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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 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	**81-1082020**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
1035 O'Brien Drive Menlo Park, CA	**94025**
(Address of Principal Executive Offices)	(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	Name of Each Exchange on which Registered
Class A common stock, par value $0.00001 per share	BLLN	The Nasdaq Stock Market LLC

Securities registered pursuant to section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). o

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

The Registrant was not a public company as of the last business day of its most recently completed second fiscal quarter and therefore cannot calculate the aggregate market value of its voting and non-voting common equity held by non-affiliates as of such date. The Registrant's Class A common stock began trading on the Nasdaq Global Select Market on November 6, 2025.

As of March 6, 2026, there were 41,413,162 shares of Class A common stock and 4,552,650 shares of Class B common stock, each with a par value of $0.00001 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive proxy statement, or the 2026 Proxy Statement, relating to its annual meeting of stockholders to be held in 2026, or the 2026 Annual Meeting, to be filed with the Securities and Exchange Commission, or the SEC, within 120 days after the end of the fiscal year to which this Annual Report on Form 10-K relates, are incorporated herein by reference where indicated. Except with respect to information specifically incorporated by reference in this Annual Report on Form 10-K, such proxy statement is not deemed to be a part hereof.

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Special Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K (this Annual 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 Annual Report, including statements regarding our future operating results and financial position, our business strategy and plans, 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 Annual 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 artificial intelligence (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 non-invasive prenatal test (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;
- 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;
- our ability to remediate the material weakness in our internal control over financial reporting or additional material weaknesses or other deficiencies in the future or to maintain effective disclosure controls and procedures and internal control over financial reporting; and
- other risks and uncertainties, including those listed in Part I, Item 1A “Risk factors.”

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

These forward-looking statements are subject to a number of risks, uncertainties, and assumptions, including those described in Part I, Item 1A “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 Annual 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 Annual 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 Annual 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 Annual 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.

You should read this Annual Report and the documents that we reference in this Annual Report and have filed as exhibits with the understanding that our actual future results, levels of activity, performance and achievements may be different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

Part I

Item 1. Business

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).

Our superior technology platform has enabled us to build category-defining prenatal and oncology products. Our products reveal actionable insights from a simple blood draw that are fundamentally changing how diseases are diagnosed and treated, leading to a paradigm shift in personalized medicine, overcoming the technical noise that restrains the traditional next-generation sequencing (NGS) testing methods used by other diagnostic companies. We believe our novel smNGS platform technologies combined with our AI-enhanced integrated workflow, allows us to push the technology frontier forward and deliver on the full promise of non-invasive liquid biopsy.

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. In 2019, we launched our first prenatal product, UNITY. UNITY is the first NIPT that uses cfDNA to provide fetal risk assessment for recessive conditions such as sickle cell disease and cystic fibrosis without requiring a paternal sample or invasive procedures such as amniocentesis. Since then, we have established ourselves as a leader, based on revenue and American College of Obstetricians and Gynecologists (ACOG) practice advisory guidelines, in the prenatal testing market and expanded our UNITY offering to cover comprehensive prenatal genetic needs from a single maternal blood draw. While some competitors have launched competing NIPTs for recessive conditions, we believe the differentiation of our smNGS technology, as well as five years of accumulated data and publications, will allow us to maintain our competitive advantage as this type of testing becomes the standard of care and significantly improves patient outcomes.

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, when compared to comparator products in the aggregate. 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.

Backed by our commitment to continued innovation and high-quality execution, we aim to lead the next wave of advancements in precision diagnostics, delivering profound benefits to patients, providers, and the broader healthcare system.

Our Four Pillars of Differentiation

At BillionToOne, we are building a different type of molecular diagnostics company, backed by our four pillars of differentiation described below. We believe these competitive advantages are difficult for others to replicate and uniquely position us to redefine the industry.

Our breakthrough technology platform. Our revolutionary platform achieves absolute quantification at the single molecule level, enabling us to: (i) accurately quantify genetic targets by using our QCTs as amplification

controls to detect and eliminate biases and errors that would otherwise be introduced from PCR amplification during library preparation for NGS; (ii) precisely measure and analyze intermediate biochemical reactions to optimize the performance of our assays; and (iii) reduce sequencing costs by obtaining a higher quality signal at each genomic location analyzed by significantly reducing total reads required per sample. Moreover, we believe our design-based R&D approach allows us to harness this quantitative technology to mathematically model and accurately predict the clinical performance of a novel assay before testing a single patient sample, which we believe accelerates time-to-market and significantly improves our commercial launch success rate. Collectively, these platform capabilities enable us to build better products while we simultaneously decrease costs.

Our category-defining products. As demonstrated in multiple analytical and clinical studies, as well as peer reviewed publications, we have leveraged our smNGS platform to create differentiated prenatal and oncology products with 10 times greater precision versus other available tests. For example, our UNITY test has extended NIPT from detecting one million-plus base pair conditions to single base pair conditions. This advancement is already starting to impact the treatment options for babies affected by these severe recessive conditions. In addition, our Northstar Select and Response tests deliver superior sensitivity and precision, respectively, and can generate clinically relevant insights for late-stage cancer therapy selection and response monitoring that may otherwise have been missed or delayed through conventional liquid biopsy tests and/or imaging tools. We believe that each of our products has the potential to become the standard of care in its respective market. Furthermore, we believe our competitive moat will strengthen over time as we continue to enhance and expand our portfolio of ultrasensitive tests.

Our ability to deliver rapid growth at scale. The differentiated nature of our products and our relentless commitment to improving the patient and provider experience have resulted in recurring use of our tests with extremely low customer churn. Our existing accounts have created a stable and growing revenue base with increasing penetration, and we see similar adoption trends in new clinics, as we continue our expansion within existing and new territories. We believe this market setup, along with our scaling business, provides a significant opportunity for us to grow over the near and long-term horizon.

Our superior efficiency. We believe our capital efficiency and emerging profitability set us apart from other molecular diagnostics companies especially at our scale. Since inception we have produced a track record of cost efficiency. Going forward, our financial discipline will continue to be integral to our innovation efforts. By prioritizing efficiency, we have been able to consistently invest in R&D and commercial expansion while reducing losses over time and achieving profitability as measured on both income from operations and net income basis. In doing so, we believe we have established a differentiated financial profile that positions us for sustainable value creation.

Background on cfDNA and the limitations of traditional NGS technologies

cfDNA represents one of the most promising biomarkers in modern precision medicine. cfDNA is continuously shed from all tissues into the bloodstream and has a short half-life of approximately one to two hours. This transient nature gives cfDNA a unique capability to provide a real-time snapshot of cellular turnover and can be used to diagnose and monitor disease, as both genetic and epigenetic properties of cfDNA directly reflect the originating tissue.

Despite its potential, the detection of cfDNA is fundamentally challenging due to its limited quantity in blood and short half-life. Certain conditions that stem from large scale genetic changes or generate abundant quantities of cfDNA in the bloodstream can be identified by previous testing approaches. However, other serious conditions may have lower DNA shedding rates which can result in very few relevant DNA fragments in the blood. These conditions are nearly undetectable with previous cfDNA detection techniques. For example, even in a late-stage cancer patient, there may only be one mutated cell-free tumor DNA molecule found in one tube of blood.

While traditional NGS has revolutionized genomic medicine over the past decade, it faces inherent limitations when applied to the analysis of cfDNA. Conventional NGS technologies are primarily limited to presence or absence detection. For example, within germline testing, which includes nearly unlimited input DNA material, the clinically relevant changes are detected at around 50% additional disease burden. However, in cfDNA applications, these clinically relevant changes can be at the level of 0.01% of cfDNA in blood. These applications require ultrasensitive quantification at the single molecule level that we believe is only possible with our smNGS platform. Further complicating the challenge, cfDNA samples undergo numerous enzymatic, amplification, and other biochemical steps prior to sequencing. Each of these steps introduces technical noise that makes it harder for traditional sequencing technologies to accurately quantify the absolute and relative abundance of cfDNA sequences in the biological specimen, resulting in lower sensitivity and specificity.

Our Proprietary Single-Molecule Next-Generation Sequencing Platform (smNGS)

We have developed a transformative technology platform that redefines the possibilities of cfDNA analysis. In the past, the significant advancements from polymerase chain reaction (PCR) to Sanger Sequencing to NGS expanded molecular diagnostics from being limited to infectious disease testing and human genome mapping to now becoming standard of care for genetic screening.

The cornerstone of our platform is its ability to resolve and quantify individual DNA molecules with absolute precision. This single-molecule resolution provides extraordinary visibility into the biological signals present in a sample, even when the target DNA represents just one molecule among billions. Beyond mere detection, our technology enables absolute quantification of cfDNA, eliminating the reliance on relative measurements that has constrained previous approaches. This quantitative foundation allows us to transform every aspect of our operations in a measurable way, from research and development to clinical testing and quality control. While traditional diagnostic approaches have often relied on trial-and-error experiments to screen for incremental improvements, our smNGS platform does not. The quantitative nature of the data that our smNGS platform generates is critical to our success in creating ultrasensitive, differentiated molecular diagnostics.

Perhaps most significantly, we believe our smNGS technology transcends the precision-versus-scale tradeoff that has limited legacy diagnostic methods. Conventional genetic analysis techniques, such as NGS and digital droplet PCR (ddPCR), typically sacrifice either sensitivity or multiplexing, i.e., ability to interrogate many genomic loci at the same time, forcing compromises in clinical utility. We believe our platform eliminates this constraint, delivering both high sensitivity and broad genomic coverage simultaneously. This unique capability allows us to provide physicians and patients with more actionable information from cfDNA that was previously possible only with more invasive diagnostics.

Our smNGS platform is powered by several patented technologies, most notably the use of synthetic DNA fragments, called QCTs. QCTs encode the molecular information in sequencing data which are subsequently decoded using proprietary machine learning and bioinformatic algorithms, enabling us to precisely quantify cfDNA. The precision and multiplexability of QCT-powered assays make them ideal for addressing clinically significant challenges where sensitivity of rare-variant detection or quantification necessary for longitudinal measurements is essential. The power of QCTs is best exemplified when the clinical problem itself is quantitative, as in the case of fetal risk assessment of recessive conditions during pregnancy and monitoring of response to therapy in a cancer patient.

QCTs and our other smNGS technologies also serve as the backbone of our technical operations. We leverage this quantitative foundation to track samples throughout our workflows, to drive continuous operational improvement, and to support robust quality controls. For instance, QCTs detect cross-contamination down to the level of <0.001% and thereby enable the creation of carefully constructed and automated end-to-end laboratory workflows, including special laboratory infrastructure, that prevent such cross-contamination that could otherwise be a bottleneck on sensitivity and specificity of an assay.

The financial impact of our technology platform is substantial. We believe the ability to quantify biomarkers enables us to rationally design and engineer superior diagnostic tests optimized for clinical performance, scalability, and cost of goods sold (COGS). Our smNGS platform therefore drives our differentiated financial performance both by enabling the development of unique products and by de-risking clinical studies before dedicating significant resources. Our platform is a key differentiator versus our peers in the molecular diagnostics space and is protected by a robust and growing collection of patents and proprietary know-how.

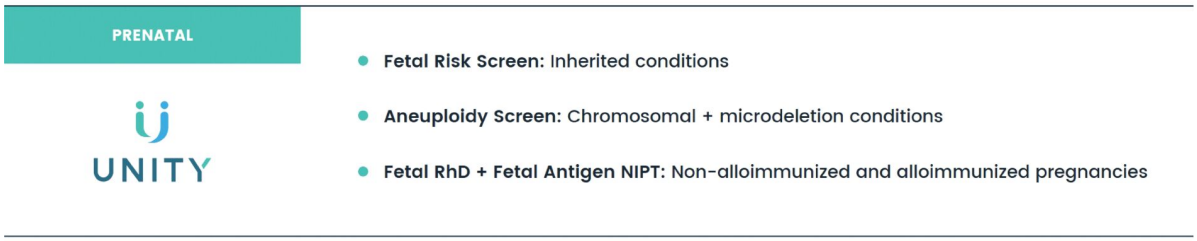
Our Solution & Suite of Products

Our product portfolio of ultrasensitive tests touches everyone from the beginning of life, with prenatal genetic testing, to the end of life, with cancer therapy selection and response monitoring.

We launched our initial prenatal product, UNITY, in 2019. Today, we believe it is becoming the new standard of care, as evidenced by two recent ACOG practice advisory changes that cited our publications in support of the change. With UNITY, we have leap-frogged the resolution of cfDNA testing from one million base-pair chromosomal abnormalities to single base-pair recessive conditions. In this highly competitive market with increasing commoditization, our differentiated UNITY Fetal Risk Screen remains the only cfDNA test for these conditions. with peer-reviewed clinical publications.

We have more recently entered the oncology market, initially focusing on addressing the highest unmet need areas of therapy selection and response monitoring in late-stage cancer patients. To date, we have launched multiple products in these markets, which are described below.

Prenatal products



Traditional prenatal screening focuses on assessing a fetus' risk for larger chromosomal changes. However, many common and severe conditions are the result of much smaller genetic changes, in single base pairs. These recessively inherited conditions, including sickle cell disease (SCD), alpha thalassemia, beta-thalassemia, cystic fibrosis (CF), and spinal muscular atrophy (SMA), are collectively more common than aneuploidy conditions like Down syndrome. Yet these conditions cannot be directly tested with traditional NIPT since each condition requires the precise quantification of fetal cfDNA.

Given the technical challenges of directly assessing the fetal risk for these conditions, current medical guidelines recommend that every pregnant patient is offered carrier screening, with father screening then required if the mother is found to be a carrier. However, studies estimate that fewer than half of fathers complete the recommended screening due to barriers related to cost, availability, and willingness. As a result, approximately 58% of pregnancies affected by these recessive conditions are undetected by traditional screening workflows.

Our UNITY Fetal Risk Screen directly addressed these challenges and is the first test that uses cfDNA to provide precise fetal risk assessments for recessive conditions without requiring a paternal sample. In addition, it reports fetal aneuploidy and 22q11.2 microdeletion, enabling complete genetic insights from a single maternal blood draw.

Our UNITY Complete portfolio

Our UNITY prenatal testing portfolio includes the first sgNIPT that uses cfDNA to achieve precise fetal risk analysis without requiring a paternal sample – a breakthrough that enhances accessibility, ease of use, and adoption across patient populations. In 2020, we added Aneuploidy and RhD NIPT to create our UNITY Complete offering. In 2022, we added other fetal red blood cell antigens for alloimmunized pregnancies at risk for HDFN without requiring a paternal sample or invasive procedures such as amniocentesis. Our portfolio delivers unmatched clinical insights through the screening for recessive conditions, aneuploidies, and fetal antigens using a single maternal blood draw. We believe our offering provides the most comprehensive view of fetal health available today.

UNITY Fetal Risk Screen

In 2019, we launched UNITY Fetal Risk Screen as the first sgNIPT that uses cfDNA to provide fetal risk assessments for recessive conditions. This breakthrough approach addresses a major gap in traditional carrier screening and enhances accessibility, speed, and accuracy for all pregnant patients. In May 2025, we expanded UNITY Fetal Risk Screen's testing menu to include up to 14 conditions, further enhancing its clinical impact.

The first step of the UNITY Fetal Risk Screen involves determining the maternal carrier status. If the mother is identified as a carrier, cfDNA analysis is performed on the same blood sample to assess fetal risk. We believe directly measuring fetal risk through a single maternal blood draw is only possible with the precision and sensitivity provided by our smNGS technology. Within two weeks, the information provided to the clinician and patient includes:

- Maternal carrier status and any information about the specific variant that may be identified;

- A personalized fetal risk score on each condition for which the pregnant mother is a carrier, ranging from <1 in 5,000 to 9 in 10, providing clear, actionable information for clinicians and patients; and
- Whether the risk is classified as low or high risk.

UNITY Fetal Risk Screen's accuracy has been validated in multiple peer-reviewed studies. A 2023 study published in Prenatal Diagnosis demonstrated 100% of "9 in 10" risk pregnancies were confirmed to be affected pregnancies. Because UNITY Fetal Risk Screen does not rely on paternal testing, which is often not completed, it detects up to three times as many affected pregnancies for these recessive conditions compared to traditional carrier screening.

UNITY Aneuploidy Screen

In 2020, we launched our UNITY Aneuploidy Screen, which we believe has become the most performant assay for aneuploidies. Compared to many competing tests, our test overcomes the significant challenge of low fetal cfDNA levels in the mother's blood, which often produces inconclusive results. This issue can be particularly pronounced for single nucleotide polymorphism-based NIPTs, which tend to have a higher fetal fraction cutoff to provide conclusive results. Our smNGS platform provides a critical signal boost that is especially noticeable at lower fetal fractions, significantly reducing inconclusive results.

In addition to robust performance above 99.7% sensitivity and 99.9% specificity for common trisomies, UNITY Aneuploidy NIPT uniquely leverages smNGS technology to enhance 22q11.2 Microdeletion Analysis, addressing a critical gap in competing prenatal screening tests. As the most common microdeletion disorder, 22q11.2 deletion syndrome (DiGeorge Syndrome) has historically resulted in low positive predictive values (PPV), reducing clinical confidence and resulting in patient anxiety. smNGS enables >95% sensitivity and >99.9% specificity, which results in an industry-leading PPV of 80% in average risk pregnancies. More than 75% of UNITY Aneuploidy orders now include 22q11.2 optional add-on testing.

UNITY Fetal RhD NIPT

Approximately 15% of pregnant individuals in the United States are RhD-negative, putting them at risk of RhD alloimmunization if they are carrying an RhD-positive fetus. To prevent this, the standard of care has been the administration of Rho(D) immune globulin (RhIG) (e.g., RhoGAM) at 28 weeks' gestation and postpartum. However, this approach lacks precision, as 40% of RhD-negative pregnancies do not require RhIG because the fetus is also RhD-negative. Administering RhIG to these pregnancies is unnecessary, costly, and limits supply availability for those who need it most. This is because RhIG availability can be limited given it is a blood product derived from human donors.

To address this issue, we launched UNITY Fetal RhD NIPT in 2020 to detect fetal D antigen. While other tests for fetal RhD detection were launched in 2024, UNITY Fetal RhD NIPT remains the only test that can accurately detect fetal RhD status when the pregnant individual has RhD and RhD-CE-D hybrid genes, which are prevalent in Black (45%) and Asian (>10%) populations. Other fetal RhD NIPTs are limited in their ability to detect these genetic complexities. UNITY Fetal RhD NIPT addresses these limitations through our revolutionary smNGS platform. Since launching, UNITY Fetal RhD NIPT has been ordered for over 150,000 patients, with data published in peer-reviewed studies demonstrating 100% concordance with neonatal outcomes and sensitivity/specificity of >99.9%.

UNITY Fetal Antigen NIPT

Alloimmunization occurs when a pregnant individual's immune system produces antibodies against fetal red blood cell (RBC) antigens. This can happen when an RhD negative pregnant mother carrying an RhD positive fetus does not receive RhIG. This can also happen with other rare RBC antigens are present, such as Kell, especially due to a blood transfusion prior to the pregnancy. This can lead to HDFN, a condition that can cause severe anemia, hydrops fetalis, or fetal demise. Managing these pregnancies is challenging. The current methods to determine fetal antigen status, such as amniocentesis, are often invasive. These invasive procedures could cause maternal and fetal blood to mix, which would exacerbate HDFN. As a result, many patients experience undue anxiety, unnecessary and expensive weekly monitoring, frequent antibody titer checks, and intensive surveillance. In approximately 65% of these pregnancies, the fetus is negative for the antigen and therefore there is no fetal risk.

To address this issue, we launched UNITY Fetal Antigen NIPT in 2022. Our UNITY Fetal Antigen NIPT addresses a critical gap in managing alloimmunized pregnancies and detects key fetal RBC antigens, including D, C, c, E, K (Kell), and Fya (Duffy), helping to guide clinical decisions and reduce unnecessary monitoring. As

the only commercially available test for fetal antigen screening in the United States, UNITY Fetal Antigen NIPT not only solves a previously unmet clinical need but has deepened our relationships with Maternal-Fetal Medicine (MFM) specialists.

UNITY Fetal Antigen NIPT's clinical accuracy has been validated in multiple peer-reviewed publications, including a Scientific Reports study demonstrating 100% concordance between test results and neonatal antigen status. UNITY Fetal Antigen NIPT offers 100% sensitivity and specificity while maintaining a no-call rate of <0.1%, ensuring highly reliable results.

In 2024, ACOG issued two clinical guideline updates, referencing UNITY Fetal RhD NIPT and UNITY Fetal Antigen NIPT data: (i) acknowledging the role of fetal RhD NIPT in triaging anti-D immunoglobulin (e.g., RhoGAM) use, particularly amid shortages, and (ii) endorsing UNITY Fetal RhD NIPT as a reasonable alternative for guiding management of alloimmunized patients who decline invasive testing. These clinical guideline updates recognized comparable performance of our assay to invasive diagnostic testing while avoiding complications. They not only validated the clinical utility of our UNITY Fetal RhD NIPT and UNITY Fetal Antigen NIPT but also further highlighted their critical role in enhancing patient care and ensuring effective management of patients across diverse populations.

In February 2026, we announced the launch of our expanded Red Blood Cell (RBC) Fetal Antigen NIPT and a first-and-only Platelet Fetal Antigen NIPT. Available exclusively through the UNITY Aneuploidy™ Screen, these offerings represent the first-and-only non-invasive prenatal tests in the U.S. designed to determine fetal antigen status across both red blood cell and platelet antigens in pregnancies affected by or at risk for HDFN and FNAIT. These conditions together affect or place at risk approximately 1.5-2.5% of pregnancies in the U.S., a rate higher than the genetic burden of aneuploidies.

UNITY Fetal Antigen CTA NIPT

In December 2023, we announced a global partnership with Johnson & Johnson to provide our UNITY Fetal Antigen clinical trial assay (CTA) in their AZALEA Phase 3 clinical trial of nipocalimab in pregnancies at risk for severe HDFN. In April 2023, the FDA granted an Investigational Device Exemption (IDE) for the assay's use in the trial. Final FDA approval of the companion diagnostics indication is dependent on the success of the Johnson & Johnson AZALEA Phase 3 clinical trial. We have also received regulatory clearances from health authorities in certain European and Latin American countries for the use of the assay in a global clinical trial. We believe that a successful completion of this Phase 3 trial may enable our test to be the first NIPT that is granted a companion diagnostics indication.

Our comprehensive customer experience and commitment to quality and innovation beyond our tests

UNITY Complete is more than just a test, it is a fully integrated, end-to-end experience that delivers a seamless workflow for both patients and providers. Over the years, we have developed various software tools to support the entire testing workflow for providers and patients, which has fueled the rapid growth of the UNITY Complete portfolio. We continuously refine our workflow to address the evolving needs of obstetric providers, in an effort to maximize efficiency, accessibility, and ease of adoption for both patients and providers. By combining unique clinical testing with workflow enhancements, we believe UNITY Complete has established a highly scalable infrastructure that streamlines every step of the journey, further solidifying that UNITY Complete is becoming the new standard in prenatal care.

Oncology products

Precision oncology continues to be a focus in the global fight to cure cancer. However, despite significant advancements and growth in the field, cancer continues to rank as the second leading cause of death worldwide, with persistently high mortality rates. Liquid biopsies, or blood-based tests that interrogate ctDNA, cfDNA released from a tumor cell, for therapy selection or disease monitoring have recently become available for clinical practice as non-invasive, rapid and readily available alternatives to traditional tissue-based biopsies. Despite the increase in uptake, current liquid biopsies developed using standard NGS methods present shortcomings, including undetected actionable mutations and delays in detection of response and progression.

In 2023, we entered the oncology market with two complementary products that leverage our smNGS platform to address these unmet needs. Northstar Select, our ultrasensitive liquid biopsy test, provides insights into appropriate therapies for stage III or IV cancer patients. We simultaneously launched Northstar Response, the only tissue-free, pan-cancer, smNGS-based liquid biopsy test that precisely measures thousands of genomic loci uniquely methylated in cancer to provide insight into dynamic changes in therapy response. The clinical value of our oncology portfolio is validated by physician adoption. More than 95% of oncologists who ordered our tests in 2025 utilized both Northstar Select and Northstar Response in tandem, highlighting their complementarity in guiding cancer care.

Our Northstar portfolio

Our Northstar portfolio for oncology consists of smNGS-based pan-cancer liquid biopsy tests that provide comprehensive therapy selection (Northstar Select) and therapy monitoring (Northstar Response) for late-stage, solid tumor cancer patients. Using a blood-only approach with a focus on sensitivity and precision, we are committed to pushing the limits of cfDNA testing to ensure patients are getting the most advanced profiling and monitoring tools available, while maintaining the convenience of a single blood draw.

Northstar Select

In January 2023, we launched Northstar Select, which is an ultrasensitive liquid biopsy test using smNGS. Northstar Select can provide insight into what therapies may be appropriate for a patient with stage III or IV cancer. Our Northstar Select test has demonstrated industry-leading performance, including two to five times lower limit of detection (LOD), which results in more than 50% more actionable mutations identified than comparator products.

In 2025, the MolDX Program, which is administered by Palmetto GBA, a Medicare administrative contractor, determined Northstar Select meets the coverage requirements under LCD L38043. The MolDX Program's thorough review process confirms Northstar Select's clinical validity and utility and enables reimbursement for Medicare and Medicare Advantage beneficiaries who are receiving the test. In the future we may seek FDA approval for certain of our tests, in particular, Northstar Select, which could provide us with competitive advantages such as including enhanced reimbursement through Advanced Laboratory Diagnostic Test (ALDT) pricing; however, it would also subject us to additional regulatory requirements, which can be costly.

Northstar Select achieves a significantly lower limit of detection than other liquid biopsy products

Liquid biopsy tests are dependent on finding tumor molecules circulating in blood that are shed from tumor cells. The tumor shedding rate is highly variable, with many cancers shedding very little ctDNA. This poses a sensitivity challenge for liquid biopsies, especially for variants at low levels, and can lead to potential false-negative results and missed treatment opportunities. The amount of a particular SNV or alteration compared to normal DNA detected by liquid biopsy tests are measured as a variant allele fraction (VAF), with over half of all treatable alterations occurring at a VAF <0.5%, and approximately one fourth occurring at <0.2%. The ability to reliably detect more alterations at a lower VAF is a significant area of unmet clinical need for ctDNA-based testing and an opportunity for technological improvement.

The limit of detection (LOD) is the lower bound limit of an assay's ability to reliably detect alterations at a specific VAF, at a 95% sensitivity. First generation liquid biopsy tests have an LOD that ranges between 0.25%—0.50%, whereas Northstar Select has demonstrated an LOD of 0.15%, representing a 2-fold higher sensitivity than these other assays. Since most treatable mutations occur at very low VAFs and studies have shown that even mutations found at <0.20% VAF respond to therapy, Northstar Select uncovers more treatment options for patients.

The sensitivity of other liquid biopsies is even more problematic for copy number variants (CNVs). During a cancer's development and evolution, certain genes may replicate in number, driving uncontrollable growth. CNVs are increasingly recognized as hallmarks of cancer. While there are therapies that target these CNVs,

CNVs are very difficult to detect in plasma due to amplification bias inherent in standard NGS approaches. smNGS-based Northstar Select solves this problem and achieves an LOD that is approximately five to eight times lower than other liquid biopsies.

Northstar Select detects >50% more actionable mutations than comparator assays

In a head-to-head clinical validation study, we compared the performance of Northstar Select against commonly used first-generation ctDNA comprehensive genomic profiling assays. Northstar Select found superior detection rates with 51% more actionable SNVs and Indels, and 109% more CNVs than conventional liquid biopsies. Moreover, the study results showed that variants detected at VAF below 0.20% were overwhelmingly detected by Northstar Select only, demonstrating Northstar's superior sensitivity. In practice, finding more actionable variants can help oncologists more effectively plan treatment for their patients, improving overall patient care.

Northstar Response

In January 2023, we launched Northstar Response, a pan-cancer smNGS-based liquid biopsy test that precisely measured more than 500 genomic loci uniquely methylated in cancer, achieving single-molecule level quantification, without the need for an upfront tissue-sample. In May 2025, along with other improvements, we updated the assay to include more than 2,200 genomic loci. The new version of the assay has a significantly lower LOD, achieving 0.01% LOD. Northstar Response provides epigenomic insight into dynamic changes in a patient's response to therapy and, based on our knowledge of all widely available tests, is the only tissue-free methylation-based assay that quantifies tumor burden with single molecule precision. We believe Northstar Response offers a convenient and more precise method to accurately monitor the molecular changes occurring during a patient's treatment course, which can enable real-time treatment decisions for physicians and patients.

Northstar Response is complementary to standard of care radiographic imaging

The ability to monitor a tumor's response to therapy and rapidly adjust treatment strategy when necessary is pivotal to improving patient outcomes, especially in late-stage cancers. Today, the most common and accepted method to assess treatment response is by measuring changes in tumor size through radiographic imaging (e.g., CT, MRI, and PET scans). Radiation exposure, infrequent scans, pseudo-progression with immuno-oncology therapy, and inability to precisely quantify changes, highlight some of the limitations of an anatomic-only based approach in treatment monitoring. Our Northstar Response test is complementary to traditional imaging and introduces real-time, single-molecule quantification to treatment monitoring with a Tumor Methylation Score (TMS). TMS is a quantitative metric that measures the extent of cancer-specific DNA methylation signal that is present in blood and reflects whether the tumor is growing or shrinking in a cancer patient when measured longitudinally. Using a DNA methylation-based approach in conjunction with our smNGS platform, we bring a new level of precision that can help determine molecular progression or therapy response at multiple time-points over the course of a patient's treatment.

Northstar Response is highly accurate at measuring changes in tumor burden across cancer types

Our pan-cancer Northstar Response assay has been analytically validated across more than 10 tumor types and has been evaluated in several clinical studies. In one study, we demonstrated that our assay could detect minute changes in cfDNA burden as small as 0.02% (e.g., an elevation of tumor fraction from 0.02% to 0.04%) demonstrating high sensitivity for a tissue-free, blood only test. The assay also achieves a coefficient of variation (CV) of less than 10% for a typical sample with 1% tumor fraction, which is at least two times lower than conventional tumor-naive, targeted-panel methods that measure VAF. It has demonstrated a strong correlation with clinical outcomes in patients with lung, colorectal, and pancreatic cancers.

We also collaborated with the University of California, San Diego on a study involving immunotherapy and immuno-chemotherapy treated advanced non-small cell lung cancer patients. In that study, which involved 60 samples from 51 patients, Northstar Response's changes in TMS measured four to ten weeks after starting treatment significantly predicted real-world progression free survival (rwPFS, $p < 0.0001$), compared to standard imaging assessments which did not reach statistical significance ($p = 0.55$). The p-value is used to determine the probability as to whether the difference between two data sets is due to chance. The smaller the p-value, the more likely the differences are not due to chance alone. In general, if the p-value is less than or equal to 0.05, the outcome is considered statistically significant. The study also showed that the test often detected treatment response and progression earlier than standard of care CT scans, with high concordance between TMS and clinical outcomes.

In collaboration with Allegheny Health Network (AHN), a separate pan-cancer validation cohort of 54 advanced stage cancer patients (lung, melanoma, and six other solid-tumor cancers) treated with immunotherapy regimens, TMS-based molecular responders had significantly better progression free survival (PFS) (HR=0.26) and OS (HR=0.18) than molecular non-responders. This was particularly remarkable given that the separation between responder and non-responder was made within the first 90 days from baseline and was predictive of durable outcomes years in advance. Molecular responders at day 90 had a significantly improved median overall survival of over two years longer compared to patients who were found to be molecular non-responders.

In addition to the aforementioned studies, we are further engaged in multiple prospective clinical validation studies spanning all solid tumor and therapy types. Our flagship NORTH study is a multi-site study with over 500 late-stage (stage III/IV) solid tumor cancer patients undergoing systemic therapies. We completed enrollment of the study in early 2025 and expect to complete sample and data collection by the end of 2025. We expect the initial results to be available in 2026. The NORTH study, along with other ongoing clinical studies, has the potential to generate sufficient clinical validity evidence for our MolDX submissions for Medicare coverage. We have also engaged with academic key opinion leaders in specific disease areas to provide more insights into the validity and utility of Northstar Response. In collaboration with University of Florida, we are conducting a 100-patient prospective study examining the clinical validity of Northstar Response focusing specifically on advanced gastrointestinal tumors. The study completed enrollment in March 2025. In collaboration with University of Miami, we are engaging in a clinical utility study to identify metastatic pancreatic ductal adenocarcinoma (mPDAC) patients who may benefit from ctDNA informed switching to second line chemotherapy based on early measures of response at four weeks following first line treatment initiation. We have also sponsored an investigator-initiated study at the Fred Hutch Cancer Center to assess the clinical validity of Northstar Response in quantifying therapy response in appendiceal and metastatic peritoneal tumors, which are more difficult to assess by imaging modalities.

Additional opportunities in oncology

We are actively developing additional diagnostic products to address critical needs across the cancer care continuum. For example, in January 2026, we launched Northstar PGx, and in February 2026 we launched Northstar Select CH. Northstar PGx and Northstar CH are add-on applications for Northstar Select, and expand the Northstar platform beyond genomic profiling to address chemotherapy safety (PGx) and clonal hematopoiesis (CH) — two critical decision points in selecting the right therapy for patients. Our current development efforts focus on MRD detection, leveraging our platform's exceptional sensitivity to identify trace amounts of tumor DNA following curative-intent surgery in earlier stage cancers. We are developing a tissue-free, pan-cancer MRD test, which we expect to be commercially available in the fourth quarter of 2026. Longer term, we believe that our smNGS-based technology could address the sensitivity challenges of early-stage cancer detection. While we have not yet started development in this area, the research work that we have done for Northstar Response and MRD is a necessary precursor for early detection development. We also believe that there is significant potential for our smNGS platform to accommodate products in this area. We believe the molecular information provided by our tests can assist in predicting the diagnostic pathway that can confirm the presence and tissue of origin of cancer. As a part of our five-year strategic plan, we have included the necessary R&D funding for development of an early detection test that builds upon our earlier work.

Our vision of powering AI-enabled personalized medicine for all

Healthcare today stands at an inflection point, poised for transformation through the convergence of unprecedented molecular insights and AI. Despite significant advances in precision medicine, particularly in oncology where treatments have evolved from being organ-based to increasingly being mutation-based, response rates for many marketed targeted therapies can be as low as single-digit percentages in their indicated patient populations. Similarly, pregnancy care follows one-size-fits-all standardized protocols despite unique patient biology. Even with broader technological advances, clinicians still cannot reliably predict or prevent major complications like preterm birth, preeclampsia, and gestational diabetes. This sobering reality underscores a fundamental challenge: many current approaches to precision medicine often rely on single biomarkers that fail to capture the full complexity of disease biology and individual patient variation. We believe that these important problems can be addressed in the future with the combination of AI and smNGS technology.

We believe AI-enabled personalized medicine can revolutionize healthcare delivery across all specialties. Truly personalized medicine requires the (i) characterization of the disease specific to each patient beyond the presence of the single mutation marker to quantification of disease biology of individuals at the single-molecule

level, and (ii) integration of this characterization with multi-modal clinical history, powered by AI. We have already built products for this characterization, and we are starting to integrate our diagnostics with this multi-modal clinical history.

Our approach to building AI-enabled precision medicine will begin with our ability to generate extraordinarily precise molecular data. As we continue to generate unique data via our smNGS platform, we are building a differentiated and clinically actionable genomics dataset. Our advantage stems from two key factors: first, our biomarker measurements achieve single-molecule precision and sensitivity, capturing the key disease-causing molecular signatures in cfDNA; and second, our response monitoring assay provides an objective measurement of how a patient is responding to a therapy. AI has recently unlocked widespread access to and analysis of multimodal patient clinical history data. This powerful combination positions us to harness AI for identifying distinct patient subgroups based on their specific biomarker profiles and for predicting how each subgroup will respond to different therapeutic approaches. By mapping these response patterns with extraordinary granularity, we believe we will be able to deliver personalized treatment recommendations based on each person's unique biology that maximize efficacy while minimizing adverse effects — moving precision medicine from aspiration to clinical reality.

Our Technology

Our smNGS platform leverages proprietary and patent-protected technologies that allow us to detect previously undetectable diseases and support physicians developing and managing treatment plans for patients. Our platform integrates our patented QCTs, proprietary machine learning algorithms embedded in sophisticated bioinformatics systems, and a quantitative, iterative, engineering-oriented assay design.

We developed our smNGS platform specifically to address the fundamental challenge of cfDNA scarcity. cfDNA is the extracellular DNA found in blood plasma that is released by all tissues as a part of both normal and pathological cellular processes. cfDNA offers non-invasive windows into the genetic make-up and disease status of different tissues throughout the body. However, the concentration of cfDNA is typically very low, and the amount of cfDNA from any given source, such as a fetus or a tumor, is even lower. For a pregnant patient, typically only 2% to 15% of the cfDNA in a standard blood draw is of fetal origin. For a cancer patient, approximately between 0.01% to 1% of the cfDNA is derived from a tumor, depending on cancer stage. Notably, there is often only one cfDNA molecule present in a sample for any given genomic location associated with disease, even in advanced cancer patients.

Breakthrough performance capabilities

Our smNGS platform performs absolute quantification of different DNA species down to the level of a single DNA molecule. In addition, smNGS can interrogate thousands of loci simultaneously on the same sample. The cumulative number of cfDNA molecules corresponding to disease can then be summed across all of these loci, thereby amplifying the scarce disease signal by thousands. This capability is especially important for applications such as tissue-free response monitoring and MRD. In contrast, traditional methods are only able to achieve modest relative quantification, far from single molecule level, precluding any applications that require precise quantification.

In comparison to other DNA analysis methods, smNGS uniquely combines precise measurements with a high degree of multiplexing, as depicted in the figure below. ddPCR, the only other established method of performing absolute quantification, is limited to multiplexing no more than one to four probes, making it impractical for clinical testing that requires interrogating more than one hundred loci to cover even a few genes of interest.

Traditional NGS methods have transformed many areas of clinical testing due to their ability to multiplex across thousands of loci, such as enabling a single clinical test to cover multiple genes. However, these NGS methods face significant limitations when applied to cfDNA analysis. The scarcity of cfDNA necessitates amplification by a factor of millions before it can be sequenced. This amplification occurs at different rates across different genomic loci, which introduces significant biases that challenge traditional NGS methods, even for relative quantification. Moreover, these NGS methods struggle with the easiest copy number analyses, such as the ability to distinguish one copy of a gene versus two copies, as may be needed for a standard germline or carrier testing. Consequently, the gold standard for clinical testing of copy number analysis is pre-NGS technologies, such as microarray and multiplex ligation-dependent probe amplification. The identification of these copy number changes in cfDNA requires detecting a change that is more than 100 times smaller, since the fraction of cfDNA that is derived from the fetus or the tumor can constitute less than 1% of the total cfDNA. Only our smNGS platform can detect CNVs in cfDNA at these levels today. Similarly, smNGS is needed for determining

fetal risk in single-gene recessive conditions and precisely quantifying response to therapy, as these problems require absolute quantification of a low cfDNA signal against a high background originating from other tissues.

The components of our platform

Our smNGS platform seamlessly integrates several tools and patented technologies, which are further described below.

Quantitative Counting Templates (QCTs)

QCTs are the foundation of our smNGS technology. They are artificial DNA fragments that we design and synthesize to mimic the properties of the human DNA loci that are being interrogated in an assay. A specific identifier is embedded into the sequence that flags the QCTs as synthetic controls, and a randomized embedded sequence ensures that each QCT is unique. QCTs are added to the biological sample at the start of the testing process so that they are subject to the same laboratory processes, including amplification and sequencing, as the disease-associated genetic molecules that the assay targets. Importantly, QCTs amplify at the same rate as the genetic targets. We can then precisely calculate the amplification and sequencing biases that were introduced during the sample processing and remove their effects from the data to absolutely quantify the number of cfDNA molecules that are present in the sample. The precise number of QCT molecules added to each specimen is calculated bioinformatically through the counting of the number of diversity regions in the sequencing data. This method is therefore “calibration-free” and does not require the exact measurement and titration of spike-in DNA concentrations, a feature that is particularly advantageous for quantitative assessments across multiple timepoints in longitudinal monitoring contexts.

QCTs are compatible with almost all NGS library preparation methods and can be used to measure both genetic and epigenetic changes, such as methylation. Our ability to absolutely quantify methylation across genomic loci allows us to combine signals from thousands of genomic loci to reduce the amplification and sample processing noise to negligible levels, thereby converting a 0.01% signal to the equivalent of a 10+% signal.

QCTs are used in our testing workflow with the following steps:

1. **Add** an aliquot of traceable and specific QCTs into the patient’s blood sample, which contains an unknown number of DNA fragments of interest (m1) among a vast background of the patient’s genome. The precise number of QCT molecules (n1) is also unknown at this stage but is determined in a subsequent step.
2. **Amplify** the cfDNA fragments of interest using PCR at the same, unknown amplification rate as QCTs.
3. **Count** the number of clusters of sequences with identifier tags (i.e., the number of distinct QCTs with different diversity regions), which is equal to the number of QCTs that were added to the sample (n1).
4. **Determine** the amplification multiplier (x) by dividing the number of total sequencing reads that map to QCTs by the number of QCTs (n1).
5. **Remove bias** by dividing the total number of sequencing reads that map to cfDNA fragments of interest by x to find the absolute number of molecules in the cfDNA sample (m1).

We believe that QCTs provide unprecedented insight into disease biology across the human genome. We have developed custom machine learning models to analyze the tiny, individualized variations across hundreds of thousands of patients, uncovering novel patterns of disease biology. These insights are incorporated into our assays to significantly improve performance. We continuously refine our understanding of disease biology to support existing and future diagnostic products.

Custom bioinformatics with machine learning

Due to the vast amounts of data generated by genetic sequencing, robust bioinformatics are required to analyze the data and identify mutations of interest. Our smNGS platform requires the use of proprietary bioinformatics to further analyze the data generated by the genetic sample and QCTs to accurately quantify the presence of disease. A selection of proprietary bioinformatic tools enabling the single-molecule sensitivity of smNGS includes the following:

- Our bioinformatic tools implement numerous quality control metrics that enable single molecule sensitivity, for instance, the QCTs' ability to identify cross-contamination between samples down to a 0.001% level.
- Our bioinformatic models enable us to effectively combine signals across thousands of loci, enabling unprecedented sensitivity.
- The close collaboration between our clinical and bioinformatics teams enables us to curate personalized reports for patients. For example, there are more than 500 types of results that our fetal risk screen can provide with a vast repertoire of risk assessment.
- Our custom bioinformatic tools enable design-based approaches to assay development, significantly reducing the time and cost of building a novel assay.

Specialized and scalable infrastructure

Our smNGS platform leverages specialized and scalable infrastructure that we have spent years building and refining. Our laboratory infrastructure has been custom designed from the ground up to support the single molecule sensitivity of our assays. The scalability of our tests has been built over time through automation, which has enabled us to maintain single molecule sensitivity while driving down COGS. While the vast majority of our laboratory processes are now fully automated, it was accomplished through a deliberate step-by-step approach of continuous implementation. In addition to the smNGS technology that we have developed, we believe that the current scalability of our assays also gives us a multi-year advantage. For example, it took an entire year to automate one single step of our sgNIPT assay, automated cfDNA extraction with the same yield as manual column-based extraction, to maintain the same single molecule sensitivity.

Once a sample is received at one of our facilities, it is processed through a single-directional workflow across four separate labs, each with strictly separated and segregated airflows and air filtration systems. Every step in the laboratory process is designed to optimize yields and support a high-quality testing process. By leveraging smNGS techniques and strictly controlling the workflow and environment, we can detect sample cross-contamination at the single molecule level and even determine the exact point in the process where the contamination occurred, including potentially at the clinic where the sample was collected. Even if QCTs were deployed in a traditional NGS lab, post-PCR contamination that is typically found in such labs would preclude the single molecule sensitivity, absent a complete redesign of not only the assays and bioinformatics, but of the entire laboratory infrastructure.

We have also utilized automation and AI throughout our infrastructure to reduce errors and increase laboratory throughput. By automating our labs, we are able to build uniformity into sample processing and can rapidly identify and triage problems as they occur. Each individual lab contains specialized equipment with bespoke programming to drive specific processes and to progress the sample through the testing workflow. In addition, we also integrate third-party large language models and AI to improve our laboratory workflows. For example, we completely redesigned and automated our biological sample accessioning process by incorporating AI and computer vision that automates labor-intensive clerical tasks. This allowed us to redeploy our laboratory personnel to higher impact areas. While our current laboratory space is already sufficient for at least four times more growth, our process engineering and automation teams continue to work on creative solutions to further scale our laboratory capacity and decrease our COGS.

IP and know-how

Our smNGS platform is protected by a suite of patents and proprietary technological know-how. Our patented technologies differentiate us from our competitors and support improved quality controls, enable nimble product iteration, and drive rational assay design that allow us to build novel products with attractive gross margin. We have multiple issued patents for our core technologies and our ancillary technology in the United States and internationally. Our core patents cover various approaches to using synthetic molecules to provide accurate counting of target molecules, which is our QCT technology, as well as protecting the following technologies:

- **Dilution tagging** is a novel method to quantify the abundance of targeted DNA molecules across a dynamic range of many orders of magnitude. This technology enables low-cost sequencing of cfDNA samples with rare sequences without the loss of quantitative information. For example, this can reduce sequencing costs by 10-50x for sequencing intensive applications, such as immune receptor repertoire profiling and single cell RNA sequencing.
- **Spike-in technology** refers to synthetic DNA controls custom-made for each assay and added to every patient sample. These DNA controls enable the calculation of relative abundance of targeted DNA molecules at a low cost.

- **qSanger technology** combines spike-in technology with custom-built, proprietary signal processing and applies it to Sanger sequencing and capillary electrophoresis, bringing the power of quantification to previously qualitative technologies. This approach brings NGS-level precision to easy-to-deploy technologies and enables their use as low-cost and high-throughput diagnostic tools.

Beyond these patented technologies, we have developed substantial proprietary techniques and know-how throughout our organization that are critical to our R&D and commercial success. We protect our IP through a comprehensive strategy including patents, trademarks, copyrights, trade secrets, confidentiality agreements, and other contractual protections. For further details on our IP portfolio, including issued and pending patents, see Part 1, Item 1 “Business—Intellectual property.”

Engineering biology approach

Our focus on quantification fundamentally transforms our R&D approach. We believe, by leveraging the precise molecular measurements enabled by our smNGS platform, we significantly reduce biological and clinical risks in our diagnostic pipeline. When designing new assays, we build mechanistic models that mathematically predict clinical performance with high confidence, transforming diagnostic development from a biology-driven trial-and-error process with inherent uncertainties into an engineering challenge with clear, solvable parameters.

We believe this engineering biology framework delivers exceptional capital efficiency. While many competitors invest heavily in exploratory biological research with uncertain outcomes, our quantification-first approach enables us to predict diagnostic performance based on biomarker measurability rather than speculative biology. We believe this targeted strategy accelerates time-to-market and significantly improves our success rate in developing category-defining products, creating substantial value for patients and shareholders alike.

We have complemented these technological advantages with an innovative organizational structure inspired by Bell Laboratories, Inc. Our R&D model organizes core scientists into focused teams reporting directly to our CEO and CTO, eliminating bureaucratic layers and accelerating decision-making. Each scientist has end-to-end responsibility across the biochemistry and bioinformatics technology stack and is empowered to drive new products from conception through commercialization. This structure enables rapid iteration with minimal resources. We believe this combination of technological foundation and organizational design will create compounding advantages that widen the gap between BillionToOne and our competitors over time.

Future uses of artificial intelligence

Productivity improvements

We have already begun to harness the transformative potential of AI to drive productivity improvements across our operations. For example, AI has significantly reduced the time required on sample accessioning, reimbursement, and healthcare operations, while substantially improving software programming productivity. These early applications represent just the beginning of our AI integration strategy. We envision an organization where AI augments virtually every functional area, creating a continuous cycle of productivity enhancement and financial performance improvement. By progressively automating routine tasks, we expect to increasingly redirect our exceptional talent toward high-value, creative activities that drive innovation and competitive differentiation. We believe this will further strengthen our differentiated financial profile by continuously improving the ratio of revenue to operating expense.

Personalized medicine

We believe that our smNGS platform is building a uniquely valuable genetics dataset due to its ability to detect single molecules at scale. We have processed over one million tests to date and our dataset continues to grow rapidly. AI can reduce medical chart extraction costs by over 90%, enabling the synthesis of smNGS molecular data and AI-extracted longitudinal clinical data for each patient. This powerful combination creates the potential for us to increasingly provide more actionable and personalized clinical reports of treatment strategies while minimizing adverse effects for patients, making our products increasingly more valuable.

Industry Background

The strengths and challenges of precision-based diagnostic solutions

Precision diagnostics has emerged as one of the most critical components of healthcare in improving patient outcomes across multiple therapeutic areas. Through the identification of actionable unique biomarkers, diagnostic tests can offer critical information for the diagnosis and treatment of diseases. Historically, directly

obtaining a sample from the fetus or the tumor for analysis has been the standard of care for prenatal and oncology diagnostics, but such procedures are highly invasive and can lead to inconclusive results. More recently, many areas of care, including prenatal and oncology, have been transformed by cfDNA diagnostics. Both genetic and epigenetic properties of cfDNA reflect the originating tissue and can be used to diagnose and monitor disease. However, while powerful, the extremely limited availability of cfDNA in blood poses significant challenges to traditional diagnostics. The fraction of cfDNA that is of fetal or tumor origin can be as low as 0.01% to 1.0% of the total cfDNA, and often there is only a single molecule that corresponds to the particular mutation of interest within a tube of blood. To address this challenge, the DNA sample must be amplified during laboratory processing by a factor of millions, which adds significant errors and biases that are then difficult to differentiate from the actual targeted mutations. It also makes quantification extremely challenging, as the original signal can be orders of magnitude smaller than these errors and biases.

The need for comprehensive prenatal testing solutions

In 2023, the U.S. Center for Disease Control and Prevention (CDC) reported approximately 3.7 million births in the United States, with about one in every 33 infants affected by congenital anomalies. These anomalies can be due to chromosomal abnormalities or single gene inherited disorders. While commonly-used cfDNA prenatal tests can detect chromosomal abnormalities, they are unable to screen for these inherited single gene conditions, such as sickle cell disease, cystic fibrosis, alpha-thalassemia, beta-thalassemia and spinal muscular atrophy (SMA). These five recessive conditions are common, clinically actionable, and recommended for universal screening by ACOG, with one in six pregnant individuals in the United States being a carrier for recessive conditions.

Inherited single gene conditions can be identified through carrier screening of the parents, followed by invasive diagnostic procedures such as amniocentesis. One of the most significant problems with traditional carrier screening is the requirement for both maternal and paternal blood draws. Obtaining the paternal blood sample is logistically challenging in an obstetricians-gynecologists (OB-GYN) setting. As reported in studies by independent publications, in at least 58% of cases when the mother is identified as a carrier, the father's carrier test is not performed, resulting in the majority of affected pregnancies to be undetected.

The significant prevalence of genetic disorders underscores the critical need for safe and effective prenatal screening methods. By identifying these disorders prenatally, we can significantly improve patient outcomes through earlier therapeutic interventions. For instance, SMA is a progressive and debilitating disorder that causes irreversible damage to affected newborns every day following birth. Administering therapy within the first six weeks of life can be the difference between lifelong physical disability and meeting age-appropriate physical milestones. Prenatal detection of SMA is critical when considering the timelines for newborn screening, confirmatory molecular diagnostics and insurance authorization for expensive therapies. Similarly, there are an increasing number of case reports where specialists prescribe therapeutics to carrier pregnant mothers with affected CF fetuses, which significantly improved newborn outcomes. In addition, novel diagnostics enable the development and use of novel therapies. We have a global exclusive partnership with Johnson & Johnson in which a therapy for preventing HDFN is administered only to those at-risk pregnancies that we identify through our non-invasive fetal testing.

We have two strategic partnerships with Johnson & Johnson. The first relates to our UNITY fetal antigen clinical trial assay in Johnson & Johnson's AZALEA Phase 3 clinical trial of nipocalimab in HDFN. The second is governed by a development and commercialization agreement we entered into with Johnson & Johnson on July 11, 2025 (as amended, the Commercialization Agreement), which governs our collaboration on a companion diagnostic product for nipocalimab. The Commercialization Agreement sets forth the roles and responsibilities, including development activities, to be performed by each party; the timelines for development activities and associated milestone payments; and target specifications for the companion diagnostic product. Under the Commercialization Agreement, Johnson & Johnson made an initial payment to us, with subsequent payments due upon achievement of specific milestones, including submission of the companion diagnostic product to the FDA for marketing approval by January 2028, and FDA approval of the companion diagnostic product, by the later of (i) December 2029 and (ii) one year after Johnson & Johnson obtains regulatory approval for nipocalimab. The cumulative amount of upfront fees, milestone payments, expenses and costs payable to us under the Commercialization Agreement will not exceed $13 million. The Commercialization Agreement will remain in effect until such time as Johnson & Johnson ceases the development and commercialization of nipocalimab. While we expect to make the FDA submission of the companion diagnostic product by January 2028, the exact timing of FDA approval will depend on the approval timeline of the associated Phase 3 clinical

trial of nipcalimab. The timing and conduct of the Phase 3 clinical trial, including submissions to the FDA, are the responsibility of Johnson & Johnson and its affiliates, as the sponsor of the trial.

The market demand for more sensitive and precise oncology tests

Cancer is the second leading cause of death according to the CDC. Despite the breadth of therapeutic options, treatment response rates can be as low as single-digit percentages due to differences in genetic and epigenetic patient profiles. Enabling more personalized cancer treatments and better outcomes requires more sensitive and precise tests to (i) select the best therapy regimen and (ii) monitor the patient's response to that treatment.

The gold standard for cancer therapy selection has been a tissue biopsy, which can be sequenced to determine the tumor profile. However, tissue biopsies can be invasive, challenging to obtain, and can lead to inconclusive results and quality control failures from the extracted DNA. They may also miss mutations due to tumor heterogeneity. In addition to tissue biopsies, non-invasive liquid biopsy tests are a rapidly growing approach to analyze tumor DNA. Faster and more convenient blood-based tests may allow earlier treatment; however, they also have lower sensitivity due to very low amounts of circulating tumor DNA (ctDNA) shed by tumors. This challenge has meant traditional liquid biopsies often miss targetable tumor mutations at lower ctDNA fractions.

Our Northstar Select test addresses these challenges by capturing tumor-specific variants with high sensitivity at low variant allele frequencies (VAF). In essence, our test enables physicians to detect mutations in cancers that other diagnostic tests might miss. The detection of these mutations can enable better, more targeted therapies that their patients would otherwise not receive. We have demonstrated the analytical and clinical validity, as well as the clinical utility, of our Northstar Select test through rigorous reviews. Analytical validity refers to how accurately and reliably the molecular diagnostic test measures the specific DNA, RNA, protein, or other molecular target it is designed to detect. Clinical validity refers to the accuracy with which a molecular diagnostic test correctly identifies the presence or absence of a specific genetic variant, biomarker, or molecular target associated with a disease or condition in the intended patient population. Clinical utility refers to the likelihood that a test will, by prompting an intervention, result in an improved health outcome.

In February 2025, these reviews resulted in the decision to grant Medicare coverage for the Northstar Select test for eligible beneficiaries with advanced solid tumors who meet the Molecular Diagnostics Services program (MolDX) coverage criteria. The clinical validation data submitted as part of the MolDX evaluation included a head-to-head concordance study, directly comparing the utility of our test to that of our leading competitors. The results demonstrated the superior sensitivity of Northstar Select by identifying 51% more single nucleotide variants (SNVs) and 109% more copy number variants (CNVs), most of which were found below the comparator assays' 95% limit of detection.

While the number of cancer treatment options continues to expand, determining whether a specific treatment is working for an individual patient remains a significant challenge that relies too heavily on subjective assessments. Currently, doctors use medical imaging (e.g., computed tomography (CT) scans, magnetic resonance imaging (MRIs), and positron emission tomography (PET) scans) as the primary tool to evaluate a patient's cancer status. However, this approach has important limitations affecting both accuracy and reliability. Tumors often contain diverse cell populations that respond differently to treatment, making overall assessment difficult. Some patients receiving immunotherapy experience "pseudoprogression," where imaging temporarily shows growth even though the treatment is working. Scar tissue forming around tumors can be hard to distinguish from active cancer. Certain areas of the body, like bones and the abdominal cavity lining, naturally provide poor contrast on imaging, making cancer changes difficult to see. Lastly, interpreting scans involves significant human judgment, introducing inconsistency between different radiologists' assessments.

The practical limitations of imaging also create problems. Most patients undergo scans only every few months, leading to critical delays in determining whether a treatment is effective. These delays can result in patients continuing ineffective therapies longer than necessary or missing opportunities to begin alternative treatments sooner. While increasing scan frequency might seem like a solution, patients face real-world barriers including limited availability of imaging equipment (especially in rural areas), the physical and financial burden of traveling to specialized imaging centers, and substantial costs that might not be fully covered by insurance. These limitations create an urgent need for better tools that can assess treatment response more accurately, consistently, and frequently to help doctors make timely and informed decisions about patient care.

Northstar Response is designed to solve these problems. Northstar Response is a tissue-free, pan-cancer, smNGS-based liquid biopsy test that precisely measures more than 2,200 genomic loci uniquely methylated in cancer. Based on our knowledge of all widely available tests, Northstar Response is the only methylation-based

assay that quantifies tumor burden with single molecule precision and provides insight into dynamic changes in a patient's response to therapy. In validation studies, Northstar Response showed a consistent ability to detect quantitative changes in tumor fraction across more than 10 different cancer types, in some cases as much as six months earlier than indicated by imaging scans. Northstar Response has been analytically and clinically validated in three peer-reviewed publications, including in collaborations with the University of California, San Diego and the University of Florida.

Northstar Response is now undergoing further validation through our large flagship study: NORTH (Northstar Oncology Response Monitoring Test Hallmark). NORTH is a multi-site study with over 500 Stage III and IV solid tumor cancer patients undergoing systemic therapies. Enrollment of the study, as well as sample and data collection, were completed in 2025, and we expect results to be available in 2026. The NORTH study, along with other ongoing clinical studies, have the potential to generate sufficient clinical validity evidence for our MolDX submissions for Medicare coverage.

Beyond late-stage cancer testing, we recognize there is a significant need for more powerful early-stage cancer testing. We are developing additional oncology products for these cancer patients, including MRD testing. Current standard of care for early-stage cancer is the surgical removal of the tumor. However, a small number of cancer cells may remain and can lead to future metastasis. MRD testing post-surgery enables healthcare providers to administer adjuvant therapy when needed and can also be used to monitor cancer recurrence over time. There are two approaches to MRD testing today, tumor-informed and tumor-naive. Tumor-informed approaches involve sequencing the cancer tissue to identify mutations which can then be tracked in blood at subsequent points in time. Tumor-informed approaches can have up to 40% failure rates due to the limited amount of tissue that can be obtained in early-stage cancers or tissue sequencing failing to identify a sufficient number of variants that can be used for MRD tracking. Moreover, the mutations that are tracked may not represent the evolution of the tumor, resulting in false negatives. Tumor-naïve approaches measure the levels of ctDNA in a patient's blood and do not require an upfront tissue sample, but to date, their lower sensitivity has been a limiting factor in their adoption. We believe that our smNGS platform will allow our planned MRD test to address the sensitivity challenges of existing tumor-naïve assays.

Publications and collaborations

We have extensive publications on our smNGS platform and products. Our UNITY Fetal Risk Screen clinical publication in Genetics in Medicine was selected for the Top 10 publications in Genomic medicine year in review 2023 by AJHG. Our hallmark publications in the Obstetrics & Gynecology journal (the Green Journal) demonstrated 100% sensitivity and specificity in approximately 860 patients for fetal RhD and other fetal RBC antigen detection, ultimately leading to the ACOG practice guideline changes.

The analytical and clinical validity of our Northstar products have also been demonstrated in peer-reviewed publications. The analytical validation of Northstar Response was published in January 2025 in Scientific Reports while additional clinical studies of the assay performance in lung and liver cancer cohorts were published in Clinical Lung Cancer and the Journal of American College of Surgeons, respectively. The analytical and clinical validation of Northstar Select, including the head-to-head comparison against other on-market assays published in August 2025, demonstrated Northstar Select's superiority in detection of SNV and CNVs as relative to commercially available competitors. Beyond peer-reviewed journal publications, we have published posters and abstracts at various medical conferences including AACR, AACR LBx, ASCO, and the International Society of Liquid Biopsy.

Commercialization

We commercialize our UNITY and Northstar tests in the United States through our direct sales force targeting physicians in the prenatal and oncology markets, respectively. As of December 31, 2025, our clinician-focused sales organization included 231 sales representatives, with 177 in prenatal and 54 in oncology. In comparison, we had a total of 137 sales representatives at the end of 2024, 120 in prenatal and 17 in oncology. We plan to continue to expand our field sales force systematically, as our prenatal sales force is less than one-third the size of our largest competitor and our oncology sales force is very small relative to many other liquid biopsy companies. Our sales representatives in prenatal are engaged in educating OB-GYNs, MFMs, genetic counselors (GCs) and others about the existence, uniqueness and clinical utility of our offerings. Our sales representatives in oncology conduct similar commercial and educational activities and primarily engage with oncologists. We have supplemented our direct sales team with medical science liaisons (MSLs) who are generally genetic counselors in prenatal and PhDs in oncology, as well as adding other support staff to help onboard clinics and to manage the physician and patient experiences.

Our sales force achieved an annualized revenue run-rate of $2.2 million per sales representative in the year ended December 31, 2025. We believe our high sales efficiency is driven by the combination of our differentiated products and our ability to provide a seamless, end-to-end solution that enhances both the patient and provider experience and significantly reduces churn. Our cohort analysis indicates that the net test retention, as defined by the total number of tests that are received from a cohort of clinics first onboarded in a particular quarter, even after accounting for any account or provider churn, is over 100% after a year for the majority of quarterly cohorts. Our sales efficiency has also increased over time, and we believe this efficiency will be maintained or further increase as we systematically grow our sales team.

We also drive physician awareness of our products by actively participating in industry conferences, publishing in relevant scientific journals, and driving dialogue with key opinion leaders and physician organizations. These efforts have already resulted in practice advisory changes within the prenatal field, including for RhD and fetal antigen NIPT. Across both prenatal and oncology, we believe that our ongoing and planned studies will help drive increased guideline expansion. Through our extensive digital marketing, we also engage directly with motivated patients, and this can lead to access to physicians in clinics that typically do not otherwise allow sales representative presence.

In international markets, which represented less than 1% of our revenue for the year ended December 31, 2025, we primarily sell through distributors, which collect and send samples to our laboratories in the United States. In these markets, the patient bears the full cost of the testing, which limits the adoption. In the future, we believe that the health economics of our tests will enable nationwide coverage via single-payor agreements. However, this is often predicated on the tests being performed locally within the country, requiring capital investments in international markets. While we believe that international expansion could significantly expand our total addressable market, we are currently focusing on expansion opportunities in the United States.

Prenatal commercialization

We sell our UNITY products through direct targeting of OB-GYNs, GCs, MFMs and others in the United States. Our penetration in prenatal is often executed via a “land-and-expand” strategy in which the adoption of UNITY by one physician in a larger clinic often leads to increased access and broader adoption of our tests by other physicians in the clinic. This approach enables us to first access clinics and then expand within those clinics by providing an excellent end-to-end service. Our high client satisfaction is evidenced by our low churn, which is an important factor in our rapid growth.

Our tests are typically ordered during the first trimester, starting as early as nine weeks into the pregnancy, and help physicians and patients assess risk across a variety of conditions. We have simplified billing process that consolidates all tests ordered into one claim and one bill. Our dedicated clinical support staff aids in our commercial and education efforts by providing workflow implementation, patient and payor billing, and report interpretation.

We also have a global partnership with Johnson & Johnson in the AZALEA Phase 3 clinical trial of nipocalimab in pregnancies at risk for severe HDFN, in which UNITY Fetal Antigen CTA is exclusively used for determining patient eligibility, and a related U.S.-specific partnership regarding development of a companion diagnostic product. Exclusivity of this arrangement is another proof point of the unique capabilities of our products. We believe this partnership and potential future partnerships or collaborations with other partners can boost awareness and adoption of our tests, while also providing us with access to patients who can benefit from our products.

We will also continue to increase the size of our direct sales force to better penetrate existing markets and to cover new territories in the United States. Our sales team was built with proven performers, and we have designed a robust training infrastructure to continue our leading sales efficiency as we continue to grow the team.

Oncology commercialization

Our oncology strategy is dedicated to the cross-selling of both Northstar Select and Northstar Response. These complementary products support physician decision-making on initial therapy selection, monitoring patient response to treatment, and informing treatment modification when necessary. The head-to-head study that showed significantly higher numbers of actionable mutations that Northstar Select found versus competing assays is an important factor in our ability to persuade oncologists to start using our tests. Each Northstar Select test is often accompanied by a Northstar Response test for the baseline measurement, followed by

additional Northstar Select and Response tests in certain cases as physicians monitor and adapt treatment plans. As of December 31, 2025, approximately 95% of our ordering providers utilize both Northstar Select and Northstar Response tests in tandem for the same patient's care. Higher reimbursement and existing Medicare coverage of our Northstar Select tests allow us to broaden the use of Northstar Response without incurring significant losses. If we were to receive increased coverage and reimbursement for Northstar Response, it would lead to a significant increase in our revenue as the adoption of the test will have already been established.

Outside of our direct sales efforts in oncology, we have signed collaboration agreements with a select number of pharmaceutical companies and institutions to support clinical development of novel precision oncology therapeutics. These collaborations utilize our existing Northstar products, as opposed to developing new assays that are specifically tailored to each agreement.

Our Growth Strategy

We are driving and leading a paradigm shift within precision diagnostics. Our vision is to leverage our novel single-molecule next-generation sequencing (smNGS) platform to develop ultrasensitive diagnostic tests that enable personalized solutions and enhance patient outcomes. Our growth strategy to achieve this goal includes the following elements:

- Drive increased adoption of our existing products in the prenatal and oncology markets. Healthcare professionals have increasingly incorporated our UNITY tests into their clinical practices to adopt what we believe will be the new standard of care. There are three main opportunities to expand our market penetration of our UNITY prenatal products. First, we believe that we have a significant opportunity for footprint expansion and are continuing to invest in increasing our sales team size to cover new geographies, with aggressive recruiting targets. Second, we believe that our current sales team has only just begun to penetrate their existing territories and, over time, more clinics will adopt our tests in an existing sales territory. Finally, we typically see significant growth once we have gained adoption in a clinic, as additional physicians in those clinics adopt our tests.

  We are in the early stages of executing the same sales strategy in oncology. We will continue to drive adoption of our tests by working closely with physicians, medical societies, payors, and patient advocacy groups to educate them on the benefits of our products. We also believe that our commitment to quality customer experience, through patient education, patient self-service, streamlined testing, and patient-friendly billing, will help maintain and enhance usage of our tests. With our Northstar product line, our commercial efforts have just begun, with our field sales team covering only a fraction of the geography. We have significant room to grow, via more geographical expansion, more penetration within existing sales territories, as well as within existing clinics.

- Build beyond our extensive library of clinical evidence to support favorable coverage and reimbursement. In prenatal, our carrier and aneuploidy tests are broadly covered by most major insurance providers, and we have broad reimbursement for the tests we provide. In addition, we have contracts with payors that account for more than 250 million covered lives in the United States as of December 31, 2025, which generally include our oncology products. We are continuing to generate persuasive clinical utility data that we believe can lead to additional payor contracts and justify guideline inclusion.

  While we believe we have industry-leading ASPs for our prenatal products, as we contract with more payors and as certain aspects of our tests are more broadly covered due to guideline inclusions, we believe that our ASP will continue to increase. In oncology, we have already secured Medicare and Medicare Advantage coverage for Northstar Select. For Northstar Response, our flagship study, NORTH, along with other ongoing clinical studies, has the potential to generate sufficient clinical validity evidence for our MolDX submissions for Medicare coverage.

- Utilize our smNGS platform and R&D capabilities to efficiently expand and improve our portfolio of category-defining molecular diagnostic tests. Our foundational smNGS platform fundamentally reduces the biological and clinical risks in our product development process. Because it achieves single molecule level sensitivity and precision at the physical LOD, we can accurately predict clinical performance in advance when designing new smNGS assays. This is complemented by our lean and innovative R&D structure which further enables efficient and high-impact product development. As a result, we are able to rapidly convert R&D investment into differentiated products. In the prenatal

market, we started with one UNITY Fetal Risk Screen and then developed multiple tests and add-ons, including UNITY Aneuploidy Screen and UNITY Fetal Antigen NIPT. In oncology, we are extending our portfolio beyond our commercial products focused on therapy selection and response monitoring. We are also developing a tissue-free, pan-cancer MRD test, which we expect to be commercially available in 2026. Longer-term we believe that our smNGS-based technology could address the sensitivity challenges of early-stage cancer detection, among other applications.

- Continue to deploy AI across our entire organization, including laboratory operations, to improve efficiency and productivity. The integration of AI across our operations has been and will continue to be a critical driver of efficiency and productivity. We have been an early adopter of AI, and every function across the company uses AI in some capacity. By continuing to automate labor-intensive processes, we expect to continue to reduce costs and significantly increase productivity across our organization.
- Leverage our growing clinical dataset with AI to improve the utility of diagnostics and enable personalized medicine. Our advanced diagnostics platform generates rich biomarker data as we test patients that can be integrated with multimodal patient clinical information such as medical records. By leveraging AI algorithms to analyze these large datasets, and combining them with our unique Northstar Response results, we believe we will be able to identify distinct patient subgroups with unique biomarker profiles and predict therapeutic response patterns with unprecedented precision. This capability will enable us to provide clinicians with personalized treatment recommendations tailored to each patient's unique biology. We believe this approach will significantly improve therapeutic outcomes by maximizing efficacy while minimizing adverse effects.

As we continue to expand our clinical data repositories and refine our AI models, we expect to further enhance our competitive advantage and accelerate the transition of precision medicine from aspiration to clinical reality across our diagnostic portfolio.

Competition

Healthcare delivery continues to focus on becoming more patient-centered with personalized solutions. This evolution is leading to more companies and product offerings in the molecular diagnostics market. As a result, each of our products faces competition from a number of established and emerging companies.

In the prenatal market, our main competitors offering NIPTs 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.

While we know of competitors, in particular Natera and Myriad, that have been working on creating competing products to UNITY that also assess fetal risk for recessive conditions non-invasively, we believe that our smNGS platform will allow us to maintain clear clinical and technical superiority as this type of testing becomes the standard of care. In addition, while product launches by our competitors can create heightened competition in our prenatal market, we also believe that it can lead to increased awareness, acceptance, and adoption of this modality of testing by both providers and medical guidelines.

In the oncology market, 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, Inc., 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.

Our competitors may offer oncology tests for therapy selection that encompass a broader range of genes, thereby positioning their products as more comprehensive. While we believe that these larger panels result in reduced sensitivity for identifying actionable variants, their expanded gene coverage enables selection of a wider array of therapies—including some that are not yet approved or immediately actionable. As the number of approved therapies continues to increase, necessitating the addition of new genetic targets and revalidation of our assays, we may incur higher costs and risk losing customers to competitors if updates to our tests are delayed.

Many of our competitors, either alone or with their collaborators, may have greater financial and/or other resources than we do, including larger and more established manufacturing capabilities and marketing, sales, and support functions. Other competitors are in the process of developing novel technologies which may lead to products that rival or replace our products. While we cannot assure you how the market will evolve, we believe our four pillars of differentiation provide competitive advantages that are difficult for others to replicate.

These statements regarding our competition are subject to a number of risks, uncertainties, factors and assumptions described under Part I, Item 1A, “Risk factors—Risks related to our business and strategy.”

Intellectual Property

The long-term success of our business depends on securing protection of our intellectual property through patent, trade secret, trademark, and other intellectual property rights. We also utilize non-disclosure agreements and proprietary information and inventions assignment agreements with employees, consultants, contractors and other third parties and maintain physical security of our premises and physical and electronic security of our information technology systems in order to strengthen the protection of our intellectual property.

As of December 31, 2025, we held nine U.S. issued patents, which expire between August 2038 and March 2043, and 45 foreign patents, which expire between August 2038 and September 2041. Additionally, we had 14 pending U.S. patent applications and 31 foreign patent applications. We also held 4 U.S. registered trademarks and 13 foreign registered trademarks as of December 31, 2025.

Our patent strategy is focused on seeking robust coverage for our core molecular counting technology (covered by U.S. Patent No. 11,629,381, with a pending U.S. divisional application, granted patents in Australia, Brazil, China, Europe Hong Kong, India, Japan and South Korea (validated in 17 countries), and pending applications in Canada, Israel, Singapore, Japan (divisional), Europe (divisional), and Hong Kong (divisional), our dilution tagging technology (covered by U.S. Patent No. 12,071,651, with a pending U.S. continuation, and issued patent in Canada and pending foreign applications in China, Europe, and Hong Kong), our custom-made Synthetic DNA controls (covered by U.S. Patent Nos. 11,646,100 and 12,176,066, with a pending U.S. continuation, an issued patent in Canada, and pending applications in China, Europe, and Hong Kong), and our proprietary signal processing technology (covered by U.S. Patent Nos. 11,430,543 and 12,183,437, also granted in Brazil, Japan, Singapore, South Korea, Israel, Canada, Australia and Europe, and pending in China, Hong Kong, and India), all of which is used to maximize readings taken from single blood draws. We have also recently filed several unpublished patent applications covering a range of techniques for improving the efficiency and accuracy of DNA sequencing-based assays. In addition, we file for patent protection in connection with our ongoing research and development activities, particularly those related to early-stage cancer detection.

Our patents and applications generally fall into three broad categories:

- detecting and monitoring cancer and other diseases by determining genetic variations and other biomarkers in biological samples;
- methods for preparing and sequencing cfDNA, techniques for enriching nucleic acid samples, identifying cfDNA, and detecting epigenomic variations (such as DNA methylation) in biological samples; and
- precision diagnostics, including biochemical and analytical techniques for obtaining and analyzing genetic information to detect genetic abnormalities in relatively small complex samples, such as fetal cfDNA using reflex single-gene noninvasive prenatal screening.

The following table includes our U.S. patents granted and U.S. patent applications published as of December 31, 2025, along with the status in other jurisdictions (excluding divisional and continuation patents and applications). All patents are utility patents. We have additional patent applications that have not yet published as of December 31, 2025.

BillionToOne Patent Portfolio

Patent Family	Patent Name	Summary	U.S. Patent Number	U.S. Exp. Date	Other Jurisdictions
P01	Dilution Tagging for Quantification of Biological Targets	Method for accurate determination of biological target abundance that can include generating a first set of molecules associated with a target sequence that includes dilution tags associated with a relative concentration profile; generating a second set of molecules including dilution tags; generating a dilution tagged mixture; amplifying the dilution tagged targets; generating a modified dilution tagged mixture from the amplified subsets; determining, for the biological sample, a count of the distinct molecules including the target sequence.	12,071,651	3/19/2041	Issued/Allowed: CA Pending: CN, EP, HK
P02	Target-Associated Molecules for Characterization Associated with Biological Targets	A method and/or system for facilitating characterization of one or more conditions that can include: generating a set of target-associated molecules; generating a reference-associated set of molecules; facilitating generation of a spike-in mixture; determining abundance metrics based on an analysis of the spike-in mixture; and facilitating the characterization of the conditions based on the abundance metrics	11,646,100	3/5/2042	Issued/Allowed: CA Pending: CN, EP, HK
P03	Sequencing Output Determination and Analysis with Target-Associated Molecules in Quantification Associated with Biological Targets	A method and/or system for generating a set of target-associated molecules (e.g., spike-in molecules) associated with biological targets; generating spike-in mixtures based on processing the set of target-associated molecules with samples including the biological targets; performing Sanger sequencing operations on the spike-in mixtures; determining abundance metrics based on chromatogram-related outputs from the Sanger sequencing operations; and/or facilitating characterization of medical conditions based on the abundance metrics.	11,430,543	6/24/2041	Issued/Allowed: AU, BE, BR, CA, DE, EP, ES, FR, IL, IT, JP, KR, NL, SG, EP, GB Pending: CN, HK, IN, SG
P04	Quality Control Templates for Ensuring Validity of Sequencing-Based Assays	A method and/or system for generating a set of quality control template (QCT) molecules; determining a set of QCT sequence read clusters based on the set of QCT molecules, such as based on variation regions of the set of QCT molecules; and based on the set of QCT sequence read clusters, determining a sequencing-related parameter, such as a contamination parameter and/or molecule count parameter, associated with the at least one of sequencing library preparation and sequencing.	11,629,381	2/17/2042	Issued/Allowed: AU, AT, BE, BR, CN, CY, DE, DK, EP, FI, FR, GR, HK, IN, IR, IE, IT, JP, KR, LI, NL, NO, PT, ES, SE, CH, GB Pending: CA, EP, HK, JP, SG

Patent Family	Patent Name	Summary	U.S. Patent Number	U.S. Exp. Date	Other Jurisdictions
P05	Homologous Genomic Regions for Characterization Associated with Biological Targets	A method and/or system for generating a co-amplified mixture based on co-amplifying a set of nucleic acid molecules (e.g., cell-free nucleic acids, etc.) from the biological sample, wherein the set of nucleic acid molecules includes a genomic region of interest associated with the medical condition; and a homologous native genomic region with partial sequence similarity to the genomic region of interest; sequencing the co-amplified mixture; determining an abundance metric for the genomic region of interest and an abundance metric for the homologous native genomic region; and/or facilitating the characterization of the medical condition based on the abundance metric for the genomic region of interest and the abundance metric for the homologous native genomic region.	11,519,024	3/25/2040	Pending: CA, EP
P08	Fragment Analysis for Quantitative Diagnostics of Biological Targets	Methods of detecting the presence or absence of diseases using quantitative approaches, including methods for determining the abundance of endogenous targets and determining the presence or absence of an aneuploidy.	Pending	N/A	Pending: CA, EP
P09	Molecule Counting of Methylated Cell-free DNA for Treatment Monitoring	Methods to quantify methylation in a DNA sample that include treating the sample to encode the presence or absence of DNA methylation, adding to the sample a set of synthetic molecules (e.g., quality control template (QCT) molecules), generating a co-amplification mixture, sequencing the co-amplification mixture, and determining a number of methylated molecules in the sample based on the number of methylated reads from the sample and a number of reads from the set of synthetic molecules.	12,043,873	3/21/2043	Pending: AU, CA, CN, EP, HK, JP, KR
P10	Non-Invasive Prenatal Testing at Early Stage of Pregnancy	A highly accurate non-invasive prenatal testing methodology that allows accurate fetal rhesus determination and fetal DNA fraction measurement in a single assay is provided. The disclosed testing may be administered as early as at week 10 of pregnancy and can be conveniently combined with prenatal genetic disease testing and detection.	11,946,104	7/7/2040	Issued/Allowed: EP, FR, DE, IT, NL, ES, CH, GB Pending: CA, EP

BR = Brazil	CN = China	IN = India	PT = Portugal
CA = Canada	CY = Cyprus	IE = Ireland	ES = Spain
CH = Switzerland	DE = Germany	IT = Italy	SE = Sweden
DK = Denmark	EP = Europe	LI = Liechtenstein	SG = Singapore
FR = France	FI = Finland	NL = Netherlands	GB = United Kingdom
IL = Israel	HK = Hong Kong	NO = Norway	

To date, we have not been engaged in patent infringement lawsuits or any other material intellectual property disputes. However, we may in the future become subject to or initiate intellectual property litigation. Moreover, our ability to compete effectively depends 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. We pursue intellectual property protection to the extent we believe it would advance our business objectives. Notwithstanding these efforts, there can be no assurance that we will adequately protect our intellectual property or provide any competitive advantage.

For more information regarding risks relating to our intellectual property, see Part I, Item 1A, “Risk factors--Risks related to our intellectual property.”

Payor Coverage and Reimbursement

Reimbursement is a critical component of our business strategy and financial success. We approach reimbursement through a comprehensive framework addressing coding, coverage, and contracting to maximize access to our tests and optimize ASP. More than 90% of our revenue in 2025 stemmed from reimbursement of our prenatal and oncology tests in the United States, making our payor strategy central to our financial performance.

While the vast majority of the carrier and aneuploidy tests we offer are covered under existing policies, we initially operated primarily out-of-network with commercial third-party payors. Our in-network coverage included 250 million covered lives as of December 31, 2025. We anticipate our covered lives will continue to increase over time, which we expect will drive progressively higher ASPs.

Reimbursement sources and status

We receive reimbursement from several distinct sources:

- Commercial third-party payors, including insurance companies and health maintenance organizations;
- Government payors, state Medicaid programs, and Medicare;
- Employee benefits health plans; and
- Individual patients, who represent a small amount of our revenue.

Commercial third-party payors

We have significantly expanded our in-network status with commercial insurers, including several of the largest national payors. We expect this in-network expansion to continue driving higher ASPs and enhance revenue predictability, due to the contracts establishing agreed-upon rates. Beyond our contracted rate agreements, we submit claims for reimbursement and receive associated payments from commercial insurers on a non-contracted basis as necessary. The amount of reimbursement allowed and collected outside of network contract rates with commercial insurers is subject to greater variability and less predictability.

In prenatal, our carrier and aneuploidy tests are broadly covered by most major insurance providers, and we have broad reimbursement for tests we provide. Our sgNIPT and fetal antigen NIPT have variable coverage, with certain payors providing reimbursement, creating opportunities for ASP growth as coverage expands. For our oncology products, Northstar Select has gained coverage from several commercial insurers. Northstar Response, while newer to market, is already reimbursed by certain commercial insurers, achieving a level of ASP that already provides positive contribution margins.

Medicare

We have obtained Medicare coverage for both our prenatal and oncology testing services. In April 2025, our Northstar Select test received a positive coverage decision and Z-code through the MolDX program administered by Palmetto GBA.

For our prenatal tests, Medicare provides coverage for patients who meet the Medicare eligibility criteria; however, this represents a very small portion of our prenatal test volume given the demographics of pregnant patients. For our oncology portfolio, Medicare coverage is crucial given the higher prevalence of cancer in the Medicare-eligible population.

We continue to advance our evidence development strategy for Northstar Response, which requires additional clinical validity and utility data for Medicare coverage. Our flagship "NORTH" study, along with other ongoing clinical studies, is designed to generate the evidence necessary for Medicare coverage, initially focusing on immunotherapy and immunotherapy-combination therapy applications.

Medicaid

We have enrolled in over 40 state Medicaid programs across the United States. These enrollments are critical for our prenatal test ASPs. We plan to expand our Medicaid participation as our geographical footprint continues to grow, ensuring access to our tests for underserved populations. While Medicaid broadly covers carrier and aneuploidy tests, reimbursement rates vary significantly across state Medicaid programs. Moreover, various managed Medicaid payors may not have any out-of-network benefits, resulting in non-payments until they agree to contract with our laboratory, creating variability in our reimbursement from this payor segment. In addition, our carrier screen test is not covered by Alabama, Michigan, or Nevada, and our aneuploidy test is not covered by Nebraska or Utah. State Medicaid coverage for our RhD and fetal antigen tests is currently uncommon. Our oncology tests 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.

Billing and claims processing

Laboratory tests are classified for reimbursement purposes under a coding system known as Current Procedure Terminology (CPT), which we and our customers must use to bill and receive reimbursement for our diagnostic tests. Once the American Medical Association (AMA) establishes a CPT code, the Centers for Medicare & Medicaid Services (CMS) establishes payment levels and coverage rules under Medicare, while state Medicaid programs and commercial health plans establish rates and coverage rules independently in accordance with applicable rules. A Proprietary Laboratory Analyses (PLA) code is part of the CPT code set and may be assigned to tests that are not covered by standard CPT codes.

We utilize a combination of established CPT codes and recently obtained PLA codes for billing and reimbursement of our tests. We use established CPT codes for certain tests, including our aneuploidy NIPT, for which CMS had a pricing rate of $759 per test as of December 31, 2025. For other proprietary tests, we use PLA codes, including our carrier panel which CMS had a pricing rate of approximately $1,825 per test as of December 31, 2025. We have also obtained PLA codes for our Northstar Select and Northstar Response tests, for which CMS had pricing rates of approximately $2,920 per test and $1,644 per test, respectively, as of December 31, 2025. The transition from miscellaneous codes to specific PLA codes has enhanced our reimbursement clarity and is expected to continue to improve our ASPs as these codes are increasingly recognized by commercial third-party payors.

Despite favorable coding and high coverage rates for many of our tests, we face reimbursement challenges in certain scenarios. For example, for out-of-network claims with Managed Medicaid plans, we may receive no reimbursement. Even for commercial insurances with out-of-network benefits, the percentage of allowed amounts that are paid may be a small fraction of the CMS rate. Challenges related to reimbursements are more fully discussed in the Part I, Item 1A, "Risk factors—Risks related to our reimbursements" included elsewhere in this Annual Report.

As a result of these challenges and rates negotiated with contracted payors, our Overall ASP is lower than the reimbursement amounts suggested by the codes. We maintain a systematic approach to appeals for denied claims, with variable success rates depending on the payor and reason for denial. Our appeals process is supported by our internal reimbursement team, who analyze denial patterns and optimize appeal strategies accordingly. Moreover, as our test volume increases, we believe this will improve our ability to secure network contracts with more commercial insurers, which should decrease claim denials and increase ASPs.

In addition, we have built a robust revenue cycle management infrastructure to optimize reimbursement for our tests, which includes internal and external resources, as well as AI-based automation for processing payor communications and streamlining claims management.

Patient access and financial assistance

We provide comprehensive patient support services, including pre-authorization support where required by payors, patient-focused education about potential financial responsibilities and personalized financial assistance for patients who indicate an inability to afford out of pocket charges. We use a combination of robotic process automation and AI for reimbursement, including sorting thousands of pages of correspondence we receive from payors on a daily basis, and submitting reconsiderations or appeals for thousands of claims that are initially denied.

Reimbursement expansion strategy

We are actively generating additional clinical validity and utility evidence to expand coverage of our tests. For our prenatal products, we continue to build evidence demonstrating improved outcomes and cost-effectiveness compared to traditional approaches. In oncology, our NORTH study and other ongoing clinical studies aim to demonstrate the clinical utility of Northstar Response in early therapy response assessment across multiple cancer types and treatment modalities.

In addition, inclusion in clinical practice guidelines is a key element of our reimbursement strategy. Recent ACOG practice advisory changes have cited our publications in support of new approaches to testing. Additionally, inclusion of our specific tests, such as sgNIPT, or broader adoption of testing categories like 22q11.2 microdeletion screening in ACOG guidelines could significantly increase coverage and ASPs. Moreover, our publication strategy prioritizes studies that address key questions relevant to clinical guideline development.

We continuously pursue strategic initiatives to enhance our reimbursement landscape, including:

- **Expansion of in-network coverage.** As we increase test volumes and publish additional evidence, we expect to secure additional in-network contracts with commercial third-party payors.
- **Medicare coverage expansion.** We are working toward Medicare coverage for Northstar Response, beginning with applications in immunotherapy response monitoring where the clinical utility is most established.
- **Clinical guideline incorporation.** We actively engage with professional societies to support the inclusion of our testing methodologies in clinical practice guidelines.
- **Test menu optimization.** We evaluate reimbursement potential when developing new tests or expanding existing test menus to ensure alignment with payor policies.
- **Payor education.** We maintain active engagement with medical directors at key payors to ensure understanding of our unique technology and clinical value proposition.

Future reimbursement landscape

The reimbursement landscape for molecular diagnostics continues to evolve, with increasing emphasis on demonstrated clinical utility and economic value. We believe our approach to evidence generation, combined with our unique technology platform and differentiated products, positions us favorably for continued improvements in reimbursement.

As we expand our menu of tests and geographical reach, we anticipate further strengthening our reimbursement profile through various initiatives, including increasing in-network coverage with commercial and Managed Medicaid payors; adding additional Medicaid participation across states, and obtaining Medicare coverage for Northstar Response. We believe these initiatives will support continued growth in our realized ASPs and gross margin over time.

Government Regulations

Our business is subject to and impacted by laws and regulations in the United States (at both the federal and state levels) and internationally that are subject to change. Some of these laws and regulations are particular to our laboratory business while others relate to conducting business generally and billing and reimbursement practices. In addition, we are subject to site inspections, claims audits, and other inquiries by certain federal and state governmental agencies.

Food and Drug Administration

In the United States, medical devices are subject to extensive regulation by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (FDC Act) and its implementing regulations, and other federal and state statutes and regulations. The laws and regulations govern, among other things, medical

device development, testing, labeling, storage, premarket clearance, de novo classification or premarket approval, post-market requirements, labeling, advertising and promotion and product sales and distribution. Unless subject to an exemption, to be commercially distributed in the United States, medical devices must receive from the FDA prior to marketing, clearance of a 510(k) premarket notification submission, grant of a request for de novo classification, or approval of an application for premarket approval (PMA).

An in vitro diagnostic product (IVD) is a type of medical device that is intended for use in the diagnosis of diseases or conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. IVDs comprise reagents, instruments, and systems intended for use in the collection, preparation and examination of specimens from the human body. IVDs can be used to detect the presence of certain chemicals, genetic information or other biomarkers related to health or disease. IVDs include tests for disease prediction, prognosis, diagnosis, and screening (e.g., carrier screening). A subset of IVDs are known as analyte specific reagents (ASRs). An ASR is a single reagent (e.g., antibody, specific receptor protein, ligand, nucleic acid sequence) that, through specific binding or chemical reaction with substances in a specimen, is intended for use in a diagnostic application for the identification and quantification of an individual chemical substance in biological specimens. Most ASRs are exempt from the premarket review processes but must comply with general controls, as described below, including applicable provisions of the quality system regulation (QSR).

Device classifications

The FDC Act classifies medical devices into one of three categories based on the risks associated with the device and the level of control necessary to provide reasonable assurance of safety and effectiveness.

- Class I devices are deemed to be low risk and are subject to the fewest regulatory controls. Many Class I devices are exempt from FDA premarket review requirements.
- Class II devices, including some software products to the extent that they qualify as a device, are deemed to be moderate risk, and generally require 510(k) clearance.
- Class III devices are generally the highest risk devices and are subject to the highest level of regulatory control to provide reasonable assurance of the device's safety and effectiveness. Class III devices typically require a PMA by the FDA before they are marketed.

A clinical trial is almost always required to support a PMA application and is sometimes required for 510(k) clearance. All clinical trials of investigational devices must be conducted in compliance with any applicable FDA and Institutional Review Board requirements. Devices that are exempt from FDA premarket review requirements must nonetheless comply with post-market general controls as described below, unless the FDA has chosen otherwise.

FDA premarket clearance and approval requirements

510(k) clearance. To obtain 510(k) clearance, a manufacturer must submit a premarket notification demonstrating to the FDA's satisfaction that the proposed device is substantially equivalent to a legally marketed predicate device. The FDA's 510(k) clearance pathway usually takes from three to 12 months from submission, but it can take longer, particularly for a novel type of product.

PMA. The PMA pathway requires valid scientific evidence demonstrating to the FDA's satisfaction the safety and effectiveness of the device for its intended use. The PMA pathway is costly, lengthy, and uncertain. The PMA review process typically takes one to three years from submission but can take longer.

De novo. If no predicate device can be identified, a device is automatically classified as Class III, requiring a PMA application. However, the FDA on its own initiative or at the request of a manufacturer can reclassify as low- or moderate-risk device for which there is no predicate through the de novo classification process. The de novo route is intended to be less burdensome than the PMA process. The de novo route has historically been used for many IVD products.

Post-market general controls. After a device, including a device exempt from FDA premarket review, is placed on the market, numerous regulatory requirements apply. These include: the QSR, labeling regulations, registration and listing, the Medical Device Reporting regulation (and the Reports of Corrections and Removals regulation.

The FDA enforces compliance with its requirements through inspection and market surveillance. If the FDA finds a violation, it can institute a wide variety of actions, ranging from issuing a Form 483 Notice of Inspectional Observations or sending an untitled or public warning letter, to enforcement actions such as fines, injunctions, and civil penalties; recall or seizure of products; operating restrictions, partial suspension or total shutdown of production; refusing requests for 510(k) clearance, de novo classification, or PMA approval of new products; withdrawing PMAs already granted; and criminal prosecution.

Research use only. Research use only (RUO) products are exempt from FDA medical device requirements provided their manufacturers comply with specified labeling and restrictions on distribution and promotion. The products must bear the statement: “For Research Use Only. Not for Use in Diagnostic Procedures.” Manufacturers of RUO products cannot make any claims related to safety, effectiveness or diagnostic utility, and RUO products cannot be intended by the manufacturer for clinical diagnostic use. An RUO product promoted for diagnostic use may be viewed by the FDA as adulterated and misbranded under the FDC Act and the manufacturer of such product could be subject to FDA enforcement activities. Our LDTs use instruments and reagents labeled as RUO.

Laboratory-developed tests. Each of our genetic tests is an LDT. The FDA considers LDTs to be tests that are 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 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. As a result, our molecular diagnostic products are not subject to FDA approval requirements.

Clinical Laboratory Improvement Amendments of 1988, College of American Pathologists, and state regulations

Clinical Laboratory Improvement Amendments (CLIA)

As a clinical laboratory, we are required to hold certain federal and state licenses, certifications or permits to conduct our business. As to federal certifications, the Clinical Laboratory Improvement Amendments of 1988 (CLIA) establishes rigorous quality standards for all commercial laboratories that perform testing on human specimens for the purpose of providing information for the diagnosis, prevention, or treatment of disease or the assessment of the health or impairment of human beings. CLIA requires such laboratories to be certified by the federal government and mandates compliance with various operational, personnel, facility, administration, quality and proficiency testing requirements intended to ensure the accuracy, reliability and timeliness of patient test results. 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.

Our laboratories located in Menlo Park and Union City, California, are CLIA certified and must comply with all applicable CLIA regulations and standards. If a clinical laboratory is found to be out of compliance with CLIA standards, CMS may impose sanctions; suspend, limit or revoke the laboratory’s CLIA certificate (and prohibit the owner, operator or laboratory director from owning, operating, or directing a laboratory for two or more years following license revocation); subject the laboratory to a directed plan of correction, on-site monitoring, civil monetary penalties, civil actions for injunctive relief, criminal penalties; or suspension or exclusion from the Medicare and Medicaid programs.

CLIA provides that a state may adopt laboratory licensure requirements and regulations that are more stringent than those under federal law and requires compliance with such laws and regulations. A number of states have implemented their own more stringent laboratory regulatory requirements. State laws may require the laboratory to obtain state licensure and/or laboratory personnel to meet certain qualifications and obtain professional licensure, specify certain quality control procedures or facility requirements, or prescribe record maintenance requirements. Moreover, several states impose the same or similar state requirements on out-of-state laboratory testing specimens collected or received from, or test results reported back to, residents within that state. Therefore, we are required to meet certain laboratory licensing requirements for those states in which we offer services or from which we accept specimens, and that have adopted laboratory regulations beyond CLIA.

College of American Pathologists (CAP)

The College of American Pathologists (CAP) maintains a clinical laboratory accreditation program. While not required to operate a CLIA-certified laboratory, many private insurers require CAP accreditation as a condition to contracting with clinical laboratories to cover their tests. In addition, some countries outside the United States

require CAP accreditation as a condition to permitting clinical laboratories to test samples taken from their citizens. Our two laboratories have each been accredited by CAP, which means that our laboratories have been certified as following CAP standards and guidelines in operating the laboratory facility and in performing tests that ensure the quality of our test results. In order to maintain CAP accreditation, we are subject to survey for compliance with CAP standards every two years. Failure to maintain CAP accreditation could have a material adverse effect on the sales of our tests and the results of our operations.

California laboratory licensing

In addition to federal certification requirements for laboratories under CLIA, we are required under California law to maintain a California state license for both our Menlo Park and Union City clinical laboratories, and to comply with California state laboratory laws and regulations, because our laboratories are located in California, and both facilities test specimens originating from California. Similar to the federal CLIA regulations, the California state laboratory laws and regulations establish standards for the operation of a clinical laboratory and performance of test services, including the education and experience requirements of the laboratory director and personnel (including requirements for documentation of competency), equipment validations, and quality management practices. All testing personnel must maintain a California state license or be supervised by licensed personnel, and our laboratory director must maintain an additional license issued by the California Department of Public Health (CDPH).

Clinical laboratories are subject to both routine and complaint-initiated on-site inspections by the state. If a clinical laboratory is found to be out of compliance with California laboratory standards, the CDPH may suspend, restrict or revoke the California state laboratory license to operate the clinical laboratory (and exclude persons or entities from owning, operating, or directing a laboratory for two years following license revocation), assess civil money penalties, and/or impose specific corrective action plans, among other sanctions. Clinical laboratories must also provide notice to CDPH of any changes in the ownership, directorship, name or location of the laboratory. Failure to provide such notification may result in revocation of the state license and sanctions under the CLIA certificate. Any revocation of a CLIA certificate or exclusion from participation in Medicare or Medicaid programs may also result in suspension of the California state laboratory license.

New York laboratory licensing

In order to test specimens in our laboratories originating from, and return test results to, New York State, both of our laboratories are required to obtain a New York state laboratory permit and comply with New York state laboratory laws and regulations. We maintain a valid permit in the state of New York for the prenatal molecular genetic testing services furnished by our Union City laboratory and we are in the application process to obtain a permit in the state of New York for the oncology molecular genetic testing services furnished by our Menlo Park laboratory.

The New York state laboratory laws, regulations and rules are equal to or more stringent than the CLIA regulations and establish standards for the operation of a clinical laboratory and performance of test services, including education and experience requirements of a laboratory director and personnel, physical requirements of a laboratory facility, equipment validations, and quality management practices. The laboratory director(s) must maintain a Certificate of Qualification issued by the New York State Department of Health (DOH) in the permitted test categories.

Under the New York state requirements, our clinical laboratory in Union City is, and our clinical laboratory in Menlo Park will be, subject to proficiency testing and on-site survey inspections conducted by the Clinical Laboratory Evaluation Program (CLEP) under the DOH. If a laboratory is found to be out of compliance with New York's CLEP standards, the DOH may suspend, limit, revoke or annul the New York laboratory permit, censure the holder of the license or assess civil money penalties. Statutory or regulatory noncompliance may result in a laboratory's operator, owners and/or laboratory director being found guilty of a misdemeanor under New York law. Clinical laboratories must also provide notice to the CLEP of any changes in ownership, directorship, name or location of the laboratory. Failure to provide such notification may result in revocation of the state license and sanctions under the CLIA certificate. Any revocation of a CLIA certificate or exclusion from participation in the Medicare or Medicaid programs may result in suspension of the New York laboratory permit.

The DOH also must approve each LDT before the test is offered to patients located in New York. Our Union City clinical laboratory has received approval from New York's CLEP to offer most of our prenatal tests that are performed in Union City. We are in the application process to obtain approval from New York's CLEP to offer our Northstar Select test that is performed in our Menlo Park laboratory.

Other state laboratory licensing laws

In addition to New York and California, certain other states require licensing of out-of-state laboratories under certain circumstances. We have obtained licenses in the states that we believe require us to do so based on our current operations, and believe we are in compliance with applicable state laboratory licensing laws, including Maryland, Pennsylvania, Rhode Island and the District of Columbia.

Potential sanctions for violation of state statutes and regulations can include significant monetary fines, the rejection of license applications, the suspension or loss of various licenses, certificates and authorizations, and in some cases criminal penalties, which could harm our business. CLIA does not preempt state laws that have established laboratory quality standards that are more stringent than federal law.

State genetic testing and privacy laws

Many states have implemented genetic testing and privacy laws imposing specific patient consent requirements and protecting test results. Under some state laws, we are prohibited from conducting genetic tests without appropriate documentation of patient (or parental/guardian) consent from the physician ordering the test. For example, Texas enacted legislation limiting use of genetic data applicable to companies offering direct-to-consumer (without health care provider involvement) genetic testing or collect, use, or otherwise analyze genetic data derived from individuals using such products or services, but exempt genetic data collected or generated by an entity subject to HIPAA. While we rely on physicians to obtain the required patient consent to perform genetic testing, the regulatory burden may be deemed to be our responsibility and such consents, or our compliance with applicable laws and regulations, could be challenged. Requirements of these laws and penalties for violations vary widely from state to state.

Federal and state health care laws

As a clinical laboratory, we are subject to certain federal and state laws and regulations relating to delivery of diagnostic healthcare. To meet the requirements of these laws and regulations, we have developed and operate a compliance program modeled after the general and specific guidance issued by the Office of Inspector General of the U.S. Department of Health and Human Services (HHS) and grounded in our company ethics and values. Although we believe that our compliance program and company culture support compliance with the various laws and regulations applicable to our business, we cannot ensure that government regulators will not identify potential deficiencies or violations in the conduct of our business activities. The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 provides for an annual, automatic adjustment of civil monetary penalties authorized under the Social Security Act to account for inflation, which are published in the Federal Register annually.

Federal physician self-referral prohibition

We are subject to the federal physician self-referral prohibition (42 U.S.C. §1395nn), commonly known as the Stark Law, and to comparable state laws. Together these restrictions generally prohibit us from billing a patient or governmental or private payor for certain designated health services, including laboratory test services, when the physician ordering the service, or a member of such physician's immediate family, has a financial relationship with our company, such as an ownership or investment interest in or compensation arrangement with us, unless the relationship meets an applicable exception. Several Stark Law exceptions are relevant to many common financial relationships involving clinical laboratories and referring physicians, including: fair market value compensation for the provision of certain laboratory items or services; payments by physicians to a laboratory; space and equipment rental arrangements, and personal services arrangements that satisfy certain criteria. No clinical laboratory may submit claims to the Medicare or Medicaid programs for items or services furnished in violation of the Stark Law. These prohibitions apply regardless of any intent by the parties to induce or reward referrals or the reasons for the financial relationship and the referral. Penalties for violating the Stark Law include significant civil penalties, such as the return of funds received for all prohibited referrals, fines, civil monetary penalties, exclusion from the federal healthcare programs, integrity oversight and reporting obligations. Any person who presents or causes to be presented a claim to the Medicare or Medicaid programs in violation of the Stark Law may be subject to civil monetary penalties – up to $30,868 as of 2024 – per claim submission, an assessment of up to three times the amount claimed, and exclusion from participation in any federal health care program. A person who engages in a scheme to circumvent the Stark Law's referral prohibition may be fined – up to $205,799 as of 2024 – for each such arrangement or scheme. Claims submitted in violation of the Stark Law may not be paid by Medicare or Medicaid, and any person collecting any amounts with respect to any such prohibited claim is obligated to refund such amounts. In addition, knowing

violations of the Stark Law may also serve as the basis for liability under the federal False Claims Act (FCA), which may result in additional civil penalties.

Federal Anti-Kickback law

The federal Anti-Kickback Statute (42 U.S.C. §1320a-7b), commonly known as AKS, makes it a felony for a person or entity, including a clinical laboratory, to knowingly and willfully offer, pay, solicit or receive any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce business that is reimbursable under any federal health care program. A person or entity does not need to have actual knowledge of the statute or specific intent to violate the AKS to have committed a violation if there is the requisite intent to commit the act. A violation of the federal Anti-Kickback Statute may result in imprisonment for up to ten years and/or criminal or civil fines – up to $104,330 (or $27,894 for each wrongful act) as of 2024 – and exclusion from participation in federal health care programs. Claims submitted in violation of the federal Anti-Kickback Statute may not be paid by a federal health care program, and any person collecting any amounts with respect to any such prohibited claim is obligated to refund such amounts. Although the AKS applies only to items and services reimbursable under any federal health care program, a number of states have passed statutes substantially similar to the AKS that apply to any payor. Penalties for violations of such state laws may include imprisonment and significant monetary penalties. Generally, courts have taken a broad interpretation of the scope of the AKS, holding that the statute may be violated if merely one purpose of a payment arrangement is to induce referrals or purchases. In addition to statutory exceptions to the AKS, regulations set forth in 42 C.F.R. § 1001.952 provide for a number of safe harbors for defined payment arrangements that will not be deemed improper remuneration. An arrangement must fully comply with each element of an applicable safe harbor to qualify for protection. Failure to meet the requirements of the safe harbor, however, does not render a payment arrangement per se illegal. Rather, the government must evaluate such arrangements on a case-by-case basis, taking into account all facts and circumstances. In addition, a knowing violation of the AKS constitutes a false or fraudulent claim under the FCA, which is discussed in greater detail below.

False Claims Act

The federal False Claims Act (31 U.S.C. §§ 3729-3733), commonly known as FCA, prohibits, among other things, a person from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval and from making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim to secure payment or retain an overpayment by the federal government. Violation of the federal False Claims Act may result in fines of up to three times the actual damages sustained by the government, plus mandatory civil penalties – up to approximately $28,619 in 2025 – per false claim or statement, imprisonment or both, reimbursement of the whistleblower's attorneys' fees, and possible exclusion from any federal health care programs. The penalties will continue to be adjusted, increasing each year to reflect changes in the inflation rate, pursuant to the 2015 Bipartisan Budget Act. In addition to actions initiated by the government itself, the statute authorizes actions to be brought on behalf of the federal government by a private party having knowledge of the alleged fraud. Because the complaint is initially filed under seal, the action may be pending for some time before the defendant is even aware of the action. If the government intervenes and is ultimately successful in obtaining redress in the matter or if the plaintiff succeeds in obtaining redress without the government's involvement, then the plaintiff will receive a percentage of the recovery. Finally, the Social Security Act includes its own provisions that prohibit the filing of false claims or submitting false statements in order to obtain payment. Several states have enacted comparable false claims laws which may be broader in scope and apply regardless of payor.

Civil Monetary Penalty Law

The Civil Monetary Penalty Law (42 U.S.C. § 1320a-7a), commonly known as CMPL, imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health care program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. In addition, a person who offers or provides to a Medicare or Medicaid beneficiary any remuneration, that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of Medicare or Medicaid payable items or services may be liable and subject to civil monetary penalties. A violation of the federal Civil Monetary Penalty statute may result in maximum civil fines – up to $124,732 in 2024 – plus treble damages and exclusion from participation in any federal health care program.

Eliminating Kickbacks in Recovery Act

The Eliminating Kickbacks in Recovery Act of 2018 (18 U.S.C. §220), commonly known as EKRA, 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. EKRA was enacted under the SUPPORT Act for the legislative purpose to help reduce opioid-related fraud and abuse. However, EKRA defines the term "laboratory" broadly and without reference to any connection to substance use disorder treatment. Moreover, EKRA applies to claims submitted to both government and commercial third-party payors. Violation of EKRA carries potential penalties of up to $200,000 in fines and imprisonment of up to ten years for each occurrence, and potential exclusion from participation in any federal health care program. The law includes a limited number of exceptions, some of which closely align with corresponding AKS safe harbors, and others that materially differ. Currently, there is no regulation interpreting or implementing EKRA, nor any guidance released by any federal agency regarding the scope of EKRA. The only case law issued to date involves decisions interpreting the EKRA as it applies to compensation of laboratory sales personnel hired as independent contractors, and the courts differ on interpretation and application of the law. These decisions are currently on appeal in the federal court of appeals. We cannot assure you that our relationships with physicians, hospitals, customers, or sales personnel will not be subject to scrutiny or will survive a challenge under EKRA. If imposed for any reason, sanctions under EKRA could have a negative effect on our business.

Because we operate a laboratory facility located in California and licensed by California's DHS, California law is applicable to our business arrangements. California's state anti-kickback statutes, Business and Professions Code Section 650 (which applies to all categories of payors) and Insurance Code Section 754, and its Medi-Cal anti-kickback statute, Welfare and Institutions Code Section 14107.2, are analogous to, and have been interpreted by the California Attorney General and California courts in substantially the same way as the federal government and the courts have interpreted, the federal Anti-Kickback Statute. A violation of Section 650 is punishable by up to one year of imprisonment, a fine up to $50,000, or both imprisonment and a fine. A violation of Section 14107.2 is punishable by imprisonment and fines of up to $10,000. The California Insurance Code includes similar prohibitions against any consideration for the referral or procurement of patients if a claim is submitted to a commercial insurer, CA Ins. Code § 750, which is punishable by criminal penalties mirroring those that apply to violations of Business and Professions Code Section 650.

Because each of our laboratories holds a New York CLEP permit, we must comply with New York state laboratory statutes and regulations, which include anti-kickback provisions, Public Health Law Section 587, and Medicaid anti-kickback provisions, 18 NYCRR Section 515.2, related to laboratory services. The New York DOH may suspend, limit, revoke or annul the New York laboratory permit or otherwise discipline the permit holder for a violation.

Data Privacy and Security

We are, or may become, subject to numerous federal, state, local and foreign laws, regulations, standards, and guidance regarding data privacy and security. The federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) created federal criminal statutes relating to privacy of personal data. HIPAA imposes privacy, security and breach reporting obligations with respect to individually identifiable health information upon "covered entities" (health plans, health care clearinghouses and certain health care providers), and their respective business associates, individuals or entities that create, received, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HIPAA mandates the reporting of certain breaches of health information to HHS, affected individuals and if the breach is large enough, the media. Entities that are found to be in violation of HIPAA, including as the result of a breach of unsecured protected health information (PHI), a complaint about privacy practices or an audit by HHS, may 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.

HIPAA also prohibits knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, 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. Like the AKS, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation.

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH) and their respective implementing regulations, impose obligations on "covered entities," including certain healthcare providers, health plans, and healthcare clearinghouses, as well as their respective "business associates" that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. Additionally, HITECH created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in U.S. federal courts to enforce HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions.

Even when HIPAA does not apply, failing to take appropriate steps to keep consumers' personal information secure may constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act, 15 U.S.C § 45(a). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Personally identifiable health information is considered sensitive data that merits stronger safeguards. The FTC's guidance for appropriately securing consumers' personal information is similar to what is required by the HIPAA Security Rule. In addition, certain state laws govern the privacy and security of personal information, including health information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Many states are considering similar laws. Failure or perceived failure to comply with these laws, where applicable, can result in material adverse effects to our business, including the imposition of significant civil and/or criminal penalties and private litigation.

As a health care provider, we are also subject to Section 4004 of the 21st Century Cures Act, or Cures Act, and regulations promulgated by HHS related to patient access to electronic PHI, or EHI, to promote interoperability and to ensure the access, exchange, or use of EHI.

Various U.S. states have implemented similar restrictive requirements regulating the use and disclosure of health information and other personal information that are not necessarily preempted by HIPAA or that regulate different information than HIPAA. The California Consumer Privacy Act (CCPA), which went into effect January 1, 2020, and California Privacy Rights Act of 2020 (CPRA), which went into effect on January 1, 2023, which created additional obligations with respect to certain data relating to consumers, significantly expands the CCPA, is an example of the increasingly stringent privacy laws at the state level in the United States. The CCPA also created a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. However, the CCPA and CPRA include an exemption for HIPAA covered entities such as our laboratory. The California Confidentiality of Medical Information Act, which protects the confidentiality of individually identifiable medical information obtained by health care providers and their contractors, is much broader than HIPAA and the data protected is also broader than HIPAA.

In addition, numerous other states' legislatures have passed or are considering similar laws that will require ongoing compliance efforts and investment. For example, Virginia passed the Virginia Consumer Data Protection Act, and Colorado passed the Colorado Privacy Act, both of which differ from the CPRA and became effective in 2023 and the Texas Data Privacy and Security Act became effective in 2024. These state privacy laws dictate how we can collect, use, store, sell, share, analyze or process personal identifying information and/or consumer or health data received or generated by our business operations.

Outside the United States, there are an increasing number of laws and regulations governing the collection, use and processing of personal data. For example, the European Union's General Data Protection Regulation (EU GDPR) applies to any company established in the European Economic Area (EEA), and to companies established outside the EEA that process personal information in connection with the offering of goods or services to data subjects in the EEA or the monitoring of the behavior of data subjects in the EEA. These regulations are often more restrictive than those in the United States and may restrict transfers of personal data from the EEA to the United States and other countries unless certain requirements are met. The EU GDPR provides that EU member states may make their own further laws and regulations limiting the processing of genetic, biometric or health data, which could limit our ability to use and share personal data or could cause our costs to increase, and harm our business and financial condition. Further, the United Kingdom's decision to leave the European Union has created uncertainty with regard to data protection regulation in the United Kingdom. As of January 1, 2021, we are also subject to the UK General Data Protection Regulation and UK Data Protection Act of 2018, which retains the GDPR in substantially similar form in the United Kingdom's

national law. Failure to comply with any of these obligations could expose us to material adverse effects, including significant fines.

It is possible that state, federal (including legislative and executive branch initiatives), and foreign healthcare reform measures may be adopted in the future.

Employees and Human Capital

Our culture and values

BillionToOne was founded on the mission of removing the fear of the unknown by providing molecular diagnostics that are accurate, fast, and accessible. To fulfill our mission, we are dedicated to fostering a high-performance culture where every individual, regardless of level or position, feels empowered to solve significant problems and make a notable impact. Our vision is to challenge the status quo that makes healthcare opaque and financially out of reach for many. We are focused on building a corporate culture that nurtures innovation, creative problem solving, and a strong sense of purpose with patient and caregiver mindsets at the forefront.

Talent development, compensation and retention

We focus on attracting, retaining, and cultivating highly-talented employees, with the goal of hiring the top 1% from the application pool. Due to our highly technical and competitive industry, we believe recruiting and retaining highly-talented personnel is key to our ability to execute our business strategy and maintain competitive margins.

We offer our employees competitive pay, equity compensation, a retirement savings package with company matching, and other benefits such as four months of paid time off at full salary for parental or family leave, as well as incentive plans. The principal purposes of these plans are to attract, retain and reward personnel through the granting of stock-based and cash-based compensation awards, in order to increase stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

Our values-based culture and our employees are a critical component of our success. We strive to create a supportive and professional environment for our employees. We expend considerable management time and attention, and financial resources, to attracting, retaining, and motivating exceptional individuals at our company.

As of December 31, 2025, we had 713 employees, all of which were full-time employees. Of these employees, 125 were engaged in research and development activities and the remaining employees are engaged in laboratory operations, sales or administrative activities. None of our employees are represented by a labor union or covered by collective bargaining agreements, and we believe our relationship with our employees is good.

Human capital resources

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. The principal purposes of our equity incentive plans are to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards and cash-based performance bonus awards.

Available information

Our website is located at https://www.billiontoone.com/. Information on our website is not part of this Annual Report on Form 10-K or any of our other securities filings unless specifically incorporated herein or therein by reference. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, including their exhibits, proxy and information statements, and amendments to those reports filed or furnished pursuant to Sections 13(a), 14, and 15(d) of the Securities Exchange Act of 1934, as amended, are available through the investor relations page of our website free of charge as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. We use the investor relations page on our website, press releases, public conference calls, public webcasts, our X handle (@BillionToOneInc) and our LinkedIn feed for purposes of compliance with Regulation FD and as a routine channel for distribution of important information to investors. In addition, our filings with the SEC may be accessed through the SEC's Interactive Data Electronic Applications system at http://www.sec.gov. All statements made in any of our securities filings, including all forward-looking statements or information, are made as of the date of the document in which the

statement is included, and we do not assume or undertake any obligation to update any of those statements or documents unless we are required to do so by law.

Item 1A. Risk Factors

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 Annual Report, including our financial statements and the related notes and Part II, Item 7 "Management's Discussion and Analysis of Financial Condition and Results of Operations." 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 Annual Report also contains forward-looking statements that involve risks and uncertainties. See the section titled "Special Note Regarding Forward-Looking Statements" In this Annual Report. 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 Class A common stock 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 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 Industry

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, 2025 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, 2025 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 testing. 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 test 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, 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 enacted in December 2025, could materially affect our business operations, supply chain, or ability to contract with U.S. government agencies. In addition to potential other restrictions on our business, BIOSECURE 2.0 prohibits 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, in the future, 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.

Similar legislative or regulatory initiatives may be adopted in the future, 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.

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 NIPTs 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 generally incurred losses since inception, and we may not be able to generate sufficient revenue to maintain profitability.

We have generally incurred losses since our inception. However, for the year ended December 31, 2025, we had a net income of $7.5 million but incurred a net loss of $41.6 million for the year ended December 31, 2024. As of December 31, 2025 we had an accumulated deficit of $274.7 million. To date, we have financed our operations principally from the sale of securities, 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 68% and 53% for the years ended December 31, 2025 and 2024, 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 sustain profitability, and 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 generally incurred net losses since our inception. While we generated net income for the year ended December 31, 2025 and 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.

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 (as amended from time to time, the Note Purchase Agreement). Under the Note Purchase Agreement we may request up to an additional $60.0 million as of December 31, 2025 and have an obligation to sell a tranche of notes in the amount of $30 million before March 31, 2026, as described in the risk factor titled "Risks related to financial and accounting matters—Future indebtedness could adversely affect our business and growth prospects." However, 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 December 31, 2025, we held nine U.S. issued patents, 45 foreign patents, 14 pending U.S. patent applications and 31 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 31 foreign patent applications as of December 31, 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 nipocalimab 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 establishing 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 polices 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 initial public offering (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". As previously disclosed, 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.
- We did not design and maintain effective 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.

To date, we have taken the steps to begin to remediate these material weaknesses and 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 unremediated. These remediation efforts are ongoing in 2026 and include:

- engaging third parties to assist with technical accounting matters and designing and implementing controls;
- hiring additional personnel, such as accounting, finance, information technology staff and other professionals with appropriate levels of knowledge and experience and designing and implementing controls to ensure appropriate segregation of duties in our finance and accounting functions;
- designing and implementing controls over user access, including restrictions over privileged access as it relates to creating and posting journal entries; and
- designing and implementing controls to properly analyze, account for, present and disclose certain financial instruments transactions.

These material weaknesses, other than that related to user and privileged access controls, resulted in immaterial adjustments to the December 31, 2024 and 2023 financial statements, which were recorded prior to the issuance of those financial statements.

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, will continue to take place in 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 are 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, 2025, we had federal NOL carryforwards of $147.0 million, which do not expire, and combined state and city NOL carryforwards of $67.9 million, which, if not utilized, begin to expire in 2026. 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, 2025, we also had federal research and development credit carryforwards of $5.5 million, which begin to expire in 2041, and state research and development credit carryforwards of $2.8 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.

As of December 31, 2025, we have drawn $50 million under the Note Purchase Agreement, and have the option, but not the obligation, to issue and sell an additional separate tranche of notes in the amounts of $25.0 million before March 31, 2026, 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. 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 the Note Purchase Agreement. In the future, any additional 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 us to maintain certain trailing six-month net revenue levels and trailing six-month gross margin ratios, and includes other covenants that restrict 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 approximately 62.3% of the voting power of our outstanding capital stock as of the date of this Annual Report. 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 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 depends 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 have any control over these analysts. If we fail to meet the expectations of these analysts, our stock price could be adversely affected. If limited securities analysts commence coverage of us, or 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 trading price for our Class A common stock would be negatively affected. 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 outstanding prior to our IPO 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 our IPO. 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 or settlement of awards 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 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 Class A 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 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

Risk Management and Strategy

In the ordinary course of our business, we collect and store proprietary, confidential, and sensitive data, including legally protected personal information, such as test results and other protected health information (PHI), credit card and other financial information, insurance information, and other personally identifiable information, as well as sensitive intellectual property and other proprietary business information, including that of our customers, payors and collaboration partners. We manage and maintain our applications and data utilizing a combination of on-site systems and cloud-based centers, and utilize internal resources and external security and infrastructure vendors to manage parts of our data centers. We are highly dependent on information technology networks and systems—our own as well as those of third-party vendors and their subcontractors—to securely process, transmit, and store a wide variety of information critical to our business, including research and development information, patient data, commercial information, and business and financial information. Our systems are designed to ensure that all sensitive data is stored appropriately in SOC 1 and SOC 2 compliant platforms.

Although we maintain measures designed to protect sensitive information from unauthorized access or loss of access, inappropriate use or disclosure, and inappropriate modification, our information technology systems and infrastructure, and those of our third-party service providers, strategic partners and other contractors, and their subcontractors or consultants, are inherently vulnerable to cybersecurity threats and, from time to time, experience such threats. As of the date of this Annual Report on Form 10-K, we are not aware of any material cybersecurity incidents or threats that have impacted our business. We continue to invest in the security and resiliency of our networks and to enhance internal controls and processes designed to help protect our systems and infrastructure, and the information they contain. For more information regarding the risks we face from cybersecurity threats, see "Part I, Item 1A. Risk Factors" included elsewhere in this Annual Report on Form 10-K.

Risk Management Processes

Our Information Security Steering Committee, led by our Vice President of Information Technology, who also serves as our Chief Information Security Officer, is responsible for the day-to-day execution of our information security strategy and operations. As appropriate, the Information Security Steering Committee coordinates cross-functionally across our information technology, engineering, legal, privacy, compliance, finance, people operations, and product teams to identify, assess, and address current and emerging cybersecurity risks.

We maintain a cybersecurity incident response plan that addresses key aspects of incident management, including detection, impact analysis, containment, mitigation, remediation, recovery, and longer-term measures designed to reduce the likelihood of future incidents. In carrying out this plan, the Information Security Steering Committee evaluates cybersecurity incidents, or multiple related incidents, against specified criteria and, if one or more such criteria are met, reports those incidents to management.

Our cybersecurity program is aligned with industry standards and best practices, including the National Institute of Standards and Technology Cybersecurity Framework (NIST CSF) and SOC 2 standards. We use a variety of tools and methodologies to monitor and manage cybersecurity risks and regularly evaluate our cybersecurity posture through activities such as vulnerability scanning, penetration testing, and the use of threat intelligence feeds. Our Information Security Team conducts periodic exercises to assess preparedness for information security incidents, including cybersecurity events. In addition, we promote a company-wide culture of cybersecurity awareness through new employee onboarding and ongoing employee training and education, including periodic phishing simulations.

We engage external experts, including cybersecurity assessors, consultants, and auditors, to assist in evaluating and attesting to our risk management systems, including through an annual SOC 2 audit covering the security, availability, confidentiality, and processing integrity trust services criteria. In recognition of the risks associated with third-party service providers, we also conduct risk assessments of selected systems and third-party service providers on an ongoing basis.

Governance

Board Oversight

Cybersecurity is an important area of focus for our board of directors. The board of directors is responsible for oversight of information security and cybersecurity risks, and we believe the board has the appropriate skills and visibility into the design and operation of our data security practices to fulfill this responsibility effectively.

Our Chief Information Security Officer and other members of management provide updates on cybersecurity matters to the board of directors on a quarterly basis, with additional updates as warranted. The board of directors also receives a quarterly cybersecurity report from our Chief Information Security Officer.

Management

Our Information Security Team, led by our Vice President of Information Technology, who also serves as our Chief Information Security Officer, is accountable for the day-to-day execution of our information security strategy and operations, including enterprise-level information security risk strategy, identification, prioritization, and mitigation.

The Information Security Steering Committee, which provides general oversight of the Information Security Team, is led by our Vice President of Information Technology/Chief Information Security Officer and is comprised of members of Company management who collectively have experience and expertise in information technology, enterprise security and risk management, cybersecurity, engineering, privacy, data security, lab operations, quality, and healthcare compliance. The Information Security Steering Committee meets monthly, and more frequently as needed to review matters including updates on existing and emerging cybersecurity risks and threats; prioritization, mitigation, and remediation activities; the status of initiatives to strengthen our information security systems; assessments of our information security program and operations; and prioritized information security incidents, if any.

Item 2. Properties

Our headquarters is located in Menlo Park, California, where we lease approximately 36,000 square feet of office and laboratory space pursuant to a lease that expires in February 2031. We also lease approximately

90,000 square feet of office and laboratory space in Union City, California, pursuant to a lease that expires in June 2033. We have an option to extend this lease for an additional five years.

To support our planned growth, we have also entered into a lease for a new facility with 220,000 square feet of office and custom laboratory space located in Austin, Texas, expected to commence on or before September 30, 2027, and expiring in June 2043, with an option to extend for an additional seven years. Once the facility is fully utilized, we expect our potential testing capacity to be nearly triple our current capabilities. We also have commercial leases for patient service centers in various cities, for an aggregate of approximately 8,000 square feet as of December 31, 2025. We expect to enter into additional leases for patient service centers in the ordinary course.

We believe that our current facilities are adequate to meet our current needs and that, should it be needed, suitable additional or alternative space will be available to accommodate our operations.

Item 3. 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, reference Part I, Item 1A, "Risk factors—Risks related to our business and strategy—We are 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 4. Mine Safety Disclosures

None.

Part II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

On November 6, 2025, our Class A common stock began trading on the NASDAQ Global Select Market under the symbol "BLLN." Prior to this time, there was no public market for our Class A common stock.

Holders of Record

As of March 6, 2026, there were 421 holders of record of our Class A common stock and 2 holders of record of our Class B common stock. The actual number of Class A stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares of our Class A common stock are held in street name by brokers and other nominees. The number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

We have never declared or paid any dividends on our capital stock, and we do not currently intend to pay any cash dividends on our Class A common stock and Class B common stock in the foreseeable future. We currently intend to 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. In addition, the terms of the Note Purchase Agreement place restrictions on our ability to pay cash dividends on our capital stock. Furthermore, we may, from time to time, 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 and Class B common stock.

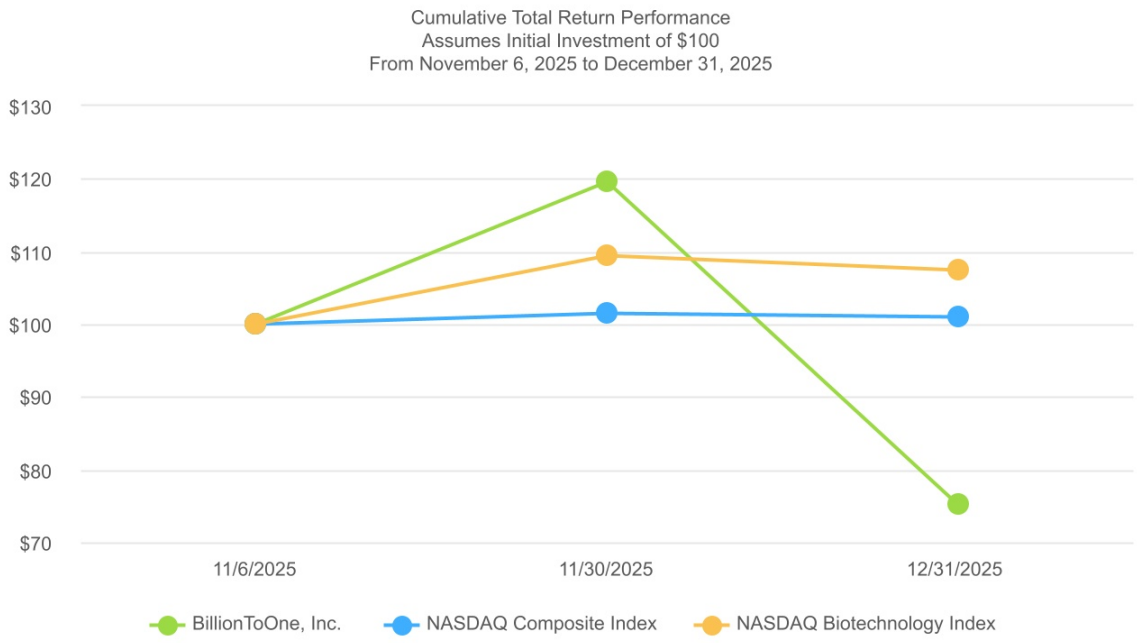
Securities Authorized for Issuance Under Equity Compensation Plans

Information about securities authorized for issuance under our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report on Form 10-K.

Performance Graph

This graph is not "soliciting material" is not deemed "filed" with the SEC and is not to be incorporated by reference into any of our filings under the Securities Act or the Exchange Act, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

The following graph below shows the cumulative total return to our stockholders between November 6, 2025 (the date that our Class A common stock commenced trading on the Nasdaq Global Select Market) through December 31, 2025 relative to the Nasdaq Composite Index and the Nasdaq Biotechnology Index. The graph assumes that $100 was invested in each of our Class A common stock, the Nasdaq Composite Index and the Nasdaq Biotechnology Index at their respective closing prices on November 6, 2025 and assumes reinvestment of gross dividends. The stock price performance shown in the graph represents past performance and should not be considered an indication of future stock price performance.



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 included the exercise in full by the underwriters of their option to purchase 682,665 shares of our Class A common stock, at a price to the public of $60.00 per share. We received net proceeds of $286.9 million after deducting underwriting discounts and commissions of $22.0 million and deducting offering expenses of $5.1 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, and William Blair & Company, L.L.C. acted as representatives of the underwriters. All of the shares issued and sold in the IPO were registered under the Securities Act pursuant to the Registration Statement, and the IPO terminated after the sale of all securities registered pursuant to the Registration Statement.

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.

Recent Sales of Unregistered Equity Securities

From October 1, 2025, to (but not including) November 6, 2025 (the date of filing of our registration statement on Form S-8, File No. 333-291314), we issued and sold to certain directors, officers, employees, consultants, and other service providers an aggregate of 232,987 shares of our common stock upon the exercise of options under our 2018 Stock Plan, at exercise prices ranging from $0.56 to $30.78 per share, for an aggregate purchase price of approximately $1.4 million.

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.

On November 14, 2025, we issued 9,660 shares of Class A common stock to Comerica Ventures Incorporated upon the exercise of its outstanding redeemable convertible preferred stock warrant, for an exercise price of $2.59 per share, for aggregate cash consideration of approximately $25,000.

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.

Purchases of Equity Securities by the Issuer and Affiliated Parties

None.

Item 6. Reserved

Item 7. 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 audited financial statements and related notes included elsewhere in this Annual Report. The following discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results and timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of many factors, including, but not limited to, those discussed under Part I, Item 1A "Risk Factors" and elsewhere in this Annual Report. See also the section titled "Special Note Regarding Forward-Looking Statements" in this Annual Report.

A discussion regarding our financial condition and results of operations for the fiscal year ended December 31, 2025 compared to the fiscal year ended December 31, 2024 is presented below. A discussion regarding our financial condition and results of operations for the fiscal year ended December 31, 2024 compared to the fiscal year ended December 31, 2023 can be found in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" in the final prospectus for our IPO dated as of November 5, 2025 and filed with the SEC pursuant to Rule 424(b)(4) on November 6, 2025.

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. 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 over one million smNGS-based tests that we have processed since our initial launch, over 50% of them, or approximately 616,000 tests, were processed in the year ended December 31, 2025.

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, Medicaid, Medicare, the patient, or a combination 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 effects of ASP increases, cost of goods sold (COGS) decreases, and improved operational efficiency have been the main drivers of our ability to generate net income for the year ended December 31, 2025.

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 616,000 tests for the year ended December 31, 2025, compared to 410,000 and 272,000 for the years ended December 31, 2024 and December 31, 2023, respectively. 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 610,000 tests for the year ended December 31, 2025, compared to 405,000 and 264,000 delivered and billable tests for the years ended December 31, 2024 and December 31, 2023, respectively.

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 Part I, Item 1A "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 years ended December 31, 2025 and 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 increase 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 items 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 a tenant improvement package. We expect to occupy this facility in 2027, and open for processing commercial samples 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.

Key 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. During the year ended December 31, 2025, 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 clinical trial support services 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 strategic partnerships with Johnson & Johnson that utilize our testing capabilities as part of a project to perform clinical trials and the development and commercialization of a companion diagnostic. Revenue from these strategic partnership agreements are recognized as services are performed and costs are incurred. Our revenue derived from these agreements has not been material to our results of operations.

Cost of revenue

Our cost of revenue consists primarily of expenses related to reagents and consumables, test kits, personnel-related expenses such as salaries, stock-based compensation expense and related benefits for its operations and support personnel, shipping costs, overhead allocations, depreciation expense, facilities-related expenses and other services used in connection with delivering our 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 consist primarily of personnel-related expenses such as salaries, stock-based compensation expense 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 they are 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, stock-based compensation expense and related benefits for our sales, marketing, and general and administrative employees. Selling, general and administrative expenses also include our commission payments, marketing related expenses in promoting our brand and tests, and training costs for sales employees. All selling, general and administrative costs are expensed in the period as incurred.

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 are associated with 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.

Other income (expense)

Interest income

Interest income consists of income earned on our short-term cash and cash equivalents which include money market funds.

Interest expense

Interest expense is 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. Interest on our finance leases is also recorded in interest expense.

Net gain on extinguishment of debt

Net 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 original agreement which we 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 it 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 and state 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

The following table sets forth information derived from our statements of operations for each of the periods presented:

	Year Ended December 31,		
	2025	2024	2023
	(in thousands)		
Revenue	$ 305,112	$ 152,582	$ 71,729
Cost of revenue(1)	96,654	71,667	54,421
Gross profit	208,458	80,915	17,308
Operating expenses:			
Research and development(1)	49,384	36,596	22,414
Selling, general and administrative(1)	143,051	91,465	64,389
Total operating expenses	192,435	128,061	86,803
Income (loss) from operations	16,023	(47,146)	(69,495)
Other income (expense):			
Interest income	7,750	5,819	3,456
Interest expense	(95)	(2,386)	(3,272)
Net gain on extinguishment of debt	-	7,289	-
Change in fair value of term loan	(8,509)	(3,137)	-
Change in fair value of convertible notes	-	(835)	(12,921)
Other expense, net	(7,410)	(1,145)	(442)
Total other income (expense)	(8,264)	5,605	(13,179)
Income (loss) before provision for income taxes	7,759	(41,541)	(82,674)
Provision for income taxes	305	29	9
Net income (loss)	$ 7,454	$ (41,570)	$ (82,683)

(1) Includes stock-based compensation expense as follows:

	Year Ended December 31,		
	2025	2024	2023
	(in thousands)		
Cost of revenue	$ 1,789	$ 1,183	$ 683
Research and development	3,951	2,341	1,450
Selling, general and administrative	10,175	4,838	2,721
Total stock-based compensation expense	$ 15,915	$ 8,362	$ 4,854

The following table sets forth our statements of operations data expressed as a percentage of revenue:

	Year Ended December 31,		
	2025	2024	2023
Revenue	100 %	100 %	100 %
Cost of revenue	32 %	47 %	76 %
Gross profit	68 %	53 %	24 %
Operating expenses:			
Research and development	16 %	24 %	31 %
Selling, general and administrative	47 %	60 %	90 %
Total operating expenses	63 %	84 %	121 %
Income (loss) from operations	5 %	(31)%	(97)%
Other income (expense):			
Interest income	3 %	4 %	5 %
Interest expense	— %	(2)%	(5)%
Net gain on extinguishment of debt	— %	5 %	— %
Change in fair value of term loan	(3)%	(2)%	— %
Change in fair value of convertible notes	— %	(1)%	(18)%
Other expense, net	(2)%	(1)%	(1)%
Total other income (expense)	(2)%	3 %	(19)%
Income (loss) before provision for income taxes	3 %	(28)%	(116)%
Provision for income taxes	— %	— %	— %
Net income (loss)	3 %	(28)%	(116)%

Comparison of years ended December 31, 2025 and 2024

Revenue

	Year Ended December 31,		Change	
	2025	2024	($)	%
	(in thousands, except percentage)			
Revenue	$ 305,112	$ 152,582	$ 152,530	100%

Revenue increased $152.5 million, or 100%, for the year ended December 31, 2025 compared to the year ended December 31, 2024. This increase was driven primarily by a 51% increase in the total volume of delivered and billable tests to approximately 610,000 for the year ended December 31, 2025 from approximately 405,000 for the year ended December 31, 2024. The increase in revenue was also attributable to an increase in our Overall ASP of 35%. Overall ASP is the weighted average 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. The number of tests that are delivered and billable in a given period represents that number of billable tests for which we deliver a result to the ordering provider in such period.

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

that we have with payors for our prenatal tests which drove increases in ASP during the year ended December 31, 2025 as compared to 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; when utilized, the new PLA code is typically reimbursed at a higher rate than the codes for which we previously billed, which also contributed to an increase in ASP's during the year ended December 31, 2025 compared to the year ended December 31, 2024. We also benefited from an increased attachment and ordering rate of 22q11.2 micro deletion testing (our 22q test) in conjunction with our aneuploidy test and the resulting incremental reimbursement, and we benefited from more payors covering our RhD test. Furthermore, our ASP's 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.

We believe our plans to continue to expand our field sales force for our prenatal products and oncology products will benefit our test volumes. In addition, we believe our Overall ASP will benefit from the opportunity to enter into contracts with additional payors for our prenatal tests, as well as the coverage decision by MolDx in the first quarter of 2025 for Northstar Select, which should continue to result in lower denial rates by Medicare Advantage payors. We plan to submit additional dossiers to MolDX for coverage evaluations for Northstar Response, which, if successful, would significantly increase our Northstar Response ASP's in the future.

Cost of revenue

	Year Ended December 31,		Change	
	2025	2024	($)	%
	(in thousands, except percentage)			
Cost of revenue	$ 96,654	$ 71,667	$ 24,987	35%

Cost of revenue increased $25.0 million, or 35%, for the year ended December 31, 2025 compared to the year ended December 31, 2024. The increase was primarily due to an increase of $16.9 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 $8.0 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

	Year Ended December 31,		Change	
	2025	2024	($)	%
	(in thousands, except percentage)			
Gross profit	$ 208,458	$ 80,915	$ 127,543	158%
Gross margin	68 %	53 %		

Gross profit increased $127.5 million, or 158%, for the year ended December 31, 2025 compared to the year ended December 31, 2024. The increase was primarily due to an increase in the number of tests processed and a higher Overall ASP in conjunction with a lower Overall Cost-Per-Test as we continued to actively reduce variable expenses and increase efficiency from our fixed costs. 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. The number of tests that are accessioned in a given period represents the number of billable tests that we receive for processing during such period. We refer to this number as our “Total Test Volume.”

Gross margin increased to 68% for the year ended December 31, 2025 from 53% for the year ended December 31, 2024 for the reasons described above.

The increase in our Overall ASP contributed to approximately 86% of the improvement in our gross profit margin for the year ended December 31, 2025. In addition, as part of our long-term strategy we are focused on reducing costs per test for each of our offerings, which if successful will result in a reduction in our Overall Cost Per Test. A decrease in our Overall Cost Per Test contributed to approximately 14% of the improvement in our gross profit margin for the year ended December 31, 2025.

For the year ended December 31, 2025 and 2024, our cost of goods sold consisted of variable costs of 57% and 54%, respectively, and fixed costs of 43% and 46%, respectively. The increase in variable costs was attributable primarily to an increase in test volume from prenatal testing, partially offset by targeted costs reduction efforts and efficiencies gained in in our lab from the increased test volume in both prenatal and oncology testing.

We anticipate that cost initiatives and leveraging fixed costs should continue to reduce our Overall Cost Per Test.

Operating expenses

Research and development expenses

	Year Ended December 31,		Change	
	2025	**2024**	**($)**	**%**
	(in thousands, except percentage)			
Research and development	$ 49,384	$ 36,596	$ 12,788	35%

Research and development expenses increased $12.8 million, or 35%, for the year ended December 31, 2025 compared to the year ended December 31, 2024. The increase was primarily due to a $10.1 million increase in personnel costs, which included a $1.6 million increase in stock-based compensation expense, and a $3.2 million increase in materials, equipment expenses and overhead allocations. This was partially offset by a $0.3 million decrease in expense related to clinical studies, and a $0.2 million decrease in consulting and other costs. The increase was primarily driven by a net increase in our R&D headcount of 31 employees during the year ended December 31, 2025 as compared to the year ended December 31, 2024 to support our product development and innovation efforts.

Selling, general and administrative expenses

	Year Ended December 31,		Change	
	2025	**2024**	**($)**	**%**
	(in thousands, except percentage)			
Selling, general and administrative	$ 143,051	$ 91,465	$ 51,586	56%

Selling, general and administrative expenses increased $51.6 million, or 56%, for the year ended December 31, 2025 compared to the year ended December 31, 2024. The increase was primarily due to a $40.6 million increase in salaries, commissions and related expenditures, which included a $5.2 million increase in stock- based compensation expense, a $5.3 million increase in facilities and other costs, a $5.2 million increase in professional fees and a $0.4 million increase in marketing costs. These increases were driven by a net increase of 105 employees during the year ended December 31, 2025 as compared to the year ended December 31, 2024 to support our sales, marketing and corporate strategies.

Other income (expense)

Interest income

	Year Ended December 31,		Change	
	2025	2024	($)	%
	(in thousands, except percentage)			
Interest income	$ 7,750	$ 5,819	$ 1,931	33%

Interest income increased $1.9 million, or 33%, for the year ended December 31, 2025 compared to the year ended December 31, 2024. The increase was primarily due to a higher average balance of cash and cash equivalents, compared to the prior year, due to the proceeds from our IPO.

Interest expense

	Year Ended December 31,		Change	
	2025	2024	($)	%
	(in thousands, except percentage)			
Interest expense	$ (95)	$ (2,386)	$ 2,291	(96%)

Interest expense decreased $2.3 million, or 96%, for the year ended December 31, 2025 compared to the year ended December 31, 2024. The decrease was attributable to the payoff of the Western Alliance Bank debt; the principal on this debt was no longer outstanding during the year ended December 31, 2025. The Western Alliance Bank debt was replaced by the Oberland Capital debt in August 2024. The Oberland Capital debt is accounted for using the fair value method and interest expense related to the Oberland Capital debt was recorded in the change in fair value of term loan.

Net gain on extinguishment of debt

	Year Ended December 31,		Change	
	2025	2024	($)	%
	(in thousands, except percentage)			
Net gain on extinguishment of debt	$ —	$ 7,289	$ (7,289)	(100%)

Net gain on extinguishment of debt was $7.3 million for the year ended December 31, 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 year ended December 31, 2025.

Change in fair value of term loan

	Year Ended December 31,		Change	
	2025	2024	($)	%
	(in thousands, except percentage)			
Change in fair value of term loan	$ (8,509)	$ (3,137)	$ (5,372)	171%

Change in fair value of term loan increased $5.4 million, or 171% for the year ended December 31, 2025 compared to the year ended December 31, 2024. The increase was due to a change in fair value of the Oberland Capital debt of $5.7 million, primarily driven by changes in the overall market resulting in lower interest rates, and interest expense of $4.1 million, which includes revenue participation payments associated with the Oberland Capital debt. We made a policy election to include interest expense related to the Oberland Capital debt in the change in fair value of term loan.

Change in fair value of convertible notes

	Year Ended December 31,		Change	
	2025	2024	($)	%
	(in thousands, except percentage)			
Change in fair value of convertible notes	$ —	$ (835)	$ 835	(100%)

Change in fair value of convertible notes decreased $0.8 million, or 100%, for the year ended December 31, 2025 compared to the year ended December 31, 2024. The decrease was due to a change in fair value of the 2022 Convertible Notes that were extinguished in 2024.

Other expense, net

	Year Ended December 31,		Change	
	2025	2024	($)	%
	(in thousands, except percentage)			
Other expense, net	$ (7,410)	$ (1,145)	$ (6,265)	547%

Other expense, net increased $6.3 million, or 547%, for the year ended December 31, 2025 compared to the year ended December 31, 2024, which was primarily driven by increases in the fair value of our common stock warrant liability of $6.7 million and redeemable convertible preferred stock warrant liability of $0.6 million. In connection with our IPO, the redeemable convertible preferred stock warrants became warrants to purchase common stock. Upon exercise of the common stock warrants, the Company performed a final fair value adjustment of the warrant at the time of the exercise.

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 income (loss) from operations, 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 income (loss) from operations 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:

	Year Ended December 31,		
	2025	2024	2023
	(in thousands)		
Net income (loss)	$ 7,454	$ (41,570)	$ (82,683)
Provision for income taxes	305	29	9
Interest (income)	(7,750)	(5,819)	(3,456)
Interest expense	95	2,386	3,272
Depreciation and amortization	6,910	7,040	5,874
EBITDA	$ 7,014	$ (37,934)	$ (76,984)

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; change in value of convertible notes; and change in fair value of warrant liabilities. A reconciliation of net income (loss), the most directly comparable GAAP financial measure, to Adjusted EBITDA is presented below:

	Year Ended December 31,		
	2025	2024	2023
	(in thousands)		
Net income (loss)	$ 7,454	$ (41,570)	$ (82,683)
Provision for income taxes	305	29	9
Interest (income)	(7,750)	(5,819)	(3,456)
Interest expense	95	2,386	3,272
Depreciation and amortization	6,910	7,040	5,874
Stock-based compensation expense	15,915	8,362	4,854
Net (gain) on extinguishment of debt	—	(7,289)	—
Change in fair value of term loan	8,509	3,137	—
Change in fair value of convertible notes	—	835	12,921
Change in fair value of warrant liabilities	7,364	964	440
Adjusted EBITDA	$ 38,802	$ (31,925)	$ (58,769)

Non-GAAP income (loss) from operations

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

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

	Year Ended December 31,		
	2025	2024	2023
	(in thousands)		
Income (loss) from operations	$ 16,023	$ (47,146)	$ (69,495)
Stock-based compensation expense	15,915	8,362	4,854
Non-GAAP income (loss) from operations	$ 31,938	$ (38,784)	$ (64,641)

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 expense, net gain on extinguishment of debt, change in fair value of term loan, change in fair value of convertible notes and change in fair value of warrant liabilities. 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:

	Year Ended December 31,		
	2025	2024	2023
	(in thousands)		
Net income (loss)	$ 7,454	$ (41,570)	$ (82,683)
Stock-based compensation expense	15,915	8,362	4,854
Net (gain) on extinguishment of debt	—	(7,289)	—
Change in fair value of term loan	8,509	3,137	—
Change in fair value of convertible notes	—	835	12,921
Change in fair value of warrant liabilities	7,364	964	440
Non-GAAP net income (loss)	$ 39,242	$ (35,561)	$ (64,468)

Liquidity and capital resources

Since our inception, prior to our IPO, we 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 December 31, 2025, our principal sources of liquidity were cash and cash equivalents of $496.0 million and working capital of $512.6 million. On November 7, 2025, we closed our IPO of our Class A common stock. The total net proceeds received were approximately $286.9 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 $274.7 million as of December 31, 2025, though we did have positive income from operations and positive cash flows in the year ended December 31, 2025, we may be unable to sustain positive income from operations and positive cash flows in future periods. We believe that 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% 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 internal rate of return (IRR) for the purchasers of 10% over the seven year term of the loan. 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, 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 IRR for the purchasers of 12.25%; (4) if the payment is made within 60 months of 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 December 31, 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:

	Year Ended December 31,		
	2025	2024	2023
	(in thousands)		
Net cash provided by (used in) operating activities	$ 24,595	$ (41,375)	$ (53,672)
Net cash provided by (used in) investing activities	(8,922)	(5,433)	82,838
Net cash provided by financing activities	288,825	141,017	13,405

Operating activities

Net cash provided by operating activities during the year ended December 31, 2025 was $24.6 million. Net income of $7.5 million included $39.2 million in non-cash charges primarily resulting from $15.9 million of stock-based compensation, $6.9 million of depreciation and amortization, $5.0 million of amortization of operating right-of-use assets, and aggregate $10.7 million of change in fair value of the common stock warrant liability and term loan. Operating assets had outflows of $28.0 million primarily resulting from a $16.9 million increase in accounts receivable, $8.8 million increase in inventory, and $2.3 million increase in prepaid expenses and other current assets. Operating liabilities had inflows of $5.9 million primarily resulting from an aggregate $4.4 million increase in accounts payable and accrued expense and other current liabilities balances, aggregate $5.3 million increase in accrued commissions, compensation and employee benefits and $0.7 million increase in deferred revenue, offset by a $4.4 million decrease in operating lease liabilities.

Net cash used in operating activities during the year ended December 31, 2024 was $41.4 million. Net loss of $41.6 million included $17.0 million in non-cash charges primarily resulting from $8.4 million of stock-based compensation, $7.0 million of depreciation and amortization, $4.6 million amortization of operating right-of-use assets, and aggregate $3.2 million of change in fair value of the common stock warrant liability, term loan and convertible notes, offset by the $7.3 million gain on extinguishment of debt. Operating assets had outflows of $21.1 million primarily resulting from $15.6 million increase in accounts receivable due to higher product sales and timing of customer payments, $4.0 million increase in other non-current assets, prepaid expenses and current assets and $1.5 million increase in inventory due to build up for anticipated demand. Operating liabilities had inflows of $4.3 million primarily resulting from, $6.8 million increase in accrued commissions, compensation and employee benefits due to increased employee headcount and increased sales which increased commissions and bonuses and $1.6 million increase in accounts payable and accrued expenses due to increase testing volumes and timing of payments, offset by a $3.8 million decrease in operating lease liabilities.

Investing activities

Net cash used in investing activities during the year ended December 31, 2025 was $8.9 million primarily due to purchases of property and equipment.

Net cash used in investing activities during the year ended December 31, 2024 was $5.4 million primarily due to purchases of property and equipment.

Financing activities

Net cash provided by financing activities during the year ended December 31, 2025 was $288.8 million primarily due to proceeds from our IPO, net of underwriting discounts and commissions, of $292.0 million, and $3.1 million in proceeds from exercise of stock options, net of repurchases, offset by $4.6 million of payments of deferred offering costs and $1.8 million in principal payments on finance lease liabilities.

Net cash provided by financing activities during the year ended December 31, 2024 was $141.0 million primarily due to $130.0 million in proceeds from issuance of series d redeemable convertible preferred stock, net of issuance costs, $49.8 million in proceeds from issuance of debt, net, and $1.1 million in proceeds from exercise

of stock options, net of repurchases, partially offset by $36.7 million repayment of debt upon extinguishment and related exit fee, $2.4 million in principal payments on finance lease liabilities, and $0.5 million in repurchase of common stock outstanding.

Contractual obligations and commitments

Operating lease commitments. Our operating lease commitments primarily include our labs and corporate offices. As of December 31, 2025, we had fixed lease payment obligations of $67.8 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 December 31, 2025, we had fixed lease payment obligations of $0.9 million, with $0.5 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 elsewhere in this Annual Report on Form 10-K. 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, Medicare or the patient or a combination upon delivery of test results. 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, Medicaid and Medicare 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

Prior to the completion of the IPO, there was no public market for the Company's common stock. Accordingly, 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, 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.

After the completion of the IPO, our Board of Directors determines 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 included elsewhere in this Annual Report on Form 10-K 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 7A: Quantitative and Qualitative Disclosures about Market Risk

We are exposed to market risk 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 and foreign currency exchange rates and inflation risk.

Interest Rate Risk

We are exposed to market risk for changes in interest rates related primarily to our cash, cash equivalents and restricted cash, and our indebtedness. As of December 31, 2025, we had cash, cash equivalents and restricted cash of $496.0 million held primarily in cash deposits and money market funds. As of December 31, 2025, we had a net balance of $57.2 million outstanding under our Oberland Capital Note Purchase Agreement, which is subject to quarterly interest payments. A hypothetical 100 basis point increase or decrease in interest rates would not be material to our financial condition or results of operations.

Foreign Currency Risk

Our operations are currently conducted almost entirely in the United States as international markets represented less than 1% of our revenue during the year ended December 31, 2025. 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 would 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. As of December 31, 2025, the effect of a hypothetical 10% change in foreign currency exchange rates would not be material to our financial condition or results of operations. To date, we have not entered into any hedging arrangements with respect to foreign currency risk.

Inflation Risk

We are also exposed to inflation risk and inflationary factors, such as increases in raw material and overhead costs, which could impair our operating results. Although we do not believe that inflation has had a material impact on our financial position or results of operations to date, a high rate of inflation in the future may have an adverse effect on our ability to maintain current levels of gross margin and operating expenses as a percentage of revenue.

Item 8. Financial Statements and Supplementary Data

BillionToOne, Inc.
Index to Financial Statements

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of BillionToOne, Inc.

Opinion on the Financial Statements

We have audited the accompanying 2025 and 2024 financial statements of BillionToOne, Inc. and the 2023 consolidated financial statements of BillionToOne, Inc. and its subsidiary (collectively referred to as the “Company"), which comprise the balance sheets as of December 31, 2025 and 2024, and the related statements of operations and comprehensive income (loss), of redeemable convertible preferred stock and stockholders' equity (deficit) and of cash flows for each of the three years in the period ended December 31, 2025, including the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2025 in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP
Florham Park, New Jersey
March 11, 2026

We have served as the Company’s auditor since 2022.

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

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 495,975	$ 191,477
Accounts receivable	41,617	24,709
Inventories	17,545	8,733
Prepaid expenses and other current assets	5,421	2,898
Total current assets	560,558	227,817
Property and equipment, net	20,361	17,111
Operating lease right-of-use assets, net	46,742	51,739
Other non-current assets	4,993	5,392
Total assets	$ 632,654	$ 302,059
Liabilities, redeemable convertible preferred stock, and stockholders' deficit		
Current liabilities:		
Accounts payable	7,184	4,304
Accrued expenses and other current liabilities	7,247	3,882
Accrued commissions	3,912	2,756
Accrued compensation and employee benefits	12,551	8,419
Common stock warrant liability	9,282	-
Deferred revenue, current	2,188	2,806
Operating lease liabilities, current	5,079	4,393
Financing lease liabilities, current	519	1,826
Total current liabilities	47,962	28,386
Operating lease liabilities, non-current	45,723	50,802
Financing lease liabilities, non-current	348	874
Deferred revenue, non-current	1,290	-
Long-term debt	57,226	51,481
Other non-current liabilities	-	2,763
Total liabilities	152,549	134,306
Commitments and contingencies (Note 7)		
Redeemable convertible preferred stock, $0.00001 par value; 50,000,000 and 29,544,989 shares authorized as of December 31, 2025 and 2024, respectively; 0 and 29,084,235 shares issued and outstanding as of December 31, 2025 and 2024, respectively; aggregate liquidation preference of $0 and $422,458 as of December 31, 2025 and 2024, respectively	-	419,409
Stockholders' equity:		
Common stock, $0.00001 par value; 0 and 51,100,000 shares authorized as of December 31, 2025 and 2024, respectively; 0 and 10,925,950 shares issued and outstanding as of December 31, 2025 and 2024, respectively	-	-
Class A common stock, $0.00001 par value; 800,000,000 shares authorized as of December 31, 2025; 41,252,105 shares issued and outstanding as of December 31, 2025	-	-
Class B common stock, $0.00001 par value; 10,000,000 shares authorized as of December 31, 2025; 4,552,650 shares issued and outstanding as of December 31, 2025	-	-
Additional paid-in capital	756,644	30,545
Accumulated other comprehensive loss	(1,792)	-
Accumulated deficit	(274,747)	(282,201)
Total stockholders' equity	480,105	(251,656)
Total liabilities, redeemable convertible preferred stock, and stockholders' equity	$ 632,654	$ 302,059

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

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

	Year Ended December 31,		
	2025	2024	2023
Revenue	$ 305,112	$ 152,582	$ 71,729
Cost of revenue	96,654	71,667	54,421
Gross profit	208,458	80,915	17,308
Operating expenses:			
Research and development	49,384	36,596	22,414
Selling, general and administrative	143,051	91,465	64,389
Total operating expenses	192,435	128,061	86,803
Income (loss) from operations	16,023	(47,146)	(69,495)
Other income (expense):			
Interest income	7,750	5,819	3,456
Interest expense	(95)	(2,386)	(3,272)
Net gain on extinguishment of debt	-	7,289	-
Change in fair value of term loan	(8,509)	(3,137)	-
Change in fair value of convertible notes	-	(835)	(12,921)
Other expense, net	(7,410)	(1,145)	(442)
Total other income (expense)	(8,264)	5,605	(13,179)
Income (loss) before provision for income taxes	7,759	(41,541)	(82,674)
Provision for income taxes	305	29	9
Net income (loss)	$ 7,454	$ (41,570)	$ (82,683)
Less: Net income (loss) attributable to participating securities	(4,535)	-	-
Net income (loss) attributable to common stockholders	$ 2,919	$ (41,570)	$ (82,683)
Other comprehensive loss, net of taxes:			
Change in fair value of term loan attributable to instrument-specific credit risk	(1,792)	-	-
Other comprehensive loss, net of taxes	(1,792)	-	-
Comprehensive income (loss), net of taxes	$ 5,662	$ (41,570)	$ (82,683)
Net income (loss) per share attributable to common stockholders, basic and diluted:			
Net income (loss) per share, basic	$ 0.18	$ (4.12)	$ (8.45)
Net income (loss) per share, diluted	$ 0.14	$ (4.12)	$ (8.45)
Weighted-average shares used in calculating net income (loss) per share attributable to common stockholders, basic and diluted:			
Weighted-average shares used in calculating net income (loss) per share, basic	15,875,091	10,079,925	9,782,770
Weighted-average shares used in calculating net income (loss) per share, diluted	21,230,752	10,079,925	9,782,770

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

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

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balance at January 1, 2023	22,701,179	$ 249,527	10,424,709	$ -	$ 16,140	$ -	$ (157,948)	$ (141,808)
Issuance of common stock upon exercise of stock options	-	-	147,352	-	518	-	-	518
Partial repayment of promissory note by executive	-	-	-	-	51	-	-	51
Stock-based compensation	-	-	-	-	4,854	-	-	4,854
Vesting of early exercises	-	-	-	-	15	-	-	15
Net loss	-	-	-	-	-	-	(82,683)	(82,683)
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 settlement 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	-	-	380,639	-	1,146	-	-	1,146
Stock-based compensation	-	-	-	-	8,362	-	-	8,362
Repurchase of common stock	-	-	(26,750)	-	(546)	-	-	(546)
Vesting of early exercises	-	-	-	-	5	-	-	5
Net loss	-	-	-	-	-	-	(41,570)	(41,570)
Balance at December 31, 2024	29,084,235	$ 419,409	10,925,950	$ -	$ 30,545	$ -	$ (282,201)	$ (251,656)
Conversion of redeemable convertible preferred stock to Class A and Class B common stock in connection with initial public offering	(29,084,235)	(419,409)	29,084,235	-	419,409	-	-	419,409
Issuance of Class A common stock in connection with initial public offering, net of underwriting discounts and commissions and issuance costs	-	-	5,233,765	-	286,928	-	-	286,928
Issuance of Class A common stock upon exercise of stock options	-	-	551,145	-	2,924	-	-	2,924
Stock-based compensation	-	-	-	-	15,915	-	-	15,915
Exercise of Class A common stock warrants	-	-	9,660	-	870	-	-	870
Repayment of promissory notes by executives	-	-	-	-	51	-	-	51
Vesting of early exercises	-	-	-	-	2	-	-	2
Other comprehensive loss	-	-	-	-	-	(1,792)	-	(1,792)
Net income	-	-	-	-	-	-	7,454	7,454
Balance at December 31, 2025	-	$ -	45,804,755	$ -	$ 756,644	$ (1,792)	$ (274,747)	$ 480,105

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

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

	Year Ended December 31,		
	2025	**2024**	**2023**
Cash flows from operating activities:			
Net income (loss)	$ 7,454	$ (41,570)	$ (82,683)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Stock-based compensation	15,915	8,362	4,854
Depreciation and amortization	6,910	7,040	5,874
Amortization of debt discount costs and accretion of exit fees	-	341	540
Debt issuance costs on term loan expensed upon election of fair value option	-	453	-
Amortization of operating right-of-use assets	4,997	4,648	589
Loss on disposal of fixed assets	55	126	-
Change in fair value of common stock warrant liability	6,749	880	392
Change in fair value of redeemable convertible preferred stock warrant liability	615	84	48
Net gain on extinguishment of debt	-	(7,289)	-
Change in fair value of convertible notes	-	835	12,921
Change in fair value of term loan	3,953	1,481	-
Changes in operating assets and liabilities:			
Accounts receivable	(16,908)	(15,619)	(2,588)
Inventories	(8,812)	(1,535)	(1,412)
Prepaid expenses and other current assets	(2,193)	(860)	2,232
Other non-current assets	(60)	(3,101)	491
Accounts payable	1,775	877	151
Accrued expenses and other current liabilities	2,578	697	733
Accrued commissions	1,156	905	387
Accrued compensation and employee benefits	4,132	5,859	737
Deferred revenue	672	(218)	3,024
Operating lease liabilities	(4,393)	(3,771)	38
Net cash provided by (used in) operating activities	24,595	(41,375)	(53,672)
Cash flows from investing activities:			
Proceeds from maturities of certificates of deposit	-	-	90,000
Deposits paid for financing leases	-	(31)	(988)
Purchase of domain name	(41)	-	-
Purchases of property and equipment	(8,881)	(5,402)	(6,174)
Net cash provided by (used in) investing activities	(8,922)	(5,433)	82,838

BillionToOne, Inc.
Statement of Cash Flows—Continued
(in thousands)

	Year Ended December 31,		
	2025	**2024**	**2023**
Cash flows from financing activities:			
Proceeds from issuance of Class A common stock in connection with the Company's initial public offering, net of underwriting discounts and commissions	292,044	-	-
Payments of deferred offering costs	(4,612)	-	-
Proceeds from issuance of debt, net	-	49,775	15,000
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	(1,777)	(2,376)	(2,090)
Repurchase of common stock outstanding	-	(546)	-
Payment of debt issuance costs on term loan	-	(228)	-
Proceeds from exercise of stock options, net of repurchases	3,094	1,084	444
Proceeds from exercise of common stock warrants	25	-	-
Proceeds from repayment of promissory notes by executives	51	-	51
Proceeds from issuance of Series D redeemable convertible preferred stock, net of issuance costs	-	129,996	-
Net cash provided by financing activities	288,825	141,017	13,405
Net increase in cash and cash equivalents	304,498	94,209	42,571
Cash and cash equivalents at beginning of year	191,477	97,268	54,697
Cash and cash equivalents at end of year	$ 495,975	$ 191,477	$ 97,268
Supplemental cash flow disclosure:			
Cash payments for interest	$ 4,651	$ 3,915	$ 2,584
Cash paid for income taxes	$ 487	$ 9	$ -
Supplemental non-cash investing and financing activities:			
Conversion of redeemable convertible preferred stock into shares of Class A common stock in connection with the Company's initial public offering	$ 419,409	$ -	$ -
Purchases of property and equipment in accounts payable and accrued expenses and other current liabilities	$ 2,391	$ 1,001	$ -
Issuance of Series C-1 redeemable convertible preferred stock upon settlement of convertible notes	$ -	$ 39,886	$ -
Offering costs in accounts payable and accrued expenses and other current liabilities	$ 504	$ -	$ -
Right-of-use assets obtained in exchange for new finance lease liabilities	$ -	$ 395	$ 2,795
Exercise of stock options for which cash has not been received	$ 3	$ 173	$ 102
Settlement of common stock warrant liability	$ 845	$ -	$ -

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

BillionToOne, Inc.
Notes to Financial Statements

(1) Description of Business

BillionToOne, Inc. (the "Company") 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 its 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. Accordingly, in 2023, the financial statements were consolidated while in 2024 and 2025 they were not. All intercompany transactions and balances have been eliminated upon consolidation.

Initial Public Offering

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 $286.9 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 (such conversion, the "Reclassification"). Following the Reclassification, and immediately prior to the closing of the IPO, 2,227,542 shares of Class A common stock held by Oguzhan Atay, the Company's Chief Executive Officer and Co-Founder, and 2,325,108 shares of Class A common stock held by David Tsao, the Company's Chief Technology Officer and Co-Founder, were exchanged at a 1:1 ratio for shares of Class B common stock.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make 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: 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, and valuation of debt, convertible notes and common stock warrants. These estimates are inherently subject to judgment and actual results could differ from those estimates.

Emerging Growth Company

The Company is an emerging growth company, as defined by the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). Under the JOBS Act, emerging growth companies may delay adopting new or revised accounting standards that have different effective dates to public and private companies until the earlier of the date that (i) the Company is no longer an emerging growth company or (ii) the Company affirmatively and irrevocably opts out of the extended transition period as permitted in the JOBS Act. As a result, these financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates. The Company expects to avail itself of the extended transition period for any other new or revised accounting standards during the period in which it remains an emerging growth company.

Liquidity

Prior to the completion of its IPO, the Company's available liquidity and operations had been financed primarily through the issuance of convertible notes, redeemable convertible preferred stock, debt and sale of the Company's products. The Company has generated significant losses from operations and negative cash flows from operating activities in the past as reflected in its accumulated deficit of $274.7 million and $282.2 million as of December 31, 2025 and 2024, respectively, though the Company did generate income from operations and positive cash flows from operating activities during the year ended December 31, 2025. For the year ended December 31, 2025, $24.6 million in cash was provided by operating activities, compared to $41.4 million used in operating activities for the year ended December 31, 2024. The Company continues to invest in the development and commercialization of its existing and future products and, consequently, will need to generate additional revenues to achieve future profitability and may need to raise additional equity or debt financing. The Company believes its existing cash and cash equivalent balances and cash generated from sales will be sufficient to meet its cash needs for at least the next 12 months.

These financial statements were prepared under the assumption that the Company will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business, and do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

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 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.

Cash and Cash Equivalents

The Company's cash and cash equivalents consist of all highly liquid investments deposited with banks, including money market funds. The money market funds are managed in accordance with regulatory requirements applicable to money market funds, including restrictions on the maturity of the underlying investments. These investments are considered highly liquid and readily convertible to cash.

Concentration of Credit Risk

Financial instruments that potentially expose the Company to significant concentration of credit risk consist primarily of cash and cash equivalents and accounts receivable. The Company's cash and cash equivalents are generally held with large financial institutions. Certain deposits held with these financial institutions are in excess of the amount of FDIC insured limits provided on such deposits.

As of December 31, 2025, 2024 and 2023, no customers represented more than 10% of accounts receivable, and for the years ended December 31, 2025, 2024 and 2023, no customers represented more than 10% of the Company's revenue.

Fair Value of Financial Instruments

The Company records all financial assets and liabilities that are recognized or disclosed at fair value in the financial statements on a recurring basis. Other financial instruments, including cash and cash equivalents, are recorded at cost, which approximates fair value. Additionally, the carrying amounts of accounts receivable, prepaid expenses and other current assets, accounts payable and accrued expenses and other current liabilities approximate fair value due to their relatively short-term nature.

The accounting guidance for fair value provides a framework for measuring fair value, clarifies the definition of fair value, and expands disclosures regarding fair value measurements. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. The accounting guidance establishes a three-tiered hierarchy, which prioritizes the inputs used in the valuation methodologies in measuring fair value as follows:

Level 1 input	Quoted prices (unadjusted) in active markets for identical assets or liabilities that the reporting entity can access at the measurement date.
Level 2 input	Inputs other than the quoted prices included within Level 1 that are observable for the assets or liabilities, either directly or indirectly.
Level 3 input	Unobservable inputs for the assets or liabilities. Unobservable inputs shall be used to measure fair value to the extent that relevant observable inputs are not available, thereby allowing for situations in which there is little, if any, market activity for the asset or liability at the measurement date.

A financial instrument’s categorization within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement. Reclassifications of financial instruments between levels of the fair value hierarchy are reported as transfers in or out as of the beginning of the period in which the reclassifications occur.

The Company's cash and cash equivalents include money market funds which are quoted in an active market and classified within Level 1 of the fair value hierarchy, which are measured at fair value based on the closing price as of the reporting date. The Company measures certain of its liabilities at fair value on a recurring basis, including warrants, due to their terms, and certain debt agreements where the Company has elected the fair value option. Any changes in fair value caused by instrument-specific credit risk are presented separately in other comprehensive loss. See Note 3 for further details.

During the year ended December 31, 2025, there was a change in the fair value of the term loan where the Company elected the fair value option that related to changes in credit risk. During the years ended December 31, 2024 and 2023, there was no change in the fair value of debt agreements where the Company elected the fair value option that related to changes in credit risk.

Accounts Receivable and Allowances

The Company regularly assesses the collectability of accounts and reviews the allowance by considering factors such as historical experience, the age of the accounts receivable balances, and current economic conditions that may affect a customer’s ability to pay. Based on this assessment for credit losses the Company determined an allowance for credit losses was not needed given the payors from whom such receivables are collectible and the relatively short duration over which the majority of receivables are collected.

There was no allowance for credit losses as of December 31, 2025, 2024 and 2023. Account balances are written off against the allowance after all means of collection have been exhausted without success. During the years ended December 31, 2025, 2024 and 2023, there were no write-offs of accounts receivable.

Inventories

Inventories consist primarily of supplies for prenatal testing, consumables and lab supplies (including reagents) which are stated at the lower-of-cost or net realizable value. The supplies are consumed at the point samples are collected, and as the Company performs its testing service and accordingly, the Company does not maintain any work-in-process or finished goods inventory. The cost of inventory is determined on an average cost method. Inventory that is obsolete or in excess of forecasted demand is written down to its estimated net realizable value. The Company periodically reviews its inventory and writes off inventory that are determined to

be obsolete based on market factors, utilization rates and product expiration dates. Inventory write-downs are recognized as cost of revenue in the accompanying statements of operations and comprehensive income (loss). During the years ended December 31, 2025, 2024 and 2023, inventory write-downs totaled approximately $0.3 million, $0.1 million and $0.1 million, respectively, and were related to expired and unusable inventory.

Property and Equipment, Net

Property and equipment, net is stated at historical cost less accumulated depreciation and amortization. Depreciation and amortization on property and equipment is calculated using the straight-line method over the estimated useful lives of the assets which are as follows:

Machinery and equipment	5 years
Furniture and fixtures	5 years
Automobiles	5 years
Computer hardware	3 years
Computer software	3 years
Leasehold improvements	Shorter of 10 years or remaining lease term

Maintenance and repairs are charged to expenses as incurred.

The Company entered into finance leases for certain lab equipment. The Company records amortization of assets leased in connection with finance lease arrangements as depreciation expense.

Impairment of Long-Lived Assets

The Company evaluates long-lived assets for indicators of possible impairment when events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets held and used is measured by comparison of the carrying amount of an asset or an asset group to estimated undiscounted future net cash flows expected to be generated by the asset or asset group. If the carrying amount of an asset exceeds these estimated future cash flows, an impairment charge is recognized by the amount by which the carrying amount of the assets exceeds the fair value of the asset or asset group. There were no such impairment losses during the years ended December 31, 2025, 2024 and 2023.

Leases

The Company determines if an arrangement is a lease, or contains a lease, by evaluating whether there is an identified asset and whether the Company controls the use of the identified asset throughout the period of use. The Company determines the classification of the lease, whether operating or financing, at the lease commencement date, which is the date the leased assets are made available for use.

If the Company determines a lease exists, the Company then determines whether the lease should be classified as an operating or finance lease. A lease is classified as a finance lease when one or more of the following criteria are met: (1) the lease transfers ownership of the asset by the end of the lease term, (2) the lease contains an option to purchase the asset that is reasonably certain to be exercised, (3) the lease term is for a major part of the remaining useful life of the asset, (4) the present value of the lease payments equals or exceeds substantially all of the fair value of the asset or (5) the asset is of such a specialized nature that it is expected to have no alternative use to the lessor at the end of the lease term. A lease is classified as an operating lease if it does not meet any of these criteria. Operating leases consist of the Company's real estate facilities and finance leases consist of the Company's lab equipment.

At the lease commencement date, the Company records a right-of-use ("ROU") asset and a lease liability for all leases, except for short-term leases with an original term of 12 months or less, whereby the Company has elected a practical expedient not to recognize an ROU asset or lease liability for short term leases.

ROU assets are measured based on the corresponding lease liability adjusted for (i) payments made to the lessor at or before the commencement date, (ii) initial direct costs incurred and (iii) tenant incentives under the lease. All ROU assets are periodically reviewed for impairment in accordance with standards that apply to long-lived assets. Lease liabilities are recognized at the lease inception date based on the present value of lease

payments over the lease term discounted based on the more readily determinable of (i) the rate implicit in the lease or (ii) the Company's incremental borrowing rate (which is the estimated rate the Company would be required to pay for a collateralized borrowing equal to the total lease payments over the term of the lease). Because the Company's leases generally do not provide an implicit rate, the Company estimates its incremental borrowing rate based on the information available such as credit rating, lease term and collateral at lease commencement date for borrowings with a similar term.

Lease expense for operating leases consists of the fixed lease payments recognized on a straight-line basis over the lease term plus variable lease payments as incurred. Lease expense for finance leases consists of the depreciation recognized on a straight-line basis over the lease term and interest expense on the lease liability based on the discount rate at lease commencement.

The Company does not assume renewals or early terminations unless it is reasonably certain the Company will exercise these options at commencement. The Company elected the practical expedient which allows the Company to not allocate consideration between lease and non-lease components. Variable lease payments are recognized in the period in which the obligation for those payments are incurred.

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, the patient, or a combination upon delivery of test results.

The Company enters into contracts with third-party payors, including insurance carriers, Medicaid and Medicare, 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 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 ("J&J") 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 J&J 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 J&J for the development and commercialization of a companion diagnostic (CDx), intended for use with a new drug candidate of J&J. 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 receives payment 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 each of 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 December 31, 2025, the Company's remaining performance obligations beyond one year were approximately $3.3 million.

Disaggregation of revenue

The following table presents disaggregation of revenue by Prenatal, Oncology and Clinical trial support and other services for the years ended December 31, 2025, 2024 and 2023:

	Year Ended December 31,		
	2025	2024	2023
	(in thousands)		
Prenatal	$ 277,105	$ 145,901	$ 68,803
Oncology	24,953	2,944	-
Clinical trial support and other services	3,054	3,737	2,926
Total revenue	$ 305,112	$ 152,582	$ 71,729

Substantially all revenue recognized for the years ended December 31, 2025, 2024 and 2023 was generated in the United States.

Revenue related to performance obligations satisfied in prior periods

For the years ended December 31, 2025, 2024 and 2023, the Company recorded $8.7 million, $11.0 million and $2.7 million, respectively, as revenue related to performance obligations satisfied in prior periods.

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 December 31, 2025, 2024 and 2023, the deferred revenue balance was $3.5 million, $2.8 million and $3.0 million, respectively. As of December 31, 2025, $1.3 million of the deferred revenue balance was classified as non-current and $2.2 million was classified as current. All deferred revenue as of December 31, 2024 and 2023 was classified as current. For the years ended December 31, 2025 and 2024, revenue recognized from deferred revenue at the beginning of the period was $2.1 million and $3.0 million, respectively. No revenue was recognized from deferred revenue at the beginning of the period during the year December 31, 2023.

Cost of Revenue

The Company's cost of revenue consists primarily of expenses related to reagents and consumables, test kits, personnel-related expenses such as salaries, stock-based compensation expense and related benefits for its operations and support personnel, shipping costs, overhead allocations, depreciation expense, facilities-related expenses and other services used in connection with delivering the Company's services.

Advertising Costs

Advertising costs are expensed as incurred. These amounts are included in selling, general and administrative expense in the statements of operations and comprehensive income (loss) and amounted to approximately $1.2 million, $1.3 million and $0.4 million for the years ended December 31, 2025, 2024 and 2023, respectively.

Research and Development

Research and development expenses consist primarily of personnel-related expenses such as salaries, stock-based compensation expense and related benefits for the Company's 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 the Company's general overhead expenses. These costs are expensed in the period as incurred.

Selling, General and Administrative

Selling, general and administrative expenses consist primarily of personnel-related expenses such as salaries, stock-based compensation expense and related benefits for the Company's sales, marketing, and general and administrative employees. Selling, general and administrative expenses also include the Company's commission payments, marketing related expenses in promoting the Company's brand and tests, and training costs for the sales employees. All selling, general and administrative costs are expensed in the period as incurred.

Income Taxes

Income taxes are accounted for under the asset-and-liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statements carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance is provided on deferred tax assets when it is more-likely-than-not that some portion or all of the net deferred tax assets will not be realized. The Company evaluates uncertain tax positions taken or expected to be taken in the course of preparing its tax return to determine whether the tax positions are more-likely-than-not of being sustained upon challenge by the applicable tax authority based on the technical merits of the position. The Company recognizes the effect of income tax positions only if those positions are more-likely-than-not of being sustained. Recognized income tax positions

are measured at the largest amount that is greater than a 50% likelihood of being realized upon ultimate settlement. Changes in recognition or measurement are reflected in the period in which the change in judgment occurs. The Company recognizes interest and penalties related to income tax matters in provision for income taxes.

Comprehensive Income (Loss)

The components of comprehensive loss consist of net income (loss) and changes in fair value due to instrument-specific credit risk on the term loan. During the years ended December 31, 2024 and 2023, the Company did not have any other comprehensive income (loss) and, therefore, the net income (loss) and comprehensive (income) loss was the same.

Redeemable Convertible Preferred Stock

The Company records shares of redeemable convertible preferred stock at their respective fair values on the dates of issuance, net of issuance costs. The redeemable convertible preferred stock is recorded outside of permanent equity because while it is not mandatorily redeemable, redemption is contingent upon the occurrence of certain events considered not solely within the Company's control. The Company has not adjusted the carrying values of the redeemable convertible preferred stock to the liquidation preferences of such shares because it is uncertain whether or when a deemed liquidation event would occur that would obligate the Company to pay the liquidation preferences to holders of shares of redeemable convertible preferred stock. Subsequent adjustments to the carrying values to the liquidation preferences will be made only when it becomes probable that such a deemed liquidation event will occur. In connection with the IPO, the redeemable convertible preferred stock was automatically converted into shares of Class A common stock. See Note 11 for further information.

Redeemable Convertible Preferred Stock Warrants

Freestanding warrants to purchase shares of redeemable convertible preferred stock are classified as liabilities on the balance sheets at their estimated fair value because the underlying shares of redeemable convertible preferred stock are contingently redeemable and, therefore, may obligate the Company to transfer assets at some point in the future. Warrants to purchase shares of redeemable convertible preferred stock are recorded at fair value upon issuance and remeasured to fair value. Redeemable convertible preferred stock warrants are subject to re-measurement at each balance sheet date, and any change in fair value is recognized as other expense, net in the statements of operations and comprehensive income (loss). See Note 3 for further information. In connection with the IPO, the redeemable convertible preferred stock warrants were automatically converted to common stock warrants and subsequently exercised into Class A common stock. See Note 11 for further information.

Common Stock Warrants

Certain freestanding warrants to purchase shares of common stock are classified as liabilities on the balance sheets at their estimated fair value as the warrants allow the holders to put the warrants to the Company, in certain circumstances, in exchange for a cash payment. Those puttable warrants to purchase shares of common stock are recorded at fair value upon issuance and remeasured to fair value. Common stock warrants are subject to re-measurement at each balance sheet date and any change in fair value is recognized as other expense, net in the statements of operations and comprehensive income (loss) (See Note 3).

Stock-Based Compensation

The Company measures 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-Merton option valuation model (the "Black-Scholes Model"). The model requires the Company to make assumptions and judgments about the variable inputs used in the Black-Scholes Model, including expected term, the volatility of the Company's 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. The Company accounts for forfeitures as they occur.

The Company has 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.

The Company grants restricted stock units ("RSUs") to employees and directors as part of its equity incentive plans. RSUs represent the right to receive shares of the Company's Class A common stock upon vesting. The grant-date fair value of RSUs is measured based on the closing price of the Company's Class A common stock on the date of grant and is recognized as stock-based compensation expense on a straight-line basis over the requisite service period. The Company accounts for forfeitures as they occur.

Deferred Offering Costs

Deferred offering costs, consisting of legal, accounting, and other fees and costs relating to the Company's IPO are capitalized within other non-current assets on the balance sheets. The deferred offering costs were offset against the proceeds received by the Company upon the closing of the IPO. At the closing of the IPO, $5.1 million of deferred offering costs were reclassified to additional paid-in capital within stockholders' deficit and $0.5 million of IPO costs are accrued for and remain unpaid as of December 31, 2025.

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 services delivered to patients, the Company's primary customers; both the prenatal and oncology testing products utilize the Company's proprietary molecular diagnostic technology platform. The Company's 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 and comprehensive income (loss).

Recently Adopted Accounting Pronouncements

In December 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("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. The Company adopted this ASU for its year ended December 31, 2025 and included the expanded income-tax related disclosures. See Note 12 for further information.

Recently Issued Accounting Pronouncements Not Yet Adopted

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 and related 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 underlying 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 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 December 31, 2025 (in thousands):

	Level 1	Level 2	Level 3	Total
Current assets:				
Money market funds	$ 359,813	$ -	$ -	$ 359,813
Total assets	$ 359,813	$ -	$ -	$ 359,813
Liabilities:				
Common stock warrants	$ -	$ 9,282	$ -	$ 9,282
Term loan	-	-	57,226	57,226
Total liabilities	$ -	$ 9,282	$ 57,226	$ 66,508

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):

	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

As of December 31, 2025, Level 3 instruments consist of the Company's term loan due to the lack of relevant observable market data for the respective fair value inputs of the instrument.

As of December 31, 2024, Level 3 instruments consist of the Company's common stock warrant liabilities, redeemable convertible preferred stock warrant liabilities and term loan due to the lack of relevant observable market data for the respective fair value inputs for each instrument.

In August 2024, the Company entered into a term loan agreement 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 10).

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

	December 31, 2025	December 31, 2024
Discount rate	7.10 %	9.37 %
Annual interest rate	8.00 %	8.00 %
Expected term (years) – Scenario 1	4.25	5.32
Expected term (years) – Scenario 2	5.60	6.69

The fair values of the common stock warrant and redeemable convertible preferred 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 December 31, 2025, 2024 and 2023 is as follows:

	December 31,		
	2025	2024	2023
Stock price	$ 81.84	$ 20.32	$ 13.41
Exercise price	$2.80 - $10.92	$2.80 – $10.92	$2.80 – $10.92
Volatility	53.5 %	84.0 %	60.0 %
Expected term (years)	0.3	2.30	1.5
Risk-free rate	3.63 %	4.14 %	4.50 %
Dividend yield	- %	- %	- %

The redeemable convertible preferred stock warrant liability was reclassified to equity upon the exercise of the underlying warrants; as such, the redeemable convertible preferred stock warrant liability fair value was determined as of the date of exercise, on November 14, 2025 (see Note 10). The fair value of the warrants on the date of exercise is equal to the intrinsic value, as the expected term is reduced to zero. The intrinsic value

was determined based on the closing price of the Company's Class A common stock on the date of exercise of $90.00, less the exercise price of $2.59.

The significant assumptions used in preparing the option pricing model for valuing the redeemable convertible preferred stock warrant liability as of December 31, 2024 and 2023, respectively, are as follows:

	December 31,	
	2024	2023
Stock price	$ 25.83	$ 17.45
Exercise price	$ 2.59	$ 2.59
Volatility	84.0 %	60.0 %
Expected term (years)	2.3	1.5
Risk-free rate	4.14 %	4.50 %
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 year ended December 31, 2024, the Company settled the convertible notes through the issuance of Series C-1 redeemable convertible preferred stock to the noteholders (See Note 9).

The significant assumptions used in preparing the discounted cash flow for valuing the convertible notes as of immediately prior to 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%

The following table presents 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	Convertible Notes	Term Loan
Balance at January 1, 2024	$ 1,653	$ 146	$ 47,686	$ -
Additions	-	-	-	50,000
Adjustment to fair value	880	84	835	1,481
Gain on extinguishment	-	-	(8,635)	-
Settlements	-	-	(39,886)	-
Balance at December 31, 2024	2,533	230	-	51,481
Adjustment to fair value	-	-	-	5,745
Transfers from Level 3 to Level 2	(2,533)	(230)	-	-
Balance at December 31, 2025	$ -	$ -	$ -	$ 57,226

For the years ended December 31, 2025, 2024 and 2023, 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 common stock warrant liability is recorded within common stock warrant liability on the balance sheet as of December 31, 2025. The common stock warrant liability and redeemable convertible preferred stock warrant liability are recorded within other non-current liabilities on the balance sheets as of December 31, 2024. The term loan is recorded within long-term debt on the balance sheets as of December 31, 2025 and 2024.

For the years ended December 31, 2024 and 2023, 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 year ended December 31, 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 9).

For the year ended December 31, 2025, the Company recognized losses related to the change in the fair value of the term loan as follows: (i) the portion attributable to instrument-specific credit risk was recognized in other comprehensive loss, and (ii) the remaining portion was recognized in earnings within change in fair value of term loan in the statements of operations and comprehensive income (loss). Amounts recognized in other comprehensive loss are accumulated in accumulated other comprehensive loss and are not reclassified to earnings in subsequent periods. For the year ended December 31, 2024, the Company recognized losses 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 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 year ended December 31, 2025, the Company transferred its common stock warrant liability and redeemable convertible preferred stock warrant from Level 3 to Level 2 of the fair value hierarchy upon the completion of its IPO, as observable market data for the Company's publicly traded Class A common stock became available for the valuation. As a result, unobservable inputs previously used in the valuation were observable.

During the year ended December 31, 2024, the Company had no transfers of financial assets or liabilities between different levels of the fair value hierarchy.

(4) Property and Equipment, Net

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

	December 31,	
	2025	2024
Machinery and equipment	$ 29,151	$ 14,585
Equipment under finance leases	4,966	11,210
Furniture and fixtures	3,742	3,391
Computer hardware	2,421	1,770
Construction in progress	2,224	2,747
Leasehold improvements	495	290
Computer software	587	227
Automobiles	40	40
Property and equipment, gross	43,626	34,260
Less: Accumulated depreciation and amortization	(23,265)	(17,149)
Property and equipment, net	$ 20,361	$ 17,111

Depreciation and amortization expense for the years ended December 31, 2025, 2024 and 2023 was $6.9 million, $7.0 million and $5.9 million, respectively. Amounts included in construction in progress consist of purchases of lab equipment that have not yet been placed into service.

Refer to Note 8 for additional details related to leased equipment.

(5) Accrued Expenses and Other Current Liabilities

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

	December 31,	
	2025	2024
Accrued professional services	$ 2,591	$ 898
Accrued inventory purchases	995	443
Accrued fixed asset purchases	1,006	798
Accrued property and other taxes	188	443
Accrued information technology purchases	462	250
Accrued legal expenses	968	191
Accrued phlebotomy expenses	200	171
Accrued insurance expenses	-	159
Accrued rent	174	160
Accrued clinical expenses	35	98
Other	628	271
Accrued expenses and other current liabilities	$ 7,247	$ 3,882

(6) Redeemable Convertible Preferred Stock

Immediately prior to the closing of the Company's IPO, all of the 29,084,235 shares of the Company's outstanding redeemable convertible preferred stock were automatically converted into 29,084,235 shares of common stock; in connection with the IPO, all shares of common stock underlying the redeemable convertible preferred stock were reclassified into an equivalent number of shares of the Company's Class A common stock. Upon conversion, the redeemable convertible preferred stock was cancelled, retired, and eliminated from the shares of stock that the Company is authorized to issue and shall not be reissued by the Company. Accordingly, following the IPO and as of December 31, 2025, no shares of redeemable convertible preferred stock were outstanding.

As of December 31, 2024, and immediately prior to the conversion into common stock upon completion of the IPO, 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	29,544,989	29,084,235	$ 419,409	$ 422,458

The rights, preferences and privileges of the Company's redeemable convertible preferred stock were as follows:

(i) *Dividends*

The holders of shares of redeemable convertible preferred stock shall be entitled to receive dividends prior and in preference to any declaration of dividends on common stock. Dividends are payable only when and if declared by the Company's Board of Directors and are not cumulative. After dividends paid on redeemable convertible preferred stock, any dividends or distribution should be distributed to the holders of common and redeemable convertible preferred stock on an as-converted basis. No dividends have been declared or paid through December 31, 2025.

(ii) *Liquidation Preference*

In the event of liquidation as approved by the Board of Directors, dissolution, or winding up of the Company, the holders of Series D shall be entitled to receive out of the proceeds or assets of this corporation available for distribution to its stockholders, prior and in preference to any distribution of proceeds to the holders of common stock, an amount per share equal the sum of 1.2 times the original issue price of $28.0204, plus declared but unpaid dividends on such shares and (ii) the holders of each other series of redeemable convertible preferred stock shall be entitled to receive the assets of the Company available for distribution, prior and in preference to any distribution of proceeds to the holders of common stock, an amount per share equal to the sum of the applicable original issue price for such series of redeemable convertible preferred stock, plus declared but unpaid dividends on such share. If, upon occurrence of such event, the proceeds distributed among the holders of redeemable convertible preferred stock shall be insufficient to permit the payment to such holders of the full preferential amounts, then the entire proceeds available for distribution shall be distributed ratably among the holders of the redeemable convertible preferred stock in proportion to the full preferential amount.

(iii) *Conversion*

Each share of redeemable convertible preferred stock is convertible into common stock at any time after the issuance of the shares at the option of the holder (each share of 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 is convertible to Common Stock). The conversion rate is determined by dividing the original issue price (as adjusted for any recapitalization) by the conversion price. The original issue prices of 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 are $0.4001, $0.8002, $1.0003, $1.9409, $0.8725, $2.5879, $10.6130, $6.2429, $25.4937, $19.6143, and $28.0204, respectively. The initial conversion price per share for each series of redeemable convertible preferred stock shall be the original issue price applicable to such series (1:1 conversion ratio), however that conversion price shall be subject to adjustment. There have been no adjustments to the conversion price since original issuance.

Each share of redeemable convertible preferred stock shall automatically be converted into such shares of common stock at the conversion rate at the time in effect for such series redeemable convertible preferred stock at the closing of this corporation's sale of its common stock in public offering, that results in at least $100,000,000 of gross proceeds; at this corporation's initial listing of common stock on national securities exchange; in a Special Purpose Acquisition Company transaction, or the date or occurrence of an event specified by vote of redeemable convertible preferred stock (voting together as a single class and not as separate series, and on an as-converted basis).

(iv) *Voting Rights*

The holder of each share of redeemable convertible preferred stock shall have the right to one vote for each share of common stock into which such redeemable convertible preferred stock could then be converted.

Thus, the holders of redeemable convertible preferred stock shall have the same voting rights as the holders of common stock.

As long as at least 1,449,050 shares of Series A redeemable convertible preferred stock remain outstanding, the holders of such shares of Series A redeemable convertible preferred stock shall be entitled to elect two directors of the Company at any election of directors. As long as at least 1,225,790 shares of Series C redeemable convertible preferred stock remain outstanding, the holders of such shares of Series C redeemable convertible preferred stock shall be entitled to elect one director of the Company at any election of directors. As long as at least 1,164,058 shares of Series D redeemable convertible preferred stock remain outstanding, the holders of such shares of Series D redeemable convertible

preferred stock shall be entitled to elect one director of the Company at any election of directors. The holders of outstanding common stock shall be entitled to elect four directors of this Corporation at any election of directors.

(v) *Redemption*

The holders of redeemable convertible preferred stock have no voluntary rights to redeem shares. A liquidation, dissolution or winding up of the Company, a greater than 50% change in control, or a sale of substantially all of its assets would constitute a redemption event. Although the redeemable convertible preferred stock is not mandatorily or currently redeemable, given the shares are redeemable upon an event outside the Company's control, all shares of redeemable convertible preferred stock have been presented outside of permanent equity on the balance sheets. The carrying values of redeemable convertible preferred stock have not been accreted to their redemption values as redemption events are not probable to occur.

(7) 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 December 31, 2025 and 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 December 31, 2025 and 2024.

(8) Leases

Operating Leases

In February 2021, the Company entered into a lease agreement for office and laboratory space in Menlo Park, CA which will expire in February 2031. In December 2023, the Company entered into a lease agreement for office and laboratory space in Union City, CA, which will expire in June 2033. The Union City, CA lease contains a one-time tenant option to extend the lease term by a period of five years which the Company is not reasonably certain to exercise and which has been excluded from recognition in the Company's right-of-use assets and lease liabilities. The Company records rent expense associated with operating lease liabilities in operating expenses in the statements of operations and comprehensive income (loss).

In April 2024, the Company entered into a lease agreement for premises to be constructed in Austin, TX. The lease is expected to commence prior to September 30, 2027 at an initial rental rate of $12.3 million per year. The lease agreement includes annual rent increases of 3% and is for a term of fifteen years and nine months. The agreement also includes a seven-year extension option that can be exercised by the Company. As part of the lease agreement, the Company remitted to the landlord $2.0 million in respect of a security deposit and $1.0 million in respect of the first month's rent payment, which were recorded in other non-current assets on the balance sheets for the years ended December 31, 2025 and 2024.

The Company's operating lease costs were $9.4 million, $9.4 million and $5.5 million during the years ended December 31, 2025, 2024 and 2023, respectively. The Company's variable lease expense totaled $4.4 million, $4.4 million and $3.2 million for the years ended December 31, 2025, 2024 and 2023, respectively. The Company's short-term lease costs totaled $0.2 million during the year ended December 31, 2025 and were not material during the years ended December 31, 2024 and 2023.

Other information related to the Company's operating leases was as follows for the years ended December 31, 2025, 2024 and 2023 (in thousands):

	2025	2024	2023
Cash paid for amounts included in the measurement of operating lease liabilities within operating cash flows	$ 8,810	$ 8,516	$ 4,872

As of December 31, 2025 and 2024, the weighted average remaining operating lease term was 6.8 years and 7.8 years, respectively.

As of December 31, 2025 and 2024, the weighted average discount rate used to estimate operating lease liabilities was 8.4% and 8.4%, respectively.

As of December 31, 2025, future lease payments under operating leases were as follows (in thousands):

Year ending December 31:	
2026	$ 9,115
2027	9,430
2028	9,757
2029	10,094
2030	10,444
Thereafter	18,938
Total lease payments	$ 67,778
Less: imputed interest	(16,976)
Present value of operating lease liabilities	$ 50,802

Financing Leases

As of December 31, 2025 and 2024, the weighted average remaining financing lease term was 1.7 years and 1.8 years, respectively.

As of December 31, 2025 and 2024, the weighted average interest rate for the Company's financing leases was 5.4% and 6.5%, respectively.

As of December 31, 2025, future lease payments under financing leases were as follows (in thousands):

Year ending December 31:	
2026	$ 543
2027	362
Total lease payments	$ 905
Less: interest expense	(38)
Present value of financing lease liabilities	$ 867

Other information related to the Company's financing leases were as follows for the years ended December 31 (in thousands):

	2025	2024	2023
Amortization of right-of-use assets:	$ 1,855	$ 3,436	$ 3,085
Operating cash flows from financing leases (interest paid):	104	243	361
Total finance lease cost	$ 1,959	$ 3,679	$ 3,446

(9) 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.

Due to the presence of certain embedded derivatives within the Notes, the Company elected to account for the Notes using the fair value option and changes in fair value related to the Notes are recorded in other expense, net in the Company's statements of operations and comprehensive income (loss). Changes in fair value attributable to credit risk were immaterial to the financial statements through their conversion date. Inputs for fair value were determined by evaluating the probability of various conversion scenarios and applicable market interest rates.

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 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).

The Notes were subordinated in right of payment to all indebtedness between the Company and Western Alliance Bank ("WAB"). The Note Holders agreed, that as long as any debt remains outstanding with WAB or WAB has obligations to make additional credit extensions to the Company, the Note Holders would not have received any payment other than a conversion of the Notes into equity securities, unless otherwise agreed by WAB in writing. The priority to WAB excluded payments in cash, including interest, but did not preclude conversion of the Notes and related interest in shares. As the Note was extinguished during 2024, no payments of cash were made to the Note Holders in principal or interest for the Notes.

(10) Long-term Debt

Oberland Note Purchase Agreement

In August 2024, the Company entered into a note purchase agreement (as amended from time to time, 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, revenue participation payments, and a lump sum payment due on August 5, 2031 consisting of outstanding principal plus an amount that results in a 10% internal rate of return over the seven year term of the loan.

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 was 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 principal amount of $30.0 million prior to March 31, 2026 as the Company has achieved the thresholds triggering this tranche during the year ended December 31, 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 $50.0 million tranche.

The fourth tranche of up to $25.0 million in principal is available at the mutual agreement of the Company and Oberland Capital 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") for the purchasers of 12.25%; (4) if the payment is made within 60 months of issuance, an amount that would generate an IRR for the purchasers of 11.75%; (5) if the payment is made thereafter but before 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%.

Under the terms of the 2024 Notes, on the last day of each fiscal quarter commencing with the fiscal quarter ended March 31, 2025, excluding any fiscal quarter with respect to which the Company's aggregate cash and cash equivalents is greater than 1.1 times the aggregate principal amount of the 2024 Notes issued (the "Liquidity Condition") at all times during such fiscal quarter, the Company is required to achieve minimum thresholds for both trailing six month revenues and trailing six month gross margin. If the Liquidity Condition is not satisfied, the Company is required to have trailing six-month Net Revenue of not less than the amount shown for each applicable period in the table below, as well as a trailing six-month Gross Margin of not less than 30%, each as defined in the 2024 Notes. The Company was in compliance with all material financial covenants as of December 31, 2025.

Period	Minimum Trailing Six-Month Net Revenue Threshold (in millions)
Q1 2025	$ 56.1
Q2 2025	$ 65.6
Q3 2025	$ 74.8
Q4 2025	$ 82.8
Q1 2026	$ 87.2
Q2 2026	$ 101.8
Q3 2026	$ 117.2
Q4 2026	$ 120.0
Thereafter	$ 120.0

The 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 outstanding will be payable to Oberland Capital. Amounts paid under the revenue participation agreement during the years ended December 31, 2025 and 2024 were interest payments on the debt. The revenue participation payments are additional financing costs of the loan and are included in the computation of the IRR measurements described above. Beginning with the fiscal year beginning January 1, 2025, the Company was required to make revenue participation payments under the agreement. As of December 31, 2025, the Company has 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). Changes in fair value caused by instrument-specific credit risk are presented separately in other comprehensive income (loss). The Company also elected to present interest incurred on the 2024 Notes in the change in fair value of term loan; interest expense under the Oberland Capital arrangement was $4.1 million and $1.6 million for the years ended December 31, 2025 and 2024, respectively.

The Company's total indebtedness as of December 31, 2025 and 2024 is as follows (in thousands):

	December 31,	
	2025	2024
Long-term debt	$ 57,226	$ 51,481
Long-term debt, net	57,226	51,481
Less: current portion	-	-
Long-term debt, noncurrent portion	$ 57,226	$ 51,481

Future principal payments of the Company's long-term debt as of December 31, 2025 and 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 other non-current liabilities on the Company's balance sheet as of December 31, 2024. In connection with the IPO, the redeemable convertible preferred stock warrants became warrants to purchase common stock based on the terms of the loan and security agreement. In November 2025, the warrants were exercised, resulting in the issuance of 9,660 shares of Class A common stock.

Western Alliance Bank Debt

In October 2021, the Company entered into a loan and security agreement (the "2021 LSA") with WAB, which provided the Company with three tranches of capital advances totaling $15.0 million. The loan was collateralized by all property of the Company other than its Intellectual Property ("IP"). The advanced principal accrued interest based on the floating prime rate per annum. The first tranche of $5.0 million was advanced on October 12, 2021 and the second tranche was advanced on December 17, 2021, both with a maturity date of October 12, 2025 and interest-only payments, at the floating rate, through May 1, 2023 and 30 equal monthly payments thereafter, of principal and interest. The Company drew down the third tranche on January 3, 2022 and elected to extend the interest only period by an additional 6 months followed by 24 months of amortization. The loans include a final payment of 3.75% of the advanced amount, or $562,500, due upon the earlier of maturity or termination of the loan. The final payment was accreted to interest expense over the term of the loan. The term loan advances are secured by a lien on the Company's assets.

In July 2022, the Company amended the 2021 LSA with WAB, such that WAB made four tranches of capital advances available to the Company for an aggregate amount up to $35.0 million ("2022 LSA Amendment").

Under the 2022 LSA Amendment, the first tranche of $20.0 million in principal was advanced on July 22, 2022 and was used to pay off the existing $15.0 million in principal outstanding to WAB under the 2021 LSA, resulting in net proceeds to the Company of $5.0 million. The second tranche of $5.0 million in principal was advanced on January 25, 2023 and the third tranche of $5.0 million in principal was advanced on July 7, 2023. The fourth tranche of $5.0 million was advanced on October 11, 2023. The term loans had a maturity date of July 1, 2027. The term loans were interest-only through July 31, 2025, followed by 24 equal payments of principal plus interest. The loans required a final payment of 4.25% of the total advanced amount, which resulted in an exit fee liability of $1.5 million payable at the maturity of the debt. The final payment was accreted to the debt balance and recognized as interest expense over the term of the loan.

The term loan advances were secured by a lien on the Company's assets. The Company was subject to certain financial and reporting covenants, including a requirement for the Company to meet certain test volumes, measured quarterly on a trailing two quarter basis.

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 was due 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 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 became exercisable as the Company made 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.

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 expense, net in the statements of operations and comprehensive income (loss) (See Note 3).

The issuance date fair value of the warrants was determined using the option pricing model, with the following assumptions (in thousands, except percentages):

	2021 LSA	2022 LSA Amendment
Grant date	October 12, 2021	July 22, 2022
Dividend yield	0%	0%
Risk-free interest rate	1.59%	2.77%
Expected volatility	70%	78%
Expected term (in years)	10.00	10.00
Total grant date fair value	$ 170	$ 312

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.

In connection with the Company's IPO, WAB entered into a lock-up agreement with the Company, pursuant to which WAB may not sell, transfer, or otherwise dispose of the underlying shares of Class A common stock for a period of 180 days following the date that the Company files its final prospectus.

(11) Common Stock

In connection with the closing of its IPO, on November 7, 2025, the Company's amended and restated Certificate of Incorporation was amended and as of December 31, 2025 the Company was authorized to issue 800,000,000 shares of Class A common stock, par value $0.00001 per share, and 10,000,000 shares of Class B common stock, par value $0.00001 per share. Total common stock outstanding as of December 31, 2025 was 41,252,105 shares of Class A common stock and 4,552,650 shares of Class B common stock. There were no shares of Class A common stock and no shares of Class B common stock authorized or outstanding as of December 31, 2024.

The holders of Class A common stock are entitled to vote on all corporate matters at a ratio of one vote per share together with the holders of Class B common stock. The holders of Class B common stock are entitled to

vote on all corporate matters at a ratio of 15 votes per share together with the holders of Class A common stock. The holders of Class A common stock and Class B 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. As of December 31, 2025, no dividends had been declared or paid.

All of the outstanding shares of the Company's Class B common stock will convert automatically on a one-to-one basis into shares of the Company's Class A common stock upon the earliest of (i) 7 years from the date of filing the Post-IPO Certificate of Incorporation, and (ii) the date specified by a vote of the holders of Class B common stock representing a majority of the outstanding shares of Class B common stock. In addition, each share of Class B common stock held by a Co-Founder and such Co-Founder's permitted transferees will automatically convert into one share of Class A common stock upon the earlier of (i) the date that is between 90 days and 270 days, as determined by the Board of Directors, after the death or incapacitation of such Co-Founder or (ii) the date that is between 61 and 180 days, as determined by the Board of Directors, after the date on which such Co-Founder is no longer serving as an officer or director of the Company.

The Company is required to reserve and keep available out of its authorized but unissued shares of Class A common stock such a number of shares sufficient to affect the conversion of all outstanding shares of common stock warrants, all outstanding shares of Class B common stock, options granted under the Company's 2018 Stock Plan and 2025 Equity Incentive Plan, shares available for grant under the Company's 2025 Equity Incentive Plan, restricted stock units outstanding and shares available for issuance under the Employee Stock Purchase Plan.

The amount of such shares of the Company's Class A common stock reserved for these purposes at December 31, 2025, is as follows:

Common stock warrants	121,566
Outstanding shares of Class B common stock	4,552,650
Options to purchase common stock	9,552,013
Restricted stock units outstanding	33,332
Shares available for future issuance under the Employee Stock Purchase Plan	548,880
Shares available for future grants	3,356,974
Total Class A common stock reserved	18,165,415

Stock Plans

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.

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.

In connection with the IPO, the Company adopted the 2025 Equity Incentive Plan (the "2025 Plan"), which became effective in October 2025, although no awards could be granted under the 2025 Plan until the IPO date. 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. On the effective date of the 2025 Plan, the maximum number of shares of Class A common stock authorized for issuance was 3,297,972 shares of Class A common stock, plus up to 10,034,626 shares under the 2018 Plan that (i) remain available for issuance on the IPO date and (ii) that are outstanding on the IPO date and that are subsequently forfeited, expire, are reacquired by the Company or lapse unexercised, subject to annual adjustment on the first day of each fiscal year through January 1, 2035. The 2025 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 2025 Plan generally expire within 10 years from the date of grant

and are 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.

Incentive and non-statutory stock options may be granted with exercise prices not less than 100% of the fair value of the Class A common stock on the date of grant, as determined by the Board of Directors. As of December 31, 2025, the Company had authorized up to 3,390,306 shares of Class A common stock reserved for issuance under the 2025 Plan.

In further connection with the IPO, the Company adopted the 2025 Employee Stock Purchase Plan (the "2025 ESPP"), which became effective in October 2025. As of December 31, 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.

Stock-based Compensation

The Company recognizes stock-based compensation expense for all stock-based payment awards based on the estimated fair value on the date of the grant. The Company recognizes the compensation cost on a straight-line basis over the requisite service period of the award. The fair value of stock options granted is estimated using the Black-Scholes Model utilizing the assumptions noted below:

- *Fair value of common stock.* Prior to the completion of the IPO, there was no public market for the Company's common stock. Accordingly, the fair value of the Company's common stock was determined by the Board of Directors. The Board of Directors considered numerous objective and subjective factors to determine the fair value of the Company's common stock options at each meeting in which awards are approved. The factors considered included, but were not limited to: (i) the results of contemporaneous independent third party valuations of the Company's common stock; (ii) the prices, rights, preferences and privileges of the Company's redeemable convertible preferred stock relative to those of its common stock; (iii) the lack of marketability of the Company's common stock; (iv) actual operating and financial results; (v) current business conditions and projections; and (vi) the likelihood of achieving a liquidity event, such as an initial public offering or sale of the Company, given prevailing market conditions. For awards granted subsequent to the IPO, fair value of the Company's common stock is based on the quoted market price on the grant date.
- *Expected volatility*. Expected volatility is a measure of the amount by which the stock price is expected to fluctuate. Since the Company does not have sufficient trading history of its common stock, it estimates the expected volatility of its stock options at their grant date by taking the weighted average historical volatility of a group of comparable publicly traded companies over a period equal to the expected life of the options.
- *Expected term*. Expected term represents the period over which the Company anticipates stock-based awards to be outstanding. The Company uses the simplified method to calculate the expected term estimate based on the options' vesting term and contractual terms. Under the simplified method, the expected life is equal to the average of the stock-based award's weighted average vesting period and its contractual term.
- *Risk-free interest rate*. The Company uses the average of the published interest rates of U.S. Treasury zero-coupon issues with terms consistent with the expected term of the awards for its risk-free interest rate.
- *Expected dividends*. The Company historically has not paid dividends on common stock and has no plans to issue dividends in the foreseeable future.

The weighted average assumptions used to calculate the fair value of option grants issued under the 2025 Plan and 2018 Plan during the years ended December 31, 2025, 2024 and 2023, respectively, were as follows:

	2025	2024	2023
Fair value of common stock	$ 29.54	$ 16.47	$ 11.07
Dividend yield	- %	- %	- %
Risk-free interest rate	4.1 %	4.1 %	4.0 %
Expected volatility	73 %	68 %	74 %
Expected term (in years)	6.21	6.01	5.99

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	Weighted-Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of January 1, 2025	6,849,412	$ 7.28	7.5	$ 73,992
Granted	3,640,368	22.85		
Exercised	(551,145)	5.58		
Forfeited or expired	(386,622)	15.84		
Outstanding as of December 31, 2025	9,552,013	$ 12.96	7.6	$ 657,915
Vested and exercisable as of December 31, 2025	4,977,698	$ 6.43	6.2	$ 375,351
Vested and expected to vest as of December 31, 2025	9,552,013	$ 12.96	7.6	$ 657,915

The intrinsic value is calculated as the difference between the exercise price of the underlying stock option award and the estimated fair value of the Company's common stock. The total intrinsic values of options exercised during the years ended December 31, 2025, 2024 and 2023 were $20.0 million, $4.7 million and $1.2 million, respectively.

During the year ended December 31, 2025, the weighted average grant-date fair value of options granted was $21.37 per share, and the fair value of options vested during the period was $13.8 million. During the year ended December 31, 2024, the weighted average grant-date fair value of options granted was $10.89 per share, and the fair value of options vested during the period was $7.2 million. During the year ended December 31, 2023, the weighted average grant-date fair value of options granted was $7.75 per share, and the fair value of options vested during the period was $4.4 million. The grant-date fair value is being expensed over the vesting period of the options, on a straight-line basis, as the services are being provided.

As of December 31, 2025 there was approximately $79.9 million of total unrecognized compensation cost related to unvested options, which is expected to be recognized over the weighted average period of 4.0 years. Also, in June 2025, the Board of Directors granted stock options of 1,003,102 shares to the Company's CEO 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 options is June 11, 2025 and the stock options vest monthly over six years.

Restricted Stock Unit Activity

A summary of the Company's restricted stock unit activity and related information is as follows:

	Shares	Weighted-Average Grant Date Fair Value (per share)
Nonvested as of January 1, 2025	-	$ -
Issued	33,332	108.94
Vested	-	-
Forfeited	-	-
Nonvested as of December 31, 2025	33,332	$ 108.94

As of December 31, 2025, there was approximately $3.4 million of total unrecognized compensation cost related to outstanding restricted stock units, which is expected to be recognized over the weighted average period of 2.8 years.

There was no restricted stock award activity during the year ended December 31, 2024.

Stock-Based Compensation Expense

The table below shows stock-based compensation expense included in the statements of operations and comprehensive income (loss) for the years ended December 31, 2025, 2024, and 2023 (in thousands):

	2025	2024	2023
Cost of revenue	$ 1,789	$ 1,183	$ 683
Research and development	3,951	2,341	1,450
Selling, general and administrative	10,175	4,838	2,721
Total stock-based compensation	$ 15,915	$ 8,362	$ 4,854

Options Subject to Early Exercise

Subject to Board of Directors approval at the grant date per the 2018 Plan and the 2025 Plan, 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 repurchase right. Under the repurchase right, the Company may buy back any unvested shares at their original exercise price in the event of an employee’s termination prior to full vesting. If an option does not permit early exercise, then such option shall not be exercisable with respect to unvested shares. The consideration received for an exercise of an unvested option is considered to be a deposit of the exercise price and the related dollar amount is recorded as a liability. The liabilities are reclassified into equity as the awards vest. As of December 31, 2025 and 2024, the liability was $0.2 million and not material, respectively, and included in accrued expenses and other current liabilities on the accompanying balance sheets related to 4,950 and 521 shares of early-exercised common stock options, respectively. Early exercised stock options are legally issued and outstanding and are included in issued and outstanding common shares.

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 $0.4 million for the year ended December 31, 2024 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. For the year ended December 31, 2025, the Company did not acquire any shares of common stock, as such no additional stock-based compensation expense was recorded in the period.

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 the Company's former CFO. 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. For the year ended December 31, 2025, the Company did not repurchase any shares of common stock in a similar transaction, as such no additional stock-based compensation expense was recorded in the period.

Option Exercises Under Promissory Notes

In January 2019, the Company granted and approved the purchase of 700,000 restricted stock awards in aggregate at a price of $0.06 per share to two executives, and in exchange, the executives entered into full recourse promissory notes (the "Recourse Notes") for the amount of the exercise price of the restricted shares. The loans are due seven years from the loan date, except in the case of termination, public filing event, or disposition of common stock acquired via these notes in which case the loan becomes due sooner. The Notes carry interest rates of 2.89%, compounded annually. The balance of the Recourse Notes may be prepaid in whole or in part, at any time without penalty. Each loan is secured by the shares exercised by the loans, in addition to any and all other assets of the borrower. The terms of the loan require the loans to be repaid prior to termination or public offering. In October 2025, the executives fully repaid the promissory notes, resulting in net proceeds to the Company of $51,000.

In June 2021, the Company granted and approved the purchase of option awards at a price of $2.80 per share to an executive, and in exchange, the executive entered into a full recourse promissory note for the amount of the exercise price of the restricted shares. The loan is due five years from the loan date, except in the case of termination, public filing event, or disposition of common stock acquired via these notes in which case the loan becomes due sooner. The Recourse Note bears interest of 1.00% per annum, compounded annually. The balance of the Note may be prepaid in whole or in part, at any time without penalty. Each loan is secured by the shares exercised by the loans, in addition to any and all other assets of the borrower. In November 2022, the executive partially repaid the promissory note, resulting in net proceeds to the Company of $62,000. In June 2023, the executive fully repaid the promissory note, resulting in net proceeds to the Company of $51,000.

The Recourse Notes issued were collateralized by the shares issued in exchange for the notes and were nonrecourse for accounting purposes, as the Company did not intend nor has a history of demanding repayment of loan amounts in excess of the fair value of the shares. As such, for accounting purposes the exercised awards continue to be treated as unexercised awards and are not reflected as outstanding in the financial statements until the notes are repaid and the underlying awards have vested.

Incremental stock-based compensation expense was not material.

(12) Income Taxes

The components of the provision for income taxes for the years ended December 31, 2025, 2024 and 2023 are as follows (in thousands):

	2025	2024	2023
Current:			
Federal	$ 92	$ -	$ -
State	213	29	9
	305	29	9
Deferred:			
Federal	-	-	-
State	-	-	-
	-	-	-
Total provision for income taxes	$ 305	$ 29	$ 9

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant

components of the Company's deferred tax assets as of December 31, 2025 and 2024 are as follows (in thousands):

	2025	2024
Deferred tax assets:		
Net operating loss carryforwards	$ 34,636	$ 36,725
Capitalized R&D expenditure	6,059	11,477
Accruals and reserves	3,061	2,322
R&D credits	4,817	3,768
Lease liability	12,108	13,126
Stock-based compensation	1,397	859
Other	-	21
Total deferred tax asset	62,078	68,298
Deferred tax liabilities:		
Depreciation and amortization	(2,207)	(320)
Right of use asset	(11,140)	(12,304)
Total deferred tax liabilities	(13,347)	(12,624)
Less: valuation allowance	(48,731)	(55,674)
Net deferred tax assets	$ -	$ -

The changes in the valuation allowance for the years ended December 31, 2025, 2024 and 2023 are as follows (in thousands):

	2025	2024	2023
Valuation allowance - beginning of period	$ 55,674	$ 45,555	$ 29,436
Additions/(reductions) recognized in income tax provision	(6,943)	10,119	16,119
Valuation allowance - end of period	$ 48,731	$ 55,674	$ 45,555

The following table presents a reconciliation of the income tax expense computed at the statutory federal rate and the Company's income tax expense for the year ended December 31, 2025 (in thousands, except percentages):

	2025	
Tax at the federal statutory rate	$ 1,630	21 %
Domestic federal		
Nontaxable or nondeductible items		
Meals	963	12 %
Stock-based compensation	2,582	33 %
Change in fair value of term loan	2,376	31 %
Other	147	2 %
Research and development credits	(1,689)	(22)%
Changes in tax laws or rates enacted in the current period	-	- %
Change in valuation allowance	(6,464)	(83)%
Foreign tax effects	-	- %
State and local income taxes, net of federal benefits	169	2 %
Change in unrecognized tax benefit	591	8 %
Total provision for income taxes	$ 305	4 %

The following table presents a reconciliation of the income tax expense computed at the statutory federal rate and the Company's income tax expense for the years ended December 31, 2024 and 2023 (in thousands):

	2024	2023
Tax at the federal statutory rate	$ (8,725)	$ (17,250)
Other nondeductible items	792	550
Stock-based compensation	1,359	832
Research and development credits	(994)	(796)
Change in valuation allowance	10,119	16,058
State taxes, net of federal benefits	(1,443)	(2,113)
Debt extinguishment gain or loss	(1,814)	-
Change in fair value of term loan	689	2,749
Other	46	(21)
Total provision for income taxes	$ 29	$ 9

The Company's actual tax expense differed from the statutory federal income tax expense using a tax rate of 21% for the years ended December 31, 2025 and 2024, primarily due to nondeductible expenses, research and development tax credits, change in fair value of term loan, the change in valuation allowance, and state income taxes. For the tax year ended December 31, 2025, the States of Minnesota, Idaho and Georgia made up the majority of the domestic state income taxes, net of federal tax effect.

As of December 31, 2025 and 2024, the Company had a net operating loss carryforwards of $147.0 million and $154.9 million for federal purposes, and $67.9 million and $78.6 million for state and city purposes, respectively. If not utilized, these carryforwards will begin to expire in 2026 for state and city purposes. The federal carryforwards do not expire.

Federal net operating losses incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited. Some but not all states conform to the federal treatment of net operating losses.

As of December 31, 2025 and 2024, the Company had research and development tax credit carryforwards for federal tax purposes of $5.5 million and state research and development tax credit carryforwards of $2.8 million. As of December 31, 2024, the Company had research and development tax credit carryforwards for federal tax purposes of $4.1 million and state research and development tax credit carryforwards of $2.1 million. The federal research and development tax credit carryforwards will expire at various dates beginning in the year 2041. The Company's state research and development tax credit carryforwards do not expire.

Utilization of the net operating loss ("NOL") carryforwards and credits may be subject to a substantial annual limitation due to the ownership change limitations provided by the Internal Revenue Code of 1986, as amended, and similar state provisions. The annual limitation may result in the expiration of NOL carryforwards and credits before utilization. Current laws impose substantial restrictions on the utilization of NOL carryforwards and credits in the event of an "ownership change" within a three-year period as defined by the Internal Revenue Code Section 382 ("Section 382"). If there should be an ownership change, the Company's ability to utilize its NOL carryforwards and credits could be limited. The Company experienced an ownership change on March 31, 2019, which limited its ability to utilize its NOL carryforwards generated prior to that date. The Company experienced another ownership change on November 5, 2025, which did not limit its ability to utilize its NOL carryforwards in the current year.

Based on the available objective evidence, management believes it is more likely than not that the net deferred tax assets of the Company will not be fully realizable for the years ended December 31, 2025 and 2024. Accordingly, the Company has established a full valuation allowance against its net deferred tax assets due to the uncertainty surrounding the realization of such assets. The valuation allowance decreased by approximately $6.9 million and increased by approximately $10.1 million during the years ended December 31, 2025 and 2024, respectively.

Below are the Company's income taxes paid (net of tax refund) during the year ended December 31, 2025 (in thousands):

	2025
US Federal	$ 240
US State and Local	
Illinois	80
Minnesota	34
Other	133
Total US State and Local	247
Total taxes paid	$ 487

The Company records unrecognized tax benefits, where appropriate, for all uncertain income tax positions. The Company recorded unrecognized tax benefits for uncertain tax positions of $3.2 million and $2.2 million as of December 31, 2025 and 2024, respectively, none of which would impact the effective tax rate if recognized, because the benefit would be offset by an increase in the valuation allowance.

A reconciliation of the beginning and ending balance of total unrecognized tax benefits is as follows (in thousands):

	2025	2024
Unrecognized tax benefits - beginning of period	$ 2,184	$ 1,410
Increases related to current year's tax positions	984	774
Unrecognized tax benefits - end of period	$ 3,168	$ 2,184

The Company's policy is to recognize interest and penalties accrued on any unrecognized tax benefits as a component of income tax expense. During the year ended December 31, 2025 and 2024, the Company recognized no interest and penalties associated with unrecognized tax benefits.

Due to the net operating loss carryforwards, all years remain open for income tax examination by tax authorities in the United States, various states and foreign tax jurisdictions in which the Company files tax returns.

On July 4, 2025, the One Big Beautiful Bill Act ("2025 Tax Act") was enacted in the United States. This legislation includes multiple changes, such as restoration of immediate expensing of domestic research and development expenditures under Section 174, reduction of GILTI and FDII deductions under Section 250, and reinstatement of 100% bonus depreciation for qualified property acquired after January 19, 2025, to name a few. The Company elected to immediately expense current year domestic research and development expenditures and to expense prior year's capitalized domestic research and development expenditures ratably over two years. Additionally, the Company claimed 100% bonus depreciation for qualified property acquired after January 19, 2025.

(13) 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 year ended December 31, 2025, 2024 and 2023, the Company contributed $3.5 million, $2.4 million, and $1.7 million to this plan, respectively.

(14) Related Party Transactions

In February 2024, the Company repurchased 26,750 shares of common stock that were held by the former CFO. See Note 11 for additional information on this transaction.

In June 2025, the Company granted stock options to certain founders and executive officers under the Company's 2018 Plan. These grants were approved by the Board of Directors. See Note 11 for additional information on this transaction.

There were no other material related party transactions during the years ended December 31, 2025 and 2024.

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

The Company applies the two-class method when computing net income (loss) per share attributable to common shareholders when shares meet the definition of participating securities. The two-class method determines net income (loss) per share of common stock and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires net income (loss) available to common stockholders for the period to be allocated between common stock and participating securities based upon their respective rights to receive dividends as if all income for the period had been distributed. The holders of the Company's redeemable convertible preferred stock would be entitled to dividends in preference to common stockholders, if declared. Such dividends are not cumulative. Any remaining earnings would be distributed among the holders of redeemable convertible preferred stock and common stock pro rata on an as-converted basis. The holders of the Company's redeemable convertible preferred stock are not contractually obligated to participate in the Company's losses.

Basic net income (loss) per share is computed by dividing the net income (loss) attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period, less shares subject to repurchase. 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. For periods in which the Company reports net losses, diluted net income (loss) per common share is the same as basic net income (loss) per common share as all potentially dilutive securities are anti-dilutive.

The following table sets forth the computation of basic and dilutive net income (loss) per share attributable to common stockholders for the years ended December 31, 2025, 2024 and 2023 (in thousands, except per share amounts):

	2025	2024	2023
Basic net income (loss) per share:			
Numerator:			
Net income (loss)	$ 7,454	$ (41,570)	$ (82,683)
Less: Net income attributable to participating securities	(4,535)	—	—
Net income (loss) attributable to common stockholders	2,919	(41,570)	(82,683)
Denominator:			
Weighted-average shares used in calculating net income (loss) per share, basic	15,875,091	10,079,925	9,782,770
Net income (loss) per share, basic	$ 0.18	$ (4.12)	$ (8.45)
Diluted net income (loss) per share:			
Numerator:			
Net income (loss) attributable to common stockholders	$ 2,919	$ (41,570)	$ (82,683)
Denominator:			
Weighted-average shares used in calculating net income (loss) per share, basic	15,875,091	10,079,925	9,782,770
Effect of dilutive securities:			
Outstanding stock options	4,701,545	—	—
Warrants to purchase redeemable convertible preferred stock	7,559	—	—
Warrants to purchase common stock	98,193	—	—
Restricted stock awards in exchange for non-recourse note	548,364	—	—
Weighted-average shares used in calculating net income (loss) per share, diluted	21,230,752	10,079,925	9,782,770
Net income (loss) per share, diluted	$ 0.14	$ (4.12)	$ (8.45)

Potentially dilutive securities that were not included in the diluted per share calculations because they would be anti-dilutive were as follows for the years ended December 31, 2025, 2024 and 2023:

	2025	2024	2023
Redeemable convertible preferred stock	24,658,373	29,084,235	22,701,179
Outstanding stock options	—	6,849,412	6,193,236
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	4,950	521	—

(16) Subsequent Events

In March 2026, the Company entered into an amendment to its clinical trial agreement with J&J, to extend the study until six months after J&J receives the final performance study. The amendment provides for continued performance of clinical trial services under substantially similar terms. No material upfront payments were made in connection with the amendment.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Limitations on Effectiveness of Disclosure 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 December 31, 2025. 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 December 31, 2025, due to the material weaknesses in our internal control over financial reporting as described below.

Management performed additional procedures, including supplementary analyses and enhanced review procedures, to provide reasonable assurance regarding the reliability of the financial statements. Notwithstanding the material weaknesses and based on the additional analyses and procedures performed, Management has concluded that the financial statements included in this Annual Report on Form 10-K 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.

Internal Control over Financial Reporting

This Annual Report on Form 10-K does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of the company's registered public accounting firm due to a transition period established by the rules of the Securities and Exchange Commission for newly public companies. 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.

We previously reported material weaknesses in our internal control over financial reporting, and they remained unremediated as of December 31, 2025, relating to the following:

- 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.

- We did not design and maintain effective 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.

These material weaknesses, other than that related to user and privileged access controls, resulted in immaterial adjustments to the December 31, 2024 and 2023 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.

Remediation Efforts

We continue to make progress towards remediating these material weaknesses. These remediation measures are ongoing as of the date of this Form 10-K and include:

- engaging third parties to assist with technical accounting matters and designing and implementing controls;
- hiring additional personnel, such as accounting, finance, information technology staff and other professionals with appropriate levels of knowledge and experience and designing and implementing controls to ensure appropriate segregation of duties in our finance and accounting functions;
- designing and implementing controls over user access, including restrictions over privileged access as it relates to creating and posting journal entries; and
- designing and implementing controls to properly analyze, account for, present and disclose certain financial instruments transactions.

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 December 31, 2025.

The Company remains committed to remediating the material weaknesses and Management, with the oversight of our Audit Committee, has devoted and will continue to devote considerable effort to remediate the material weaknesses identified above.

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 fiscal quarter ended December 31, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

Trading Arrangements

During the quarter ended December 31, 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 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

Part III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this Item 10 of Form 10-K will be included in our 2026 Proxy Statement to be filed with the SEC in connection with the solicitation of proxies for our 2026 Annual Meeting of Stockholders and is incorporated herein by reference. The information required by this Item regarding delinquent filers pursuant to Item 405 of Regulation S-K, if any, will be included under the caption “Section 16(a) Beneficial Ownership Reporting Compliance” in the 2026 Proxy Statement and is incorporated herein by reference.

We have adopted a Code of Conduct that applies to all of our employees, executive officers and directors, including our principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions. The Code of Conduct is publicly available on our website at investors.billiontoone.com. This website address is intended to be an inactive, textual reference only; none of the material on this website is part of this Annual Report. We intend to promptly disclose on our website or in a Current Report on Form 8-K in the future (i) the date and nature of any amendment (other than technical, administrative or other non-substantive amendments) to the Code of Conduct that applies to our principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions, or our directors and relates to any element of the code of ethics definition enumerated in Item 406(b) of Regulation S-K and (ii) the nature of any waiver, including an implicit waiver, from a provision of the Code of Conduct that is granted to one of these specified individuals that relates to one or more of the elements of the code of ethics definition enumerated in Item 406(b) of Regulation S-K, the name of such person who is granted the waiver and the date of the waiver.

We have adopted an Insider Trading Policy governing the purchase, sale and/or other dispositions of our securities by our directors, officers and employees. A copy of the Insider Trading Policy is filed as an exhibit to this Annual Report. In addition, it is our practice to comply with the applicable laws and regulations relating to insider trading.

Item 11. Executive Compensation

The information required by this Item 11 of Form 10-K will be included in our 2026 Proxy Statement and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by this Item 12 of Form 10-K will be included in our 2026 Proxy Statement and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this Item 13 of Form 10-K will be included in our 2026 Proxy Statement and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services

The information required by this Item 14 of Form 10-K will be included in our 2026 Proxy Statement and is incorporated herein by reference.

Part IV

Item 15. Exhibits and Financial Statement Schedules

(a) The following documents are filed as part of this Annual Report:

(1) Financial Statements. The financial statements filed as part of this Annual Report are included in Part II, Item 8 of this Annual Report.

(2) Financial Statement Schedules. Financial statement schedules have been omitted in this Annual Report because they are not applicable, not required under the instructions, or the information requested is set forth in the financial statements or notes thereto.

(3) Exhibits. The following is a list of exhibits filed, furnished or incorporated by reference as part of this Annual Report on Form 10-K.

Index to 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 the Registrant	8-K	001-42934	3.2	November 10, 2025	
4.1	Amended and Restated Investors' Rights Agreement, dated May 14, 2024, by and among the Registrant and the investors listed on Schedule A thereto.	S-1	333-290761	4.1	October 07, 2025	
4.2	Warrant to Purchase Stock, issued to Western Alliance Bank, dated October 12, 2021	S-1	333-290761	4.3	October 07, 2025	
4.3	Warrant to Purchase Stock, issued to Western Alliance Bank, dated July 22, 2022.	S-1	333-290761	4.4	October 07, 2025	
10.1	Note Purchase Agreement, dated August 2, 2024, 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	10.1	October 07, 2025	
10.2	Amendment No. 1 to the Note Purchase Agreement, dated 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	
10.3	Lease Agreement for Union City facility, dated April 10, 2022.	S-1	333-290761	10.3	October 07, 2025	
10.4	Amendment No. 1 to Lease Agreement for Union City facility, dated October 11, 2023.	S-1	333-290761	10.4	October 07, 2025	
10.5	Lease Agreement for Menlo Park facility, dated May 21, 2020.	S-1	333-290761	10.5	October 07, 2025	
10.6	Amendment No. 1 to Lease Agreement for Menlo Park facility, dated August 7, 2021.	S-1	333-290761	10.6	October 07, 2025	
10.7†	Development and Commercialization Agreement with Janssen Biotech, Inc., dated July 11, 2025	S-1/A	333-290761	10.10	October 17, 2025	
10.8	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	
10.9	Amendment No. 2 to Development and Commercialization Agreement with Janssen Biotech, Inc., dated January 6, 2026					X

10.10+	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	
10.11+	2018 Stock Plan and forms of agreements thereunder.	S-1/A	333-290761	10.13	October 17, 2025	
10.12+	2025 Equity Incentive Plan and forms of agreements thereunder.	S-8	333-291314	99.2	November 06, 2025	
10.13+	2025 Employee Stock Purchase Plan.	S-8	333-291314	99.3	November 06, 2025	
10.14+	Executive Severance Plan	S-1/A	333-290761	10.16	October 17, 2025	
10.15+	Amended and Restated Non-Employee Director Compensation Policy					X
10.16+	Offer Letter, by and between the Registrant and Oguzhan Atay.	S-1	333-290761	10.16	October 07, 2025	
10.17+	Offer Letter, by and between the Registrant and David Tsao.	S-1	333-290761	10.17	October 07, 2025	
10.18+	Offer Letter, by and between the Registrant and Ross Taylor.	S-1	333-290761	10.18	October 07, 2025	
10.19+	Offer Letter, by and between the Registrant and Nancy Johnson.	S-1	333-290761	10.19	October 07, 2025	
10.20+	Annual Incentive Plan					X
19.1	Insider Trading Policy					X
23.1	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm.					X
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
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
97.1	Policy Relating to Recovery of Erroneously Awarded Compensation					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.

Item 16. Form 10-K Summary

Not applicable.

Signatures

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

BillionToOne, Inc.

Date: March 11, 2026

By: /s/ Oguzhan Atay

Oguzhan Atay

Chief Executive Officer

(Principal Executive Officer)

Power of Attorney

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Oguzhan Atay and Ross Taylor and each of them, as his or her true and lawful attorneys-in-fact and agents, each with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully for all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that each of said attorneys-in-fact and agents, or his or her substitute or substitutes may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Oguzhan Atay Oguzhan Atay	*Chief Executive Officer and Director* *(Principal Executive Officer)*	March 11, 2026
/s/ Ross Taylor Ross Taylor	Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 11, 2026
/s/ David Tsao David Tsao	Chief Technology Officer and Director	March 11, 2026
/s/ Thomas Bremner Thomas Bremner	Director	March 11, 2026
/s/ Firat Ileri Firat Ileri	Director	March 11, 2026
/s/ Krishna Swaroop Kolluri Krishna Swaroop Kolluri	Director	March 11, 2026
/s/ Anthony Pagano Anthony Pagano	Director	March 11, 2026
/s/ Akshay Rai Akshay Rai	Director	March 11, 2026

Second Amendment to the Development and Commercialization Agreement

This Second Amendment to the Development and Commercialization Agreement ("Second Amendment"), effective as of the date of the last signature below, is by and between BillionToOne, Inc., having offices at 1035 O'Brien Dr., Menlo Park, California 94025 ("BTO") and Janssen Biotech, Inc., having offices at 800 Ridgeview Avenue, Horsham, PA 19044 ("Janssen"). BTO and Janssen are sometimes referred to herein individually as a "Party" and collectively as the "Parties."

WHEREAS, the Parties have entered into a Development and Commercialization Agreement, effective as of July 11, 2025, as amended (the "Agreement"), have agreed to amend the Agreement by executing this Second Amendment.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual promises and covenants herein contained, and for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, BTO and Janssen hereby agree to amend the Agreement as provided herein:

1. Extension of Period for Amending the Collaboration Agreement. Section 13.2.7 of the Agreement is hereby amended and restated in its entirety as follows:

> 13.2.7 Termination for Failure to Amend the Prior Collaboration Agreement. If an amendment to the Prior Collaboration Agreement extending the term thereof is not executed by the parties thereto prior to March 6, 2026, Janssen may terminate this Agreement on ten (10) days' prior notice to BTO.

2. Except as specifically amended herein, all terms and conditions of the Agreement shall remain in full force and effect. In the event of any conflict between the Agreement and this Second Amendment, the provisions of this Second Amendment shall prevail.

This Second Amendment to the Agreement is signed on the dates set forth below by duly authorized representatives of BTO and Janssen, respectively.

BillionToOne, Inc.	**Janssen Biotech, Inc.**
By: /s/ Thomas Lynch	By: /s/ Biljana Naumovic
Name: Thomas Lynch	Name: Biljana Naumovic
Title: General Counsel	Title: Managing Director
Date: 06 January 2026	Date: 06 January 2026

BILLIONTOONE, INC.

AMENDED AND RESTATED
NON-EMPLOYEE DIRECTOR COMPENSATION POLICY

(Amended and Restated on December 27, 2025)

This Amended and Restated Non-Employee Director Compensation Policy (the "***Policy***") summarizes the compensation arrangements for non-employee and non-executive members (each, a "***Director***") of the Board of Directors (the "***Board***") of BillionToOne, Inc. (the "***Company***"). The Policy initially became effective upon the Company's initial public offering and was amended and restated, effective as of the date set forth above and the Policy shall remain effective as hereby set forth until changed by the Board. Members of the Board who are also employees of the Company will not be entitled to any additional compensation on behalf of their service on the Board.

Cash Compensation. Each Director shall receive an annual cash retainer of $50,000. To the extent the Board appoints a "Chair," such Director shall be paid an additional cash retainer of $50,000 and to the extent the Board appoints a "Lead Independent Director," such Director shall be paid an additional annual cash retainer of $35,000.

Directors shall receive an additional annual cash retainer, as set forth below, for their service on Board committees as follows:

Committee	Chairperson	Member
Audit	$20,000	$10,000
Compensation	$15,000	$7,500
Nominating and Corporate Governance	$10,000	$5,000

If the Board should hereafter appoint one or more additional Board committees, the Director members of such committee shall not be paid any additional retainer fees unless otherwise determined by the Board in its sole discretion.

Directors will not receive any additional fees for attending our Board and committee meetings, but we will reimburse Directors for their reasonable expenses incurred in connection with attending such meetings.

All cash retainers shall be paid in arrears in quarterly installments within 30 days after the fiscal quarter end.

Equity Compensation. Directors shall receive restricted stock unit awards (each, an "***RSU award***") granted under the Company's 2025 Equity Incentive Plan (the "***Plan***") or any successor thereto. Unless otherwise determined by the Board in its sole discretion, approval of this

compensation policy also represents automatic approval of the RSU awards, on the terms described below as well as the terms and conditions of the Plan and the approved form of award agreement, by the Board effective as of the applicable grant date specified below (the "***Grant Date***").

(i) **IPO Grant**. In connection with the Company's initial public offering ("***IPO***"), each Director serving as a member of the Board immediately following the IPO will receive an RSU award having a value of $500,000, with the number of restricted stock units subject to the award determined using the per-share "price to public" for the Company's shares of our Class A common stock as set forth on the cover page of the final prospectus for the IPO (the "***IPO Grant***"). The Grant Date for the IPO Grant will be the effective date of the registration statement filed by the Company with the U.S. Securities and Exchange Commission for the IPO. Subject to the Director's continuing service, the IPO Grant will vest in equal annual installments over a 3-year period, and the vesting date in each year will be the anniversary of the Grant Date (or if there is no corresponding date, the last date of the month).

(ii) **Initial Grant**. Each Director whose initial appointment or election as a member of the Board occurs after the IPO will receive in connection with such appointment or election an RSU award having a value of $500,000 (the "***Initial Grant***"). The Grant Date for an Initial Grant shall be the date of the Director's appointment or election. The number of shares subject to the Initial Grant will be determined using the arithmetic mean of the closing prices of shares of our Class A common stock over the 30-trading day period ending on the Grant Date or, if the Grant Date is not a trading day, the arithmetic mean of the closing prices of shares of our Class A common stock over the 30-trading day period ending on the last trading day prior to the Grant Date. Subject to the Director's continuing service, the Initial Grant will vest in equal annual installments over a 3-year period, and the vesting date in each year will be the anniversary of the Grant Date (or if there is no corresponding date, the last date of the month).

(iii) **Annual Grant**. Each Director who is re-elected at, or continues serving as a Director after, an annual meeting of our stockholders will receive an RSU award having a value of $270,000 (the "***Annual Grant***"). The Grant Date for the Annual Grant will be the date of the annual meeting of stockholders. The number of shares subject to the Annual Grant will be determined using the arithmetic mean of the closing prices of shares of our Class A common stock over the 30-trading day period ending on the Grant Date or, if the Grant Date is not a trading day, the arithmetic mean of the closing prices of shares of our Class A common stock over the 30-trading day period ending on the last trading day prior to the Grant Date. Subject to the Director's continuing service, an Annual Grant will vest in full on the earlier of (A) the date of the next annual meeting of stockholders, or (B) the one-year anniversary of the Grant Date.

(iv) **Accelerated Vesting**. Upon a transaction constituting a "Change in Control" as defined in the Plan or in the event of a Director's service ends on account of the Director's death or "disability" (as defined in the Plan), all outstanding equity awards granted to the Director pursuant hereto shall fully vest upon the effective date of such transaction or the Director's death or disability.

BILLIONTOONE
ANNUAL INCENTIVE PLAN
(Effective as of March 3, 2026)

Article I. PURPOSE AND DURATION

Section 1.01 Purpose. This BillionToOne Annual Incentive Plan, as amended from time to time (the "Plan") is intended to: (a) attract and retain top performing employees; (b) motivate employees by tying compensation to the performance of the Company or any portion thereof, as applicable; and (c) reward exceptional individual performance that supports overall Company objectives.

Section 1.02 Duration. The Plan is effective for performance periods beginning as of January 1, 2026, and will remain in effect until terminated pursuant to Article 8.

Article II. DEFINITIONS AND CONSTRUCTION

Section 2.01 Definitions. Wherever used in the Plan, the following terms shall have the meanings set forth below and, when the meaning is intended, the initial letter of the word is capitalized:

(a) "Administrator" means, with respect to Executive Officers, the Committee, and with respect to all other Participants, the Chief Executive Officer of the Company.

(b) "Affiliate" means any corporation or other entity (including, without limitation, partnerships and joint ventures) controlled by the Company.

(c) "Base Salary" of a Participant means the Participant's base salary as of the last day of the Performance Period.

(d) "Board" means the Board of Directors of the Company.

(e) "Class A Stock" shall mean a number of actual whole (not fractional) shares of the Company's Class A Common Stock (or any successor class of common stock).

(f) "Class A Grant Date Value" shall mean be determined using the average closing price of shares of Class A Stock over the 30-trading day period ending on the date of payment, or if such date is not a trading day, on the last trading day prior to such date.

(g) "Company" means BillionToOne, Inc., and its subsidiaries.

(h) "Committee" means the Compensation Committee of the Board.

(i) "Exchange Act" means the Securities Exchange Act of 1934, as amended. Any reference to a particular provision of the Exchange Act shall be deemed to include any successor provision thereto.

(j) "Executive Officer" means an employee of the Company who is an "officer" within the meaning of Rule 16a-1(f) promulgated under the Exchange Act or, if at any time the

Company does not have a class of securities registered pursuant to Section 12 of the Exchange Act, an employee of the Company who would be deemed an "officer" within the meaning of Rule 16a-1(f) if the Company had a class of securities so registered, as determined by the Board in its discretion.

(k) "Participant" means an Executive Officer or other employee who has been granted a Performance Award by the Administrator.

(l) "Performance Award" means an opportunity granted to a Participant to receive a payment based in whole or part on the extent to which one or more Performance Goals for one or more Performance Measures are achieved for the Performance Period, subject to the conditions described in the Plan and that the Administrator otherwise imposes.

(m) "Performance Measures" means the category or categories of performance that must be achieved, as determined by the Administrator at the time of grant of a Performance Award. Performance Measures may be measured (1) for the Company on a consolidated basis, (2) for any one or more affiliates or divisions of the Company and/or (3) for any other business unit or units of the Company as defined by the Administrator. In addition, the Administrator may exercise discretion in determining eligibility for a Performance Award based on an individual or strategic performance evaluation as a condition to receiving all or any portion of an award payment.

(n) "Performance Goal" means the level(s) of performance for a Performance Measure that must be attained in order for a payment to be made under a Performance Award, and/or for the amount of payment to be determined based on the Performance Scale.

(o) "Performance Period" means a period of one fiscal year of the Company, or such other period as selected by the Administrator, such as with respect to non-Executive Officers, two periods of six months each (first half and second half of the Company's fiscal year) during which corporate and individual performance may be measured.

(p) "Performance Scale" means, with respect to a Performance Measure, a scale from which the level of achievement may be calculated for any given level of actual performance for such Performance Measure as determined by the Administrator.

(q) "Section 409A" means Section 409A of the Internal Revenue Code of 1986, as amended, and the regulations and other interpretive guidance issued thereunder, including any such regulations or guidance that may be amended or issued after the effective date hereof.

Article III. ELIGIBILITY

Section 3.01 Eligibility. Subject to Compensation Committee approval, all Executive Officers and such other employees as designated by the Chief Executive Officer, shall be eligible to participate in the Plan.

Section 3.02 New Hires; Promotions. New Participants who become eligible after the beginning of the Performance Period due to new hire or promotion will receive an appropriate

proration of the Performance Award based on length of employment or length in an eligible position, as applicable. For clarification, no new hire (of non-Executive Officers) commencing employment with the Company on or after April 1st (with respect to any full fiscal year Performance Period or with respect to any partial fiscal year Performance Period ending on or prior to June 30th of such fiscal year) or October 1st (with respect to any partial-fiscal year Performance Period ending on or after July 1st of such fiscal year) will be eligible for a Performance Award during that Performance Period.

Section 3.03 Termination of Employment. Except as otherwise provided under the terms of an employment or severance arrangement between a Participant and the Company, no Participant shall earn a Performance Award for a Performance Period unless the Participant is employed by the Company (or is on an approved leave of absence) on the payment date (determined in accordance with Section 5.02).

Article IV. CONTINGENT PERFORMANCE AWARDS

At the time of grant of a Performance Award, the Administrator shall determine for each award the Performance Measure(s), the Performance Goal(s) for each Performance Measure, the Performance Scale (which may vary for different Performance Measures), and the amount payable to the Participant if and to the extent the Performance Goals are met (as measured from the Performance Scale). The target bonus amount payable to a Participant may be designated as a flat dollar amount, as a percentage of the Participant's base salary (as may be pro-rated on an annual basis as applicable), or as may be determined by any other means as the Administrator may specify at the time the Performance Award is granted.

Article V. PAYMENT

Section 5.01 Evaluating Performance and Computing Awards.

(a) As soon as practicable following the close of a Performance Period, the Administrator shall determine whether and to what extent the Performance Goals and other material terms of the Performance Award issued for such period were achieved and shall determine whether any discretionary adjustments under Subsection (b) shall be made. The Administrator may appropriately adjust any evaluation of performance under a Performance Goal. The Administrator (or its delegate) shall then determine the award amount payable to a Participant under the Performance Award.

(b) The Administrator may adjust (up or down) each Participant's potential award amount under any Performance Award, based upon individual/strategic performance and/or any

other factors, in the Administrator's sole discretion; provided that, in no event shall the final award amount to any individual Participant be greater than two hundred and forty percent (240%) of the target award amount for such Participant under a Performance Award; provided further that, aggregate payouts under the Plan for a fiscal year shall not exceed two hundred percent (200%) of the aggregate target bonus amounts of all Participants (determined at the end of the Performance Period).

(c) There is no minimum award or guaranteed payment with respect to any Performance Award individually or in aggregate; all Performance Awards under the Plan are discretionary on the part of the Company, and the Company reserves the right, at all times, to reduce the payment with respect to a Performance Award or to pay no amount, in its sole discretion.

Section 5.02 Timing and Form of Payment. When the payment due to the Participant has been determined, payment shall be made in a cash lump sum or fully vested shares of the Company's Class A Stock, typically as soon as practicable after the Administrator has determined the extent to which the Performance Goals have been achieved. In no event will payment be made after the later of: (a) 2½ months after the end of the Company's first taxable year when the Performance Award is no longer subject to such "substantial risk of forfeiture" (under Section 409A), or (b) 2½ months after the end of a Participant's first taxable year when the Performance Award is no longer subject to such "substantial risk of forfeiture;" unless a later date is established by the Company, or the Company permits the Participant to designate a later date, in either case only as permitted under Section 409A. Shares of fully vested Class A Stock payable under the Plan shall be granted pursuant to the Company's 2025 Equity Incentive Plan and shall be deemed an "Other Award" thereunder, and the number of shares of Class A Stock payable to a Participant shall be determined by dividing the Class A Grant Date Value by the dollar value of that portion (rounded down to the nearest whole share and with any fractional share paid out in cash).

Section 5.03 Recoupment. Compensation received by the Participant under the Plan shall be subject to the terms of any recoupment or clawback policy that may be adopted by the Company from time to time (including the BillionToOne, Inc. Clawback Policy, as amended from time to time) and to any requirement of applicable law, regulation or listing standard that requires the Company to recoup or clawback compensation paid under this Plan.

Article VI. RIGHTS OF PARTICIPANTS

Section 6.01 No Funding. No Participant shall have any interest in any fund or in any specific asset or assets of the Company by reason of any Performance Award under the Plan. No amounts awarded or accrued under the Plan shall be funded, set aside or otherwise segregated

prior to payment and the obligation to pay any Performance Award under the Plan shall at all times be an unfunded and unsecured obligation of the Company. In furtherance of the foregoing, it is intended that the Company has merely a contractual obligation to make payments to Participants when due hereunder and Participants shall have the status of general creditors of the Company or the Affiliate that employs the Participant.

Section 6.02 No Transfer. No Participant may assign, pledge, or encumber his or her interest under the Plan, or any part thereof.

Section 6.03 No Implied Rights; Employment. Nothing contained in this Plan shall be construed to:

(a) Give any employee or Participant any right to receive any award other than in the sole discretion of the Administrator;

(b) Limit in any way the right of the Company to terminate a Participant's employment at any time; or

(c) Be evidence of any agreement or understanding, express or implied, that a Participant will be retained in any particular position or at any particular rate of remuneration.

Article VII. ADMINISTRATION

Section 7.01 General. The Plan shall be administered by the Administrator.

Section 7.02 Authority. In addition to the authority specifically provided herein, the Administrator shall have full power and discretionary authority to: (a) administer the Plan, including but not limited to the power and authority to construe and interpret the Plan; (b) correct errors, supply omissions or reconcile inconsistencies in the terms of the Plan or any Performance Award; (c) establish, amend or waive rules and regulations, and appoint such agents, as it deems appropriate for the Plan's administration; and (d) make any other determinations, including factual determinations, and take any other action as it determines is necessary or desirable for the Plan's administration.

Section 7.03 Decision Binding. The Administrator's determinations and decisions made pursuant to the provisions of the Plan and all related orders or resolutions of the Compensation Committee or the Board shall be final, conclusive and binding on all persons who have an interest in the Plan or an award, and such determinations and decisions shall not be reviewable.

Article VIII. AMENDMENT AND TERMINATION

Each of the Compensation Committee and the Board has the authority to terminate, change, modify or amend the provisions of the Plan at any time in its sole discretion, including during or after a Performance Period, which termination, change, modification or amendment may have retroactive effect. Furthermore, the Chief Executive Officer has the authority to make amendments to the Plan that do not significantly increase the cost of the Plan or increase or create the opportunity for an increase in the amount which an Executive Officer receives under the Plan, and which in Chief Executive Officer's determination (a) clarify the terms of the Plan; (b) assist in the administration of the Plan; (c) are necessary or advisable for the Plan to comply with applicable law; or (d) are necessary or advisable for Performance Awards to be exempt from or comply with the requirements of Section 409A.

Article IX. TAX WITHHOLDING

The Company shall have the right to deduct from all cash payments made hereunder (or from any other payments due a Participant) any foreign, federal, state, or local taxes required by law to be withheld with respect to such cash payments. With respect to the portion of any payment under the Plan that is payable in Class A Stock, Section 12 of the Company's 2025 Equity Incentive Plan is incorporated herein by reference.

Article X. SECTION 409A

The Plan is intended to be exempt from or to comply with Section 409A and shall be administered and interpreted accordingly. Notwithstanding any other provision of the Plan, if any provision of the Plan conflicts with the requirements of Section 409A, the requirements of Section 409A shall supersede any such provision. To the extent that any provision of this Plan is ambiguous, such provision shall be interpreted in a manner that will permit the Plan to be exempt from or comply with Section 409A. In no event will the Company be liable for any additional tax, interest or penalties that may be imposed on a Participant by Section 409A or any damages for failing to comply with Section 409A.

Insider Trading Policy

1. PURPOSE

1.1 BillionToOne, Inc. (the "***Company***") opposes the unauthorized disclosure of any non-public information obtained in the course of service with the Company, and the misuse of material non-public information in securities trading. This Insider Trading Policy ("***Policy***") prohibits the unauthorized disclosure and misuse of any non-public information, including the misuse of material non-public information in securities trading.

This Policy sets forth the Company's requirements for (i) the handling of non-public information, and (ii) trading in Company securities. You are responsible for complying with this Policy and applicable laws and regulations. You should use your best judgment at all times and consult with your personal legal and financial advisors, as needed. The rules relating to insider trading can be complex, and a violation of insider trading laws can carry severe consequences. If you have questions as to how this Policy applies to you or to a particular situation, please contact the Company's General Counsel.

2. SCOPE

2.1 This Policy applies generally to all directors, officers, and employees of the Company, as well as others designated by the Compliance Officer from time to time. In this Policy, "we," "our," and "Company" refer to BillionToOne, Inc. and any subsidiaries of the Company (if applicable). References in this Policy to "you" (as well as general references to directors, officers, employees and agents of the Company) should also be understood to include members of your immediate family, persons with whom you share a household, persons who are your economic dependents and any other individuals or entities whose transactions in securities you direct, control or influence (including, for example, a trust or a venture or other investment fund, if you influence, direct or control transactions by the entity). You are responsible for making sure that these other individuals and entities comply with this Policy.

3. BACKGROUND ON INSIDER TRADING

3.1 Legal Prohibitions on Insider Trading. U.S. federal securities laws and regulations prohibit directors, officers, employees and other individuals who possess material non-public information from trading on the basis of that information. Your transactions will be considered "on the basis of" material non-public information if you are aware of the material non-public information at the time of the transaction. It is not a defense that you did not use the information for purposes of the transaction.

Disclosing material non-public information directly or indirectly to others who then trade based on that information or making recommendations or expressing opinions as to transactions in securities while aware of material non-public information (which is sometime referred to as

"***tipping***") is also illegal. Both the "tipper" who provides the information, recommendation or opinion and the "tippee" who trades based on it may be liable.

These illegal activities are commonly referred to as "***insider trading***." State securities laws and securities laws of other jurisdictions also impose restrictions on insider trading.

In addition, the Company, as well as individual directors, officers and other supervisory personnel, may be subject to liability as "controlling persons" for failure to take appropriate steps to prevent insider trading by those under their supervision, influence or control.

1.2 Detection and Prosecution of Insider Trading. The U.S. Securities and Exchange Commission (the "***SEC***"), the Financial Industry Regulatory Authority ("***FINRA***") and NASDAQ use sophisticated electronic surveillance techniques to investigate and detect insider trading, and the SEC and the U.S. Department of Justice pursue insider trading violations vigorously. Regulators have successfully prosecuted cases involving trading through foreign accounts, trading by family members and friends and trading involving only a small number of shares.

1.3 Penalties for Violation of Insider Trading Laws and this Policy.

(a) Civil and Criminal Penalties. As of the effective date of this Policy, potential penalties for insider trading violations under U.S. federal securities laws include:

- damages in a private lawsuit;
- disgorging any profits made or losses avoided;
- imprisonment for up to 20 years;
- criminal fines of up to $5 million for individuals and $25 million for entities;
- civil fines of up to three times the profit gained or loss avoided;
- a bar against serving as an officer or director of a public company; and
- an injunction against future violations.

Civil and criminal penalties also apply to tipping. The SEC has imposed large penalties in tipping cases even when the tipper did not trade or gain any benefit from the tippee's trading.

(b) Penalties for Controlling Persons. As of the effective date of this Policy, the penalty for insider trading violations of controlling persons is a civil fine of up to the greater of $2.560 million or three times the profit gained or loss avoided as a result of the insider trading violations, as well as potential criminal fines and imprisonment.

(c) Disciplinary Actions. If the Company has a reasonable basis to conclude that you have failed to comply with this Policy, you may be subject to disciplinary action, up to and including dismissal for cause, whether or not your failure to comply with this Policy results in a violation of law. It is not necessary for the Company to wait for the filing or conclusion of any civil or criminal action against you before taking disciplinary action. In addition, the Company may give stop transfer and other instructions to the Company's transfer agent to enforce compliance with this Policy.

4. POLICY – GENERAL TERMS

4.1 Persons Covered by this Policy. As noted above in Scope, this Policy applies to all directors, officers and employees of the Company, and others designated by the Compliance Officer from time to time. References in this Policy to "you" (as well as general references to directors, officers, employees and agents of the Company) should also be understood to include members of your immediate family, persons with whom you share a household, persons who are your economic dependents and any other individuals or entities whose transactions in securities you direct, control or influence (including, for example, a trust or a venture or other investment fund, if you influence, direct or control transactions by the entity).

This Policy shall not apply to any trust, venture or other investment fund that engages in the investment of securities in the ordinary course of its business (e.g., an investment fund or partnership) if such entity has established its own insider trading controls and procedures in compliance with applicable securities laws and you have represented to the Company that such affiliated entities: (a) engage in the investment of securities in the ordinary course of their respective businesses; (b) have established insider trading controls and procedures in compliance with applicable securities laws; and (c) are aware such securities laws prohibit any person or entity who has material, nonpublic information concerning the Company from purchasing or selling securities of the Company or from communicating such information to any other person under circumstances in which it is reasonably foreseeable that such person is likely to purchase or sell securities).

You are responsible for making sure that these other individuals and entities comply with this Policy.

4.2 Types of Transactions Covered by This Policy. Except as discussed in Section 9 (Limited Exceptions), this Policy applies to all transactions involving Company securities. It also applies to all transactions involving the securities of other companies about which you possess material non-public information obtained in the course of your service with the Company. This Policy applies to purchases, sales and other transfers of common stock, options, warrants, preferred stock, debt securities (such as debentures, bonds and notes) and other securities. This Policy also

applies to any arrangements that affect economic exposure from changes in the prices of these securities (*e.g.*, transactions in derivative securities (such as exchange-traded put or call options), hedging transactions, short sales and certain decisions with respect to participation in benefit plans). This Policy also applies to any offers by you with respect to the transactions discussed above. There are no exceptions from insider trading laws or this Policy based on the size of the transaction.

4.3 Responsibilities Regarding the Non-Public Information of Other Companies. This Policy prohibits the unauthorized disclosure or other misuse of any non-public information of other companies, such as the Company's vendors, collaborators, suppliers and competitors. This Policy also prohibits insider trading and tipping based on the material non-public information of other companies. The Company's Investor Relations and Communications Policy contains additional information on restrictions applicable to the use or disclosure of material non-public information.

1.4 Applicability of This Policy after Your Departure. You are expected to comply with this Policy until such time as (a) you are no longer affiliated with the Company, (b) you no longer possess any material non-public information subject to this Policy, and (c) if your transactions in Company securities are subject to a blackout period at the time you cease to be affiliated with the Company, the end of such blackout period.

1.5 No Exceptions Based on Personal Circumstances. There may be instances where you suffer financial harm or other hardship or are otherwise required to forego a planned transaction because of the restrictions imposed by this Policy. Personal financial emergency or other personal circumstances will not limit your liability under securities laws and will not excuse a failure to comply with this Policy.

1.6 Compliance Officer. You should direct any questions, requests or reports to the Company's General Counsel (for purposes of this Policy, the "***Compliance Officer***"). The Compliance Officer is generally responsible for the administration of this Policy. The Compliance Officer may select others to assist with the execution of his or her duties.

4.7 Reporting Violations. It is your responsibility to help enforce this Policy. You should be alert to possible violations and promptly report violations or suspected violations of this Policy to the Compliance Officer. If your situation requires that your identity be kept secret, your anonymity will be preserved to the greatest extent reasonably possible. If you wish to remain anonymous, you may: leave an anonymous message on the Compliance Helpline at the toll-free number 1-844-237-8881, online at http://billiontoone.ethicspoint.com, or via mobile device at billiontoonemobile.ethicspoint.com. If you make an anonymous report, please provide as much detail as possible, including any evidence that you have.

5. POLICIES REGARDING MATERIAL NON-PUBLIC INFORMATION

5.1 What is "Material" Information? Information is "***material***" if there is a substantial likelihood that a reasonable investor would consider it important in deciding whether to buy, hold or sell securities or would view the information as significantly altering the total mix of information in the marketplace. In general, any information that could reasonably be expected to affect the market price of a security is likely to be material. Both positive and negative information may be material.

It is not possible to define all categories of material information. However, some examples of information that could be regarded as material include information with respect to:

- Financial results, financial condition, earnings pre-announcements, guidance, projections or forecasts; note that information about the results of the Company's operations for even a portion of a quarter might be material in helping predict the Company's financial results for the quarter;
- Restatements of financial results, or material impairments, write-offs or restructurings;
- Changes in independent auditors, or notification that the Company may no longer rely on an audit report;
- Business plans or budgets;
- Creation of significant financial obligations, or any significant default under or acceleration of the payment of any financial obligation;
- Impending bankruptcy or financial liquidity problems;
- Significant developments involving business relationships, including entering into, modifying, or terminating significant agreements or orders with suppliers, collaborators, manufacturers or other business partners;
- Product introductions, modifications, defects or recalls or significant pricing changes or other announcements of a significant nature;
- Significant developments in research and development or relating to intellectual property;
- A significant cybersecurity incident, such as a data breach, or any other significant disruption, loss, potential loss, breach or unauthorized access of the Company's property or assets, whether at the Company's facilities or through the Company's information technology infrastructure;
- Significant legal or regulatory developments, whether actual or threatened;
- Significant issues related to the reimbursement of the Company's products;
- Major events involving the Company's securities, including calls of securities for redemption, adoption of stock repurchase programs, option repricings, stock splits,

changes in dividend policies, public or private securities offerings, modification to the rights of security holders, or notice of delisting of our securities from trading on a securities exchange;

- The existence of a special blackout period in which you may not trade securities;

- Significant corporate events, such as a pending or proposed merger, joint venture or tender offer, a significant investment, the acquisition or disposition of a significant business or asset or a change in control of the Company; and
- Major personnel changes, such as changes in senior management or layoffs.

If you have any questions as to whether information should be considered "material," you should consult with the Compliance Officer. In general, it is advisable to resolve any close questions as to the materiality of any information by assuming that the information is material.

5.2 What is "Non-Public" Information? Information is considered "***non-public information***" until it has been broadly disseminated to the public for long enough to be reflected in the price of the security. Unless you have seen material information publicly disseminated (for example, by the issuance of a press release or a filing with the SEC), you should assume the information is non-public.

As a general rule, you should consider information to be non-public until the beginning of the second trading day after the information has been broadly disseminated to the public in a press release, a public filing with the SEC, a pre-announced public webcast or another broad, non-exclusionary form of public communication. If, for example, the Company were to make an announcement after the close of the trading day on a Monday afternoon, you should not trade in the Company's securities until the beginning of the trading day on Wednesday. However, depending upon the form of the announcement and the nature of the information, it is possible that information may not be fully absorbed by the marketplace until later. Any questions as to whether information is non-public should be directed to the Compliance Officer.

The term "***trading day***" means a day on which national stock exchanges are open for trading.

5.3 Maintaining the Confidentiality of Non-Public Information. All officers, employees and agents (such as consultants and independent contractors) of the Company are required to sign and comply with an agreement addressing confidential information and invention assignment. In addition to your individual obligations under your confidentiality and inventions assignment agreement, this Policy prohibits the unauthorized use or disclosure of non-public information relating to the Company or other companies. All non-public information you obtain in the course of your service with the Company may only be used for legitimate Company business purposes. In addition, you should handle others' non-public information in accordance with the terms of any relevant nondisclosure agreements, and the use of any such non-public information should be limited to the purpose for which it was disclosed.

You must use all reasonable efforts to safeguard non-public information in the Company's possession.

5.4 No Trading on Material Non-Public Information. Except as discussed in "Limited Exceptions" below, you may not, directly or indirectly through others, engage in any transaction involving the Company's securities while aware of "***material non-public information"*** relating to the Company. It does not matter that you did not use the information in your transaction.

Similarly, you may not engage in transactions involving the securities of any other company if you are aware of material non-public information about that company (except if the transactions are similar to those presented in Limited Exceptions below). This prohibition includes "shadow trading" in addition to insider trading. "Shadow trading" is a practice whereby an insider uses confidential information regarding one company to trade in the securities of another company whose stock price may be impacted (positively or negatively) when the confidential information becomes public. For example, you may be aware of a proposed transaction involving a prospective business relationship or transaction with another company. If information about that transaction constitutes material non-public information for that other company, you would be prohibited from engaging in transactions involving the securities of that other company (as well as transactions involving Company securities, if that information is material to the Company). "Materiality" is company-specific—information that is not material to the Company may be material to another company.

5.5 No Disclosing Material Non-Public Information. You may not disclose non-public information about the Company or any other company, unless required by law, or unless (i) disclosure is required for legitimate Company business purposes, (ii) you are authorized to disclose the information and (iii) appropriate steps have been taken to prevent misuse of that information (including entering an appropriate nondisclosure agreement that restricts the disclosure and use of the information, if applicable). This restriction also applies to internal company communications and to communications with agents (such as consultants and independent contractors) of the Company. In cases where disclosing non-public information to third parties is required, you should coordinate with the Company's Legal function.

In addition, you may not make recommendations or express opinions on the basis of material non-public information as to trading in the securities of companies to which such information relates. You are prohibited from engaging in these actions whether or not you derive any profit or personal benefit from doing so. This prohibition against disclosure of material non-public information includes disclosure (even anonymous disclosure) via the Internet, blogs, investor forums, chat rooms, social media, or the like.

5.6 Responding to Outside Inquiries for Information. In the event you receive an inquiry from someone outside of the Company, such as a stock analyst or news reporter, for information, you should refer the inquiry to the Chief Financial Officer. Your disclosure of information could result in SEC enforcement actions against the Company, including injunctions and severe monetary penalties. Please consult the Company's *Investor Relations and Communications Policy* for more details.

6. TRADING BLACKOUT PERIODS

6.1 Blackout Periods Generally. To limit the likelihood of trading at times when there is a significant risk of insider trading exposure, the Company has instituted regular trading blackout periods and may institute special trading blackout periods from time to time.

It is important to note that whether or not you are subject to blackout periods, you remain subject to the prohibitions on trading on the basis of material non-public information and any other applicable restrictions in this Policy.

1.2 Quarterly Blackout Periods. Except as discussed in Limited Exceptions below, all members of the Company's Board of Directors and all employees of the Company (as set forth on **Schedule I**) must refrain from conducting transactions involving the Company's securities during quarterly blackout periods. From time to time, the Company may identify other persons who should be subject to quarterly blackout periods, and the Compliance Officer may update and revise **Schedule I** as appropriate.

Even if you are not specifically identified as being subject to quarterly blackout periods, you should exercise caution when engaging in transactions during quarterly blackout periods because of the heightened risk of insider trading exposure. This period is a particularly sensitive time for transactions involving the Company's securities due to the fact that, during these periods, individuals may often possess or have access to material non-public information relevant to the expected financial results for the quarter.

Quarterly blackout periods begin twenty-one (21) calendar days prior to the end of the last month of each fiscal quarter and end at the beginning of the second trading day following the date of public disclosure of the financial results for that fiscal quarter. If, for example, the Company were to release results for a completed fiscal quarter after the close of the trading day on a Monday afternoon, you should not trade in Company securities until the beginning of the trading day on Wednesday.

The Company will notify you when each quarterly blackout period starts and ends so that you will know when you may and may not engage in any transaction involving the Company's securities. You are responsible for complying with the blackout period (and other applicable restrictions) described in this Policy regardless of whether you receive notification from the Company about the period.

6.3 Special Blackout Periods. From time to time, the Company may also prohibit members of the Board of Directors, employees and agents (such as consultants and independent contractors) from engaging in transactions involving the Company's securities when, in the judgment of the Compliance Officer, a trading blackout is warranted. The Company will generally impose special blackout periods when there are material developments known to the Company that have not yet been disclosed to the public. For example, the Company may impose a special blackout period in anticipation of announcing interim earnings guidance or a significant transaction or business development. Special blackout periods may be declared for any reason.

The Company will notify you if you are subject to a special blackout period, in which case you may not engage in any transaction involving the Company's securities until instructed that it is permissible, and you should not disclose the existence of the special blackout period to others.

6.4 No Safe Harbors. There are no unconditional "safe harbors" for trades made at particular times, and you should exercise good judgment at all times. Even when a quarterly blackout period is not in effect, you may be prohibited from engaging in transactions involving the Company's securities because you possess material non-public information, are subject to a special blackout period, or are otherwise restricted under this Policy.

7. PRE-CLEARANCE OF TRADES

7.1 Pre-Clearance by the Compliance Officer Prior to Trading. Except as discussed in Limited Exceptions below (a) all members of the Board of Directors, (b) all employees at or above the level of director, and (c) all members of the Legal and Finance functions must refrain from engaging in any transaction involving the Company's securities without first obtaining pre-clearance of the transaction from the Compliance Officer. The Compliance Officer may not engage in a transaction involving the Company's securities unless the Chief Financial Officer has pre-cleared the transaction. Individuals subject to pre-clearance requirements are listed on **Schedule II**. From time to time, the Company may identify other persons who should be subject to the pre-clearance requirements set forth above, and the Compliance Officer may update and revise **Schedule II** as appropriate.

These pre-clearance procedures are intended to decrease insider trading risks associated with transactions by individuals with regular or special access to material non-public information. In addition, requiring pre-clearance of transactions by directors and officers facilitates compliance with Rule 144 resale restrictions under the Securities Act of 1933, as amended, and the liability and reporting provisions of Section 16 under the Securities Exchange Act of 1934, as amended (the "***Exchange Act***"). Pre-clearance of a trade, however, is not a defense to a claim of insider trading and does not excuse you from otherwise complying with insider trading laws or this Policy. Further, pre-clearance of a transaction does not constitute an affirmation by the Company or the Compliance Officer that you are not in possession of material non-public information.

The Compliance Officer is under no obligation to approve a transaction submitted for pre-clearance, and may determine not to permit the transaction. A form of pre-clearance request has been included as Appendix B. Before executing any transaction, the pre-clearance form should be completed and submitted to the Compliance Officer for pre-clearance.

8. ADDITIONAL TRADING RESTRICTIONS AND GUIDANCE

8.1 Specific Transactions. This section addresses certain types of transactions that may expose you and the Company to significant risks. You should understand that, even though a transaction may not be expressly prohibited by this section, you are responsible for ensuring that

the transaction otherwise complies with this Policy, including the general prohibition against insider trading as well as pre-clearance procedures and blackout periods, if applicable.

(a) Short Sales. This Policy prohibits short sales (i.e., the sale of a security that must be borrowed to make delivery) and "selling short against the box" (i.e., a sale with a delayed delivery) with respect to Company securities. Short sales may signal to the market possible bad news about the Company or a general lack of confidence in the Company's prospects, and an expectation that the value of the Company's securities will decline. In addition, short sales are effectively a bet against the Company's success and may reduce the seller's incentive to improve the Company's performance. Short sales may also create a suspicion that the seller is engaged in insider trading.

(b) Derivative Securities and Hedging Transactions. This Policy prohibits transactions in publicly-traded options, such as puts and calls, and other derivative securities with respect to the Company's securities. This prohibition extends to any hedging or similar transaction designed to decrease the risks associated with holding the Company's securities. Stock options, restricted stock units, restricted stock, stock appreciation rights and other securities issued pursuant to the Company's benefit plans or other compensatory arrangements with the Company are not subject to this prohibition. Transactions in derivative securities may reflect a short-term and speculative interest in the Company's securities and may create the appearance of impropriety, even where a transaction does not involve trading on material non-public information. Trading in derivatives may also focus attention on short-term performance at the expense of the Company's long-term objectives. In addition, the application of securities laws to derivatives transactions can be complex, and persons engaging in derivatives transactions run an increased risk of violating securities laws.

(c) Using Company Securities as Collateral for Loans. You may not pledge Company securities as collateral for loans without the approval of the Compliance Officer. If you default on the loan, the lender may sell the pledged securities as collateral in a foreclosure sale. The sale, even though not initiated at your request, is still considered a sale for your benefit. If made at a time when you are aware of material non-public information or otherwise are not permitted to trade in Company securities, the sale may result in inadvertent insider trading violations, Section 16 violations (for officers and directors), violations of this Policy and unfavorable publicity for you and the Company.

(d) Holding Company Securities in Margin Accounts. You may not hold Company securities in margin accounts without the approval of the Compliance Officer. Under

typical margin arrangements, if you fail to meet a margin call, the broker may be entitled to sell securities held in the margin account without your consent. The sale, even though not initiated at your request, is still considered a sale for your benefit. If made at a time when you are aware of material non-public information or are otherwise not permitted to trade in Company securities, the sale may result in inadvertent insider trading violations, Section 16 violations (for officers and directors), violations of this Policy and unfavorable publicity for you and the Company.

(e) Placing Open Orders with Brokers. Except in accordance with an approved trading plan (as discussed below), you should exercise caution when placing open orders, such as limit orders or stop orders, with brokers, particularly where the order is likely to remain outstanding for an extended period of time. Open orders may result in the execution of a trade at a time when you are aware of material non-public information or otherwise are not permitted to trade in Company securities, which may result in inadvertent insider trading violations, Section 16 violations (for officers and directors), violations of this Policy and unfavorable publicity for you and the Company. If you are subject to blackout periods or pre-clearance requirements, you should inform your broker when you place any open order at the time the order is placed.

9. LIMITED EXCEPTIONS

9.1 Limited Exceptions to the Restrictions in this Policy. The following are certain limited exceptions to the restrictions imposed by the Company under this Policy. Please be aware that even if a transaction is subject to an exception to this Policy, you will need to separately assess whether the transaction complies with applicable law. For example, even if a transaction is indicated as exempt from this Policy, you may need to comply with the "short-swing" trading restrictions under Section 16 of the Exchange Act, if applicable. You are responsible for complying with applicable law at all times.

(a) Transactions Pursuant to a Trading Plan that Complies with SEC Rules (10b5-1 plans). The SEC has enacted rules that provide an affirmative defense against alleged violations of U.S. federal insider trading laws for transactions pursuant to trading plans that meet certain requirements. In general, these rules, as set forth in ***Rule 10b5-1*** under the Exchange Act, provide for an affirmative defense if you enter into a contract, provide instructions or adopt a written plan for trading securities when you are not aware of material non-public information. The contract, instructions or plan must (i) specify the amount, price and date of the transaction, (ii) specify an objective method for determining the amount, price and date of the transaction and/or (iii) place any subsequent discretion for determining the amount, price and date of the transaction in another person who is not, at the time of the transaction, aware of material non-public information.

Transactions made pursuant to a written trading plan that (i) complies with the affirmative defense set forth in Rule 10b5-1, (ii) complies with the requirements set forth in Appendix A hereto, and (iii) is approved by the Compliance Officer, are not subject to the restrictions in this Policy against trades made while aware of material non-public information or to the pre-clearance procedures or blackout periods established under this Policy. In approving a trading plan, the Compliance Officer may, in furtherance of the objectives expressed in this Policy, impose criteria in addition to those set forth in Rule 10b5-1. You should therefore confer with the Compliance Officer prior to entering into any trading plan.

The SEC rules regarding trading plans are complex, and you must comply with them completely for your trading plan to be effective. The description provided above is only a summary, and the Company strongly advises that you consult with your personal legal advisor if you intend to adopt a trading plan. While trading plans are subject to Company review and approval, you are ultimately responsible for compliance with Rule 10b5-1 and this Policy.

The Compliance Officer must keep a copy of each adopted trading plan. The Company may publicly disclose information regarding trading plans that you may enter (including but not limited to the information required by Regulation S-K Item 408), and you, or the Company on your behalf, will identify any Rule 10b5-1 transactions as such on Forms 4 and 5, if applicable.

(b) Receipt and Vesting of Stock Options, Restricted Stock Units, Restricted Stock and Stock Appreciation Rights. The trading restrictions under this Policy do not apply to the grant or award of stock options, restricted stock units, restricted stock or stock appreciation rights issued or offered by the Company. The trading restrictions under this Policy also do not apply to the vesting, cancellation or forfeiture of stock options, restricted stock units, restricted stock or stock appreciation rights in accordance with applicable plans and agreements. The trading restrictions do apply, however, to any subsequent sales of any such securities or the shares underlying such securities and any other market sale for the purpose of generating the cash needed to pay withholding taxes related to the settlement of restricted stock units or stock option exercises.

(c) Cash or Cashless Net Exercise of Stock Options. The trading restrictions under this Policy do not apply to the exercise of stock options for cash under the Company's equity incentive plans. Likewise, the trading restrictions under this Policy do not apply to the exercise of stock options in a stock-for-stock exercise with the Company or an election to have the Company withhold securities to cover tax obligations in connection with an option exercise. However, the trading restrictions under this Policy do apply to (i) the sale of any securities issued upon the exercise of a stock option, (ii) a cashless exercise of a stock option through a broker, because this involves selling a portion of the underlying shares to cover the costs of exercise, and (iii) any other market sale for the purpose of generating the cash needed to pay the exercise price of an option or to pay withholding taxes related to the settlement of restricted stock units or stock option exercises.

(d) Purchases from the Employee Stock Purchase Plan. The trading restrictions in this Policy do not apply to elections with respect to participation in the Company's employee stock purchase plan or to purchases of securities under the plan. However, the trading restrictions do apply to any subsequent sales of any such securities acquired therefrom.

(e) Stock Splits, Stock Dividends and Similar Transactions. The trading restrictions under this Policy do not apply to a change in the number of securities held as a result of a stock split or stock dividend applying equally to all securities of a class, or similar transactions.

(f) Bona Fide Gifts and Inheritance. The trading restrictions under this Policy do not apply to bona fide gifts involving the Company's securities or transfers by will or the laws of descent and distribution. However, (i) if you have reason to believe that the recipient intends to sell the Company's securities while you are aware of material nonpublic information or, (ii) if (A) you are subject to the trading restrictions specified above under the heading Trading Blackout Periods, and (B) you have reason to believe that the recipient intends to sell the Company's securities during a blackout period, then the trading restrictions apply. In other words, you cannot use a gift to conduct a transaction that otherwise would be prohibited under this Policy. Also, if you are subject to Section 16 of the Exchange Act, please note that gifts and estate planning transactions are reportable on Forms 4 within 2 days. You should consider market reactions and increased scrutiny with respect to gifts especially during blackout windows. In addition, the trading restrictions under this Policy apply to any gifted or inherited securities if the recipient, for example, an immediate family member, is subject to this Policy. See Persons and Transactions Covered by this Policy above. Please also note that under the Company's equity incentive plans, a stock option or other equity award generally may not be gifted or transferred except under very limited circumstances.

(g) Change in Form of Ownership. Transactions that involve merely a change in the form in which you own securities are not subject to the trading restrictions under this Policy. For example, you may transfer shares to an inter vivos trust of which you are the sole beneficiary during your lifetime.

(h) Other Exceptions. Any other exception from this Policy must be approved by the Compliance Officer, in consultation with the Board of Directors or an independent committee of the Board of Directors.

10. COMPLIANCE WITH SECTION 16 OF THE SECURITIES EXCHANGE ACT

10.1 Obligations under Section 16. Section 16 of the Exchange Act, and the related rules and regulations, set forth (a) reporting obligations, (b) limitations on "short-swing" transactions and (c) limitations on short sales and other transactions applicable to directors, officers, large shareholders and certain other persons.

The Company's Board of Directors has determined that those persons listed on **Schedule III** are required to comply with Section 16 of the Exchange Act, and the related rules and regulations, because of their positions with the Company. The Compliance Officer may amend **Schedule III** from time to time as appropriate to reflect the election of new officers or directors, any change in

the responsibilities of officers or other employees and any promotions, demotions, resignations or departures.

Schedule III is not necessarily an exhaustive list of persons subject to Section 16 requirements at any given time. Even if you are not listed on **Schedule III**, you may be subject to Section 16 reporting obligations because of your shareholdings, for example.

1.2 Notification Requirements to Facilitate Section 16 Reporting. To facilitate timely reporting of transactions pursuant to Section 16 requirements, if you are subject to Section 16 reporting requirements you must provide, or must ensure that your broker provides, the Company with detailed information (e.g., trade date, number of shares, exact price, etc.) regarding your transactions involving the Company's securities, including gifts, transfers, pledges and transactions pursuant to a trading plan, both prior to the transaction (to confirm compliance with pre-clearance procedures, if applicable) and on the date of the transaction.

1.3 Personal Responsibility. The obligation to file Section 16 reports, and to otherwise comply with Section 16, is personal. The Company is not responsible for an individual's failure to comply with Section 16 requirements.

11. AMENDMENT

11.1 The Company is committed to continuously reviewing and updating this Policy and any other Company policies and procedures. The Company therefore reserves the right to amend, alter or terminate this Policy at any time and for any reason, subject to applicable law.

12. EXPECTATIONS

12.1 This Policy will be made available to all Company board members and employees when they commence service with the Company, and thereafter will be made available to all board members and employees via the Company's internal communication channels. A current copy of the Company's policies regarding insider trading may be obtained by contacting the Compliance Officer. You are required to acknowledge that you understand, and agree to comply with, this Policy. If you have any questions about this Policy, please contact the Company's Compliance Officer (General Counsel).

* * *

Nothing in this Policy creates or implies an employment contract or term of employment.

The policies in this Policy do not constitute a complete list of Company policies or a complete list of the types of conduct that can result in discipline, up to and including discharge.

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 (No. 333-291314) of BillionToOne, Inc. of our report dated March 11, 2026 relating to the financial statements, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP
Florham Park, New Jersey
March 11, 2026

Exhibit 31.1

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 Annual Report on Form 10-K 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: March 11, 2026

By: /s/ Oguzhan Atay
Oguzhan Atay
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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 Annual Report on Form 10-K 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: March 11, 2026

By: /s/ Ross Taylor
Ross Taylor
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

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 Annual Report of BillionToOne, Inc. (the "Company") on Form 10-K for the period ending December 31, 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: March 11, 2026

By: /s/ Oguzhan Atay
Oguzhan Atay
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

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 Annual Report of BillionToOne, Inc. (the "Company") on Form 10-K for the period ending December 31, 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: March 11, 2026

By: /s/ Ross Taylor

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

1. PURPOSE

1.1 The purpose of this Policy is to describe the circumstances in which Executive Officers will be required to repay or return Erroneously Awarded Compensation to members of the Company Group. This Policy is designed to comply with, and shall be interpreted to be consistent with, Section 10D of the Securities Exchange Act of 1934, as amended, Rule 10D-1 promulgated thereunder and the Listing Standards. Each Executive Officer shall be required to sign and return to the Company the Acknowledgment Form attached hereto as Exhibit A pursuant to which such Executive Officer will agree to be bound by the terms of and comply with this Policy.

2. SCOPE

2.1 This procedure applies to all Executive Officers of the Company, as defined herein.

3. DEFINITIONS

3.1 As used in this Policy, the following capitalized terms shall have the meanings set forth below.

(a) "***Accounting Restatement***" shall mean an accounting restatement of the Company's financial statements due to the Company's material noncompliance with any financial reporting requirement under U.S. securities laws, including any required accounting restatement (i) that corrects an error in previously issued financial statements that is material to the previously issued financial statements (a "Big R" restatement), or (ii) that corrects an error that is not material to previously issued financial statements, but would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period (a "little r" restatement). An Accounting Restatement does not include situations in which financial statement changes did not result from material noncompliance with financial reporting requirements, such as, but not limited to, retrospective: (i) application of a change in accounting principles; (ii) revision to reportable segment information due to a change in the structure of the Company's internal organization; (iii) reclassification due to a discontinued operation; (iv) application of a change in reporting entity, such as from a reorganization of entities under common control; (v) adjustment to provisional amounts in connection with a prior business combination; and (vi) revision for stock splits, reverse stock splits, stock dividends or other changes in capital structure.

(b) "***Board***" shall mean the Board of Directors of the Company.

(c) "***Clawback Eligible Incentive Compensation***" shall mean, in connection with an Accounting Restatement and with respect to each individual who served as an Executive Officer

at any time during the applicable performance period for any Incentive-Based Compensation (whether or not such Executive Officer is serving at the time the Erroneously Awarded Compensation is required to be repaid to the Company Group), all Incentive-Based Compensation Received by such Executive Officer (i) on or after the Effective Date, (ii) after beginning service as an Executive Officer, (iii) while the Company has a class of securities listed on a national securities exchange or a national securities association, and (iv) during the applicable Clawback Period.[1]

(d) "***Clawback Period***" shall mean, with respect to any Accounting Restatement, the three completed fiscal years of the Company immediately preceding the Restatement Date and any transition period (that results from a change in the Company's fiscal year) of less than nine months within or immediately following those three completed fiscal years.

(e) "***Committee***" shall mean the Compensation Committee of the Board.

(f) "***Company***" shall mean BillionToOne, Inc., a Delaware corporation.

(g) "***Company Group***" shall mean the Company, together with each of its direct and indirect subsidiaries.

(h) "***Effective Date***" shall mean the effective date of this Policy, which date is the date the Company becomes a public reporting company under the Exchange Act.

(i) "***Erroneously Awarded Compensation***" shall mean, with respect to each Executive Officer in connection with an Accounting Restatement, the amount of Clawback Eligible Incentive Compensation that exceeds the amount of Incentive-Based Compensation that otherwise would have been Received had it been determined based on the restated amounts as reflected in the Accounting Restatement, computed without regard to any taxes paid. For Incentive-Based Compensation based on (or derived from) stock price or total shareholder return, where the amount of Erroneously Awarded Compensation is not subject to mathematical recalculation directly from the information in the applicable Accounting Restatement, the amount shall be determined by the Committee based on a reasonable estimate of the effect of the Accounting Restatement on the stock price or total shareholder return upon which the Incentive-Based Compensation was Received (in which case, the Company shall maintain documentation of such determination of that reasonable estimate and provide such documentation to Nasdaq).

[1] Recovery of compensation is not required (1) with respect to any compensation Received while an individual was serving in a non-executive capacity prior to becoming an Executive Officer or (2) from any individual who is an Executive Officer on the Restatement Date but who was not an Executive Officer at any time during the performance period for which the Incentive-Based Compensation is Received.

(j) "***Executive Officer***" shall mean each individual who is or was designated as an "officer" of the Company in accordance with 17 C.F.R. 240.16a-1(f). Identification of an executive officer for purposes of this Policy would include, at a minimum, executive officers identified pursuant to 17 C.F.R. 229.401(b). As of the Effective Date (and subject to later amendments to the above-referenced rules), Executive Officer covers the Company's president, principal financial officer, principal accounting officer (or if there is no such accounting officer, the controller), any vice-president of the Company in charge of a principal business unit, division or function (such as sales, administration or finance), any other officer who performs a significant policy-making function, or any other person (including any executive officer of the Company's affiliates including a parent or subsidiary of the Company) who performs similar policy-making functions for the Company.

(k) "***Financial Reporting Measures***" shall mean measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements (including "non-GAAP financial measures," such as those appearing in earnings releases), and any measures that are derived wholly or in part from such measures. For the avoidance of doubt, a Financial Reporting Measure need not be presented within the Company's financial statements or included in a filing with the SEC. Stock price and total shareholder return shall for purposes of this Policy also be considered Financial Reporting Measures.

(l) "***Incentive-Based Compensation***" shall mean any compensation that is granted, earned or vested based wholly or in part upon the attainment of a Financial Reporting Measure. For the sake of clarity, examples of compensation that are not considered Incentive-Based Compensation include, but are not limited to: (i) base salaries; (ii) discretionary cash bonuses; (iii) awards (either of cash or equity) that are based solely upon subjective, strategic or operational metrics or measures; and (iv) equity awards that vest solely upon continued service or the passage of time.[2]

[2] The Dodd-Frank statutory language specifies that Incentive-Based Compensation to which recovery must apply under a compliant clawback policy "includ[es] stock options awarded as compensation." Importantly, stock options (and similar equity awards, such as restricted stock, RSUs and SARs) would be treated as Incentive-Based Compensation only if the granting, vesting or earning of the award is based, in whole or in part, on satisfying a Financial Reporting Measure (FRM) performance goal. Therefore, equity awards that are granted irrespective of attaining any FRM performance goal and vest solely on the basis of continued service or the passage of time would not be considered Incentive-Based Compensation. The strike price of an option, on its own, would not make an option Incentive-Based Compensation subject to the clawback policy (even though the option is only in-the-money when the Company's stock price is above the strike price). In addition, any incentive awards that are granted, earned or vested solely on the basis of whether nonfinancial (e.g., strategic, operational or subjective) measures have been achieved would not be subject to the clawback policy.

(m) "***Listing Standards***" shall mean Nasdaq Listing Rule 5608.

(n) "***Nasdaq***" shall mean The Nasdaq Stock Market.

(o) "***Policy***" shall mean this Policy for the Recovery of Erroneously Awarded Compensation, as the same may be amended, restated, supplemented or otherwise modified from time to time.

(p) "***Received***" shall, with respect to any Incentive-Based Compensation, mean actual or deemed receipt, and Incentive-Based Compensation shall be deemed received in the Company's fiscal period during which the Financial Reporting Measure specified in the Incentive-Based Compensation award is attained, even if grant or payment of the Incentive-Based Compensation occurs after the end of that period.

(q) "***Restatement Date***" shall mean the earlier to occur of (i) the date the Board, a committee of the Board or the officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare an Accounting Restatement, or (ii) the date a court, regulator or other legally authorized body directs the Company to prepare an Accounting Restatement, in each case regardless of if or when the restated financial statements are filed.

(r) "***SEC***" shall mean the U.S. Securities and Exchange Commission

4. RECOVERY OF ERRONEOUSLY AWARDED COMPENSATION

4.1 In the event the Company is required to prepare an Accounting Restatement, the Committee shall determine the amount of any Erroneously Awarded Compensation for each Executive Officer in connection with such Accounting Restatement, shall thereafter provide each Executive Officer with a written notice containing the amount of Erroneously Awarded Compensation and a demand for repayment or return, as applicable, and shall take all other actions necessary and appropriate to recover such Erroneously Awarded Compensation from the applicable Executive Officers reasonably promptly.

4.2 The Committee shall determine, in its sole discretion, the timing and method for recovering Erroneously Awarded Compensation reasonably promptly based on all applicable facts and circumstances and taking into account the time value of money and the cost to shareholders of delaying recovery. Such methods may include, without limitation, (i) seeking reimbursement of all or part of any cash or equity-based award, (ii) cancelling prior cash or equity-based awards, whether vested or unvested or paid or unpaid, (iii) cancelling or offsetting against any planned future cash or equity-based awards, (iv) forfeiture of deferred compensation, subject to compliance with Section 409A of the Internal Revenue Code and the regulations

promulgated thereunder, and (v) any other method authorized by applicable law or contract. Subject to compliance with any applicable law, the Committee may effect recovery under this Policy (i) from any amount otherwise payable to the Executive Officer, including amounts payable to such individual under any otherwise applicable Company plan or program, including base salary, bonuses or commissions, and compensation previously deferred by the Executive Officer, and (ii) from any amount of compensation approved, awarded, granted, payable or paid to the Executive Officer prior to, on or after the effective date of the Listing Standards. For the avoidance of doubt, except as set forth in Section 4.4 below, in no event may the Company Group accept an amount that is less than the amount of Erroneously Awarded Compensation in satisfaction of an Executive Officer's obligations hereunder.

4.3 To the extent that an Executive Officer fails to repay all Erroneously Awarded Compensation to the Company Group when due, the Company shall, or shall cause one or more other members of the Company Group to, take all actions reasonable and appropriate to recover such Erroneously Awarded Compensation from the applicable Executive Officer.[3] The applicable Executive Officer shall be required to reimburse the Company Group for any and all expenses reasonably incurred (including legal fees) by the Company Group in recovering such Erroneously Awarded Compensation in accordance with the immediately preceding sentence.

4.4 Notwithstanding anything herein to the contrary, the Company shall not be required to recover Erroneously Awarded Compensation from any Executive Officer if the following conditions are met and the Committee determines that recovery would be impracticable:

(a) The direct expenses paid to a third party to assist in enforcing the Policy against an Executive Officer would exceed the amount to be recovered, after the Company has made a reasonable attempt to recover the applicable Erroneously Awarded Compensation, documented such attempt(s) and provided such documentation to Nasdaq;

(b) Recovery would violate home country law of the Company where that law was adopted prior to November 28, 2022, after the Company has obtained an opinion of home country counsel, acceptable to Nasdaq, that recovery would result in such a violation and a copy of the opinion is provided to Nasdaq; or

[3] Unpaid amounts will be subject to public disclosure in the Company's proxy statement, including (i) the aggregate dollar amount of Erroneously Awarded Compensation that remains outstanding at the end of the last completed fiscal year and (ii) for each current and former Named Executive Officer, the dollar amount of outstanding Erroneously Awarded Compensation still owed that had been outstanding for 180 days or longer since the date the Company determined the amount the officer owed.

(c) Recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company Group, to fail to meet the requirements of 26 U.S.C. 401(a)(13) or 26 U.S.C. 411(a) and regulations thereunder.

5. REPORTING AND DISCLOSURE

5.1 The Company shall file all disclosures with respect to this Policy in accordance with the requirements of the federal securities laws, including the disclosure required by the applicable SEC filings. The Company shall also file a copy of this Policy and any amendments thereto as an exhibit to its annual report on Form 10-K.

6. NO INDEMNIFICATION OF EXECUTIVE OFFICERS

6.1 Notwithstanding the terms of any indemnification or insurance policy or any contractual arrangement with any Executive Officer that may be interpreted to the contrary, no member of the Company Group shall be permitted to indemnify any Executive Officer against, or pay or reimburse the premiums for an insurance policy to cover, (i) the loss of any Erroneously Awarded Compensation that is repaid, returned or recovered pursuant to the terms of this Policy, or (ii) any claims relating to the Company Group's enforcement of its rights under this Policy. Further, no member of the Company Group shall enter into any agreement that exempts any Incentive-Based Compensation from the application of this Policy or that waives the Company Group's right to recovery of any Erroneously Awarded Compensation, and this Policy shall supersede any such agreement (whether entered into before, on or after the Effective Date).

7. COMMITTEE INDEMNIFICATION

7.1 Any members of the Committee, and any other members of the Board who assist in the administration of this Policy, shall not be personally liable for any action, determination or interpretation made with respect to this Policy and shall be fully indemnified by the Company to the fullest extent under applicable law and Company policy with respect to any such action, determination or interpretation. The foregoing sentence shall not limit any other rights to indemnification of the members of the Board under applicable law or Company policy.

8. EFFECTIVE DATE

8.1 This Policy shall be effective as of the Effective Date.

9. AMENDMENT; TERMINATION

9.1 The Committee may amend, modify, supplement, rescind or replace all or any portion of this Policy at any time and from time to time in its discretion and shall amend this Policy as it deems necessary, including as and when it determines that it is legally required by any federal securities laws, SEC rule or the rules of any national securities exchange or national securities association on which the Company's securities are listed. The Committee may terminate this Policy at any time. Notwithstanding anything in this Section 9 to the contrary, no amendment or termination of this Policy shall be effective if such amendment or termination would (after taking into account any actions taken by the Company contemporaneously with such amendment or termination) cause the Company to violate any federal securities laws, SEC rule or the rules of any national securities exchange or national securities association on which the Company's securities are listed.

10. OTHER RECOUPMENT RIGHTS; COMPANY CLAIMS

10.1 The Committee intends that this Policy will be applied to the fullest extent of the law and with respect to all Incentive-Based Compensation granted to an Executive Officer, whether pursuant to a pre-existing contract or arrangement, or one that is entered into after the Effective Date. Any right of recoupment under this Policy is in addition to, and not in lieu of, any other remedies or rights of recoupment that may be available to the Company Group under applicable law, regulation or rule or pursuant to the terms of any similar policy in any employment agreement, equity award agreement or similar agreement and any other legal remedies available to the Company Group.[4]

10.2 Nothing contained in this Policy, and no recoupment or recovery as contemplated by this Policy, shall limit any claims, damages or other legal remedies the Company or any of its affiliates may have against an Executive Officer arising out of or resulting from any actions or omissions by the Executive Officer.

11. SUCCESSORS

11.1 This Policy shall be binding and enforceable against all Executive Officers and their beneficiaries, heirs, executors, administrators or other legal representatives.

12. EXPECTATIONS

[4] In circumstances in which both the Dodd-Frank and SOX Section 304 clawback provisions could provide for recovery of the same Incentive-Based Compensation, if an Executive Officer reimburses the Company pursuant to SOX, the amount recoverable under the Company's Dodd-Frank clawback policy should be deducted by the amount of the reimbursement. The SEC notes that recovery under the Company's Dodd-Frank clawback policy would not preclude recovery under SOX to the extent any applicable amounts have not been reimbursed to the Company.

12.1 If you have any questions about this Policy, please contact the BillionToOne General Counsel. Any requests for exceptions to this Policy must be submitted in writing.

13. APPENDIX

1.1 Appendix I: ACKNOWLEDGEMENT FORM

Exhibit A

BILLIONTOONE, INC. POLICY FOR THE

RECOVERY OF ERRONEOUSLY AWARDED COMPENSATION

ACKNOWLEDGMENT FORM

By signing below, the undersigned acknowledges and confirms that the undersigned has received and reviewed a copy of the BillionToOne, Inc. Policy for the Recovery of Erroneously Awarded Compensation (as may be amended, restated, supplemented or otherwise modified from time to time, the "***Policy***"). Capitalized terms used but not otherwise defined in this Acknowledgment Form (this "***Acknowledgment Form***") shall have the meanings ascribed to such terms in the Policy.

By signing this Acknowledgment Form, the undersigned acknowledges and agrees that the undersigned is and will continue to be subject to the Policy and that the Policy will apply both during and after the undersigned's employment with the Company Group. Further, by signing below, the undersigned agrees to abide by the terms of the Policy, including, without limitation, by promptly returning any Erroneously Awarded Compensation (as defined in the Policy) to the Company Group to the extent required by, and in a manner permitted by, the Policy. In the event of any inconsistency between the Policy and the terms of any employment agreement to which the undersigned is a party, or the terms of any compensation plan, program or agreement under which any compensation has been granted, awarded, earned or paid, the terms of the Policy shall govern.

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Date