otherwise receive a premium for their shares. Among others, our Certificate of Incorporation and Bylaws include the following provisions:

- the dual-class structure that provides holders of shares of our Class B common stock with the ability to significantly influence the outcome of matters requiring stockholder approval, even if they own significantly less than a majority of the shares of our outstanding capital stock;
- the delegation to our Board of Directors of the exclusive right to expand the size of our Board of Directors and to elect directors to fill a vacancy created by any such expansion or the resignation, death or removal of a director, which will prevent stockholders from being able to fill vacancies on our Board of Directors;
- the division of our Board of Directors into three classes, with each class serving staggered three-year terms, which may delay the ability of stockholders to change the membership of a majority of our Board of Directors;
- limitations on convening special stockholder meetings once our Class B common stock no longer represents a majority of voting power of our outstanding capital stock, which could make it difficult for our stockholders to adopt desired governance changes;
- advance notice procedures, which apply for stockholders to nominate candidates for election as directors or to bring matters before an annual meeting of stockholders, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of our company;
- a prohibition on stockholder action by written consent once our Class B common stock no longer represents a majority of voting power of our outstanding capital stock, which means that our stockholders will only be able to take action at a meeting of stockholders;

- no authorization of cumulative voting, which limits the ability of minority stockholders to elect director candidates;
- once our Class B common stock no longer represents a majority of voting power of our outstanding capital stock, directors will only be able to be removed for cause and only by the affirmative vote of two-thirds of the voting power of our then-outstanding capital stock;
- once our Class B common stock no longer represents a majority of voting power of our outstanding capital stock, certain amendments to our Certificate of Incorporation and Bylaws will require the approval of two-thirds of the voting power of our then-outstanding capital stock; and
- the authorization of undesignated or “blank check” preferred stock, the terms of which may be established and shares of which may be issued without further action by our stockholders, which could be used to significantly dilute the ownership and voting rights of a hostile acquirer.

These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our management. In addition, as a Delaware corporation, we are also subject to Section 203 of the Delaware General Corporation Law (DGCL), which prevents stockholders holding more than 15% of our outstanding capital stock from engaging in certain business combinations unless (i) prior to the time such stockholder became an interested stockholder, the Board of Directors approved the transaction that resulted in such stockholder becoming an interested stockholder, (ii) upon consummation of the transaction that resulted in such stockholder becoming an interested stockholder, the interested stockholder owned 85% of the common stock or (iii) following Board of Directors approval, the business combination receives the approval of the holders of at least two-thirds of our outstanding common stock not held by such interested stockholder.

Any provision of our Certificate of Incorporation, Bylaws or Delaware law that has the effect of delaying, preventing, or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock. Even in the absence of a takeover attempt, the existence of these provisions may adversely affect the prevailing market price of our common stock if they are viewed by investors as discouraging future takeover attempts or other transactions that may be in the best interests of our stockholders or that may otherwise enable them to obtain a greater return on their investment, which may impair your ability to sell shares of our Class A common stock at a price greater than the price you paid for them or at all.

Our Certificate of Incorporation provides that the Court of Chancery of the State of Delaware and the U.S. federal district courts are the exclusive forums for substantially all disputes between us and 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 Certificate of Incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the DGCL, our Certificate of Incorporation or our Bylaws or any action asserting a claim against us that is governed by the internal affairs doctrine, unless we consent in writing to the selection of an alternative forum to the extent permitted by law.

This provision does not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act of 1933, as amended (the Securities Act) creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. Our Certificate of Incorporation further provides that the U.S. federal district courts will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, including all causes of action asserted against any defendant named in such complaint. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our Certificate of Incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

We believe these provisions may benefit us by providing increased consistency in the application of Delaware law and federal securities laws by chancellors and judges, as applicable, particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. However, these provisions may result in increased costs to stockholders to bring a claim, may limit investors’ ability to bring a claim in a judicial forum that they find favorable, and may have the effect of discouraging lawsuits against our directors and officers.

We do not anticipate paying dividends on our Class A common stock in the foreseeable future. As a result, your ability to achieve a return on your investment will depend on appreciation in the price of our Class A common stock.

We have never declared or paid any dividends on our capital stock, and we do not anticipate paying any cash dividends on our Class A common stock in the foreseeable future. We anticipate that we will retain all available funds and any future earnings to support operations and to finance the growth and development of our business. Any future determination to pay dividends will be made at the discretion of our Board of Directors, subject to applicable laws, and will depend upon, among other factors, our results of operations, financial condition, contractual restrictions, and capital requirements. Our ability to declare or pay dividends is also subject to the restrictions and limitations set forth in the Note Purchase Agreement. Furthermore, we may also enter into other loan or credit agreements or similar borrowing arrangements that may further restrict our ability to declare or pay dividends on our Class A common stock. Consequently, investors who purchase Class A common stock may be unable to realize a return on their investment except by selling such shares after price appreciation, which may never occur. Our inability or decision not to pay dividends, particularly when others in our industry have elected to do so, could also adversely affect the market price of our Class A common stock.

General risk factors

Our failure to timely and effectively implement controls and procedures required by Section 404 of the Sarbanes-Oxley Act could have a material adverse effect on our business.

We will be required to provide management's assessment regarding internal control over financial reporting in our second Annual Report on Form 10-K. In addition, at such time as we are no longer an "emerging growth company," we will be required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act requiring our auditors to provide an opinion on the effectiveness of our internal controls over financial reporting. While we have begun implementation of such controls and procedures, management may not be able to effectively and timely implement controls and procedures that adequately respond to these increased regulatory compliance and reporting requirements as and when they become applicable. If we are not able to implement the additional requirements of Section 404 in a timely manner or with adequate compliance, we and our auditors may not be able to assess whether our internal controls over financial reporting are effective, which may subject us to adverse regulatory consequences and could harm investor confidence and the market price of our Class A common stock.

In addition to the material weaknesses in internal control over financial reporting identified in connection with the preparation of our financial statements, subsequent testing by us or our independent registered public accounting firm may reveal additional deficiencies in our internal control over financial reporting that are deemed to be material weaknesses. During the evaluation and testing process of our internal controls, if we identify additional material weaknesses in our internal control over financial reporting, we will be unable to certify that our internal control over financial reporting is effective. We cannot assure you that there will not be additional material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition or results of operations. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have additional material weaknesses or a significant deficiency in our internal control over financial reporting, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our Class A common stock could decline, and we could be subject to sanctions or investigations by the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

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

We are an "emerging growth company," as defined in the JOBS Act, and we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies," including the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a non-binding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. Pursuant to Section 107 of the JOBS Act, as an emerging growth company, we have elected to use the extended

transition period for complying with new or revised accounting standards until those standards would otherwise apply to private companies. As a result, our financial statements may not be comparable to the financial statements of issuers who are required to comply with the effective dates for new or revised accounting standards that are applicable to public companies, which may make our common stock less attractive to investors. In addition, if we cease to be an emerging growth company, we will no longer be able to use the extended transition period for complying with new or revised accounting standards.

We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year following the fifth anniversary of our IPO, (ii) the last day of the first fiscal year in which our annual gross revenue is \$1.235 billion or more, (iii) the date on which we have, during the previous rolling three-year period, issued more than \$1.0 billion in non-convertible debt securities, and (iv) the date on which we are deemed to be a "large accelerated filer."

We cannot predict if investors will find our Class A common stock less attractive if we choose to rely on these exemptions. For example, if we do not adopt a new or revised accounting standard, our future operating results may not be as comparable to the operating results of certain other companies in our industry that adopted such standards. 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 the market price of our Class A common stock may be more volatile.

The requirements of being a public company may strain our resources, divert management's attention, and affect our ability to attract and retain qualified Board of Directors members.

As a public company listed in the U.S., we will incur significant legal, accounting, and other expenses. In addition, changing laws, regulations, and standards relating to corporate governance and public disclosure, including regulations implemented by SEC and Nasdaq, may increase legal and financial compliance costs and make some activities more time consuming. These rules might also make it more difficult for us to obtain certain types of insurance, including director and officer liability insurance, and we might be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. We cannot predict or estimate the amount of additional costs we will incur as a public company or the specific timing of such costs, and any such costs may adversely affect our business, financial condition and results of operations.

These laws, regulations, and standards are subject to varying interpretations, and as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. We intend to invest resources to comply with evolving laws, regulations, and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If, notwithstanding our efforts, we fail to comply with new laws, regulations, and standards, regulatory authorities may initiate legal proceedings against us and our business may be adversely affected.

In addition, as a result of our disclosure obligations as a public company, we have reduced strategic flexibility and will be under pressure to focus on short-term results, which may adversely affect our ability to achieve our long-term goals. As a result of disclosure of information in filings required of a public company, our business and financial condition will become more visible, which may result in threatened or actual litigation, including by stockholders and competitors. If such claims are successful, our business and operating results could be adversely affected, and even if the claims do not result in litigation or are resolved in our favor, these claims, and the time and resources necessary to resolve them, could divert the resources of our management and adversely affect our business and operating results.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

As a public company, we must design our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and 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, 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. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make a required related party transaction disclosure. 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 due to error or fraud may occur and not be detected.

We may be subject to securities litigation, which is expensive and could divert management attention.

The market price of our Class A common stock may be volatile and, in the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

Item 2. Unregistered Sales Of Equity Securities And Use Of Proceeds

Recent Sales of Unregistered Equity Securities

From July 1, 2025 to (but not including) November 6, 2025 (the date of the filing of our Registration Statement on Form S-8), we issued and sold to our directors, officers, employees, consultants and other service providers an aggregate of 270,747 shares of our Class A common stock upon the exercise of stock options under our 2018 Stock Plan, at exercise prices ranging from \$0.45 to \$30.78 per share, for an aggregate purchase price of \$1,501,102.62.

From July 1, 2025 to (but not including) November 6, 2025, we granted to our directors, officers, employees, consultants and other service providers options to purchase 1,224,549 shares of our Class A common stock under our 2018 Stock Plan at exercise prices ranging from \$23.15 to \$30.78 per share.

On November 7, 2025, we exchanged a total of 4,552,650 shares of Class A common stock held by Oguzhan Atay, our Chief Executive Officer and Co-Founder, and David Tsao, our Chief Technology Officer and Co-Founder, and certain related entities for an equivalent number of shares of Class B common stock pursuant to the terms of certain exchange agreements. No additional consideration was paid in connection with the exchange. We believe the offers, sales, and issuances of the above securities were exempt from registration under the Securities Act pursuant to Section 3(a)(9) of the Securities Act because our securities were exchanged by us with our existing security holders exclusively where no commission or other remuneration was paid or given directly or indirectly for soliciting such exchange.

None of the foregoing transactions involved any underwriters, underwriting discounts or commissions, or any public offering. We believe the offers, sales and issuances of the above securities were exempt from registration under the Securities Act (or Regulation D or Regulation S promulgated thereunder) by virtue of Section 4(a)(2) of the Securities Act because the issuance of securities to the recipients did not involve a public offering, or in reliance on Rule 701 because the transactions were pursuant to compensatory benefit plans or contracts relating to compensation as provided under such rule. The recipients of the securities in each of these transactions represented their intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were placed upon the stock certificates issued in these transactions. All recipients had adequate access, through their relationships with us, to information about us. The sales of these securities were made without any general solicitation or advertising.

Use of Proceeds

On November 7, 2025, we closed our IPO in which we issued and sold 5,233,765 shares of our Class A common stock, which includes the exercise in full by the underwriters of their option to purchase from the Company 682,665 shares of the Company's Class A common stock, at a price to the public of \$60.00 per share. We received net proceeds of \$286.4 million after deducting underwriting discounts and commissions of \$22.0 million and deducting offering expenses of \$5.6 million. No payments for such expenses were made directly or indirectly to (i) any of our officers or directors or their associates, (ii) any persons owning 10% or more of any class of our equity securities or (iii) any of our affiliates.

All shares sold were registered pursuant to a registration statement on Form S-1 (File No. 333-290761), as amended (the "Registration statement"), which became effective on November 5, 2025. The offering terminated after the sale of all securities registered pursuant to the Registration Statement. J.P. Morgan Securities LLC,

Piper Sandler & Co., Jefferies LLC, William Blair & Company, L.L.C., Stifel, Nicolaus & Company, Incorporated, Wells Fargo Securities, LLC, and BTIG, LLC acted as representatives of the underwriters for the IPO.

There has been no material change in the expected use of the net proceeds from our IPO as described in the final prospectus dated as of November 5, 2025 and filed with the SEC pursuant to Rule 424(b)(4) on November 6, 2025.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

None.

Item 5. Other Information

Disclosure of Trading Arrangements

During the fiscal quarter ended September 30, 2025, none of our directors or officers (as defined in Rule 16a-1(f) under the Exchange Act) adopted or terminated a “Rule 10b5-1 trading arrangement” or a “non-Rule 10b5-1 trading arrangement,” as each term is defined in Item 408 of Regulation S-K.

Item 6. Exhibits

(a) Exhibits

| Exhibit No | Description of Exhibit | Form | File No. | Exhibit Number | Filing Date | Filed or Furnished Herewith |
|------------|---|-------|------------|----------------|-------------------|-----------------------------|
| 3.1 | Amended and Restated Certificate of Incorporation of the Registrant | 8-K | 001-42934 | 3.1 | November 10, 2025 | |
| 3.2 | Amended and Restated Bylaws of Registrant | 8-K | 001-42934 | 3.2 | November 10, 2025 | |
| 10.1 | Amendment No. 1 to the Note Purchase Agreement, dated as September 4, 2025, by and among by and among the Registrant, the purchasers party thereto, and BWCB SA LLC (an entity affiliated with Oberland Capital Management, LLC), as purchaser’s agent. | S-1 | 333-290761 | 10.2 | October 07, 2025 | |
| 10.2 | Development and Commercialization Agreement with Janssen Biotech, Inc., dated July 11, 2025 | S-1/A | 333-290761 | 10.10 | October 17, 2025 | |
| 10.3 | Amendment No. 1 to Development and Commercialization Agreement with Janssen Biotech, Inc., dated October 15, 2025 | S-1/A | 333-290761 | 10.11 | October 17, 2025 | |
| 10.4+ | Form of Indemnification Agreement by and between the Registrant and each of its directors and executive officers | S-1 | 333-290761 | 10.11 | October 07, 2025 | |
| 10.5+ | 2025 Equity Incentive Plan | S-1/A | 333-290761 | 10.14 | October 17, 2025 | |
| 10.6+ | 2025 Employee Stock Purchase Plan | S-1/A | 333-290761 | 10.15 | October 17, 2025 | |
| 10.7+ | Executive Severance Plan | S-1/A | 333-290761 | 10.16 | October 17, 2025 | |
| 31.1 | Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 | | | | | X |
| 31.2 | Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 | | | | | X |

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|---------|---|---|
| 32.1* | Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 | X |
| 32.2* | Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 | X |
| 101.INS | Inline XBRL Instance Document (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document) | |
| 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 formatted as Inline XBRL and contained in Exhibit 101 | |

+ Indicates a management contract or compensatory plan or arrangement.

† The Registrant has omitted portions of the exhibit (indicated by "[*]") as permitted under Item 601(b)(10) of Regulation S-K because such information is both (i) not material and (ii) information that the Registrant treats as private or confidential. The Registrant hereby undertakes to furnish supplemental copies of the unredacted exhibit upon request by the SEC.

* The certifications furnished in Exhibits 32.1 and 32.2 are not deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liability of that section, nor shall they be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended.

Signatures

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

Date: December 10, 2025

BillionToOne, Inc.

By: /s/ Oguzhan Atay

Oguzhan Atay
Chief Executive Officer
(Principal Executive Officer)

Date: December 10, 2025

By: /s/ Ross Taylor

Ross Taylor
Chief Financial Officer
(Principal Financial and Accounting Officer)

**CERTIFICATION 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**

I, Oguzhan Atay, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of BillionToOne, 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)) 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) [Omitted];
 - (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: December 10, 2025

By:

/s/ Oguzhan Atay

Oguzhan Atay
Chief Executive Officer
(Principal Executive Officer)

**CERTIFICATION 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**

I, Ross Taylor, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of BillionToOne, 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)) 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) [Omitted];
 - (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: December 10, 2025

By:

/s/ Ross Taylor

Ross Taylor
Chief Financial Officer
(Principal Financial and Accounting Officer)

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of BillionToOne, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: December 10, 2025

By:

/s/ Oguzhan Atay

Oguzhan Atay
Chief Executive Officer
(Principal Executive Officer)

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of BillionToOne, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: December 10, 2025

By:

/s/ Ross Taylor

Ross Taylor
Chief Financial Officer
(Principal Financial and Accounting Officer)