As submitted confidentially to the Securities and Exchange Commission on June 20, 2025. This draft registration statement has not been filed publicly with the Securities and Exchange Commission and all information contained herein remains strictly confidential.

Registration Statement No. 333-

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

BILLIONTOONE, INC.

(Exact name of Registrant as specified in its charter)

Delaware	**8071**	**81-1082020**
(State or other jurisdiction of incorporation or organization)	**(Primary Standard Industrial Classification Code Number)**	**(I.R.S. Employer Identification Number)**

1035 O'Brien Drive
Menlo Park, CA 94025
(650) 460-2551
(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)

Oguzhan Atay
Chief Executive Officer
BillionToOne, Inc.
1035 O'Brien Drive
Menlo Park, CA 94025
(650) 460-2552
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

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Approximate date of commencement of proposed sale to the public: As soon as practicable after this Registration Statement is declared effective.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. ☐

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

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 7(a)(2)(B) of the Securities Act. ☐

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

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The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to Completion, dated , 2025

Preliminary prospectus

shares



Class A common stock

This is an initial public offering of shares of Class A common stock of BillionToOne, Inc. We are offering shares of our Class A common stock to be sold in this offering. The initial public offering price is expected to be between $ and $ per share.

Prior to this offering, there has been no public market for our common stock. We intend to apply to list our Class A common stock on the Nasdaq Global Market under the symbol "BLLN," and this offering is contingent upon obtaining such approval.

Following this offering, we will have two classes of common stock: Class A common stock and Class B common stock. The rights of the holders of Class A common stock and Class B common stock are identical, except with respect to voting, conversion and transfer rights. Each share of Class A common stock is entitled to one vote per share. Each share of Class B common stock is entitled to 10 votes per share and is convertible at any time into one share of Class A common stock. See the section titled "Description of capital stock." Oguzhan Atay, our Chief Executive Officer and Co-Founder, and David Tsao, our Chief Technology Officer and Co-Founder, will beneficially own 100% of our outstanding Class B common stock and, as a result, will together beneficially own approximately % of the voting power of our outstanding capital stock immediately following this offering, assuming no exercise of the underwriters' option to purchase additional shares of Class A common stock. As a result, following this offering, our Co-Founders, together, may have significant influence over the outcome of matters submitted to our stockholders for approval, including the election of our directors and the approval of any change of control transaction.

We are an "emerging growth company" as defined under the U.S. federal securities laws and, as such, have elected to comply with certain reduced public company reporting requirements. See the section titled "Prospectus summary—Implications of being an emerging growth company."

	Per share	Total
Initial public offering price	$	$
Underwriting discounts and commissions(1)	$	$
Proceeds to BillionToOne, Inc., before expenses	$	$

(1) See the section titled "Underwriting" for a description of the compensation payable to the underwriters.

At our request, the underwriters have reserved up to 5% of the shares of Class A common stock being offered by this prospectus for sale, at the initial public offering price, to our officers, directors and employees through a directed share program. See the section titled "Underwriting – Directed share program."

We have granted the underwriters an option for a period of 30 days to purchase up to additional shares of Class A common stock.

Investing in our Class A common stock involves a high degree of risk. See "Risk factors" beginning on page 19.

Neither the Securities and Exchange Commission nor any other state securities commission has approved or disapproved of these securities or passed on the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the shares to purchasers on or about , 2025.

J.P. Morgan **Piper Sandler** **Jefferies** **William Blair**
Stifel **Wells Fargo Securities** **BTIG**

, 2025

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EXPLANATORY NOTE

Pursuant to the applicable provisions of the Fixing America's Surface Transportation Act, we are omitting our unaudited financial statements as of and for the three months ended March 31, 2025 and 2024. While this financial information is otherwise required by Regulation S-X, we reasonably believe that it will not be required to be included in the prospectus at the time of the contemplated offering. We intend to amend this registration statement to include all financial information required by Regulation S-X at the date of such amendment before distributing a preliminary prospectus to investors.

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BILLION TO ONE

We strive to remove the fear of the unknown.

Our revolutionary technology allows us to push beyond the current limitations in diagnostics so we can detect disease one molecule at a time.

We provide patients with powerful and precise information about the state of their health for themselves and their children.

And it's only the beginning of what we seek to do.

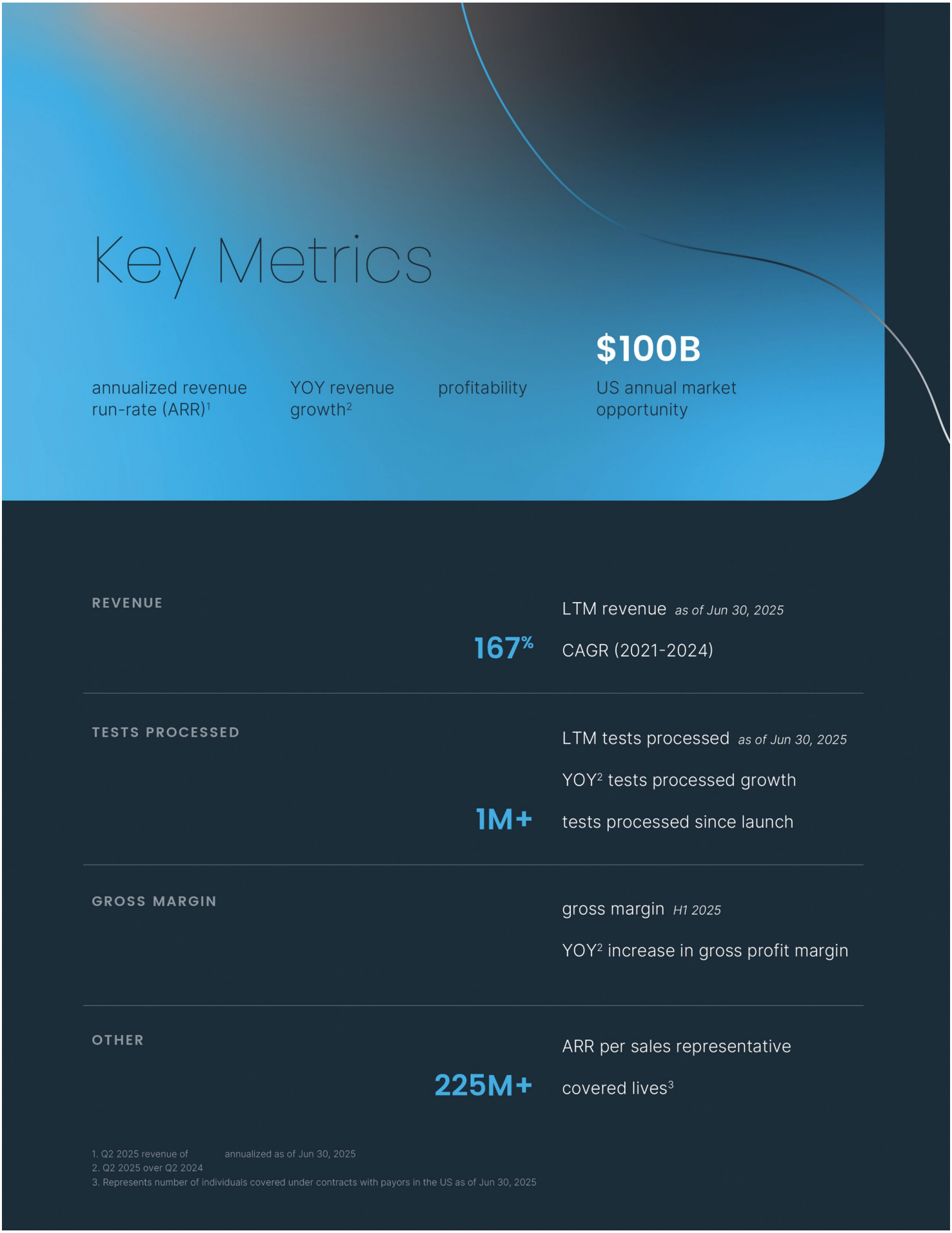

Key Metrics
annualized revenue run-rate (ARR)[1]
YOY revenue growth[2]
profitability
$100B
US annual market opportunity
REVENUE
LTM revenue as of Jun 30, 2025
167%
CAGR (2021-2024)
TESTS PROCESSED
LTM tests processed as of Jun 30, 2025
YOY[2] tests processed growth
1M+
tests processed since launch
GROSS MARGIN
gross margin H1 2025
YOY[2] increase in gross profit margin
OTHER
ARR per sales representative
225M+
covered lives[3]
1. Q2 2025 revenue of annualized as of Jun 30, 2025
2. Q2 2025 over Q2 2024
3. Represents number of individuals covered under contracts with payors in the US as of Jun 30, 2025

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Our Impact



Marina was excited about her pregnancy at 9 weeks.*

That was when she took the BillionToOne's **UNITY Fetal Risk™ Screen** test, which revealed she was a carrier for cystic fibrosis. However, the same report also showed her baby had an extremely low risk of having the disease (1 in 10,000). While initially surprised, Marina felt much less anxious and more at ease with her pregnancy than she would have with traditional carrier screening. Traditional methods would have only identified her carrier status and required her partner to undergo further testing to assess the baby's risk.

Juan was unfortunately diagnosed with stage IV lung cancer.*

After his initial biopsy, Juan's doctor requested BilliontoOne's **Northstar Select®** blood test to help him determine which treatment would work best. Northstar Select uncovered *EGFR* mutation at 0.05% variant allele fraction (VAF), a highly actionable cancer variant that has a known targeted therapy. Cancers at this low level of VAF are often missed by other cancer tests. Thanks to Northstar Select, Juan was able to start on the best therapy for his cancer and his doctor can easily monitor his progress using **Northstar Response®**.



* Actual customer stories. Names have been changed to preserve patients' privacy and the photos are actor portrayals.

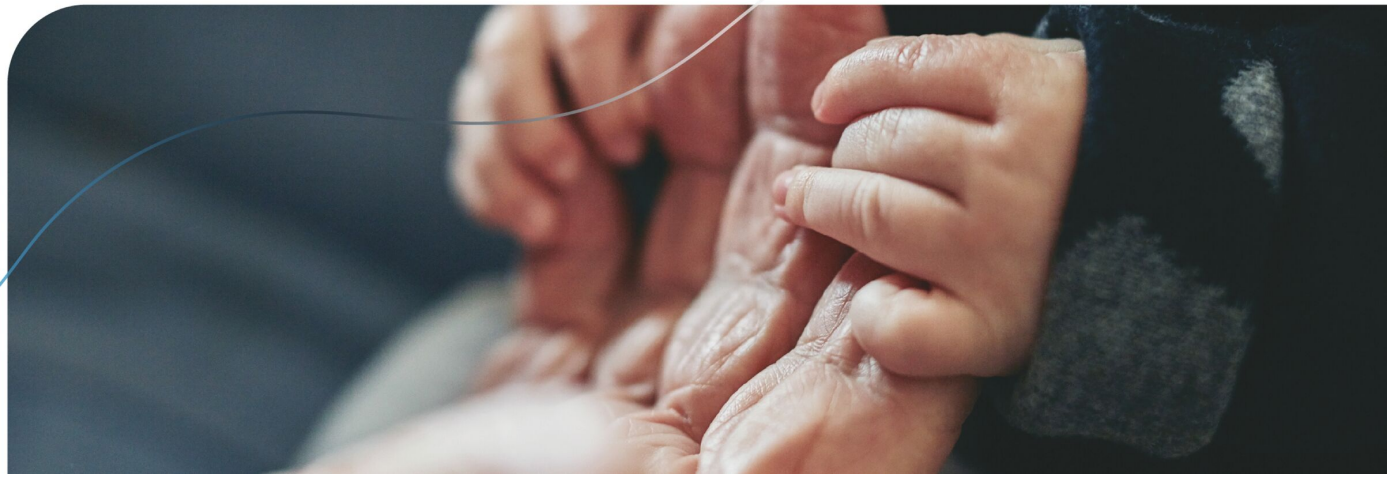


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Our Revenue Growth

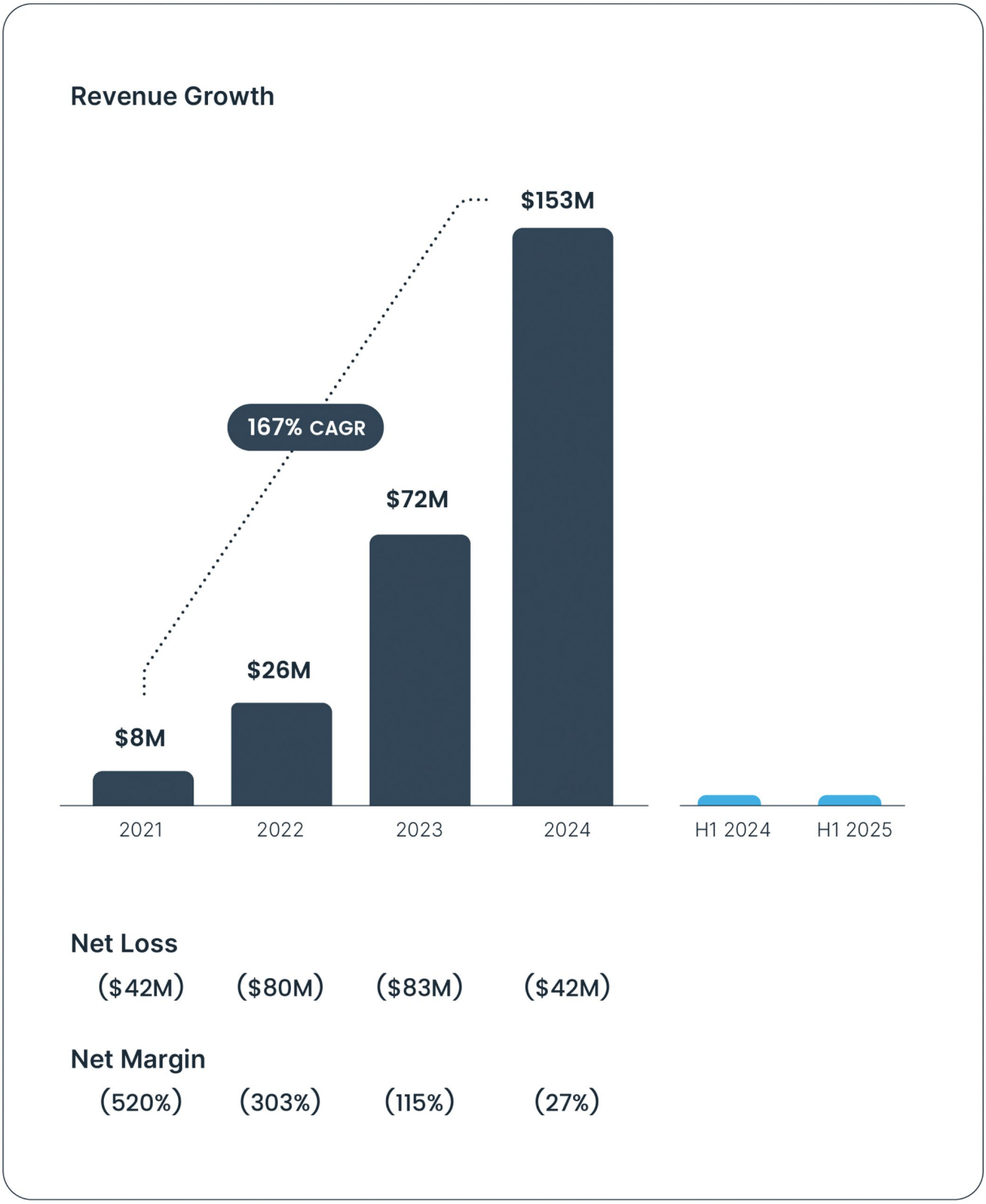


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Through and including , 2025 (the 25th day after the date of this prospectus), all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

We have not, and the underwriters have not, authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectus prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the shares of Class A common stock offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus or in any applicable free writing prospectus is current only as of its date, regardless of its time of delivery or any sale of shares of our Class A common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside the United States: Neither we nor any of the underwriters have taken any action that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons who have come into possession of this prospectus in a jurisdiction outside the United States are required to inform themselves about and to observe any restrictions relating to this offering and the distribution of this prospectus.

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Letter from Our Co-Founder & CEO

BillionToOne was born from a single question that continues to drive everything we do: What is the most challenging, most impactful global healthcare problem that physics allows us to solve, but that no one else will tackle?

As interdisciplinary scientists with PhDs, we were not interested in incremental improvements or well-trodden paths. My co-founder, David, and I wanted to confront problems of true consequence and provide solutions that could transform millions of lives. This pursuit led us to sickle cell disease and beta-thalassemia. These are the most common genetic disorders worldwide and classified by the World Health Organization as among the greatest global healthcare burdens.

Prenatal detection of these conditions required us to develop a novel technology capable of reaching the physical limit of detection and precision. However, this challenge did not stop us. In fact, it invigorated our resolve to create solutions for these burdensome genetic conditions.

We knew that if we developed such a technology, we would unlock the full potential of cell-free DNA, the most remarkable biomarker that represents every tissue in blood. It was only through our interdisciplinary approach that combines physics, applied mathematics, and molecular biology that we have been able to invent a breakthrough technology that could tackle this problem.

Since then, our diagnostics innovations have already changed the diagnostics paradigm in multiple areas. Just from a single maternal blood sample, our prenatal tests detect whether a developing baby is at risk for many severe but actionable diseases, early on during pregnancy. Our oncology tests first detect the most important features of a tumor that determine the best course of therapy for that patient from a blood draw. They then enable the physicians to know precisely how well the therapy is working, and when it stops working, often many months ahead of imaging scans.

While we have state-of-the-art laboratories today, we have never forgotten that we started with half a bench at a Stanford University accelerator space. It was more difficult to raise the initial $300,000 than the $300,000,000 that followed it. Our name, BillionToOne, reflects our technological breakthrough as we believe it is the only platform that can detect a single DNA letter of a single DNA molecule among the three billion other letters in our genome. But, it also reflects our founding spirit. The domain was simply the only relevant one that we could acquire for just $12. And we refused to spend more for a name at that stage.

This decision is an example of a set of principles that have guided our growth to becoming a pioneer in precision diagnostics. These principles are not only management's philosophy. They are the operating system of our company and foundation of our success.

Our Guiding Principles

- *Relentless resourcefulness.* In our earliest days, we traveled to Turkey to collect the first specimens from pregnant patients and to India, where beta-thalassemia is much more common, to conduct our first clinical studies. It was an unnerving process every time we cleared customs with our reagents, knowing that each sample we can test represented not just data points, but a crucial step toward helping real families facing devastating genetic conditions. This was not just about frugality. This and many similar examples of resourcefulness ended up significantly accelerating our progress.

- *Patients-first.* The weight of what we do has been clear to us from the very early days when we started receiving tests not just for general screening, but from high-risk pregnant mothers who already had previous babies with these severe conditions and wanted to rely on us to avoid amniocentesis. In fact, our first-ever clinical test was for SMA, a devastatingly progressive condition in which every day matters for treatment efficacy. I vividly remember doing a custom report design with David until 2 a.m. to best represent our result. While we have automated almost all analysis and reporting over time, we maintain this personal touch to this day. Our genetic counselors, scientists, and laboratory directors, and sometimes still I, personally look at individual patient data when needed.

- *Audacious goals.* We set targets that initially seem impossible. In 2020, we set a small set of ambitious goals that we wanted to achieve by 2025. These goals ranged from changing medical guidelines to processing one million molecular diagnostic tests. At the time, we were in a tiny lab and even tinier office. Our daily test volume was approximately five tests per day, and our small team would 'high five' each time we were notified with a ping indicating a sample was picked up. Even our executive team thought our 5-year goals bordered on fantasy. However, each sample represented a patient receiving insights that could change the course of their healthcare journey, invigorating us to push harder. By March 2025, we conducted our millionth test and achieved every one of our seemingly impossible 2025 goals, by breaking them down into quarterly milestones and executing with precision.

- *Disciplined and focused.* Achieving such audacious goals has only been possible because we have been ruthless in saying "No" to any and all distractions. We did not get distracted by early-stage M&A discussions, investment outreaches outside of fundraising periods, seemingly lucrative partnerships, and me-too product expansions that could generate significant additional revenue. Anything that was outside the scope of our 5-year goals was not worked on.

- *Pressure is a privilege.* Our executive team adopts the motto, “pressure is a privilege.” If you are asked to deliver stretch goals, the implication is that we trust in your abilities to get the job done. We have found this trust to be well placed. Every time our executives are asked to deliver on ambitious goals, they see it as a badge of trust. And every time they run into a problem, they see it as an opportunity. When COVID-19 resulted in Ob/Gyn clinics restricting access to sales reps threatening our survival, we did not retreat. At a time that the US government had limited N95 masks, we were able to find and import them, preserving our ability to have safe conversations with the Ob/Gyns. We grew our test volume more than 10x during 2020, surpassing every quarterly goal that we had set before COVID-19. More recently, when we set a goal to decrease our COGS by approximately ~20% in a single year, instead of remarking on the difficulty of the goal, we broke it down to pieces, worked together as a team, and not only achieved but surpassed this challenging goal. This mindset has become one of our core strengths.

- *Step-by-step deliberate approach.* While others in our industry poured hundreds of millions of dollars into fully automated labs that locked down their assays and made further improvements hugely expensive, we identified bottlenecks systematically, automating our facilities step-by-step. This deliberate progression has allowed us to remain nimble and build a proprietary and scalable laboratory infrastructure while continuously improving our products. It also provided us with the financial discipline that has become a competitive advantage.

- *20-Mile March.* We embrace what Jim Collins calls the "20-Mile March" philosophy. We play the long game with fanatical discipline and relentless execution regardless of external conditions. We do not overextend in good times or retreat in challenging ones. When the markets were rewarding growth at all costs, we prioritized sustainable growth over flashy but hollow and expensive expansion. Even during the darkest days of market volatility, we maintained our pace of growth, continuing to hire and grow past our competitors. This approach has enabled us to achieve what many thought impossible: growing our revenue by more than % year-over-year while trending to achieve positive operating income (after adjusting for stock based compensation expense) — a feat almost unheard of in molecular diagnostics.

- *1%’ers.* Our hiring process is so rigorous that we select only 1% of all applicants. But this is not just about hiring the smartest or most talented people. This is about creating a collaborative culture that pushes the limits of what each individual could achieve on their own. This is about building a team that is empowered and capable of solving problems that have stumped the entire industry for decades. This is the philosophy of ONE. Walking through our labs and offices, you can feel the difference. Challenges are met not with complaints but with creative solutions. People move with purpose. This is not just another healthcare company; it is a gathering of minds determined to rewrite what is possible in molecular diagnostics.

We believe that these guiding principles enabled us to achieve a unique profile that combines powerful technology, category-defining products, and a differentiated financial position of % year-over-year growth and emerging profitability. We believe that these elements will make BillionToOne a generational company that can redefine the industry and achieve our goal of becoming the first molecular diagnostics company in the S&P 500.

The Opportunity & Long-Term Vision

The precision diagnostics market represents one of the greatest opportunities in healthcare today. As our understanding of the disease processes deepens, the ability to deliver precise, actionable information to clinicians becomes increasingly valuable. Our technology platform enables us to unlock this information and gives us an advantage to succeed in multiple high-growth markets, with our current products addressing a more than $20 billion total addressable market (TAM), while our planned pipeline of products in development can increase this to over $100 billion.

These numbers only hint at our true opportunity. The true opportunity is to not only change the standard of care for diagnostics but also enable new treatment paradigms. We are already seeing this. Our partnership with Johnson & Johnson has the potential to enable a therapy for hemolytic disease in fetuses and newborns, a high-risk condition that can result in fetal death. We are hearing more and more about pregnant mothers taking CF therapies for their affected babies during pregnancy, and their CF newborns not needing NICU stays or sometimes even passing newborn screening, an incredible outcome. Our goal is to make such success stories standard-of-care in the next five years.

Our next five-year goals for 2030 are much more ambitious and, in some instances, more than 10 times higher than 2025 goals we have already achieved. Yet, this time, our current investors who have witnessed our journey and executives on our team firmly believe they are achievable. They believe because they have seen our track record and know what is possible when a unique combination of talent, culture, and technology converges on a mission that matters.

I personally believe that when we look back a decade from now, we will see that the largest impact on pregnancy and cancer care of the past 100 years will have come from BillionToOne, powered by our technology and our people. That belief is what drives us. That is why we work tirelessly.

Why Go Public Now

This offering represents a pivotal moment in our journey. The capital we raise will accelerate our research and development initiatives, expand our commercial footprint, and enable us to bring our life-changing diagnostics to more patients.

But this offering is about more than capital. It is about setting the stage for our next phase of growth and impact. It is about building the foundation for a company that will stand among the most consequential healthcare innovators of our time.

We are not building just another successful company; we are changing the very landscape of healthcare. Millions of patients whose lives will be transformed may never know our name, but they will benefit from what we have built.

We invite you to join us in writing this next chapter of medical history.

Sincerely,



Oguzhan Atay, PhD
Co-Founder & CEO

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Glossary

As used in this prospectus, unless we state otherwise or the context otherwise requires:

ACOG: American College of Obstetricians and Gynecologists

ASP: Average selling price—The average payment BillionToOne receives per test (inclusive of any non-payments)

CF: Cystic fibrosis—A genetic disorder that can be detected by UNITY tests

cfDNA: Cell-free DNA—Extracellular DNA in blood plasma

CNV: Copy number variant—A variation in gene copies that Northstar Select can detect

ctDNA: Circulating tumor DNA—Cell-free DNA released from tumor cells

MolDX: Molecular Diagnostic Services program – establishes coverage and reimbursement for Medicare beneficiaries

MRD: Minimal residual disease—cfDNA remaining after surgery or treatment

NGS: Single-molecule next-generation sequencing

NIPT: Non-invasive prenatal testing—Testing that uses cell-free DNA from maternal blood to assess fetal genetic risks

PCR: Polymerase Chain Reaction- a laboratory technique that amplifies, or creates multiple copies of, a specific DNA sequence

QCT: Quantitative Counting Templates—BillionToOne's patented synthetic DNA fragments that are the foundation of the smNGS platform

SCD: Sickle cell disease—A hereditary red blood cell disorder that can be detected by UNITY tests

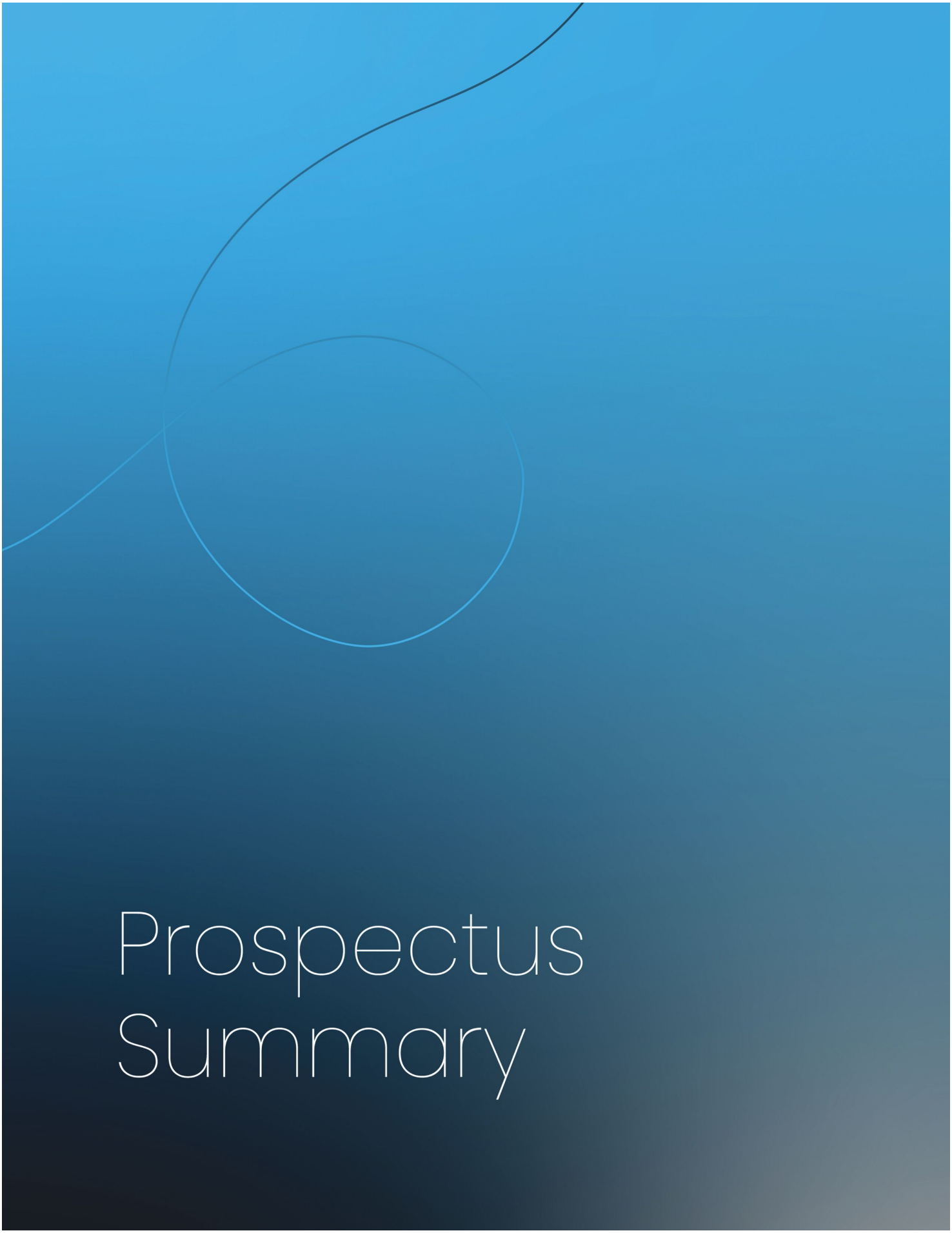
sgNIPT: Single-gene non-invasive prenatal testing—A type of test pioneered by BillionToOne that can detect single-gene disorders without paternal sample

SMA: Spinal muscular atrophy—A genetic disorder that can be detected by UNITY tests

smNGS: Single-molecule next-generation sequencing—BillionToOne's platform technology that enables detection and quantification of blood-based genetic targets with single molecule sensitivity

SNV: Single nucleotide variant—A variation in a gene's sequence that Northstar Select can detect

TMS: Tumor Methylation Score – Northstar Response's metric that measures the quantity of cancer-specific DNA methylation in blood for monitoring response to a cancer therapy


Prospectus
Summary

Prospectus summary

This summary highlights information contained elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before investing in our Class A common stock, you should carefully read this entire prospectus, including our financial statements and the related notes included elsewhere in this prospectus and the information set forth under the sections titled "Risk factors," "Special note regarding forward-looking statements," and "Management's discussion and analysis of financial condition and results of operations." Unless the context otherwise requires the terms "BillionToOne," "company," "our," "us" and "we" in this prospectus to refer to BillionToOne, Inc.

Overview

BillionToOne is transforming healthcare by redefining molecular diagnostics. Our revolutionary single molecule NGS (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 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 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. 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, which we estimate has an annual market opportunity of over $100 billion in the United States alone.

Founded with the mission to remove the fear of the unknown through powerful and accessible smNGS-based diagnostics, we have swiftly transitioned from a research and development (R&D) focused company to a proven commercial organization. In 2019, we launched our first prenatal product, UNITY. UNITY is the first non-invasive prenatal test (NIPT) 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 established ourselves as a leader in the prenatal testing market and expanded our UNITY offering to cover comprehensive prenatal genetic needs from a single maternal blood draw. While we know of competitors working to develop and launch competing NIPTs for recessive conditions, we believe the differentiation of our smNGS technology and 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. 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. To date, we have processed more than one million smNGS-based tests, including tests in the 12 months ended June 30, 2025. For the year ended December 31, 2024, we generated revenue of $152.6 million, representing 113% year-over-year growth, with a gross margin of 53% and net loss of $41.6 million. Our business model has demonstrated improving operational leverage, which we believe will enable us to reach, on a non-GAAP income from operations basis, positive operating income after adjusting for stock based compensation expense for the six months ended June 30, 2025. During this period, we generated revenue of , with a gross margin of and a net income of , representing year-over-year revenue growth. This translates to a net income improvement of approximately , from a net loss of in the six months ended June 30, 2024 to a net income of in the same period in 2025.

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 eliminating biases introduced from next-generation sequencing (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. Moreover, we believe our design-based R&D approach allows us to harness this technology 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. Additionally, while our current products already address an estimated annual

market opportunity of over $20 billion in the United States, we believe that our R&D pipeline could eventually expand this annual addressable market to over $100 billion. 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, demonstrated by limiting our accumulated deficit of $282.2 million as of December 31, 2024, which is a small fraction of the losses incurred by some of our competitors. The important factors resulting in this efficiency are (i) our gross margins of % for the three months ended June 30, 2025, which has increased percentage points year-over-year, (ii) our high sales efficiency driven by differentiated products, with our annualized revenue run-rate per sales representative at over $ million for the three months ended June 30, 2025, and (iii) disciplined operational practices supplemented by automation and AI. 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. 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. Today, we are experiencing another step change as we believe our smNGS platform enables the absolute quantification of cfDNA and we believe overcomes the technical noise that restrains the traditional NGS testing methods used by other diagnostic companies. This breakthrough capability enables our non-invasive diagnostic tests to achieve performance characteristics previously only possible with invasive tissue biopsies from the affected organ.

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 and suite of products

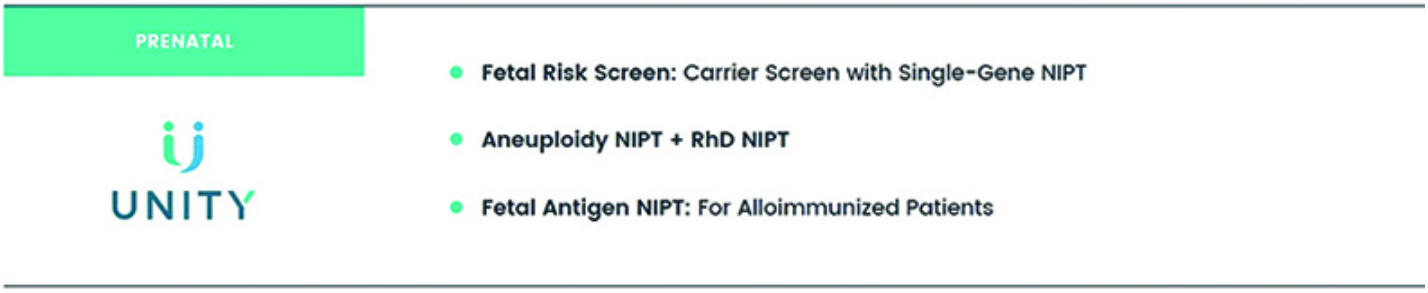
Our product portfolio of ultrasensitive tests touches everyone from the beginning of life, with prenatal genetic testing, to the end of life, with cancer therapy selection and response monitoring.

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.

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. We intend to expand our oncology test offerings into testing of earlier stage cancer patients, including through MRD testing and potentially for early cancer detection.

To date, we have launched multiple products across these large addressable markets. We performed more than smNGS-based tests in the last 12 months ended June 30, 2025, with significant room to further grow test volume in both markets.

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 SCD, alpha thalassemia, beta-thalassemia, CF, and 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 Complete 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. We estimate the prenatal market represents an annual opportunity of over $2.5 billion in the United States.

Oncology products



Non-invasive liquid biopsy tests are a rapidly growing approach to detect and measure tumor DNA, driven by the increasing focus on molecular-targeted cancer treatments. However, current imaging and conventional liquid biopsy approaches present critical shortcomings, including missed actionable mutations and delays in detecting treatment 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. In a head-to-head study presented at American Society of Clinical Oncology (ASCO) annual meeting in 2024, our test demonstrated superior performance by detecting 51% more pathogenic and actionable SNVs and 109% more CNVs than conventional liquid biopsies. Northstar Select targets the therapy selection cancer diagnostics market, which we estimate is an annual United States market opportunity of over $6 billion.

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. Validation studies showed Northstar Response's consistent ability to detect 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 targets the cancer therapy response diagnostics market, which we estimate is an annual United States market opportunity of over $15 billion.

The clinical value of our oncology portfolio is validated by physician adoption. More than 95% of oncologists who order our tests utilize both Northstar Select and Northstar Response in tandem, highlighting their complementarity in guiding cancer care.

Additional opportunities in oncology

We are actively developing additional diagnostic products to address critical needs across the cancer care continuum. 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 estimate the annual United States market opportunity for MRD to be over $30 billion. Longer term, we believe that our smNGS-based technology could address the sensitivity challenges of early-stage cancer detection; however, we have not yet started development in this area. We estimate the annual United States market opportunity for early detection to be over $50 billion.

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 artificial intelligence (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.

While our AI-enabled vision represents the future of our platform, our commercial success today demonstrates the fundamental value of our existing products. Our existing products in prenatal and oncology have already demonstrated strong growth from zero to $ million annualized revenue run-rate (ARR) in six years. As we expand into new and larger markets, we believe that our foundational smNGS platform will position us to become a generational healthcare company.

Our growth strategy

We are driving and leading a paradigm shift within precision diagnostics. Our vision is to leverage our novel 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.
- Build beyond our extensive library of clinical evidence to support favorable coverage and reimbursement.
- Utilize our smNGS platform and R&D capabilities to efficiently expand and improve our portfolio of category-defining molecular diagnostic tests.

- Continue to deploy AI across our entire organization, including laboratory operations, to improve efficiency and productivity.
- Leverage our growing clinical dataset with AI to improve the utility of diagnostics and enable personalized medicine.

Risk factors summary

Our business is subject to a number of risks of which you should be aware before making an investment decision. These risks include the following:

- 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.
- 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.

The summary risk factors described above should be read together with the text of the full risk factors in the section titled "Risk factors" and the other information set forth in this prospectus, including our financial statements and the related notes. The risks summarized above or described in full elsewhere in this prospectus are not the only risks that we face. Additional risks and uncertainties not presently known to us, or that we currently deem to be immaterial, may also materially adversely affect our business, financial condition, results of operations, and future growth prospects.

Channels for disclosure of information

Following the closing of this offering, in addition to filings with the Securities and Exchange Commission (SEC), we intend to announce material information to the public via the investor relations page on our website, press releases, public conference calls, public webcasts, our X handle (@BillionToOneInc) and our LinkedIn feed.

Any updates to the list of disclosure channels through which we will announce information will be posted on the investor relations page on our website.

Corporate and other information

We commenced operations in 2016 as a Delaware corporation. Our principal executive offices are located at 1035 O'Brien Drive, Menlo Park, CA 94025. Our telephone number is (650) 460-2551. Our website address is www.billiontoone.com. The information contained on, or that can be accessed through, our website is not incorporated by reference into this prospectus, and you should not consider any information contained on, or that can be accessed through, our website as part of this prospectus.

"BillionToOne" and the BillionToOne logo, and other trademarks or service marks of BillionToOne, Inc. appearing in this prospectus are the property of BillionToOne, Inc. This prospectus contains additional trade names, trademarks, and service marks of others, which are the property of their respective owners. Solely for convenience, trademarks and trade names referred to in this prospectus may appear without the ® or ™ symbols.

Implications of being an emerging growth company

We qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012 (the JOBS Act). An emerging growth company may take advantage of specified reduced reporting and other burdens that are otherwise applicable generally to public companies. These provisions include:

- a requirement to have only two years of audited financial statements and only two years of related selected financial data and management's discussion and analysis of financial condition and results of operations disclosure in this prospectus;
- an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act of 2002;

- an exemption from implementation of new or revised financial accounting standards until they would apply to private companies and from compliance with any new requirements adopted by the Public Company Accounting Oversight Board requiring mandatory audit firm rotation;
- reduced disclosure obligations regarding executive compensation arrangements; and
- no requirement to seek nonbinding advisory votes on executive compensation or golden parachute arrangements.

We may take advantage of some or all these provisions until we are no longer an emerging growth company. We will remain an emerging growth company until the earlier to occur of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of this offering, (b) in which our annual gross revenue is $1.235 billion or more, or (c) in which we are deemed to be a “large accelerated filer,” under the rules of the SEC, which means the market value of our equity securities that is held by non-affiliates exceeds $700 million as of the prior June 30th, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

We have elected to take advantage of the extended transition period to comply with new or revised accounting standards and to adopt certain of the reduced disclosure requirements available to emerging growth companies. As a result of the accounting standards election, we will not be subject to the same implementation timing for new or revised accounting standards as other public companies that are not emerging growth companies, which may make comparison of our financials to those of other public companies more difficult. In addition, the information that we provide in this prospectus may be different than the information you may receive from other public companies in which you hold equity interests. Further, it is possible that some investors will find our common stock less attractive as a result of these elections, which may result in a less active trading market for our common stock and higher volatility in our stock price.

The offering

Class A common stock offered by us	shares.
Option to purchase additional shares	We have granted the underwriters an option to purchase up to additional shares of Class A common stock from us at any time within 30 days from the date of this prospectus.
Class A common stock to be outstanding immediately after this offering	shares (or shares if the underwriters exercise their option to purchase additional shares of Class A common stock in full).
Class B common stock to be outstanding immediately after this offering	shares.
Total Class A and Class B common stock to be outstanding immediately after this offering	shares (or shares if the underwriters exercise their option to purchase additional shares of Class A common stock in full).
Use of proceeds	We estimate the net proceeds from the sale of shares of our Class A common stock this offering will be approximately $ million, or $ million if the underwriters exercise their option to purchase additional shares of Class A common stock in full, assuming an initial public offering price of $ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. We currently intend to use the net proceeds from this offering, together with our existing cash and cash equivalents, for working capital and other general corporate purposes, including to fund our growth, research and development initiatives, technology development, working capital, and operating expenses. See the section titled “Use of proceeds” for additional information.
Voting rights	Each share of our Class A common stock entitles its holder to one vote on all matters to be voted on by stockholders generally. Each share of our Class B common stock entitles its holder to 10 votes on all matters to be voted on by stockholders generally. Holders of our Class A common stock and Class B common stock will generally vote together as a single class, unless otherwise required by law or our amended and restated certificate of incorporation (the Post-IPO Certificate of Incorporation).

	Oguzhan Atay, our Chief Executive Officer and Co-Founder, and David Tsao, our Chief Technology Officer and Co-Founders (each, a Founder, and together, the Co-Founders), will beneficially own 100% of our outstanding Class B common stock and, as a result, Drs. Atay and Tsao will beneficially own approximately % and approximately %, respectively, of the voting power of our outstanding capital stock immediately following this offering, assuming no exercise of the underwriters' option to purchase additional shares of Class A common stock. As a result, our Co-Founders may have significant influence over the outcome of matters submitted to our stockholders for approval, including the election of our directors and the approval of any change of control transaction. These risks are more fully described in the section titled "Risk factors." For additional information, see the sections titled "Principal stockholders" and "Description of capital stock." All of the outstanding shares of our Class B common stock will convert automatically on a one-for-one basis into shares of our Class A common stock upon the earliest of (i) seven 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 Founder and such 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 our Board of Directors, after the death or incapacitation of such Founder or (ii) the date that is between 61 and 180 days, as determined by our Board of Directors, after the date on which such Founder is no longer serving as an officer or director of the Company. See the section titled "Description of capital stock—Common stock."
Directed share program	At our request, the underwriters have reserved up to 5% of the shares of Class A common stock being offered by this prospectus for sale, at the initial public offering price, to our officers, directors and employees through a directed share program. Shares purchased through the directed share program will not be subject to a lock-up restriction, except in the case of shares purchased by any of our directors or officers. We do not know if these parties will choose to purchase all or any portion of these reserved shares, but the number of shares of our Class A common stock available for sale to the general public will be reduced to the extent these individuals or entities purchase such reserved shares. Any reserved shares that are not so purchased will be offered by the underwriters to the

	general public on the same terms as the other shares offered by this prospectus. J.P. Morgan Securities LLC will administer our directed share program. See the section titled "Underwriting–Directed share program" for additional information.
Risk factors	See the section titled "Risk factors" for a discussion of factors that you should consider carefully before deciding to invest in our Class A common stock.
Proposed Nasdaq Global Market trading symbol	"BLLN"

The number of shares of our common stock to be outstanding after this offering is based on shares of our Class A common stock and shares of our Class B common stock outstanding as of June 30, 2025, after giving effect to the Preferred Stock Conversion, the Reclassification and the Class B Stock Exchange (each as defined below), in each case as if they had occurred on June 30, 2025, and excludes:

- shares of our Class A common stock issuable upon the exercise of stock options outstanding as of June 30, 2025 under our 2018 Stock Plan, as amended (the 2018 Plan), at a weighted-average exercise price of $ per share;
- shares of our Class A common stock issuable upon the exercise of outstanding stock options that were granted subsequent to June 30, 2025 under our 2018 Plan, at a weighted-average exercise price of $ per share;
- up to 9,660 shares of our Class A common stock issuable upon the exercise of a redeemable convertible preferred stock warrant (the A-6 Warrant) for an exercise price of $2.5879 per share;
- up to 80,357 shares of our Class A common stock issuable upon the exercise of a 2021 common stock warrant (the 2021 Common Warrant) for an exercise price of $2.80 per share;
- up to 41,209 shares of our Class A common stock issuable upon the exercise of a 2022 common stock warrant (the 2022 Common Warrant) for an exercise price of $10.92 per share;
- shares of our Class A common stock reserved for future issuance under our 2025 Equity Incentive Plan (the 2025 Plan), which will become effective upon the effectiveness of the registration statement of which this prospectus forms a part, as well as any future increases in the number of shares of our Class A common stock reserved for issuance under the 2025 Plan; and
- shares of our Class A common stock reserved for future issuance under our 2025 Employee Stock Purchase Plan (ESPP), which will become effective upon the effectiveness of the registration statement of which this prospectus forms a part, as well as any future increases in the number of shares of our Class A common stock reserved for issuance under the ESPP.

Unless otherwise indicated, this prospectus reflects and assumes the following:

- the automatic conversion of all outstanding shares of our redeemable convertible preferred stock into an aggregate of shares of our common stock immediately prior to the completion of this offering (the Preferred Stock Conversion);
- the automatic adjustment of the A-6 Warrant into a warrant to purchase 9,660 shares of our common stock immediately prior to the completion of this offering;

- the filing and effectiveness of our Post-IPO Certificate of Incorporation immediately prior to the completion of this offering, which, among other things, will reclassify all outstanding shares of our common stock into an equal number of shares of Class A common stock (the Reclassification), and the adoption of our amended and restated bylaws (the Post-IPO Bylaws), which will become effective upon the filing of our Post-IPO Certificate of Incorporation;
- the exchange of an aggregate of shares of Class A common stock held by our Co-Founders, for an equivalent number of shares of our Class B common stock, to be effected immediately prior to the completion of this offering pursuant to the terms of an exchange agreement entered into with us (the Class B Stock Exchange);
- no exercise, settlement or termination of the outstanding options or warrants described above; and
- no exercise by the underwriters of their option to purchase up to additional shares of our Class A common stock in this offering.

Summary financial data

The following table sets forth our summary statements of operations data for the years ended December 31, 2023 and 2024 and the six months ended June 30, 2024 and 2025, as well as our summary balance sheet data as of June 30, 2025. We derived the summary statements of operations data for the years ended December 31, 2023 and 2024 from our audited financial statements included elsewhere in this prospectus. The summary condensed statements of operations data for the six months ended June 30, 2025 and 2024 and summary balance sheet data as of June 30, 2025 have been derived from our unaudited financial statements included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that may be expected in the future. When you read this summary financial data, it is important that you read it together with the historical financial statements and the related notes included elsewhere in this prospectus, as well as the section titled "Management's discussion and analysis of financial condition and results of operations."

	Year ended December 31,		Six months ended June 30,	
(in thousands, except per share data)	**2023**	**2024**	**2024**	**2025**
Statements of operations data:				
Revenue	$ 71,729	$ 152,582	$	$
Cost of revenue	54,421	71,667		
Gross profit	17,308	80,915		
Operating expenses:				
Research and development	22,414	36,596		
Selling, general and administrative	64,389	91,465		
Total operating expenses	86,803	128,061		
Loss from operations	(69,495)	(47,146)		
Other income (expense):				
Interest income	3,456	5,819		
Interest expense	(3,272)	(2,386)		
Net gain on extinguishment of debt	—	7,289		
Change in fair value of term loan	—	(3,137)		
Change in fair value of convertible notes	(12,921)	(835)		
Other expenses, net	(442)	(1,145)		
Total other (expense) income	(13,179)	5,605		
Loss before provisions for income taxes	(82,674)	$ (41,541)		
Provision for income taxes	9	29		
Net loss	$ (82,683)	$ (41,570)	$	$
Net loss per share, basic and diluted[1]	$ (8.45)	$ (4.12)	$	$
Weighted-average shares used in computing net loss per share, basic and diluted[1]	9,783	10,080		
Pro forma net loss per share, basic and diluted[2]				
Pro forma weighted-average shares used in computing pro forma net loss per share, basic and diluted[2]				

(1) See Note 14 to our audited financial statements included elsewhere in this prospectus for an explanation of the calculations of our basic and diluted net loss per share attributable to common stockholders and the weighted-average shares used in computing the per share amounts.

(2) Pro forma basic and diluted net loss per share attributable to common stockholders has been prepared to give effect to adjustments to our capital structure arising in connection with the completion of this offering and is calculated by dividing the pro forma net loss attributable to common stockholders by the pro forma weighted-average common shares outstanding for the period. Pro forma weighted-average common shares outstanding is computed by adjusting the weighted-average common shares outstanding to give pro forma effect to the automatic conversion of all shares of our redeemable convertible preferred stock outstanding as of June 30, 2025 into shares of common stock as if such conversion had occurred on January 1, 2024. Pro forma basic and diluted net loss per share attributable to common stockholders does not include the effect of the shares expected to be sold in this offering.

(in thousands)	As of June 30, 2025		
	Actual	Pro forma[1]	Pro forma as adjusted[2][3]
Balance sheet data:			
Cash and cash equivalents	$	$	$
Working capital[4]			
Total assets			
Total liabilities			
Long term debt			
Redeemable convertible preferred stock			
Total stockholders' (deficit) equity			

(1) The pro forma balance sheet data gives effect to (i) the Preferred Stock Conversion, (ii) the Reclassification, (iii) the Class B Stock Exchange, (iv) the conversion of the A-6 Warrant to a warrant to purchase common stock and the related reclassification of the warrant liability to stockholders' equity, and (v) the filing and effectiveness of our Post-IPO Certificate of Incorporation, all of which will occur immediately prior to the completion of this offering.

(2) The pro forma as adjusted balance sheet data reflects (i) the pro forma adjustments described in footnote (1) above; and (ii) the sale by us of shares of Class A common stock in this offering at the assumed initial public offering price of $ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

(3) Each $1.00 increase or decrease in the assumed initial public offering price of $ per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, would increase or decrease, as applicable, each of pro forma as adjusted cash and cash equivalents, working capital, total assets, and total stockholders' (deficit) equity by approximately $ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase or decrease of 1.0 million shares offered by us would increase or decrease, as applicable, each of pro forma as adjusted cash and cash equivalents, working capital, total assets, and total stockholders' (deficit) equity by approximately $ million, assuming the assumed initial public offering price per share remains the same, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. The pro forma as adjusted information is illustrative only, and we will adjust this information based on the actual initial public offering price, number of shares offered, and other terms of this offering determined at pricing.

(4) We define working capital as current assets *less* current liabilities. See our financial statements and related notes appearing elsewhere in this prospectus for further details regarding our current assets and current liabilities.

Non-GAAP financial measures

To supplement our financial statements, which are prepared and presented in accordance with generally accepted accounting principles in the United States (GAAP), we use the following 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 non-GAAP operating loss and non-GAAP net loss provide meaningful supplemental information regarding our 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.

The following table summarizes our non-GAAP financial measures for each period presented below. See the section titled "Management's discussion and analysis of financial condition and results of operations—Non-GAAP financial measures" for additional information and reconciliations of our non-GAAP financial measures to the most directly comparable financial measures prepared in accordance with GAAP.

	Year ended December 31,		Six months ended June 30,	
(in thousands)	**2023**	**2024**	**2024**	**2025**
Non-GAAP loss from operations	$ (64,641)	$ (38,784)	$	$
Non-GAAP net loss	(64,908)	(29,236)		

Risk factors

Investing in our Class A common stock involves a high degree of risk. You should carefully consider the following risks and uncertainties described below, together with all of the other information contained in this prospectus, including our financial statements and the related notes and the section titled "Management's discussion and analysis of financial condition and results of operations," before making a decision to invest in our Class A common stock. The risks and uncertainties described below are not the only ones we may face. Our business, financial results, or prospects could also be harmed by additional risks and uncertainties not currently known to us or that we currently do not believe are material to disclose. Any of the following risks could have an adverse effect on our business, financial results, and prospects and could cause the market price of our Class A common stock to decline, which would cause you to lose all or part of your investment.

Risks related to our business and strategy

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

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

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

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

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

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

Our ability to execute our growth strategy and become or remain profitable is highly dependent on the continued adoption and use of our molecular diagnostic tests, which are our primary source of revenue. Continued adoption and use of our tests will depend on several factors, including the prices we charge for our tests, the scope of coverage and amount of reimbursement available from third-party payors for our tests, the availability of clinical data that supports the value of our tests and the inclusion of our tests in industry treatment guidelines. In addition, many healthcare providers have existing relationships with companies that develop molecular diagnostic tests, including our competitors, and may continue to use their tests instead of ours. If we are unable to achieve or maintain commercial success for our tests, our business, results of operations and financial condition would be materially and adversely affected. We cannot assure that our tests will continue to maintain or gain market acceptance, and any failure to do so would materially harm our business and results of operations.

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

Our business depends on our ability to obtain and maintain adequate coverage and reimbursement from third-party payors and patients. Third-party reimbursement for our tests represents a significant portion of our revenue, 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 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.

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 constitutes the large majority of our revenue, 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 47 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 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 and payors may determine 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 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 2027, 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 these 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, could materially affect our business operations, supply chain, or ability to contract with U.S. government agencies. If a statute akin to the BIOSECURE Act is enacted, in addition to potential other restrictions on our business, it would prohibit federal agencies from contracting with entities that use biotechnology equipment or services from certain foreign entities deemed to be under the control of foreign adversaries.

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

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

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

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

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

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

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

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

the third-party providers, strategic partners and other contractors, subcontractors or consultants we use to manage this sensitive data or otherwise process it on our behalf.

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

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

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

We have contingency plans and insurance coverage for certain potential claims, liabilities and costs relating to security incidents that may arise from our business or operations; however, the coverage may not be sufficient to cover all claims, liabilities and costs arising from the incidents, including fines and penalties. Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. The ultimate resolution of any such incidents or estimating the amounts or ranges of potential loss, if any, that could result therefrom are highly uncertain. If we cannot successfully resolve a security incident or contain any potential loss, it could materially impact our ability to operate our business as well as our results of operations and financial position.

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

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

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

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

In the event of public health developments, health epidemics or outbreaks in the future, our operations could be disrupted and our business adversely impacted. Such disruptions or impacts may be similar to those faced

during the COVID-19 pandemic, such as mandated business closures in impacted areas, limitations with employee resources due to stay at home orders or sickness of employees or their families, diversion or prioritization of health care resources away from the conduct of testing, limitations on patients' access to our products, disruptions or restrictions affecting the ability of our laboratory facility to process our tests, reduced demand for certain of our products, or supply chain constraints.

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

Current or future tariffs or other restrictive trade measures may raise the costs of raw materials, components or finished goods, which may adversely impact both our product offerings and our operational expenses. Such cost increases may reduce our margins, which could negatively impact our revenue. Our manufacturers, suppliers and distribution channels are also affected by the current trade environment, and we may experience supply chain disruptions as a result of increased costs and uncertainty, as well as risks to the long-term viability of key vendors, which may impact our ability to meet customer demand or manage inventory efficiently. Tariff and other trade-related cost pressures and supply chain disruptions may lead to reputational harm if we are unable to deliver test services on expected timelines.

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

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

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

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

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

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. 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 partnership 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 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 or typical for our industry.

We also operate in a highly competitive industry, and 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. If we are involved in a dispute with a competitor, we may need to defend our practices or take actions, including pursing 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 margins 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, Natera, and Quest Diagnostics Incorporated (Quest). We also compete with companies providing carrier screening tests such as Fulgent Genetics, Labcorp, Myriad Genetics, Inc., 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, Foundation Medicine, Inc., which was acquired by Roche Holdings, Guardant Health, Neogenomics, and Tempus AI. 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. Increased competition and cost-saving initiatives on the part of governmental entities and other third-party payors are likely to result in pricing pressures, which could harm our sales, profitability or ability to gain market share. In addition, competitors may be acquired by, receive investments from or enter into other commercial relationships with larger, well-established and well-financed companies. In addition, companies or governments that control access to genetic testing through umbrella contracts or regional preferences could promote our competitors or prevent us from performing certain services. If we are unable to compete successfully against current and future competitors, we may be unable to increase market acceptance and sales of our tests, which could prevent us from increasing our revenue or achieving profitability and could cause our stock price to decline.

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

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

We have incurred significant losses since our inception. For the years ended December 31, 2023 and 2024, we incurred net losses of $82.7 million and $41.6 million, respectively. As of December 31, 2024, we had an accumulated deficit of $282.2 million. To date, we have financed our operations principally from the sale of preferred stock, convertible securities and debt and revenue generated from our tests. We have devoted substantially all of our resources to the development and commercialization of our smNGS platform and current products, and to sales and marketing and research and development activities. In addition, as a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company.

While we have been able to achieve gross margins of 24% and 53% for the years ended December 31, 2023 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 achieve and then sustain profitability, and even if we achieve profitability, we cannot be sure that we will remain profitable for any period of time. Our failure to achieve and sustain profitability in the future will make it more difficult to finance our business and accomplish our strategic objectives, which would have a material adverse effect on our business, financial condition and results of operations and cause the market price of our common stock to decline.

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

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

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

The cumulative effects of factors discussed above could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any guidance we may provide, or if the guidance we provide is below the expectations of analysts or investors, the market price of our Class A common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated guidance we may provide.

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

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

business operations. Furthermore, changing circumstances could result in lower revenues or cause us to consume capital significantly faster than we currently anticipate, and we may need to raise capital sooner or in greater amounts than currently expected because of circumstances beyond our control.

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

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

While we currently have in place a debt facility pursuant to which we may request up to an additional $ million as of June 30, 2025, as described in more detail below, we may need to raise additional capital which may not be available on satisfactory terms or at all. Furthermore, any additional capital raised through the sale of equity or convertible securities, or grant of equity or convertible securities in connection with any debt financing, will dilute stockholders' ownership interests in us and may have an adverse effect on the market price of our Class A common stock. In addition, the terms of any financing may adversely affect stockholders' holdings or rights. To the extent that we raise capital through collaborations and licensing arrangements, it may be necessary to relinquish some rights to our technologies or grant licenses on terms that may not be favorable to us.

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

Risks related to our intellectual property

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

We rely on patent protection as well as trademark, copyright, trade secret and other intellectual property rights protection and contractual restrictions to protect our proprietary technologies, all of which provide limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. As of June 5, 2025, we held nine U.S. issued patents, 41 foreign patents, 13 pending U.S. patent applications and

33 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.

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, UNITY Screen, 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 13 pending U.S. patent applications, we held 41 foreign patents and 33 foreign patent applications as of June 5, 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 has historically taken the position that it has the authority to regulate LDTs as medical devices under the Federal Food, Drug, and Cosmetic Act (FD&C Act), but it has generally exercised enforcement discretion with regard to such tests.

In May, 2024, the FDA issued a final rule that took effect on July 5, 2024, amending existing regulations to provide that in vitro diagnostic products (IVDs) are devices under the FD&C Act, including LDTs. Along with this amendment, the FDA was finalizing a policy under which the FDA will have greater oversight of IVDs offered as LDTs through a phase-out of its general enforcement discretion approach for LDTs over the course of four years. Under this new rule, LDTs may have been required to obtain premarket approval, de novo classification or 510(k) clearance. On March 31, 2025, the U.S. District Court for the Eastern District of Texas vacated the final rule in its entirety, holding that the FDA's attempt to regulate professional laboratory testing services as medical devices exceeds the authority granted to the FDA and remanded it to FDA for further consideration. The FDA did not appeal the U.S. District Court decision within the required 60-day required window. As a result, the future of the rule, and any enforcement approach by the FDA in this area, is uncertain.

Prior to the district court decision, we had begun to prepare for compliance with the proposed FDA rule. Although the FDA's enforcement approach is now uncertain, 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. 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. 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 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). 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 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 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 has historically taken the position that it has the authority to regulate LDTs as medical devices under the FD&C Act, but it has generally exercised enforcement discretion with regard to such tests. 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 will be 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 Commission'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 will be required to evaluate and determine the effectiveness of internal control over financial reporting. Beginning with our second annual report following this offering, we will be required to provide a management report on internal control over financial reporting, and our independent registered public accounting firm may be required to formally attest to the effectiveness of our internal control over financial reporting once we are no longer an "emerging growth company". Neither we nor our independent registered public accounting firm were required to, and therefore did not, perform an evaluation of the effectiveness of our internal control over financial reporting as of or for any period included in our financial statements, nor any period subsequent in accordance with the provisions of the Sarbanes-Oxley Act. However, in connection with the preparation of our financial statements, we identified material weaknesses in our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

The material weaknesses identified pertained to:

- We did not design and maintain an effective control environment commensurate with our financial reporting requirements. Specifically, we lack a sufficient complement of resources with the appropriate knowledge, experience, and training to appropriately analyze, record and disclose accounting matters commensurate with our accounting and reporting requirements. Additionally, the lack of sufficient resources resulted in an

inability to consistently establish appropriate segregation of duties in our finance and accounting functions. This material weakness contributed to the following additional material weaknesses:

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

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

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

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

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

These material weaknesses will not be considered remediated until management completes the design and implementation of the measures described above and the controls operate for a sufficient period of time and management has concluded, through testing, that these controls are effective. This remediation process, including testing the effectiveness of the remediation efforts, may extend into 2026. Additionally, we cannot ensure that we have identified all, or that we will not in the future identify additional material weaknesses. Material weaknesses may

still exist when we report on the effectiveness of our internal control over financial reporting as required under Section 404 of the Sarbanes-Oxley Act, beginning with our second annual report after the completion of this offering.

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

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

We have a significant amount of net operating loss (NOL) carryforwards that can be used to offset potential future taxable income and related income taxes. As of December 31, 2024, we had federal and state NOL carryforwards of $154.9 million and $78.6 million, respectively, which, if not utilized, begin to expire in 2036 and 2026, respectively. Federal NOLs incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal NOLs is limited. As of December 31, 2024, we also had federal research and development credit carryforwards of $4.1 million, which begin to expire in 2041, and state research and development credit carryforwards of $2.1 million, which do not expire. Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change" (generally defined as a greater than 50% change, by value, in equity ownership over any three-year period), the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. We may have experienced ownership changes in the past, and may experience ownership changes in the future, as a result of shifts in our stock ownership, some of which may not be within our control. Our ability to use these carryforwards could be limited if we experience an "ownership change" or have experienced an "ownership change" in the past.

Future indebtedness could adversely affect our business and growth prospects.

We have a debt facility with availability of up to $140.0 million, issuable in four separate tranches, pursuant a Note Purchase Agreement, dated as of August 2, 2024, by and among us, the purchasers party thereto, and BWCB SA LLC (an entity affiliated with Oberland Capital), as purchaser's agent (the Note Purchase Agreement). As of June 30, 2025, we have drawn $ million under the debt facility. The advanced principal accrues interest at a rate of 8.0% per annum. We have the option, but not the obligation, to issue and sell an additional three separate tranches of notes in the amounts of $35.0 million, $30.0 million and $25.0 million, respectively, under the Note Purchase Agreement, subject to the terms and conditions set forth in such Agreement. In the future, any indebtedness we may incur under the Note Purchase Agreement or otherwise could require us to divert funds identified for other purposes for debt service and impair our liquidity. If we cannot generate sufficient cash flow from operations to service our debt, we may need to refinance our debt, dispose of assets or issue equity to obtain necessary funds. We do not know whether we will be able to take any of these actions on a timely basis, on terms satisfactory to us or at all.

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

While we believe that our current debt level is low in comparison to our cash balance, if we increase our debt level by exercising our option to issue and sell additional tranches of notes under our debt facility or by entering into additional debt arrangements in the future, our level of indebtedness may place us at a competitive disadvantage to our competitors that are differently leveraged. Fluctuations in interest rates can increase borrowing costs. Increases in interest rates may directly impact the amount of interest we are required to pay and reduce earnings accordingly. In addition, developments in tax policy, such as the disallowance of tax deductions for interest paid on outstanding indebtedness, could have an adverse effect on our liquidity and our business, financial conditions and results of operations.

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

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

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

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

A breach of the covenants or restrictions under the Note Purchase Agreement could result in an event of default. Such a default may allow the noteholders or our other creditors to accelerate the related debt, which may result in the acceleration of any other debt to which a cross-acceleration or cross-default provision applies. In the event any note holder or any other holders of our indebtedness accelerate repayment, we may not have sufficient assets

to repay that indebtedness or be able to borrow sufficient funds to refinance it. Even if we are able to obtain new financing, it may not be on commercially reasonable terms or on terms acceptable to us. As a result of these restrictions, we may be limited in how we conduct our business; unable to raise additional debt or equity financing to operate during general economic or business downturns; or unable to compete effectively or to take advantage of new business opportunities. These restrictions, along with restrictions that may be contained in agreements evidencing or governing other future indebtedness, may affect our ability to execute our growth strategy.

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

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

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

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

Risks related to this offering and our Class A common stock

No public market for our Class A common stock currently exists, and an active public trading market may not develop or be sustained following this offering.

Prior to this offering, there has been no public market for our Class A common stock. An active public trading market for our Class A common stock may not develop following the completion of this offering or, if developed, it may not be sustained. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The initial public offering price of our Class A common stock will be determined by negotiations between us and the underwriters and may not be indicative of prices that will prevail in the open market following the completion of this offering. The market price of our Class A common stock may decline below the initial public offering price, and you may not be able to resell your shares of our Class A common stock at or above the initial offering price, or at all. The lack of an active trading market may also reduce the fair value of your shares. An inactive market may also impair our ability to raise capital by selling shares of 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 not be able to resell your shares at or above the initial public offering price.

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

Our Class A common stock, which is the stock we are offering by means of this prospectus, will have one vote per share and our Class B common stock will have 10 votes per share. After the completion of this offering, the

holders of our outstanding Class B common stock, Drs. Atay and Tsao, will together hold % of the voting power of our outstanding capital stock (or % if the underwriters exercise their option to purchase additional shares of our Class A common stock in full). See the section titled "Principal stockholders." As a result, Drs. Atay and Tsao will be 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 Post-IPO Certificate of Incorporation and Post-IPO Bylaws and the approval of any merger, consolidation, sale of all or substantially all of our assets or other major corporate transactions. In addition, if our Co-Founders continue to beneficially own shares representing in excess of 50% of the voting power of our outstanding capital stock and determine to act together in the future, we could become eligible to elect the "controlled company" exemption to the corporate governance rules for publicly listed companies. If we were to become a "controlled company" under the corporate governance rules for publicly listed companies, we would not be required to have a majority of our Board of Directors be independent, nor would we be required to have a compensation committee or an independent nominating function. If we use controlled company exemptions in the future, our status as a controlled company could cause our Class A common stock to be less attractive to certain investors or otherwise cause the market price of our Class A common stock to decline. Further, the interests of Drs. Atay and Tsao may not always coincide with, and in some cases may conflict with, our interests and the interests of our other stockholders. For instance, Drs. Atay and Tsao could attempt to delay or prevent a change in control of our company, even if such change in control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock. This concentration of ownership may also affect the prevailing market price of our common stock due to investors' perceptions that conflicts of interest may exist or arise. As a result, this concentration of ownership may not be in your best interests.

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

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

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

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

If securities or industry analysts do not publish research, if they publish inaccurate or unfavorable research about our business, or if our financial results differ from any guidance we provide to the public, the price of our Class A common stock and trading volume could decline.

The trading market for our Class A common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business, our market, and our competitors. We do not currently have and may never obtain research coverage by securities and industry analysts. We do not have any control

over these analysts. If we fail to meet the expectations of these analysts, our stock price could be adversely affected. If no or few securities analysts commence coverage of us, the trading price for our Class A common stock would be negatively affected. In the event we obtain securities or industry analyst coverage, if one or more of the analysts who cover us downgrade our Class A common stock or publish inaccurate or unfavorable research about our business, the market price of our Class A common stock would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our Class A common stock could decrease, which may cause the market price of our Class A common stock and trading volume to decline.

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

We will have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

We will have considerable discretion in the application of the net proceeds of this offering, including for any of the purposes described in the section of this prospectus titled “Use of proceeds,” and you will not have the opportunity as part of your investment decision to assess whether the net proceeds are being used appropriately. Investors will need to rely upon the judgment of our management with respect to the use of such net proceeds. Pending their use, we may invest the net proceeds from this offering in short-term, investment-grade, interest-bearing securities, such as money market accounts, certificates of deposit, commercial paper, and guaranteed obligations of the U.S. government, which may not produce income or may lose value. If we do not use the net proceeds that we receive in this offering effectively, our business, financial condition and results of operations could be harmed and the market price of our Class A common stock could decline.

As the initial public offering price is substantially higher than our net tangible book value per share of Class A common stock, you will incur immediate and substantial dilution.

If you purchase Class A common stock in this offering, you will experience substantial and immediate dilution in the pro forma net tangible book value per share after giving effect to this offering of $ per share as of , 2025, based on the initial public offering price of $ per share of Class A common stock, the midpoint of the estimated offering price range on the cover page of this prospectus, because the price that you pay will be substantially greater than the pro forma net tangible book value per share of Class A common stock that you acquire. This dilution is due in large part to the fact that our earlier investors paid substantially less than the initial public offering price when they purchased their shares. As of June 30, 2025, we had shares of our Class A common stock issuable upon the exercise of outstanding options at a weighted average exercise price of $ per share, of which were vested as of such date, and additional shares of our Class A common stock reserved for future issuance under our 2018 Plan. See the section of this prospectus titled “Dilution” for additional information.

Any additional shares of our Class A common stock that we issue, including under our equity incentive plans, would dilute the percentage ownership and voting power held by the investors who purchase Class A common stock in this offering. In the future, we may also issue additional securities if we need to raise capital, including, in connection with acquisitions, which could constitute a material portion of our then-outstanding shares of

common stock. Any such issuance could substantially dilute the ownership and voting power of our existing stockholders and cause the market price of our Class A common stock to 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. Upon the completion of this offering, based on the number of shares of our Class A common stock outstanding as of June 30, 2025, and after giving effect to the Preferred Stock Conversion, the Reclassification and the Class B Stock Exchange, as if each event had occurred on June 30, 2025, we will have an aggregate of shares of our Class A common stock outstanding (or shares if the underwriters exercise their option to purchase additional shares from us in full). This includes shares of Class A common stock that we are selling in this offering, which may be resold in the public market immediately without restriction, unless purchased by our affiliates. The resale of the remaining shares of Class A common stock, or % of our outstanding shares of Class A common stock following this offering, and all of our Class B common stock outstanding, is currently prohibited or otherwise restricted, subject to certain limited exceptions, as a result of securities law provisions, market standoff agreements entered into by certain of our stockholders with us or lock-up agreements entered into by our stockholders with the underwriters in connection with this offering. However, subject to applicable securities law restrictions, these shares will be able to be sold in the public market beginning on the 181st day after the date of this prospectus. Shares issued upon the exercise of stock options outstanding under our equity incentive plans or pursuant to future awards granted under those plans will become available for sale in the public market to the extent permitted by the provisions of applicable vesting schedules, market stand-off agreements and/or lock-up agreements, as well as Rules 144 and 701 under the Securities Act. For more information, see the section titled “Shares eligible for future sale.”

In addition, following the completion of this offering, holders of shares of our Class A common stock (including, following the Class B Stock Exchange, shares of our Class A common stock issuable upon the conversion of shares of Class B common stock) will 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. See the section titled “Shares eligible for future sale.”

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 Post-IPO Certificate of Incorporation and Post-IPO Bylaws will 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 Post-IPO Certificate of Incorporation and Post-IPO Bylaws will 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 Post-IPO Certificate of Incorporation and Post-IPO 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 Post-IPO Certificate of Incorporation, Post-IPO 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 Post-IPO Certificate of Incorporation, which will be in effect at the completion of this offering, will provide 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 Post-IPO Certificate of Incorporation, which will be in effect at the completion of this offering, will provide 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 Post-IPO Certificate of Incorporation or our Post-IPO 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 would 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 Post-IPO Certificate of Incorporation will further provide 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 Post-IPO 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 in this offering 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(a) of the Sarbanes-Oxley Act could have a material adverse effect on our business.

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

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

by the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

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

We are an "emerging growth company," as defined in the JOBS Act, and we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies," including the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a non-binding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. Pursuant to Section 107 of the JOBS Act, as an emerging growth company, we have elected to use the extended transition period for complying with new or revised accounting standards until those standards would otherwise apply to private companies. As a result, our financial statements may not be comparable to the financial statements of issuers who are required to comply with the effective dates for new or revised accounting standards that are applicable to public companies, which may make our common stock less attractive to investors. In addition, if we cease to be an emerging growth company, we will no longer be able to use the extended transition period for complying with new or revised accounting standards.

We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year following the fifth anniversary of this offering, (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 additional 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 will 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 this prospectus and 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.

Upon the completion of this offering, we will become subject to the periodic reporting requirements of the Exchange Act. 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.

Special note regarding forward-looking statements

This prospectus includes forward-looking statements that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this prospectus, 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 prospectus include, statements about:

- the level of demand for any of our products, which may vary significantly;
- our ability to increase the adoption of our products in the prenatal and oncology markets and in large healthcare systems;
- our ability to generate persuasive clinical validity and utility evidence;
- our ability to expand our portfolio of molecular diagnostic tests;
- our ability to use AI effectively and efficiently;
- our ability to execute our reimbursement strategy and expand coverage of our tests;
- our ability to replicate positive results from trials or studies conducted by us or third parties in current or future trials or studies;
- the potential for our UNITY Fetal Antigen CTA to become the first NIPT to have a companion diagnostics indication pending;

  the successful completion of Johnson & Johnson’s AZALEA Phase 3 clinical trial;
- the implementation of our business model and strategic plans;
- the size and growth potential of the total addressable markets for our current and future products and our ability to serve those markets;
- our ability to realize the benefits of current and future collaborations for the development of our products;
- our ability to maintain, expand and protect our intellectual property;
- developments relating to our competitors and our industry;
- 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 and the net proceeds from this offering;

- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing; and
- other risks and uncertainties, including those listed in the section titled “Risk factors.”

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

These forward-looking statements are subject to a number of risks, uncertainties, and assumptions, including those described in the section titled “Risk factors.” Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties, and assumptions, the forward-looking events and circumstances discussed in this prospectus 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 prospectus 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 prospectus 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 prospectus, 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 prospectus and the documents that we reference in this prospectus and have filed with the SEC as exhibits to the registration statement of which this prospectus is a part with the understanding that our actual future results, levels of activity, performance, and events and circumstances may be materially different from what we expect.

Market, industry and other data

This prospectus contains estimates, projections and other information concerning our industry, our business and the markets for our products, including data regarding the estimated size of those markets, their projected growth rates, the perceptions and preferences of patients and physicians regarding certain therapies and other patient data and reimbursement data, as well as market research, estimates and forecasts prepared by our management. We obtained the industry, market and other data throughout this prospectus from our own internal estimates and research, as well as from publicly available information, industry publications and research, surveys and studies conducted by third-parties, including governmental agencies. This information involves important assumptions and limitations, and you are cautioned not to give undue weight to such estimates.

Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to a high degree of uncertainty and risk, and actual events or circumstances may differ materially from events and circumstances that are assumed in this information based on various factors, including those discussed in the section titled “Risk factors.” These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.

Use of proceeds

We estimate that the net proceeds to us from this offering will be approximately $ million, or $ million if the underwriters exercise their option to purchase additional shares in full, based assuming an initial public offering price of $ per share, the midpoint of the estimated offering price range set forth on the cover page of this prospectus, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

Each $1.00 increase or decrease in the assumed initial public offering price of $ per share, the midpoint of the estimated offering price range set forth on the cover page of this prospectus, would increase or decrease, as applicable, net proceeds to us by $ million, assuming that the number of shares offered by us as set forth on the cover page of this prospectus remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase or decrease of 1.0 million shares offered by us would increase or decrease, as applicable, net proceeds to us by approximately $ million, assuming an initial public offering price of $ per share, the midpoint of the estimated offering price range set forth on the cover page of this prospectus, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The principal purposes of this offering are to increase our financial flexibility, increase our visibility in the marketplace, and create a public market for our Class A common stock. We currently intend to use the net proceeds from this offering, together with our existing cash and cash equivalents, for working capital and other general corporate purposes, including to fund our growth, research and development initiatives, technology development, working capital, and operating expenses. However, we do not currently have specific planned uses for the proceeds.

We may also use a portion of our net proceeds to acquire or invest in complementary products, technologies, or businesses. However, we currently have no agreements or commitments to complete any such transactions.

Our expected use of the net proceeds from this offering represents our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering or the amounts that we will actually spend on the uses set forth above. Our management will have broad discretion over the use of the net proceeds from this offering. See the section titled “Risk factors—Risks related to this offering and our Class A common stock—We will have broad discretion in the use of the net proceeds from this offering and may not use them effectively.” Pending our use of the net proceeds from this offering, we intend to invest the net proceeds in short-term, interest-bearing, investment-grade securities, certificates of deposit, or government securities.

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.

Capitalization

The following table sets forth our cash and cash equivalents and our capitalization as of June 30, 2025:

- on an actual basis;
- on an as adjusted basis to give effect to (i) the Preferred Stock Conversion, (ii) the Reclassification, (iii) the Class B Stock Exchange, (iv) the conversion of the A-6 Warrant to a warrant to purchase common stock and the related reclassification of the warrant liability to stockholders' equity and (v) the filing and effectiveness of our Post-IPO Certificate of Incorporation, all of which will occur immediately prior to the completion of this offering; and
- on a pro forma as adjusted basis to reflect (i) the pro forma adjustments set forth above and (ii) the issuance and sale of shares of Class A common stock in this offering at an assumed initial public offering price of $ per share, the midpoint of the estimated offering price range set forth on the cover page of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The pro forma and pro forma as adjusted information below is illustrative only, and our capitalization following the completion of this offering will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing. You should read the information in this table together with the sections titled "Management's discussion and analysis of financial condition and results of operations" and "Description of capital stock" and our financial statements and the related notes included elsewhere in this prospectus.

	As of June 30, 2025		
(in thousands, except for share and per share amounts)	**Actual**	**Pro forma**	**Pro forma as adjusted[(1)]**
Cash and cash equivalents	$	$	$
Long-term debt			
Redeemable convertible preferred stock, par value $0.00001 per share; shares authorized, shares issued and outstanding, actual; no shares authorized, issued and outstanding, pro forma and pro forma as adjusted	$	$	$
Stockholders' (deficit) equity:			
Preferred stock, par value $0.00001 per share; no shares authorized, no shares issued and outstanding, actual; shares authorized, no shares issued and outstanding, pro forma and pro forma as adjusted			
Common stock, par value $0.00001 per share; shares authorized, shares issued and outstanding, actual; no shares authorized, no shares issued and outstanding, pro forma and pro forma as adjusted			
Class A common stock, par value $0.00001 per share; no shares authorized, no shares issued and outstanding, actual; shares authorized, pro forma and pro forma as adjusted, shares issued and outstanding, pro forma, and shares issued and outstanding, pro forma as adjusted			
Class B common stock, par value $0.00001 per share; no shares authorized, no shares issued and outstanding, actual; shares authorized, shares issued and outstanding, pro forma and pro forma as adjusted			
Additional paid-in capital			
Accumulated deficit			
Total stockholders' (deficit) equity			
Total capitalization	$	$	$

(1) Each $1.00 increase or decrease in the assumed initial public offering price of $ per share, the midpoint of the estimated offering price range set forth on the cover page of this prospectus, would increase or decrease, as applicable, pro forma as adjusted cash and cash equivalents, additional paid-in capital, total stockholders' (deficit) equity and total capitalization by approximately $ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each 1.0 million share increase or decrease in the number of shares offered by us would increase or decrease, as applicable, pro forma as adjusted cash and cash equivalents, additional paid-in capital, total stockholders' (deficit) equity and total capitalization by approximately $ million, assuming that the assumed initial offering price to the public remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The number of shares of our common stock issued and outstanding, pro forma and pro forma as adjusted, in the table above is based on shares of our Class A common stock and shares of our Class B common stock outstanding as of June 30, 2025, after giving effect to the Preferred Stock Conversion, the Reclassification and the Class B Stock Exchange, in each case as if they had occurred on June 30, 2025, and excludes:

- shares of our Class A common stock issuable upon the exercise of stock options outstanding as of June 30, 2025 under our 2018 Plan, at a weighted-average exercise price of $ per share;
- shares of our Class A common stock issuable upon the exercise of outstanding stock options that were granted subsequent to June 30, 2025 under our 2018 Plan, at a weighted-average exercise price of $ per share;
- up to 9,660 shares of our Class A common stock issuable upon the exercise of the A-6 Warrant for an exercise price of $2.5879 per share;
- up to 80,357 shares of our Class A common stock issuable upon the exercise of the 2021 Common Warrant for an exercise price of $2.80 per share;
- up to 41,209 shares of our Class A common stock issuable upon the exercise of the 2022 Common Warrant for an exercise price of $10.92 per share;
- shares of our Class A common stock reserved for future issuance under our 2025 Plan, which will become effective upon the effectiveness of the registration statement of which this prospectus forms a part, as well as any future increases in the number of shares of our Class A common stock reserved for issuance under the 2025 Plan; and
- shares of our Class A common stock reserved for future issuance under the ESPP, which will become effective upon the effectiveness of the registration statement of which this prospectus forms a part, as well as any future increases in the number of shares of our Class A common stock reserved for issuance under the ESPP.

Dilution

If you invest in our Class A common stock in this offering, your ownership interest will be diluted to the extent of the difference between the initial public offering price per share of our Class A common stock and the pro forma as adjusted net tangible book value per share of our Class A common stock immediately after this offering.

Our historical net tangible book value (deficit) as of June 30, 2025 was $ million, or $ per share. Our historical net tangible book value (deficit) per share represents our total tangible assets less our total liabilities and redeemable convertible preferred stock (which is not included within stockholders' (deficit) equity), divided by the number of shares of common stock outstanding as of June 30, 2025.

Our pro forma net tangible book value as of June 30, 2025, was $ million, or $ per share. Our pro forma net tangible book value per share represents our total tangible assets less our total liabilities, divided by the number of shares of Class A and Class B common stock outstanding as of June 30, 2025, after giving effect to: (i) the Preferred Stock Conversion, (ii) the conversion of the A-6 Warrant to a warrant to purchase common stock and the related reclassification of the warrant liability to stockholders' equity, and (iii) the filing and effectiveness of our Post-IPO Certificate of Incorporation, all of which will occur immediately prior to the completion of this offering.

Our pro forma as adjusted net tangible book value represents our pro forma net tangible book value after giving further effect to the sale of shares of Class A common stock in this offering at an assumed initial public offering price of $ per share, the midpoint of the estimated offering price range set forth on the cover page of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. Our pro forma as adjusted net tangible book value as of June 30, 2025, was $ million, or $ per share. This amount represents an immediate increase in pro forma as adjusted net tangible book value of $ per share to our existing stockholders and an immediate dilution of $ per share to new investors participating in this offering. We determine dilution per share to investors participating in this offering by subtracting pro forma as adjusted net tangible book value per share after this offering from the assumed initial public offering price per share paid by investors participating in this offering.

The following table illustrates this dilution on a per share basis to new investors (without giving effect to any exercise by the underwriters of their option to purchase additional shares):

Assumed initial public offering price per share		$
Historical net tangible book value (deficit) per share as of June 30, 2025	$	
Increase in net tangible book value per share as of June 30, 2025 attributable to the pro forma adjustments described above		
Pro forma net tangible book value per share as of June 30, 2025		
Increase in pro forma net tangible book value per share attributable to new investors participating in this offering		
Pro forma as adjusted net tangible book value per share after this offering		
Dilution per share to new investors purchasing Class A common stock in this offering		$

The dilution information discussed above is illustrative only and will change based on the actual initial public offering price and other terms of this offering determined at pricing.

Each $1.00 increase or decrease in the assumed initial public offering price of $ per share, the midpoint of the estimated offering price range set forth on the cover page of this prospectus, would increase or decrease, as applicable, the pro forma as adjusted net tangible book value per share by $ per share and the dilution per share to investors participating in this offering by $ per share, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each 1.0 million share increase in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase the pro forma as adjusted net tangible book value per share by $ and decrease the dilution per share to investors participating in this offering by approximately $, assuming the assumed initial public offering price of $ per share, the midpoint of the estimated offering price range set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. Each 1.0 million share decrease in the number of shares offered by us, as set forth on the cover page of this prospectus, would decrease the pro forma as adjusted net tangible book value per share after this offering by $ and increase the dilution per share to new investors participating in this offering by approximately $, assuming the assumed initial public offering price of $ per share, the midpoint of the estimated offering price range set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

If the underwriters exercise their option to purchase up to additional shares in full, the pro forma as adjusted net tangible book value of our Class A common stock would increase to $ per share, representing an immediate increase in the pro forma net tangible book value per share to existing stockholders of $ per share and an immediate dilution of $ per share to investors participating in this offering, based on the assumed initial public offering price of $ per share, which is the midpoint of the estimated price range set forth on the cover page of this prospectus, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The following table summarizes, as of June 30, 2025, on the pro forma as adjusted basis described above, the number of shares of our Class A common stock, the total consideration and the average price per share (i) paid to us by our existing stockholders and (ii) to be paid by investors purchasing shares of our Class A common stock in this offering at an assumed initial public offering price of $ per share, the midpoint of the estimated offering price range set forth on the cover page of this prospectus, before deducting underwriting discounts and commissions and estimated offering expenses payable by us.

	Shares purchased		Total consideration		Weighted-average price per share
(in thousands, except share and per share data and percentages)	**Number**	**Percent**	**Amount**	**Percent**	
Existing stockholders		%	$	%	$
New investors					$
Total		100%	$	100%	

The presentation in this table regarding ownership by existing stockholders does not give effect to any purchases that existing stockholders may make through our directed share program or otherwise purchase in this offering. If the underwriters exercise their option to purchase additional shares of Class A common stock in full, the number of shares held by the existing stockholders after this offering would be reduced to shares, or % of the total number of shares of our Class A common stock outstanding after this offering, and the number of shares held by new investors would increase to shares, or % of the total number of shares of our Class A common stock outstanding after this offering.

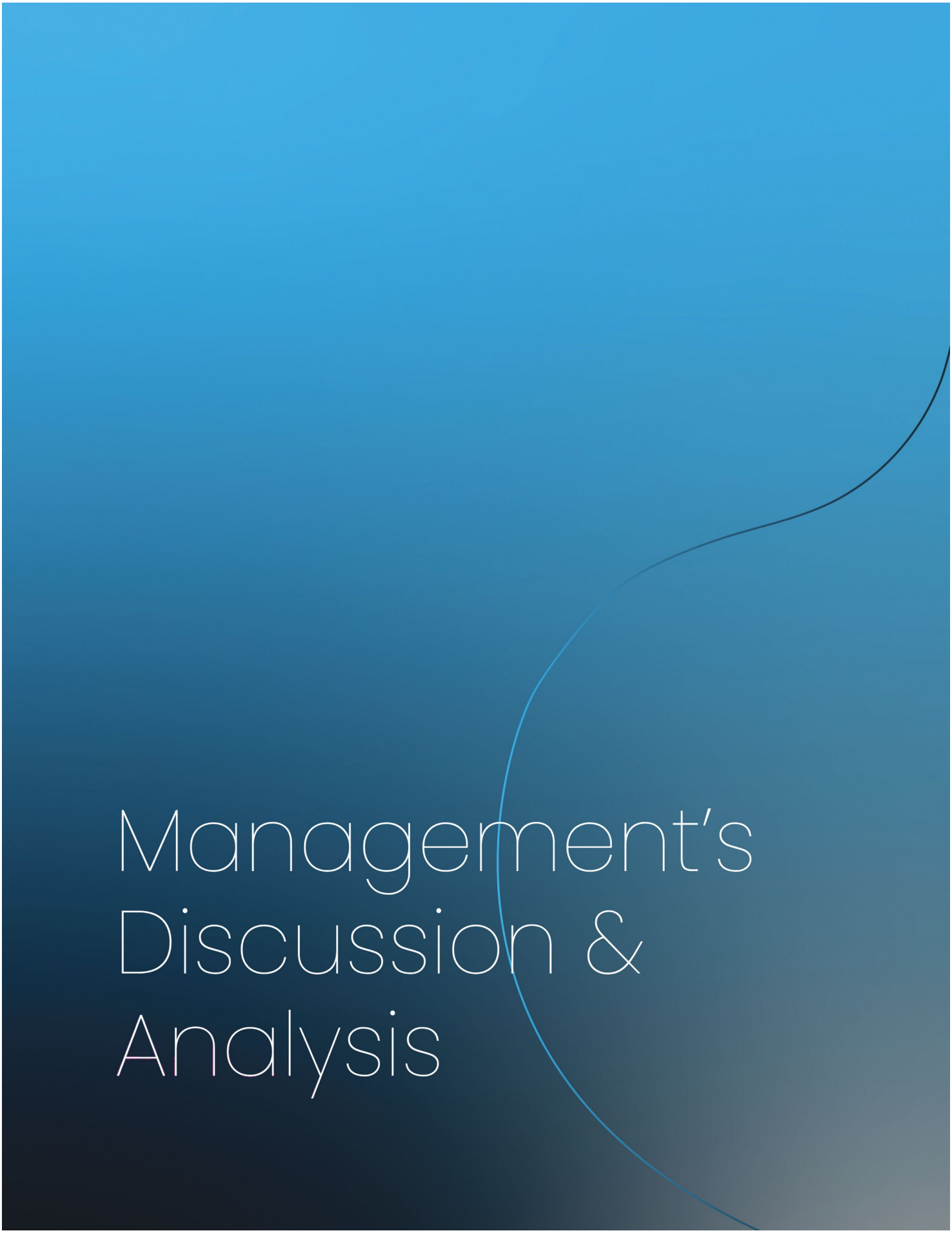
The foregoing discussion and calculations above (other than the historical net tangible book value calculations) are based on shares of our Class A common stock and shares of our Class B common stock outstanding as of June 30, 2025, after giving effect to the Preferred Stock Conversion, the Reclassification and the Class B Stock Exchange, in each case as if they had occurred on June 30, 2025, and excludes:

- shares of our Class A common stock issuable upon the exercise of stock options outstanding as of June 30, 2025 under our 2018 Plan, at a weighted-average exercise price of $ per share;
- shares of our Class A common stock issuable upon the exercise of outstanding stock options that were granted subsequent to June 30, 2025 under our 2018 Plan, at a weighted-average exercise price of $ per share;
- up to 9,660 shares of our Class A common stock issuable upon the exercise of the A-6 Warrant for an exercise price of $2.5879 per share;
- up to 80,357 shares of our Class A common stock issuable upon the exercise of the 2021 Common Warrant for an exercise price of $2.80 per share;
- up to 41,209 shares of our Class A common stock issuable upon the exercise of the 2022 Common Warrant for an exercise price of $10.92 per share;
- shares of our Class A common stock reserved for future issuance under our 2025 Plan, which will become effective upon the effectiveness of the registration statement of which this prospectus forms a part, as well as any future increases in the number of shares of our Class A common stock reserved for issuance under the 2025 Plan; and
- shares of our Class A common stock reserved for future issuance under our ESPP, which will become effective upon the effectiveness of the registration statement of which this prospectus forms a part, as well as any future increases in the number of shares of our Class A common stock reserved for issuance under the ESPP.

Any remaining shares available for issuance under our 2018 Plan will be added to the shares reserved under our 2025 Plan in effect following the completion of this offering and we will cease granting awards under the 2018 Plan.

To the extent that outstanding options or warrants are exercised, new options or other securities are issued under our equity incentive plans, or we issue additional shares of Class A common stock in the future, there will be further dilution to investors participating in this offering. In addition, we may choose to raise additional capital because of market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. If we raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

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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 financial statements as of and for the years ended December 31, 2024 and 2023 and the related notes included elsewhere in this prospectus. This discussion and analysis as well as other parts of this prospectus contain forward-looking statements that involve risks and uncertainties, including information with respect to our plans and strategy for our business. You should carefully read the sections titled "Special note regarding forward-looking statements" and "Risk factors" to gain an understanding of the factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

BillionToOne is transforming healthcare by redefining molecular diagnostics. Our revolutionary 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 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 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 sgNIPT that uses cfDNA to provide fetal risk assessment for recessive conditions such as SCD and 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 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.

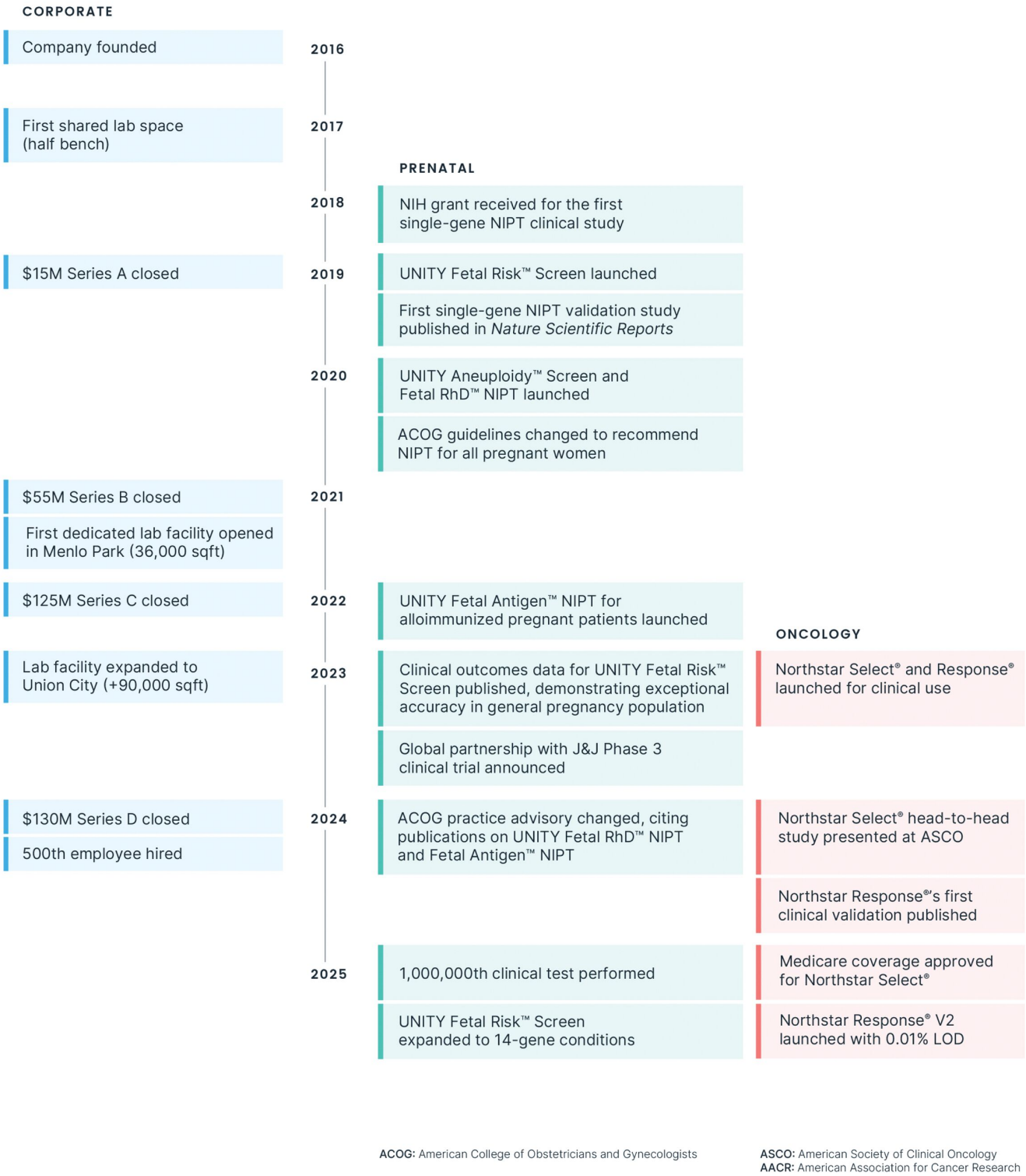
In the oncology setting, ultrasensitive tests with real-time insights are required to effectively detect, diagnose, and treat patients with a diverse range of mutations and solid tumor types across the cancer care continuum. In 2023, we successfully leveraged our smNGS platform to launch two complementary pan-cancer liquid biopsy tests – Northstar Select and Northstar Response. Our Northstar Select 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 approximately one million smNGS-based tests that we have processed since our initial launch,

more than of them, tests, were processed within the last 12 months ended June 30, 2025. For the year ended December 31, 2024, we generated revenue of $152.6 million, representing 113% year-over-year growth, with a gross margin of 53% and net loss of $41.6 million. Our business model has demonstrated improving operational leverage, which we believe will enable us to reach, on a non-GAAP income from operations basis, positive operating income after adjusting for stock based compensation expense for the six months ended June 30, 2025. During this period, we generated revenue of , with a gross margin of and a net income of , representing year-over-year revenue growth for the period. This translates to a net operating income improvement of approximately , from a net loss of for the six months ended June 30, 2024 to a net operating income of for the six months ended June 30, 2025.

Since our founding, we have developed and commercially launched multiple products and achieved a number of significant milestones as depicted in the chart below.

Key Corporate & Commercialization Milestones

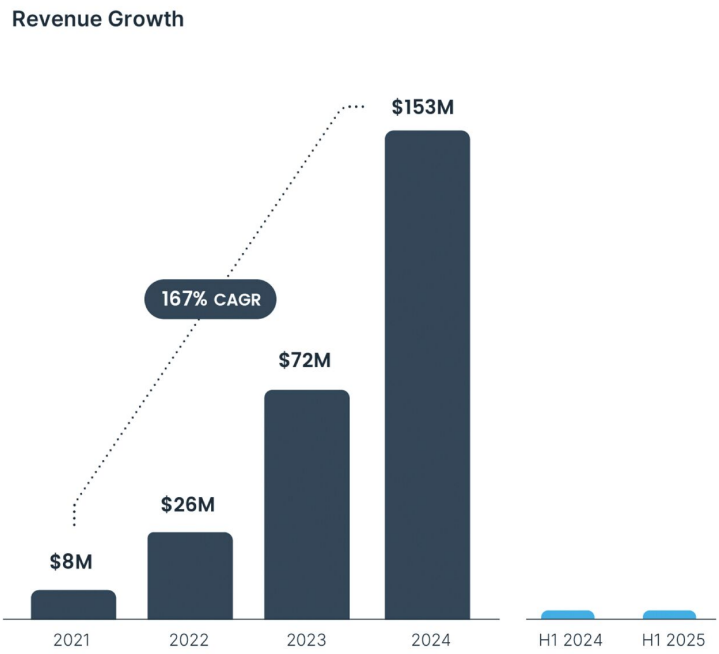


ACOG: American College of Obstetricians and Gynecologists

ASCO: American Society of Clinical Oncology
AACR: American Association for Cancer Research

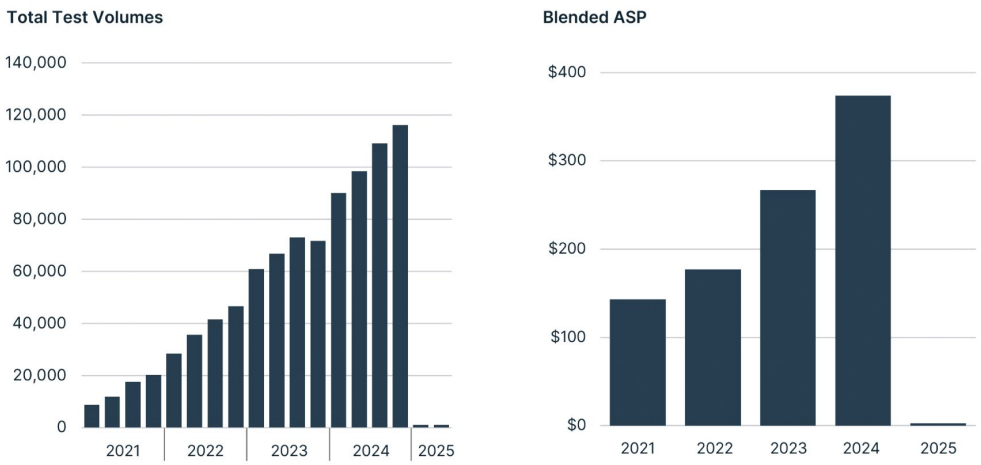
Our business model and key performance metrics

Our revenue is driven by selling and performing molecular diagnostic tests ordered by physicians and other providers. We generally bill the patients' insurance carrier, the patient, or a combination of both upon delivery of the test results. We first commercialized our prenatal products in 2019 and our oncology products in early 2023. Our revenue has grown rapidly from $8.1 million in 2021 to $152.6 million in 2024. Our pace of growth remains strong, as revenue grew 113% year-over-year in 2024 and % year-over-year in the six months ended June 30, 2025.

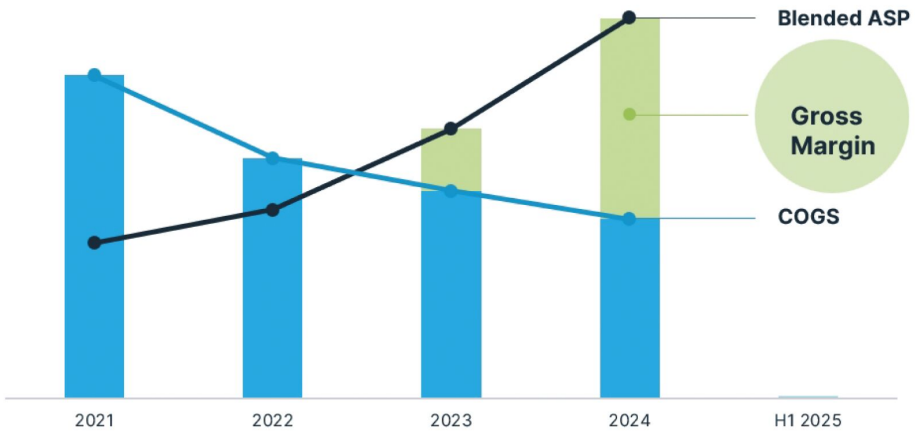


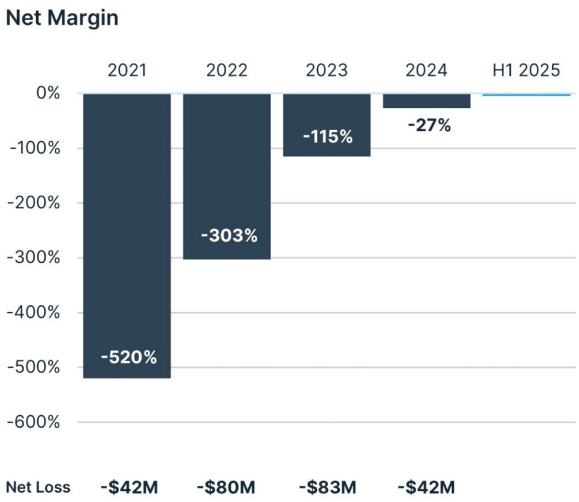
Our revenue is the function of two inputs: the number of tests ordered and the ASP that we can achieve through reimbursement. There is a flywheel effect between these two factors. The more tests that we process, the easier it becomes for us to contract with insurance companies and become an in-network 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 the in-network status results in a better patient and provider experience, with fewer requirements for prior authorization and lower patient payment responsibilities. The impact of this flywheel can be seen in the results of concurrent increases of ASP and test volumes, which enable us to grow our revenue at a rapid rate. For example, for the six months ended June 30, 2025 compared to the six months

ended June 30, 2024, our test volumes have grown year-over-year while ASPs have grown year-over-year, the combined effect of which was a year-over-year growth in our clinical revenue.



We believe that the combined effect of ASP increases, COGS decreases, and improved operational efficiency has been the main driver in decreases in our net losses. Our net losses decreased from $82.7 million in the year ended December 31, 2023 to $41.6 million in the year ended December 31, 2024, despite our heavy investments in the growth of our sales force, new product launches, and clinical studies.





Since increasing test volume drives each of these factors, either directly or indirectly, we believe that our net loss margin can continue to improve for at least the next twelve months, as long as we can continue to drive increased test volumes. However, such improvement will require continuous investments in sales force, further innovation, and new product launches, necessitating a balance between reaching profitability and investing for growth. While we are nearing operating profitability and positive cashflow, we will continue to optimize for long-term growth over short-term increases in profitability.

The market for our products is large and expanding. We have only partially penetrated the NIPT market, and in oncology, we have only just begun. We believe the superiority of our products, combined with our investments in our sales force, marketing infrastructure, enhancements to existing tests, increases in our ASP, and new product development will result in further revenue growth over the coming years.

Our strategy is to target large existing markets with our products. We believe the unique capabilities of our smNGS platform enable us to launch superior products in these markets and capture significant market share. We have successfully demonstrated this strategy in the prenatal market, and we are in the earlier phases of repeating this success in the oncology market with our therapy selection (Northstar Select) and therapy response monitoring (Northstar Response) products. We anticipate launching our first assay for MRD detection in 2026, and we believe our smNGS technology has the potential to support our entry into the early cancer detection market longer term.

Key factors affecting our results of operations and performance

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

- **Market adoption and commercial success**

  Our success and future growth depend on maintaining and expanding market acceptance and achieving commercial success in our prenatal and oncology product lines. This requires our sales teams to develop

and maintain relationships with obstetricians, maternal-fetal medicine specialists, oncologists, and other providers. In addition, our sales teams must be able to convincingly communicate the clinical utility and value of our tests in enabling personalized patient care. The commercial success of our existing tests and any new tests we develop will depend upon factors such as clinical evidence supporting their effectiveness, inclusion in clinical practice guidelines, adoption by the medical community, favorable coverage by third-party payors, and our ability to differentiate our offerings in competitive markets. In addition, our ability to maintain and expand our sales and marketing capabilities to support increased adoption of our molecular diagnostic solutions will be another key factor to our success. Our strategies to support our products' adoption and our commercial success include:

- **Increase geographic coverage:** Each field sales representative can effectively cover a small geographic region. Adding additional sales representatives enables our sales team to effectively access and convert new clinics in additional geographic regions.
- **Greater penetration within a covered territory:** As the account access, provider education, and onboarding of a new ordering provider within a clinic takes time, our sales representatives often onboard one clinic at a time. Approximately 35% of our sales team members have been in their territories for less than 18 months. As our sales representatives mature, we expect them to further penetrate their territories. Even our most tenured continue to onboard new clinics.
- **Expansion within a clinic:** Once an ordering provider within a clinic first starts to use our tests, we often see expansion of our tests to other providers within the clinic. We believe that our unique product offerings and exceptional end-to-end service drive this adoption. 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.
- **Effective marketing execution to drive adoption:** We support our field sales team with marketing collaterals, digital campaigns, webinars, and other marketing channels to help educate physicians about our products and the unique advantages and value propositions that they provide.
- **Our ability to continue innovating our test portfolio:** We are focused on continually innovating our product portfolio and capitalizing on opportunities created by our smNGS platform. This enhances our competitive position and positions us for long-term growth.

- **Payor coverage, contracting, and more effective reimbursement operations**

Our ASPs depend heavily on our success in achieving and maintaining broad coverage and adequate reimbursement for our molecular diagnostic tests from third-party payors. 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.

We believe our tests provide far higher value than the Medicare Clinical Laboratory Fee Schedule (CLFS) rates established for our tests. For instance, in a peer-reviewed publication, the break-even price for sgNIPT was estimated between $2,336 (healthcare cost-neutral price with better outcomes) and $7,233 (equivalent cost of identifying one affected pregnancy vs. sequential carrier screening). In comparison, the CLFS price for our sgNIPT was established at $879.47. We often use the calculation of health savings in our discussions with the payors to gain in-network status.

While our ASPs have significantly increased over time, they are, in aggregate, still less than ~50% of the CLFS rates for our tests. This is primarily because (i) we are not in-network with all payors, (ii) when we get in-network with a payor, we may agree to a rate that is less than 100% of the CLFS in return for more consistent in-network payments for our services, and (iii) not all of our tests are considered covered benefits by all payors. As we increase contracting and coverage of our tests, we believe that ASPs can continue to increase over time.

Historically, our market access and reimbursement teams have pursued strategies to increasing our ASPs by expanding our payor coverage and reimbursement. We believe these strategies will continue to grow our ASPs over time.

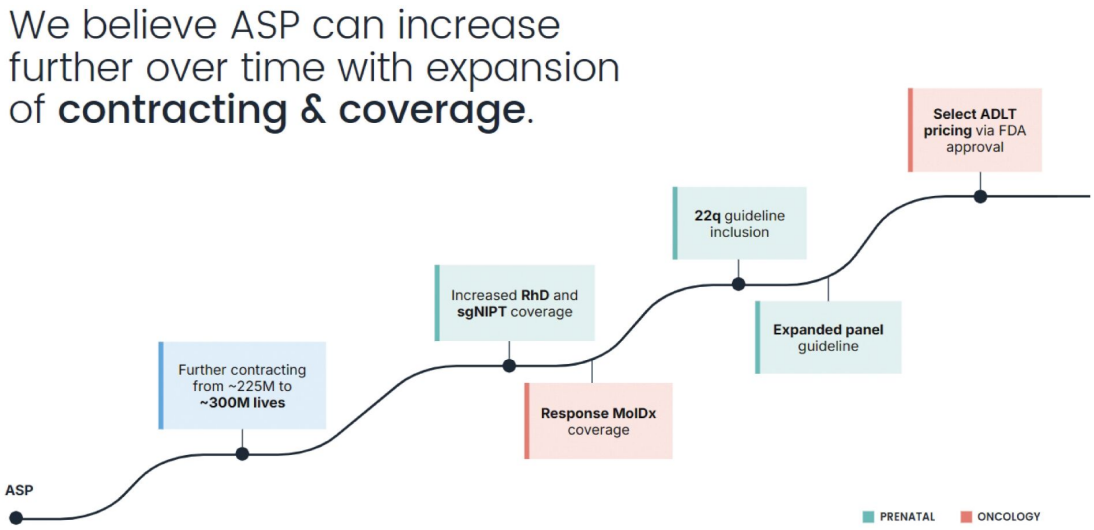
Examples include:

- **Strategic contracting with third-party payors:** We prioritize entering into contracts with major commercial insurance companies and other third-party payors. These contracts typically result in higher, more reliable reimbursement rates for our products compared to non-contracted arrangements, where reimbursement can be significantly lower or, in some cases, not provided at all. Historically, expanding our network of contracted payors has been a major driver of higher reimbursement rates, which support increased ASPs. As of December 31, 2024, our payor contracts encompass approximately 225 million covered lives within the United States, which we expect will continue to grow as we enter into additional agreements. This extensive payor network not only enhances access to our diagnostic tests for patients but also provides greater predictability and stability in our revenues.
- **Securing unique reimbursement and procedural codes:** A critical aspect of our market access strategy is to obtain specific reimbursement and procedural codes for our tests, rather than using the generic codes that may not fully capture the uniqueness and value that our tests provide. These codes facilitate appropriate billing and reimbursement from payors and drive broader clinical adoption. For instance, our UNITY Carrier Screen was assigned a PLA code, 0449U, which has received CMS pricing of $1,825, effective January 1, 2025. Similarly, our Northstar Select and Northstar Response products received PLA codes 0487U and 0486U, respectively, with CMS pricing of $2,920 and $1,644 respectively. As our codes of 0449U and 0487U have been added to the coverage policies of payors, including Medicare for the latter, our ASPs have increased.
- **Expanding payor coverage criteria and clinical utility:** Changes in payor policies, such as the expansion of coverage criteria or the recognition of new indications, can have a pronounced effect on our revenues and ASPs. In 2024, several payors began covering additional tests within our prenatal panel, specifically those for 22q11.2 deletion syndrome (22q microdeletion), RhD NIPT, and fetal antigen NIPT. Most recently, Geisinger issued a positive coverage policy for the sgNIPT component of our Fetal Risk Screen for recessive conditions. The inclusion of these tests in positive coverage policies has directly contributed to a notable improvement in the overall ASP for our prenatal product portfolio.

  Moreover, we achieved a significant milestone earlier this year with the receipt of a positive coverage determination from Medicare's MolDX for Northstar Select. As a result, Medicare coverage for Northstar Select began on February 14, 2025, expanding access for eligible patients. We plan to submit additional dossiers to MolDX for further coverage evaluations for Northstar Response, which, if successful, would significantly increase our ASPs in the future.

  Our continued engagement with medical societies and generation of clinical utility evidence may also facilitate the inclusion of our tests in future clinical practice guidelines. For instance, even with more

recent expansions, 22q11.2 microdeletion that we provide is only reimbursed in a minority of cases. We believe a change in the guidelines by ACOG would likely drive a much higher approval rate for this add-on by payors, substantially increasing the blended ASP for our tests. Achieving guideline inclusion is a benefit for patients, and it is a significant catalyst for expanded reimbursement which can further elevate our ASPs.



- **Internalizing and strengthening our reimbursement capabilities & incorporating automation and AI to reimbursement operations:**

To further optimize our reimbursement outcomes, in July 2023, we transitioned from relying on third-party vendors to managing our reimbursement function in-house. We have invested in building a high-performing, specialized team dedicated to all aspects of reimbursement, including claims management, appeals, and payor relations. 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. Since bringing this capability in-house, we have achieved dramatically improved results, evidenced by a significant and sustained increase in ASPs over the past two years.

In addition, we have integrated our internal systems end-to-end, automated many of the repetitive reimbursement procedures, and incorporated AI for significant efficiency improvements, e.g., using large language models (LLMs) to read, categorize, and react to thousands of correspondence from insurance companies that we receive every day, allowing our team to significantly increase their productivity.

This strategic move not only streamlines our operations and improves cash flow but also allows us to better advocate for the value of our diagnostic tests with payors by providing rapid feedback and responding proactively to evolving reimbursement trends.

- **Relentless focus on reducing costs and increasing operational efficiency**

Our financial results depend upon our ability to support current and future levels of demand for our prenatal screening and oncology diagnostic tests while maintaining discipline around our cost structure. Historically, we have been able to grow the size of our operational team much more slowly than our test

volume increases. This has led to significantly increased operational leverage and efficiencies on a per-test basis and has been a driver in improving our net 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. In the last approximately three years, we have reduced COGS per test by more than 50% 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. For example, AI-supported accessioning of test requisitions reduced the average accessioning time from more than three minutes to 60 seconds, saving significant labor costs, and allowing us to shift our highly talented laboratory personnel to higher impact activities. These reductions have been important contributors to the growth of our gross profit margin over time to % gross profit margin in the second quarter of 2025.

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. We estimate that these facilities can support a further four times revenue growth from the annualized run-rate (ARR) as of June 30, 2025 to almost ARR.

To further support our growth beyond our current facilities, we have also entered a lease for the construction of 220,000 square feet of laboratory space in Austin, Texas with favorable terms and tenant improvement package. We expect to occupy this facility in 2027, at which time we expect to nearly triple our current testing capacity.

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.

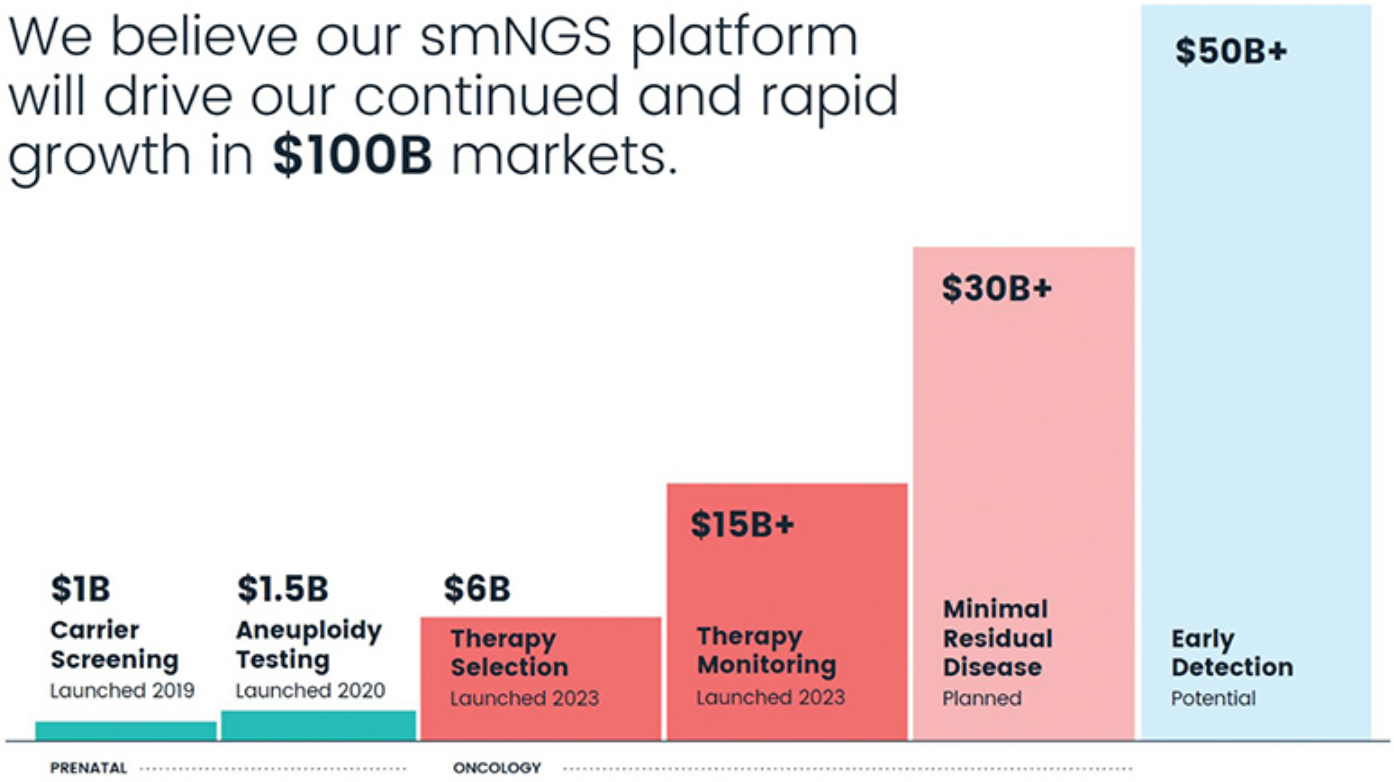
- **Continued research and development and new product innovation**

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. We incurred $22.4 million and $36.6 million in research and development expenses during the years ended December 31, 2023 and 2024, respectively.

Some of our earlier prenatal product innovations include our UNITY Complete Portfolio, which encompasses our original five gene UNITY Fetal Risk Screen, UNITY Aneuploidy Screen, UNITY Fetal RhD NIPT, and UNITY Fetal Antigen NIPT. We continue to innovate within our prenatal product portfolio. For

example, we recently launched a 14-gene version of our UNITY Fetal Risk Screen panel, which screens for more conditions than our existing five-gene guideline-focused screening panel. We estimate the 14-gene version of UNITY Fetal Risk Screen will expand the serviceable addressable market for UNITY by 70%, as some physicians prefer larger panels. We plan to continue innovating novel screening and diagnostic products for the prenatal market.

We are innovating within our oncology portfolio of products as well. For example, earlier this year, we launched a new version of our Northstar Response test, called Response V2, which provides significant improvements in precision and sensitivity over our original Response product. Importantly, Response V2's limit of detection at 0.01% tumor allele fraction already matches that of the leading tumor informed MRD assay. This level of sensitivity suggests our potential ability to develop a highly competitive tumor-naïve MRD assay using our smNGS platform. Longer-term we believe we may be able to develop products for even larger segments of the oncology diagnostic market, which we estimate represents an annual market opportunity of over $100 billion in the United States alone.



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. We market our products to health clinics and physicians primarily through our direct sales force. We generally bill directly to an insurance carrier, patient, or ordering health physician, 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.

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

Cost of revenue

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

Gross profit and gross margin

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

Operating expenses

Research and development expenses

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

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

Selling, general and administrative expenses

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

We expect selling, general and administrative expenses to increase in absolute dollars as we increase our sales and marketing personnel, increase product offerings, grow our operations and incur additional expenses associated with operating as a public company. These expenses as a result of operating as a public company

include expenses necessary to comply with the rules and regulations applicable to companies listed on Nasdaq and related compliance and reporting obligations pursuant to the rules and regulations of the SEC, as well as higher expenses for general and director and officer insurance, investor relations and other professional services.

Interest income

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

Interest expense

Interest expense is attributable to our borrowing with Western Alliance Bank, including the amortization of the debt discount. The debt with Western Alliance Bank was repaid in full in August 2024 with the proceeds from the new Oberland Capital debt. 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 agreement which we concluded was accounted for as a debt extinguishment. The gain on extinguishment consisted of the difference between the fair value of preferred equity received and the carrying amount of the 2022 Convertible Notes.

Change in fair value of term loan

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

Change in fair value of convertible notes

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

Other expense, net

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

Provision for income taxes

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

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

Results of operations

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

	Year ended December 31,	
	2023	2024
Revenue	$ 71,729	$152,582
Cost of revenue[1]	54,421	71,667
Gross profit	17,308	80,915
Operating expenses:		
Research and development[1]	22,414	36,596
Selling, general and administrative[1]	64,389	91,465
Total operating expenses	86,803	128,061
Loss from operations	(69,495)	(47,146)
Other income (expense):		
Interest income	3,456	5,819
Interest expense	(3,272)	(2,386)
Net gain on extinguishment of debt	—	7,289
Change in fair value of term loan	—	(3,137)
Change in fair value of convertible notes	(12,921)	(835)
Other expense, net	(442)	(1,145)
Total other (expense) income	(13,179)	5,605
Loss before provision for income taxes	(82,674)	(41,541)
Provision for income taxes	9	29
Net loss	$(82,683)	$ (41,570)

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

	Year ended December 31,	
	2023	2024
Cost of revenue	$ 683	$1,183
Research and development	1,450	2,341
Selling, general and administrative	2,721	4,838
Total stock-based compensation expense	$4,854	$8,362

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

	Year ended December 31,	
	2023	2024
Revenue	100%	100%
Cost of revenue	76%	47%
Gross margin	24%	53%
Operating expenses:		
Research and development	31%	24%
Selling, general and administrative	90%	60%
Total operating expenses	121%	84%
Loss from operations	(97)%	(31)%
Other income (expense):		
Interest income	5%	4%
Interest expense	(5)%	(2)%
Net gain on extinguishment of debt	—%	5%
Change in fair value of term loan	—%	(2)%
Change in fair value of convertible notes	(18)%	(1)%
Other expense, net	(1)%	(1)%
Total other (expense) income	18%	4%
Loss before provision for income taxes	(115)%	(27)%
Provision for income taxes	—	—
Net loss	(115)%	(27)%

Note: Certain figures may not sum due to rounding.

Comparison of years ended December 31, 2023 and 2024

Revenue

	Year ended December 31,			
	2023	2024	$ Change	% Change
	(dollars in thousands)			
Revenue	$71,729	$152,582	$ 80,853	113%

Revenue is comprised of revenue from our sales of our prenatal and oncology tests and our strategic partnership with Johnson & Johnson. Revenue increased $80.9 million, or 113%, for the year ended December 31, 2024 compared to the year ended December 31, 2023, primarily as a result of a 52% increase in the number of tests processed and a 41% increase in our overall ASP.

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.

Cost of revenue

	Year ended December 31,			
	2023	2024	$ Change	% Change
	(dollars in thousands)			
Cost of revenue	$54,421	$71,667	$ 17,246	32%

Cost of revenue increased $17.2 million, or 32%, for the year ended December 31, 2024 compared to the year ended December 31, 2023. The increase was primarily due to an increase of $9.2 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; an increase of $8.0 million in labor, overhead, equipment depreciation and other related costs driven by headcount growth for the year ended December 31, 2023 to the year ended December 31, 2024 to support the higher test volumes; and an increase in product support.

Gross profit and gross margin

	Year ended December 31,			
	2023	2024	$ Change	% Change
	(dollars in thousands)			
Gross profit	$17,308	$80,915	$ 63,607	368%
Gross margin	24%	53%		

Gross profit increased $63.6 million, or 368%, for the year ended December 31, 2024 compared to the year ended December 31, 2023. The increase was primarily due to an increase in tests processed and a higher ASP.

Gross margin increased from 24% for the year ended December 31, 2023 to 53% for the year ended December 31, 2024 for the reasons described above.

Operating expenses

Research and development expenses

	Year ended December 31,			
	2023	2024	$ Change	% Change
	(dollars in thousands)			
Research and development expenses	$22,414	$36,596	$ 14,182	63%

Research and development expenses increased $14.2 million, or 63%, for the year ended December 31, 2024 compared to the year ended December 31, 2023. The increase was primarily due to a $6.4 million increase in salaries and related expenditures, which included a $0.9 million increase in stock-based compensation expense, a $5.1 million increase in overhead allocation, facilities and equipment depreciation, a $2.0 million increase in expense related to clinical studies, and a $0.7 million increase in consulting and other costs. These increases were primarily driven by a net increase in R&D headcount of 24 employees from December 31, 2023 to December 31, 2024 to support the Company's product development and innovation efforts.

Selling, general and administrative expenses

	Year ended December 31,			
	2023	2024	$ Change	% Change
	(dollars in thousands)			
Selling, general and administrative expenses	$64,389	$91,465	$ 27,076	42%

Selling, general and administrative expenses increased $27.1 million, or 42%, for the year ended December 31, 2024 compared to the year ended December 31, 2023. The increase was primarily due to a $22.2 million increase in salaries, commissions and related expenditures, which included a $2.1 million increase in stock-based compensation expense, a $2.4 million increase in professional fees, a $0.8 million increase in marketing costs and a $1.7 million increase in facilities and other costs. These increases were driven by a net increase of 74 employees from the year ended December 31, 2023 to the year ended December 31, 2024 to support the Company's sales and marketing strategies.

Interest income

	Year ended December 31,			
	2023	2024	$ Change	% Change
	(dollars in thousands)			
Interest income	$3,456	$5,819	$ 2,363	68%

Interest income increased $2.4 million, or 68%, for the year ended December 31, 2024 compared to the year ended December 31, 2023. The increase was primarily due to higher average cash and cash equivalents balances.

Interest expense

	Year ended December 31,			
	2023	2024	$ Change	% Change
	(dollars in thousands)			
Interest expense	$(3,272)	$(2,386)	$ 886	(27)%

Interest expense decreased $0.9 million, or 27%, for the year ended December 31, 2024 compared to the year ended December 31, 2023. The decrease was attributed to incurring a full year's worth of interest in 2023 on the Western Alliance Bank debt compared to only a partial year of interest that was incurred in 2024, as the Western Alliance debt was replaced by the Oberland Capital debt in August 2024. The Oberland Capital debt was 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,			
	2023	2024	$ Change	% Change
	(dollars in thousands)			
Net gain on extinguishment of debt	$ —	$7,289	$ 7,289	—

Net gain on extinguishment of debt was $7.3 million for the year ended December 31, 2024. We did not record an extinguishment of debt for the year ended December 31, 2023. 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. This gain was partially offset by a $1.3 million loss on extinguishment of the Western Alliance Bank debt.

Change in fair value of term loan

	Year ended December 31,			
	2023	2024	$ Change	% Change
		(dollars in thousands)		
Change in fair value of term loan	$ —	$(3,137)	$ (3,137)	—%

Change in fair value of term loan decreased $3.1 million, for the year ended December 31, 2024 compared to the year ended December 31, 2023. The decrease was due to a change in fair value of the Oberland debt of $1.5 million in addition to the interest expenses associated with the Oberland debt of $1.6 million, which we elected to record with the change in the fair value of the loan.

Change in fair value of convertible notes

	Year ended December 31,			
	2023	2024	$ Change	% Change
		(dollars in thousands)		
Change in fair value of convertible notes	$(12,921)	$(835)	$ 12,086	(94)%

Change in fair value of convertible notes decreased $12.1 million, or 94%, for the year ended December 31, 2024 compared to the year ended December 31, 2023. The decrease was due to a change in fair value of the 2022 Convertible Notes that were extinguished in 2024; we elected to include interest expense in the change in fair value of the convertible notes.

Other expense, net

	Year ended December 31,			
	2023	2024	$ Change	% Change
		(dollars in thousands)		
Other expense, net	$(442)	$(1,145)	$ (703)	159%

Other expense, net increased $0.7 million, or 159%, for the year ended December 31, 2024 compared to the year ended December 31, 2023, which was primarily driven by increases in the fair value of our common stock warrant liability of $0.5 million, loss from divestiture of subsidiary of $0.1 million and a loss on disposal of fixed assets of $0.1 million for the year ended December 31, 2024.

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 non-GAAP operating loss and non-GAAP net 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 non-GAAP operating loss and non-GAAP net 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. 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.

Non-GAAP loss from operations

We define non-GAAP operating loss as operating loss presented in accordance with GAAP, adjusted to exclude stock-based compensation expenses. We have presented non-GAAP operating loss because we consider non-GAAP operating loss to be a useful metric for investors and other users of our financial information in evaluating our operating performance because it excludes the impact of stock-based compensation, which can vary from period to period for reasons that do not directly reflect our underlying operations. This metric also provides investors and other users of our financial information with an additional tool 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.

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

	Year ended December 31,	
	2023	**2024**
Loss from operations	$(69,495)	$(47,146)
Stock-based compensation expense	4,854	8,362
Non-GAAP loss from operations	$(64,641)	$(38,784)

Non-GAAP net loss

We monitor non-GAAP net loss income for planning and performance measurement purposes. We define non-GAAP net loss as net loss reported on our statements of operations, excluding the impact of stock-based compensation expenses, net gain on extinguishment of debt, change in fair value of the term loan, and change in fair value of convertible notes. We have presented non-GAAP net loss because we believe that the exclusion of these charges allows for a more relevant comparison of our results of operations to other companies in our industry and facilitates period-to-period comparisons as it eliminates the effect of certain factors unrelated to our overall operating performance. 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 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 loss, the most directly comparable GAAP financial measure, to non-GAAP net loss is presented below (in thousands):

	Years Ended December 31,	
	2023	2024
Net loss	$(82,683)	$(41,570)
Stock-based compensation expense	4,854	8,362
Net gain on extinguishment of debt	—	(7,289)
Change in fair value of term loan	—	3,137
Change in fair value of convertible notes	12,921	835
Non-GAAP net loss	$(64,908)	$(36,525)

Liquidity and capital resources

Since our inception, we have financed our operations primarily through the issuance of convertible notes, redeemable convertible preferred stock, debt, and cash generated from the sale of our products. As of December 31, 2024, our principal sources of liquidity were cash and cash equivalents of $191.5 million and working capital of $199.4 million. 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 $282.2 million as of December 31, 2024. 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 accrued interest at a rate of 8.0% per annum. The Note Purchase Agreement includes covenants requiring us 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 trailing six-month gross margin of not less than 30%. The Note Purchase Agreement also includes a royalty participation payment applicable to the first $100.0 million in revenue in each calendar year, and a final payment at maturity or at the time of prepayment such that Oberland Capital would earn a certain internal rate of return over the course of the loan. The first tranche of $50.0 million was advanced on September 1, 2024, with a maturity date of August 31, 2031, interest-only payments through August 31, 2031 and a lump sum payment due on August 31, 2031. The term loan advances are secured by a lien on our assets.

Cash flows

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

	Year ended December 31,	
	2023	2024
Net cash used in operating activities	$ (53,672)	$ (41,375)
Net cash provided by (used in) investing activities	82,838	(5,433)
Net cash provided by financing activities	13,405	141,017

Operating activities

Net cash used in operating activities for the year ended December 31, 2023 of $53.7 million included net loss of $82.7 million, a $2.6 million decrease in accounts receivable due to higher product sales and timing of customer payments, and a $1.4 million decrease in inventory due to build up for anticipated demand. These cash flow uses were partially offset by an increase of $3.0 million in deferred revenue related to our strategic partnership agreement, $2.2 million in prepaid expenses and other non-current assets due to timing of payment, $2.0 million in accounts payable and other accrued expenses also due to timing of payment, and non-cash charges of $25.2 million primarily consisting of change in fair value of convertible notes, depreciation and stock-based compensation.

Net cash used in operating activities for the year ended December 31, 2024 of $41.4 million included net loss of $41.6 million, a $15.6 million decrease in accounts receivable due to higher product sales and timing of customer payments, a $4.0 million decrease in other non-current assets and prepaid expenses, and a $1.5 million decrease in inventory due to build up for anticipated demand. These cash flow uses were partially offset by an increase of $6.8 million in accrued compensation, commissions and other employee benefits due to increased employee headcount and increased sales which increased commissions and bonuses, $3.1 million in accounts payable and other accrued expenses due to increased testing volumes and timing of payments and non-cash charges of $17.0 million primarily consisting of stock-based compensation, depreciation and amortization, amortization of operating right-of-use assets, change in fair value of 2022 Convertible Notes which were partially offset by the gain on extinguishment of debt.

Investing activities

Net cash provided by investing activities for the year ended December 31, 2023 of $82.8 million was the result of $90.0 million proceeds from maturities of certificates of deposit, partially offset by $6.2 million in purchases of property and equipment and $1.0 million deposits paid for financing leases.

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

Financing activities

Net cash provided by financing activities for the year ended December 31, 2023 of $13.4 million was the result of $15.0 million in proceeds from issuance of debt and $0.4 million in proceeds from exercise of stock options, partially offset by $2.1 million of principal payments on finance lease liabilities.

Net cash provided by financing activities for the year ended December 31, 2024 of $141.0 million was the result of $130.0 million in proceeds from Series D redeemable convertible preferred stock, $49.8 million in net

proceeds from issuance of debt, $1.1 million in proceeds from exercise of stock options, partially offset by $36.7 million repayment of debt upon extinguishment and the related exit fee, $2.4 million principal payments on finance lease liabilities and $0.5 million 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, 2024, we had fixed lease payment obligations of $76.6 million, with $8.8 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, 2024, we had fixed lease payment obligations of $2.8 million, with $1.9 million to be paid within 12 months and the remainder thereafter.

For additional discussion on our leases, see Note 8 to our financial statements included elsewhere in this prospectus.

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.

Quantitative and qualitative disclosures about market risk

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

Interest rate risk

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

Inflation risk

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

Foreign currency exchange rate fluctuations

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

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

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

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

Revenue

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

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

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

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

We enter into contracts with third-party payors including insurance carriers and Medicaid to set the pricing for tests provided to patients. Due to the nature of these third-party payor contract arrangements, the total consideration we expect to collect for test results is variable as they are dependent on the terms negotiated with the third-party payor. The predominance of our revenue is derived from payments by third-party insurance carriers. Additionally, we entered into an agreement with Johnson and 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 or operations.

Stock-based compensation

We measure stock-based compensation expense for all stock-based payment awards based on the estimated fair value of the awards on the date of grant. The fair value of each stock option granted is estimated using the Black-Scholes Model. The model requires us to make assumptions and judgments about the variable inputs used in the Black-Scholes Model, including expected term, the volatility of our common stock, and assumed risk-free interest rate. Stock-based compensation is recognized net of actual forfeitures on a straight-line basis over the requisite service period of the awards. We account for forfeitures as they occur.

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

Common stock valuations

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

- the results of contemporaneous valuations performed at periodic intervals by a third-party valuation firm;
- the prices, rights, preferences, and privileges of our redeemable convertible preferred stock relative to those of our common stock;

- the prices of our redeemable convertible preferred stock and common stock sold to investors in arms-length transactions;
- our actual operating and financial performance and estimated trends and prospects for our future performance;
- our stage of development;
- the likelihood of achieving a liquidity event, such as an initial public offering, direct listing, or sale of our company, given prevailing market conditions;
- the lack of marketability involving securities in a private company;
- the market performance of comparable publicly traded companies; and
- U.S. and global capital market conditions.

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

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

In addition, we also considered any secondary transactions involving our capital stock. In our evaluation of those transactions, we considered the facts and circumstances of each transaction to determine the extent to which they represented a fair value exchange. Factors considered include transaction volume, timing, whether the transactions occurred among unrelated parties, and whether the transaction involved investors with access to our financial information.

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

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

Recent accounting pronouncements

For more information, please see Note 1 to our financial statements included elsewhere in this prospectus.

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.

Internal control over financial reporting

Neither we nor our independent registered public accounting firm were required to, and therefore did not, perform an evaluation of our internal control over financial reporting as of or for any period included in our financial statements, nor any period subsequent in accordance with the provisions of the Sarbanes-Oxley Act. However, in connection with the preparation of our financial statements, we identified material weaknesses in our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

The material weaknesses identified pertained to:

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

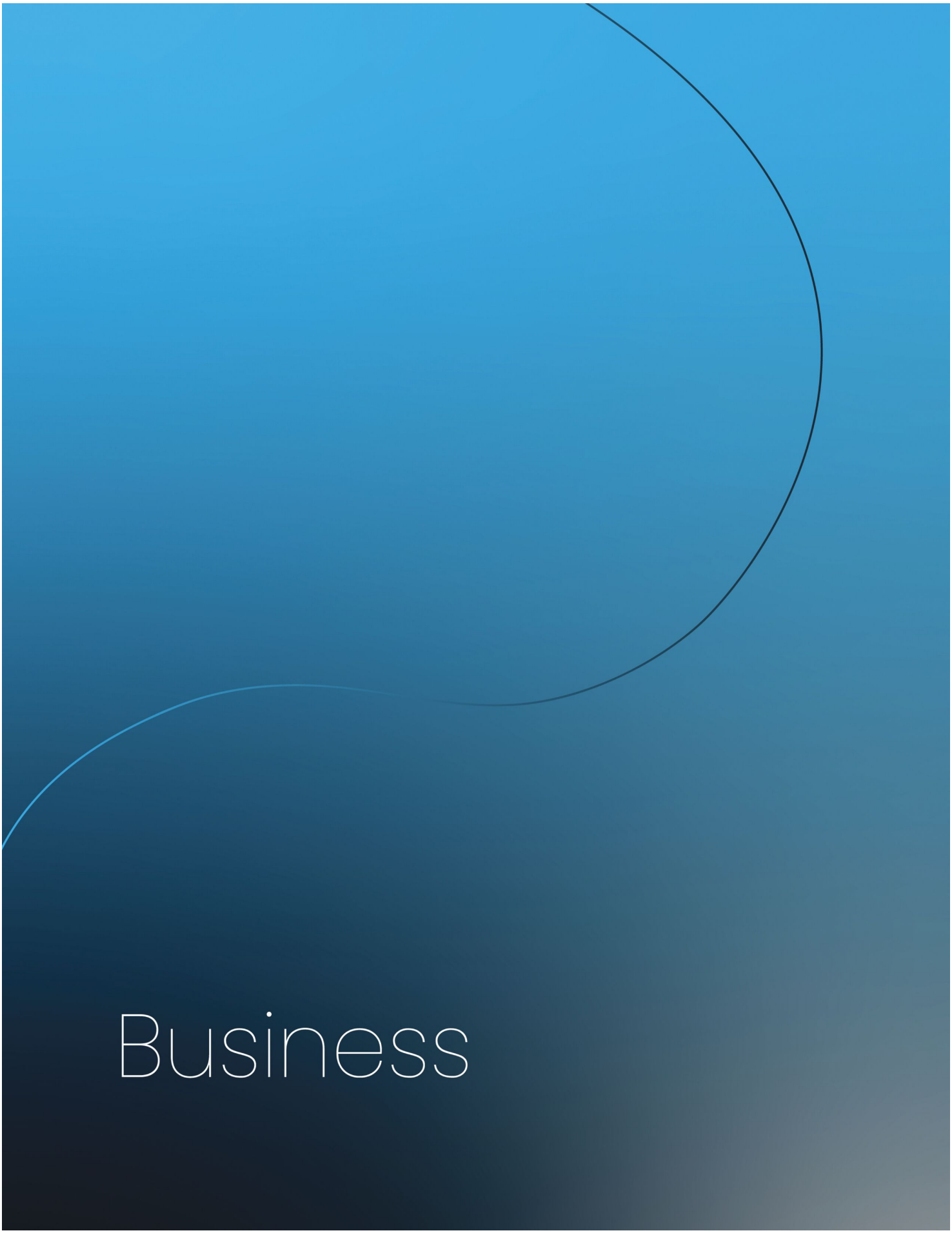
entries. This material weakness did not result in a misstatement to the financial statements; however, it could result in a misstatement of account balances or disclosures that would result in a material misstatement to the annual or interim financial statements that would not be prevented or detected.

We have taken certain measures to remediate the material weaknesses described above, including:

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

We will not be able to fully remediate these material weaknesses until these steps have been completed and have been operating effectively for a sufficient period of time. Additionally, as stated above, we have not performed an evaluation of our internal control over financial reporting. Accordingly, we cannot ensure that we have identified all, or that we will not in the future have additional, material weaknesses. While we are aiming to complete these remediation efforts by the end of 2025, these remediation efforts or testing their effectiveness may extend into 2026. 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 the completion of this offering. If we are unable to remediate the material weaknesses or if we identify additional material weaknesses in the future or otherwise fail to develop and maintain effective internal control over financial reporting, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect our business.

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Business

Overview

BillionToOne is transforming healthcare by redefining molecular diagnostics. Our revolutionary single molecule NGS (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 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 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. 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, which we estimate has an annual market opportunity of over $100 billion in the United States alone.

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 non-invasive prenatal test (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 in the prenatal testing market and expanded our UNITY offering to cover comprehensive prenatal genetic needs from a single maternal blood draw. While we know of competitors working to develop and launch competing NIPTs for recessive conditions, we believe the differentiation of our smNGS technology and 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. 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. To date, we have processed more than one million smNGS-based tests, including tests in the 12 months ended June 30, 2025. For the year ended December 31, 2024, we generated revenue of $152.6 million, representing 113% year-over-year growth, with a gross margin of 53% and net loss of $41.6 million. Our business model has demonstrated improving operational leverage, which we believe will enable us to reach, on a non-GAAP income from operations basis, positive operating income after adjusting for stock based compensation expense for the six months ended June 30, 2025. During this period, we generated revenue of , with a gross margin of and a net income of , representing year-over-year revenue growth. This translates to a net income improvement of approximately , from

a net loss of in the six months ended June 30, 2024 to a net income of in the same period in 2025.

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.



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 eliminating biases introduced from next-generation sequencing (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. Moreover, we believe our design-based R&D approach allows us to harness this technology 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. Additionally, while our current products already address an estimated annual market opportunity of over $20 billion in the United States, we believe that our R&D pipeline could eventually expand this annual addressable market to over $100 billion. 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, demonstrated by limiting our accumulated deficit of $282.2 million as of December 31, 2024, which is a small fraction of the losses incurred by some of our competitors. The important factors resulting in this efficiency are (i) our gross margins of % for the three months ended June 30, 2025, which has increased percentage points year-over-year, (ii) our high sales efficiency driven by differentiated products, with our annualized revenue run-rate per sales representative at over $ million for the three months ended June 30, 2025, and (iii) disciplined operational practices supplemented by automation and AI. 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. 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.



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. Today, we are experiencing another step change as we believe our smNGS platform enables the absolute quantification of cfDNA and we believe overcomes the

technical noise that restrains the traditional NGS testing methods used by other diagnostic companies. This breakthrough capability enables our non-invasive diagnostic tests to achieve performance characteristics previously only possible with invasive tissue biopsies from the affected organ.

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.



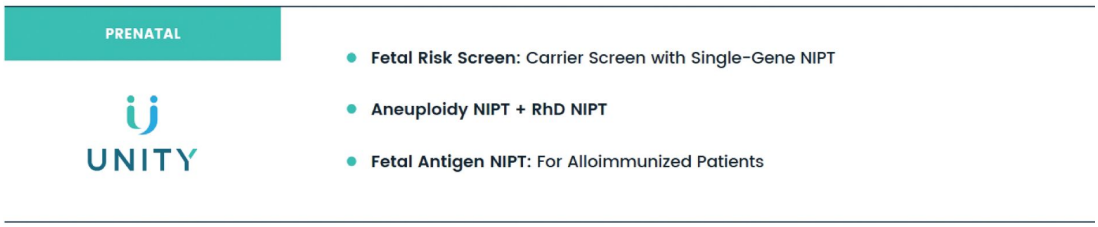
Our product portfolio of ultrasensitive tests touches everyone from the beginning of life, with prenatal genetic testing, to the end of life, with cancer therapy selection and response monitoring.

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.

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. We intend to expand our oncology test offerings into testing of earlier stage cancer patients, including through minimal residual disease (MRD) testing and potentially for early cancer detection.

To date, we have launched multiple products across these large addressable markets. We performed more than smNGS-based tests in the last 12 months ended June 30, 2025, with significant room to further grow test volume in both markets.

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 SCD, alpha thalassemia, beta-thalassemia, CF, and 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. We estimate the prenatal market represents an annual opportunity of over $2.5 billion in the United States.

Oncology products



Non-invasive liquid biopsy tests are a rapidly growing approach to detect and measure tumor DNA, driven by the increasing focus on molecular-targeted cancer treatments. However, current imaging and conventional liquid biopsy approaches present critical shortcomings, including missed actionable mutations and delays in detecting treatment 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. In a head-to-head study presented at American Society of Clinical Oncology (ASCO) annual meeting in 2024, our test demonstrated superior performance by detecting 51% more pathogenic and actionable SNVs and 109% more CNVs than conventional liquid biopsies. Northstar Select targets the therapy selection cancer diagnostics market, which we estimate is an annual United States market opportunity of over $6 billion.

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. Validation studies showed Northstar Response's consistent ability to detect 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 targets the cancer therapy response diagnostics market, which we estimate is an annual United States market opportunity of over $15 billion.

The clinical value of our oncology portfolio is validated by physician adoption. More than 95% of oncologists who order our tests utilize both Northstar Select and Northstar Response in tandem, highlighting their complementarity in guiding cancer care.

Additional opportunities in oncology

We are actively developing additional diagnostic products to address critical needs across the cancer care continuum. 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 estimate the annual United States market opportunity for MRD to be over $30 billion. Longer term, we believe that our smNGS-based technology could address the sensitivity challenges of early-stage cancer detection; however, we have not yet started development in this area. We estimate the annual United States market opportunity for early detection to be over $50 billion.

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.

While our AI-enabled vision represents the future of our platform, our commercial success today demonstrates the fundamental value of our existing products. Our existing products in prenatal and oncology have already demonstrated strong growth from zero to $ million annualized revenue run-rate (ARR) in six years. As we expand into new and larger markets, we believe that our foundational smNGS platform will position us to become a generational healthcare company.



The BillionToOne 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. These

complementary technologies achieve single-molecule precision with large scale multiplex capabilities, bypassing the tradeoff between precision and scale that limits traditional NGS methods.

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 at any given genomic location associated with disease, even in advanced cancer patients.

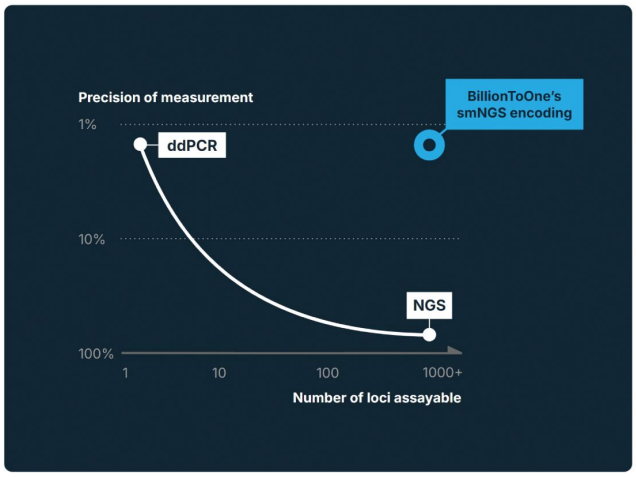
Breakthrough performance capabilities

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 or 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.

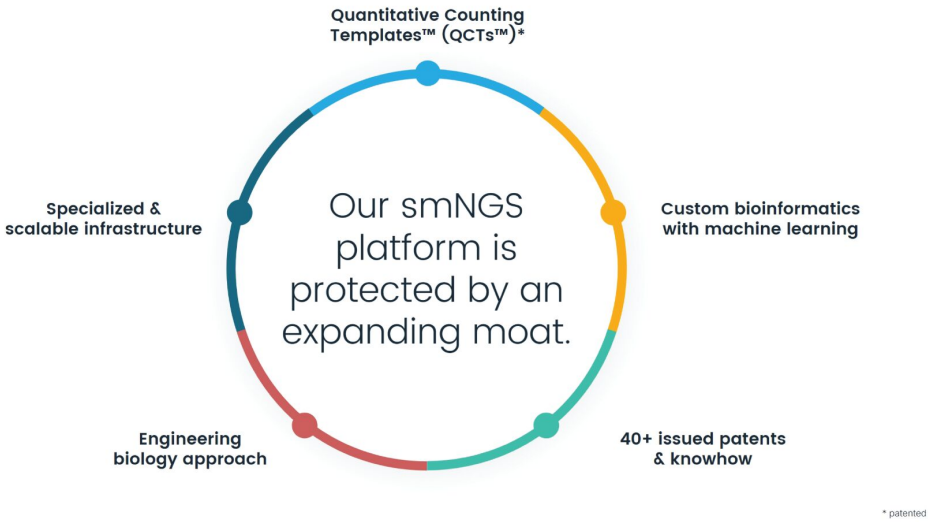
Traditional NGS methods have transformed many areas of clinical testing due to their ability to multiplex across thousands of loci, such as enabling a single clinical test to cover multiple genes. However, these NGS methods face significant limitations when applied to cfDNA analysis. The scarcity of 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, as depicted in the figure below.

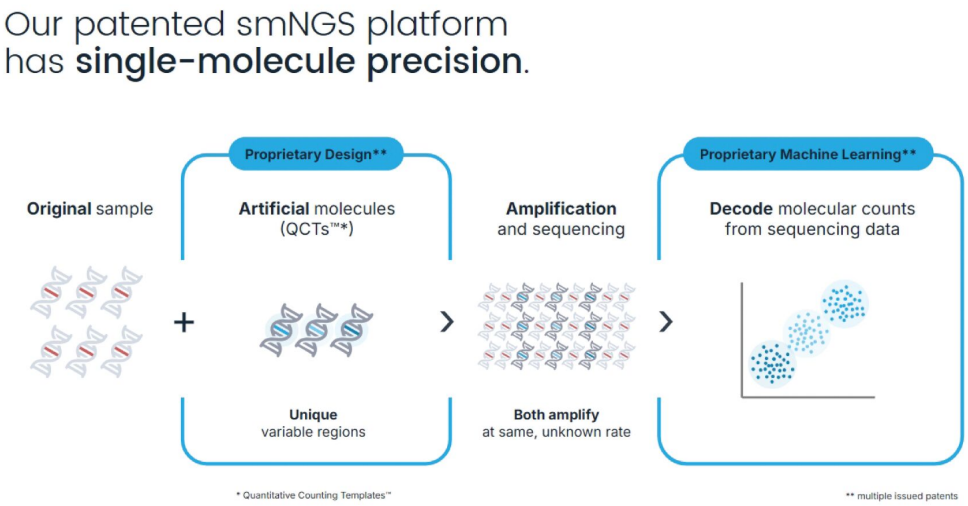


Quantitative Counting Templates (QCTs)

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. As a technology-forward organization, we have decreased our COGS by more than % in the 24 months ended June 30, 2025, in part by deploying automation and AI. 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 over 40 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 margins. 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 the section titled “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. 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.



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.

Our market entry strategy and journey

Prior to our entry, the non-invasive prenatal testing market (NIPT) almost exclusively focused on chromosomal abnormalities called aneuploidies. Other conditions such as cystic fibrosis or sickle-cell disease could only be detected by invasive methods such as amniocentesis following carrier testing of the parents. By first focusing our smNGS platform on directly assessing fetal risk for these conditions, we expanded the indication of NIPT from more than one million base pair aneuploidies to single base pair conditions. Currently, we are the second largest prenatal genetics laboratory in the United States by revenue, achieving a % revenue growth rate to $ million in the 12-month period ended June 30, 2025 from the preceding 12-month period. We estimate the market opportunity for our prenatal products to be over $2.5 billion annually in the United States.

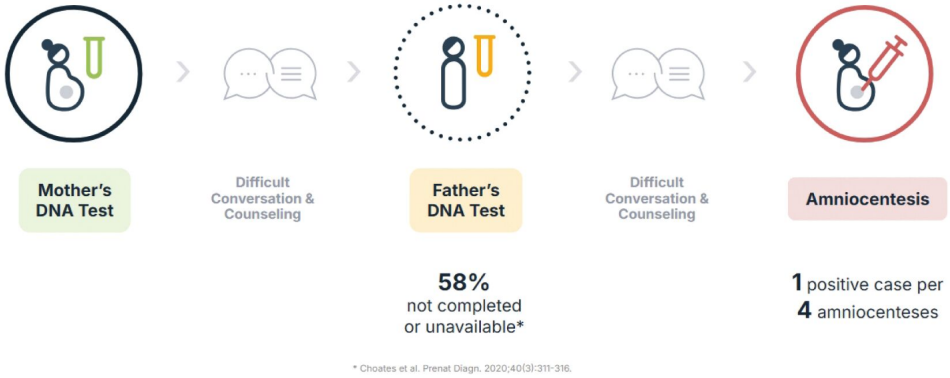
Building on our success in the prenatal market, we have applied our smNGS platform to solve similar technical challenges in the oncology market – specifically focusing on late-stage cancer. In 2023, we launched offerings in oncology specifically related to therapy selection (Northstar Select) and response monitoring (Northstar Response). We estimate the annual market opportunity for these two products to be more than $20 billion, and critically, we estimate that the market is less than 20% penetrated today by all molecular diagnostics companies. We also plan to expand our product portfolio and are developing a tissue-free, pan-cancer MRD test, which we expect to be commercially available in 2026. We estimate the annual United States market opportunity for MRD to be over $30 billion. Longer term, we believe that our smNGS-based technology could address the sensitivity challenges of early-stage cancer detection; however, we have not yet started development in this area. We estimate the annual United States market opportunity for early detection to be over $50 billion. Collectively, we estimate these addressable oncology markets represent over $100 billion annually.

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 existing 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.

The market demand for more sensitive and precise oncology tests

Cancer is the second leading cause of death according to the CDC. There are over 300 commercially available cancer treatments today, with more than 60 new therapies approved by the FDA in 2024 alone. 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. 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 SNVs and 109% more 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.

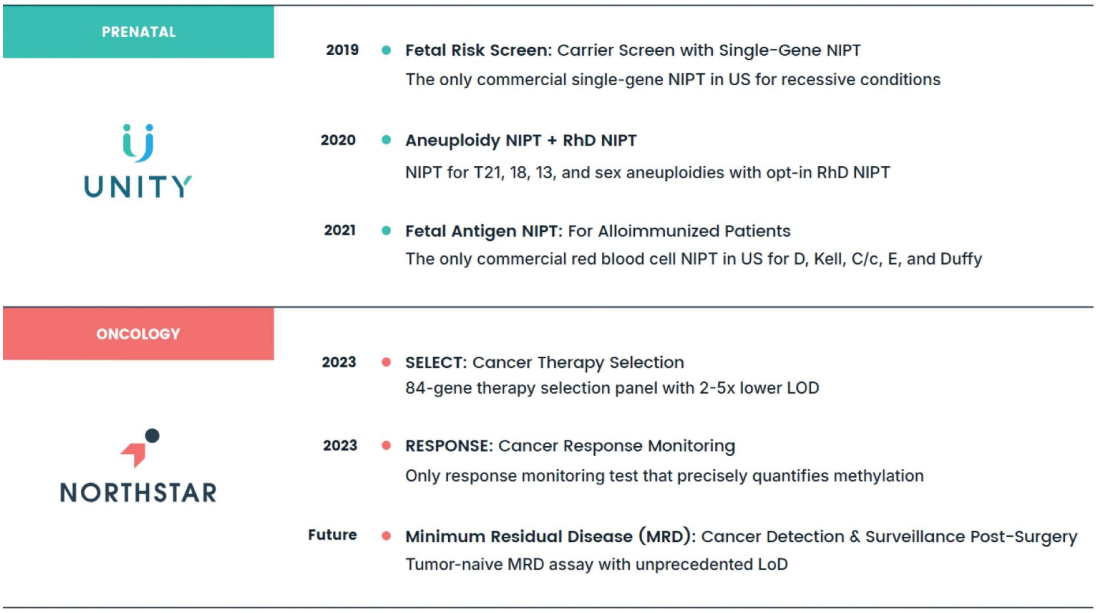
Northstar Response is now undergoing further validation through our large flagship study: NORTH (Northstar Oncology Response Monitoring Test Hallmark). NORTH is a multi-site study with over 500 Stage III and IV solid tumor cancer patients undergoing systemic therapies. Enrollment of the study was completed in early 2025 and we expect to complete sample and data collection by the end of 2025, with results 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.



Our proprietary smNGS platform enables us to create differentiated, ultrasensitive tests that approach the physical limit of detection (LOD). Our product portfolio touches everyone from the beginning of life, with prenatal genetic testing, to the end of life, with cancer therapy selection and response monitoring testing.

To date, we have launched multiple differentiated products across these large addressable markets. We performed more than smNGS-based tests in the last 12 months ended June 30, 2025, with significant room to further grow test volume in both markets.



Prenatal products

Traditional non-invasive prenatal screening focuses on assessing a fetus' risk for larger chromosomal changes, such as Down syndrome. However, several common and severe conditions are the result of much smaller genetic changes. Identifying these tiny changes within cfDNA is technically challenging and requires precise quantification to separate the contribution of relatively sparse fetal signal from the significant maternal background DNA, especially for recessive conditions such as SCD, alpha thalassemia, beta-thalassemia, CF, and SMA. Since traditional non-invasive prenatal tests (NIPTs) are unable to screen for these recessively-inherited, single-gene conditions, diagnosing these disorders in the fetus requires invasive methods such as amniocentesis or chorionic villus sampling. Prior to such invasive testing, conventional carrier screening has to be completed and requires a paternal sample. Third party studies estimate that fewer than half of the fathers complete the recommended screening due to barriers related to cost, availability, and willingness. As a result, at least 58% of pregnancies affected by these conditions are undetected. Our smNGS-based tests offer the level of precision and quantification necessary to overcome these challenges and provide a solution to this problem.

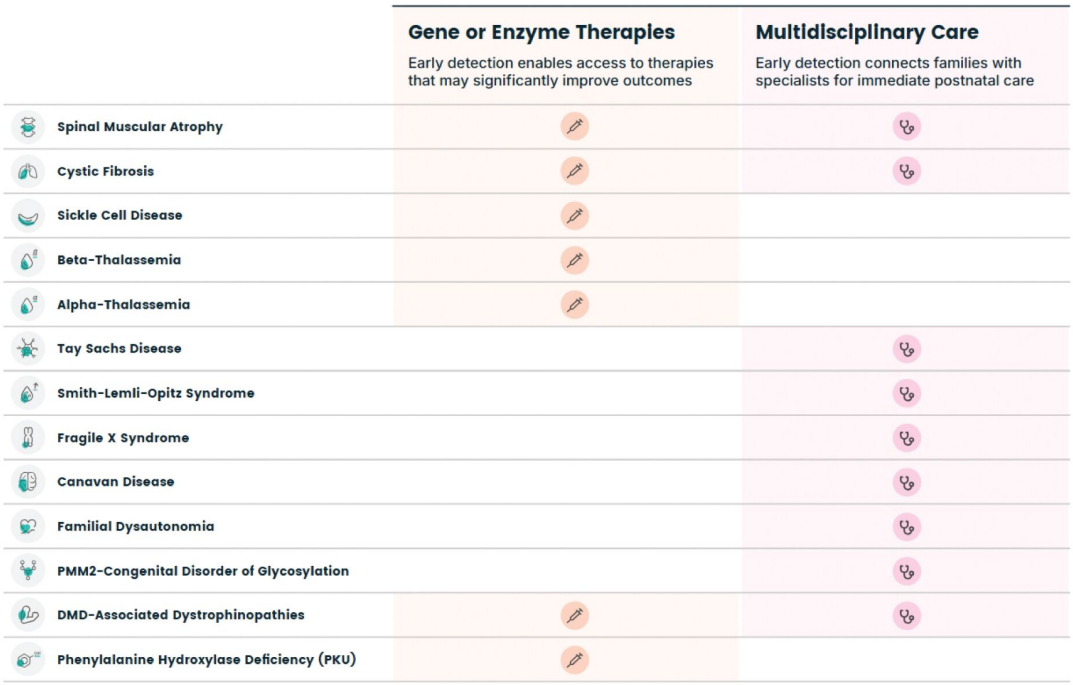
Our UNITY Complete portfolio

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

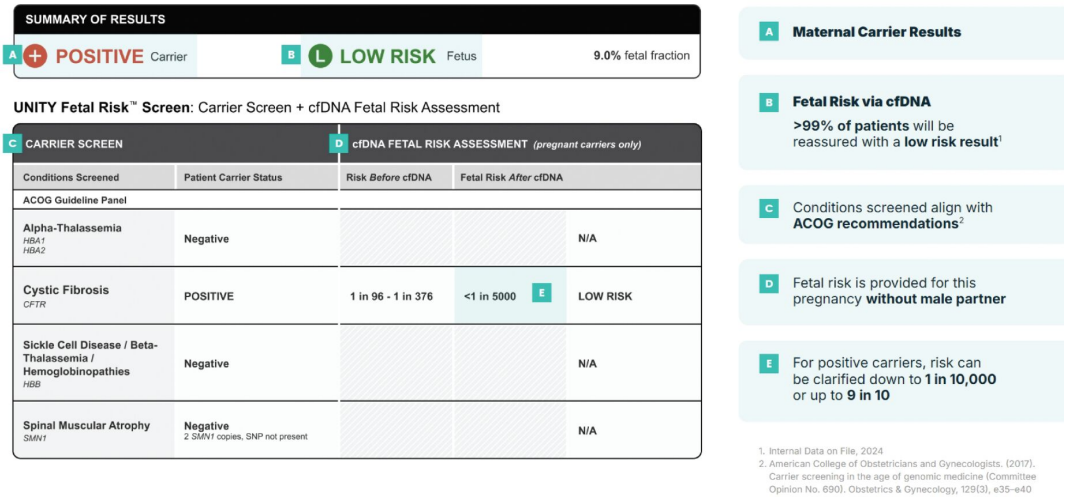
UNITY Fetal Risk Screen's testing menu to include up to 14 conditions, as shown in the below figure, further enhancing its clinical impact.



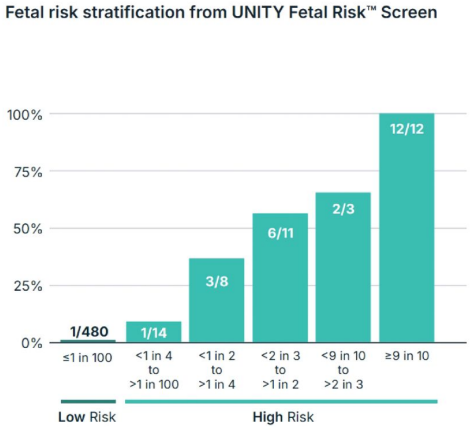
The first step of the UNITY Fetal Risk Screen involves determining the maternal carrier status. If the mother is identified as a carrier, cfDNA analysis is performed on the same blood sample to assess fetal risk. We believe directly measuring fetal risk through a single maternal blood draw is only possible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

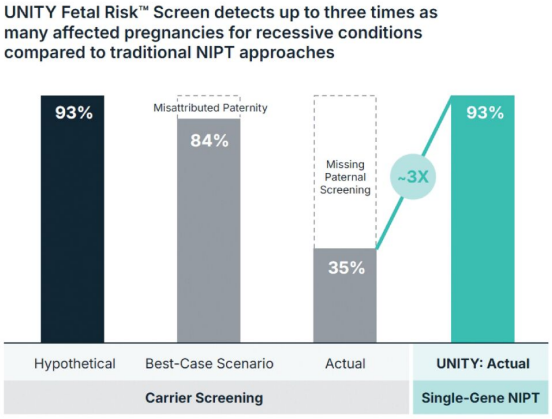
- Maternal carrier status and any information about the specific variant that may be identified;
- A personalized fetal risk score on each condition for which the pregnant mother is a carrier, ranging from <1 in 10,000 to 9 in 10, providing clear, actionable information for clinicians and patients; and

- 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

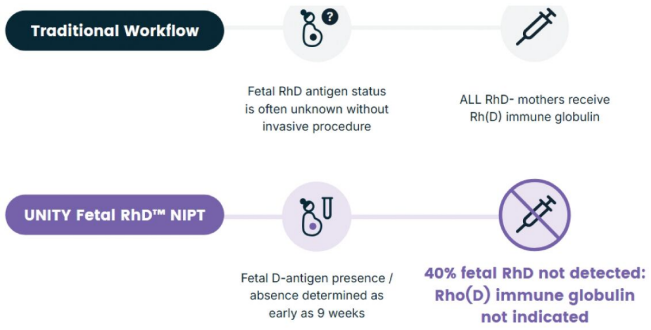
to provide conclusive results. Our smNGS platform provides a critical signal boost that is especially noticeable at lower fetal fractions, significantly reducing inconclusive results.

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 70% 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_ψ 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 a 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.

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 assays' use in the trial. We have also received regulatory clearances from health authorities in certain European and Latin American countries for the use of the assays 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 a head-to-head study presented at ASCO in 2024, we have shown that more than one-third of actionable mutations are undetected by other liquid biopsies due to lower sensitivities at lower variant allele fractions. Moreover, current products are also limited in their ability to quickly, precisely, and sensitively quantify trends in tumor progression over the course of treatment.

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.

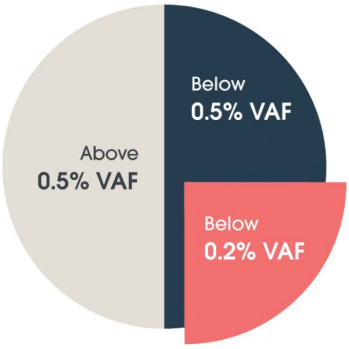
Northstar Select

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 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

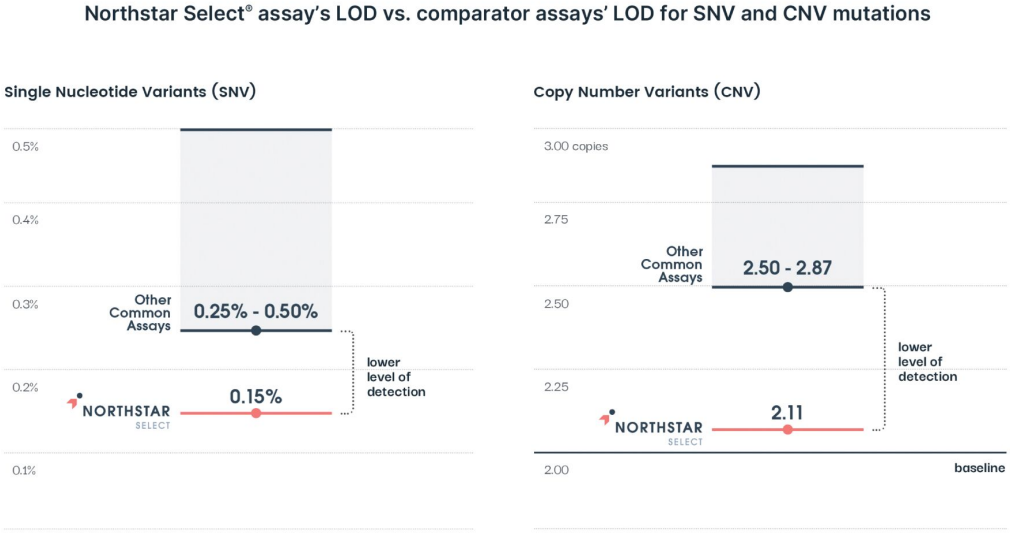
Liquid biopsy tests are dependent on finding tumor molecules circulating in blood that are shed from tumor cells. The tumor shedding rate is highly variable, with many cancers shedding very little ctDNA. This poses a sensitivity challenge for liquid biopsies, especially for variants at low levels, and 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.

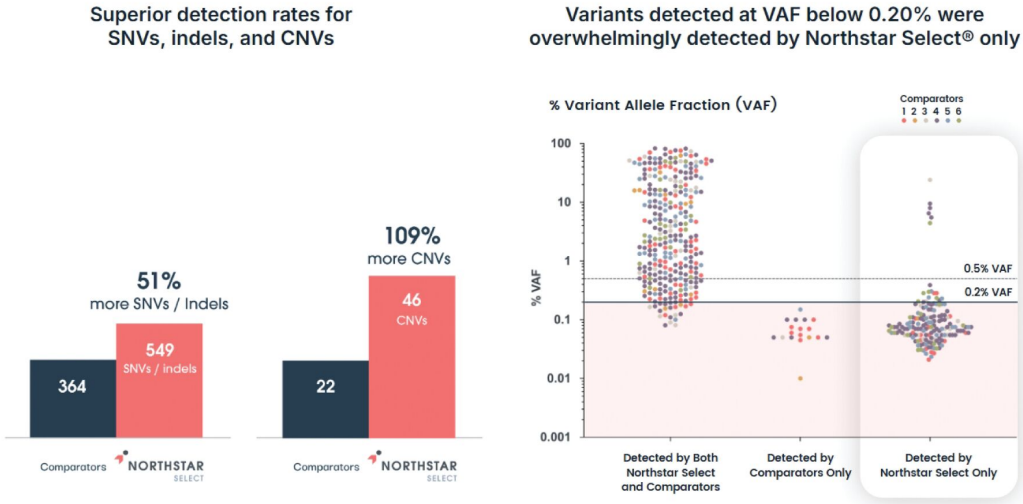
The sensitivity of other liquid biopsies is even more problematic for copy number variants (CNVs). During a cancer's development and evolution, certain genes may replicate in number, driving uncontrollable growth. CNVs are increasingly recognized as hallmarks of cancer. While there are therapies that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

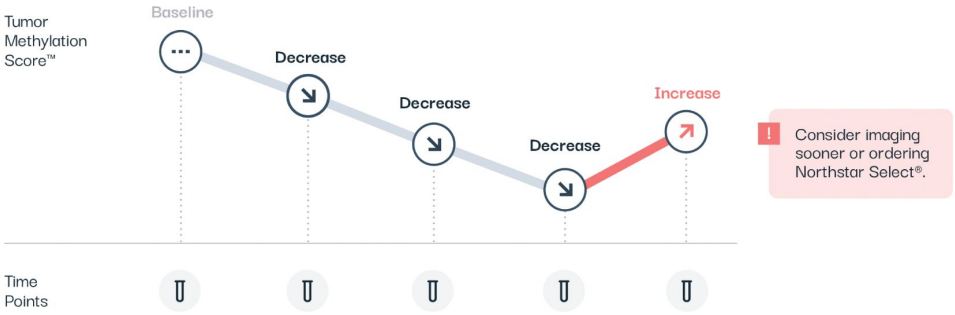


Northstar Response

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

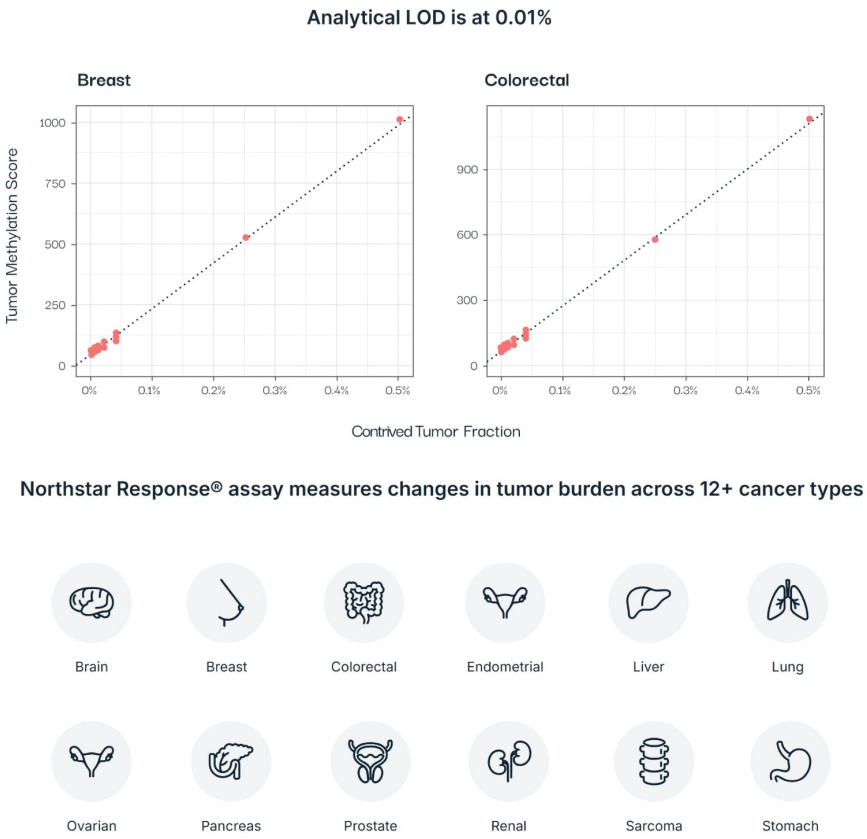
The ability to monitor a tumor's response to therapy and rapidly adjust treatment strategy when necessary is pivotal to improving patient outcomes, especially in late-stage cancers. Today, the most common and accepted method to assess treatment response is by measuring changes in tumor size through radiographic 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

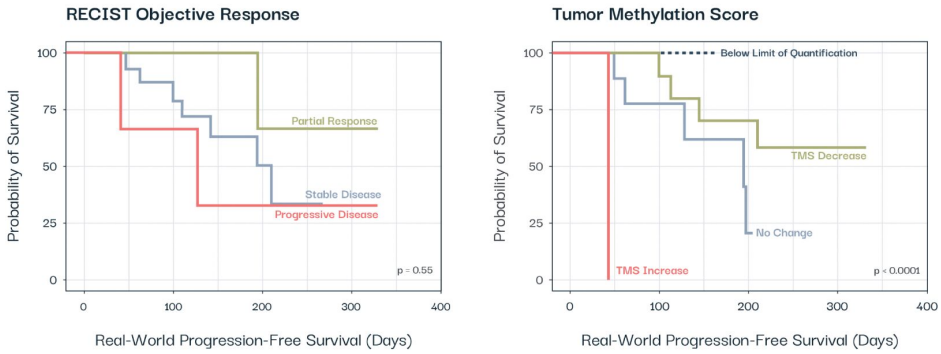
Our pan-cancer Northstar Response assay has been analytically validated across more than 10 tumor types and has been evaluated in several clinical studies. In one study, we demonstrated that our assay could detect minute changes in cfDNA burden as small as 0.02% (e.g., an elevation of tumor fraction 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.

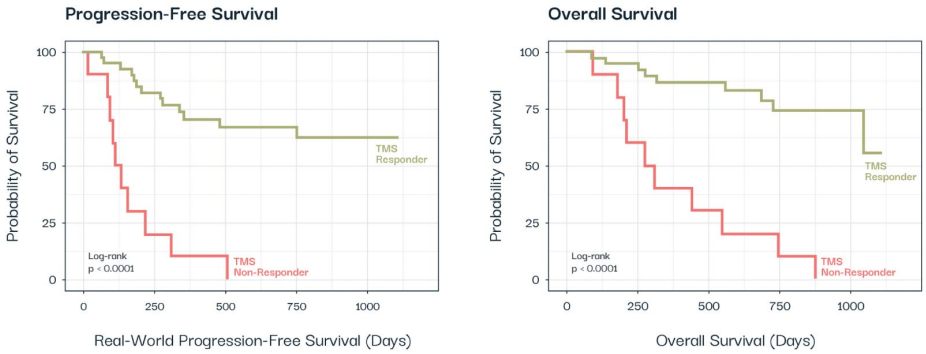


We also collaborated with University of California, San Diego on a study involving immunotherapy and immuno-chemotherapy treated advanced non-small cell lung cancer patients. In that study, Northstar Response's changes in TMS measured four to ten weeks after starting treatment significantly predicted 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.

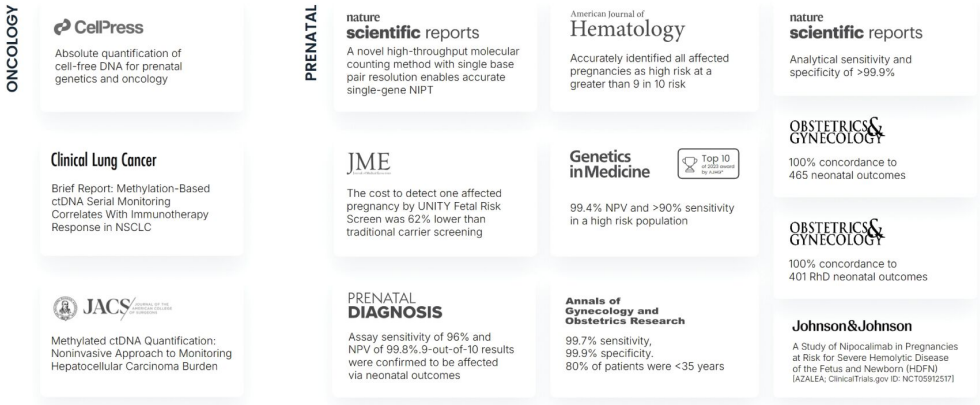
Additional opportunities in oncology

Beyond our two complementary therapy selection and monitoring tests, we are actively advancing our efforts in developing additional oncology products in MRD testing. Our Northstar Response test already achieves 0.01% LOD, which is in line with the first-generation tissue-informed MRD assays. We are making further improvements to the Northstar Response assay designed to achieve superior clinical performance than existing assays using the tumor-naive (blood only) approach. We believe there is a significant market opportunity for tumor-naive MRD assays, especially in certain cancer types such as lung, where the QC failure rates for tissue testing can exceed 40%. Longer term, we believe that our smNGS-based technology could address the sensitivity challenges of early-stage cancer detection. We have leveraged our existing relationship with Allegheny Health Network to collaborate on procuring a retrospective sample set to begin assessment of our MRD assay across multiple tumor types including CRC and endometrial cancers.

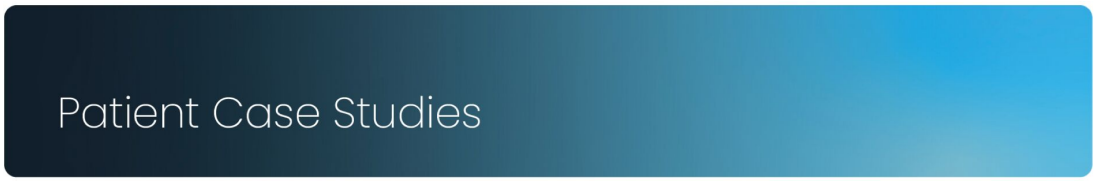
Publications and collaborations

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 is currently under peer review. Beyond the peer-reviewed journal publications below, we have published posters and abstracts at various medical conferences including AACR, AACR LBx, ASCO, and the International Society of Liquid Biopsy.



We leverage our strong clinical studies pipeline and are committed to providing strategic validation data for our liquid biopsy tests. Leveraging both internally designed prospective studies, as well as partnering with well-known and respected oncology research organizations provides both the efficiency and impact that is needed for validation of novel precision oncology tools.



UNITY Fetal Risk Screen patient case studies: Identifying cystic fibrosis during routine screening

Study 1: A patient with no prior knowledge of being a carrier for cystic fibrosis (CF) underwent routine prenatal testing, which revealed she was a carrier of CF. The couple, neither with a family history of CF, initially had a general population risk for CF of one in 3,000 to one in 6,000. However, within approximately two weeks of sample collection, results from UNITY Fetal Risk Screen indicated a nine in 10 chance of the baby being affected with CF through homozygous inheritance of delta F508, leading the patient to opt for amniocentesis and a prenatal diagnostic confirmation of CF. Subsequently, the mother received TRIKAFTA treatment during pregnancy, and the baby was able to receive further treatment at just two weeks old.

This case demonstrates how UNITY Fetal Risk Screen's personalized fetal risk assessment enabled timely intervention and specialist referrals that may not have been possible with traditional carrier screening, which often has delays and lower partner participation rates.

Study 2: In a similar case, a patient who presented with echogenic bowel on ultrasound was identified as a CF carrier with sgNIPT showing a 9 in 10 chance of the baby being affected with CF. The amniocentesis confirmed the diagnosis. After referral to a pulmonologist, the patient received TRIKAFTA during pregnancy, starting at 27 weeks of gestation. Despite earlier ultrasound findings, the baby was able to be discharged without a neonatal intensive care unit stay and passed newborn screening (NBS) for CF. It is extremely rare for a newborn with CF to pass NBS. Given the echogenic bowel on ultrasound during pregnancy, early diagnosis by UNITY and subsequent treatment enabled this newborn to have a significantly better outcome and avoid a potentially lengthy NICU stay.

UNITY Fetal Antigen NIPT patient case study: Assessing big C alloimmunization risk for streamlined care

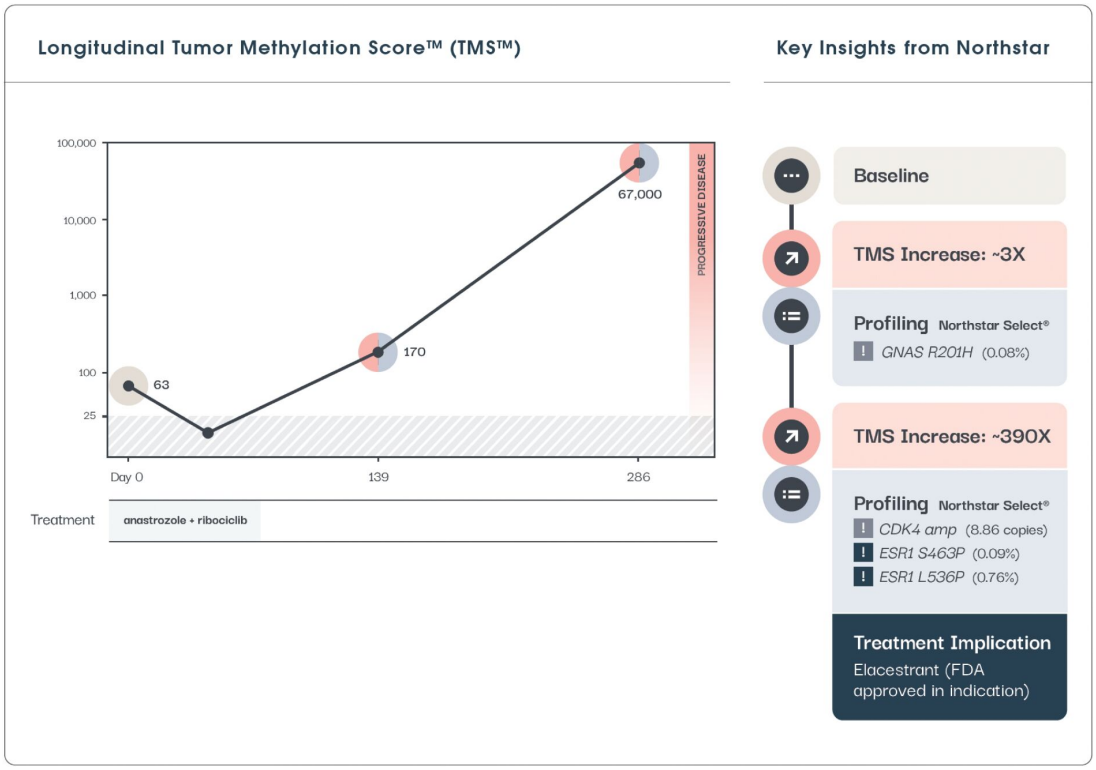
During routine prenatal lab work, a pregnant patient was found to be alloimmunized to the big C antigen. The patient's OB-GYN ordered UNITY Fetal Antigen NIPT at 14 weeks gestation to assess the fetal antigen status of the pregnancy. UNITY Fetal Antigen NIPT revealed a "not detected" result, indicating that the baby did not express the big C antigen and the pregnancy was not at risk for HDFN. As a result, the patient avoided the need for weekly intensive monitoring by a specialist, invasive procedures, and regular blood draws, significantly reducing healthcare costs and her anxiety. This early identification through the UNITY Fetal Antigen NIPT provided critical information that guided the management of her pregnancy, ensuring it progressed without complications related to alloimmunization. This case highlights the value of UNITY Fetal Antigen NIPT in streamlining prenatal care, minimizing unnecessary interventions and risks, and removing the fear of the unknown for the patient.

Northstar patient case study: Northstar Select identified a new ESR1 mutation at a very low VAF in a metastatic breast cancer patient after signs of progression using Northstar Response

A patient was diagnosed with HR positive/*HER2* negative metastatic breast cancer and was heavily pretreated with anastrozole/ribociclib. During the patient's routine follow-up three years later, the patient began Northstar Response monitoring, which indicated low baseline tumor burden (TMS=63). Longitudinal monitoring revealed progressively increasing TMS scores with a 390-fold increase found five months afterwards (TMS=67,000).

Subsequent comprehensive profiling with Northstar Select revealed an *ESR1* S463P mutation at a VAF of 0.09%, significantly below any competing therapy selection test's limit of detection, confirming the emergence of a resistance mutation to aromatase inhibitor therapy, a common challenge in treating HR-positive metastatic breast cancer. *ESR1* S463P mutations have an FDA-approved therapy, elacestrant, in this indication and provided this patient with an opportunity for treatment.

This case highlights how utilizing both Northstar Select and Response can help physicians first timely detect disease progression and identify more actionable mutations at greater sensitivity, leading to earlier interventions and better treatment options for patients.



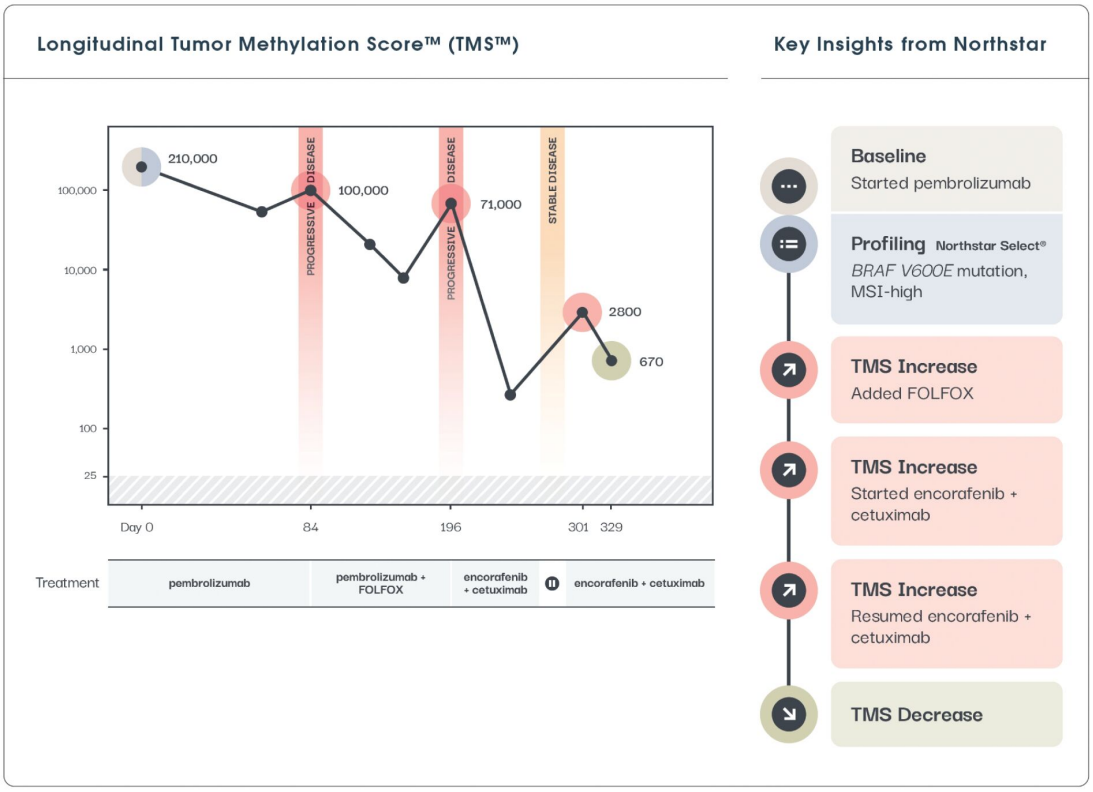
Northstar patient case study: Synergistic use of Northstar Select and Response demonstrated true precision oncology and personalized medicine

A patient with metastatic colorectal cancer, awaiting first-line treatment with pembrolizumab monotherapy, presented with a baseline TMS of 210,000, indicating a very high tumor burden. After the first cycle of

treatment, initial molecular response was observed and TMS decreased by over 50%, while therapy profiling with Northstar Select identified a druggable *BRAF* V600E mutation. Continuing with monotherapy IO alone, TMS increased above 100,000, which prompted the provider to increase treatment intensity by adding chemotherapy. Dramatic molecular response was observed, with the TMS dropping below 10,000. After the next cycle, TMS rebounded to over 71,000, prompting the physician to switch therapy strategy and treat with encorafenib + cetuximab, the approved treatment for the *BRAF* V600E mutation that Northstar Select had detected.

The patient's follow-up response demonstrated a significant decrease down to a TMS of 200, a decrease of more than 99.9% of the tumor burden compared to the pre-treatment time point. While undergoing a perioperative treatment hold for a planned ileostomy reversal procedure, scans showed radiographic stable disease while TMS demonstrated molecular progression and a rise in TMS to 2,800. Molecular progression detected by Northstar Response enabled better surgical treatment planning, and the patient resumed targeted therapy to control disease burden, indicated by a falling TMS down to 670 at the latest collection date.

In this case, longitudinal sampling and observed changes in TMS via Northstar Response offered real-time insights into the patient's treatment response, while comprehensive profiling from the same blood draw by Northstar Select helped optimize the therapeutic strategy at several key time points. This case highlights how the synergistic use of Northstar Select and Response can enable a physician to pivot to an alternative therapy expeditiously.



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, 2024, our clinician-focused sales organization included 137 sales representatives, with 120 in prenatal and 17 in oncology. In comparison, we had a total of 90 sales representatives at the end of 2023, 85 in prenatal and 5 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 $ million per sales representative in the six months ended June 30, 2025, despite approximately 35% of our territories launching less than 18 months ago. 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, 2024, 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. 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 March 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.



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 225 million covered lives in the United States, 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. For example, we have decreased our COGS by % in the 24 months ended June 30, 2025, in part by deploying automation and AI. By continuing to automate labor-intensive processes, we can 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, Natera, and Quest Diagnostics Incorporated (Quest). We also compete with companies providing carrier screening tests such as Fulgent Genetics, Labcorp, Myriad Genetics, Inc., Natera, and Quest. Each of these companies offers comprehensive carrier screening panels.

In the oncology market, our main competitors for our therapy selection and response monitoring tests include Caris Life Sciences, Foundation Medicine, Inc., which was acquired by Roche Holdings, Inc., Guardant Health, Inc., Neogenomics, 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.

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.

For further discussion of the risks we face relating to competition, see the section titled “Risk factors—Risks Related to Our Business and Strategy—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.”



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 June 5, 2025, we held 9 U.S.-issued patents, which expire between August 2038 and March 2043, and 41 foreign patents, which expire between August 2038 and September 2041. Additionally, we had 13 pending U.S. patent applications and 33 foreign patent applications. We also held 4 U.S. trademarks and 13 foreign trademarks as of December 31, 2024.

Our patent strategy is focused on seeking robust coverage for our core molecular counting technology (covered by U.S. is Patent No. 11,629,381, with a pending U.S. divisional application, granted patents in Japan, Hong Kong, India, China, Australia, and Europe (validated in 17 countries), and pending applications in Brazil, Canada, Israel, South Korea, Singapore, Japan (divisional), Europe (divisional), and Hong Kong (divisional), our dilution tagging technology (cover by U.S. Patent No. 12,071,651, with a pending U.S. continuation and pending foreign applications in Canada, 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 Japan, Singapore, South Korea, Israel, Canada, Australia and Europe, and pending in Brazil, 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.

To date, we have not been engaged in patent infringement lawsuits or any other intellectual property disputes. However, we may in the future become subject or initiate to 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 intellectual property, see the section titled “Risk Factors—Risks Related to Our Intellectual Property.”



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. Over 95% of our revenue stems 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 payors, resulting in lower payments and higher denials, creating challenges in terms of revenue growth and generating headwinds for provider adoption. It is a testament to the uniqueness of our products that we have achieved substantial growth despite initially having limited in-network status. Today, we have dramatically expanded our in-network coverage to include 225 million covered lives as of December 31, 2024. We anticipate our covered lives will continue to increase over time, which we expect will drive progressively higher ASPs.

Our reimbursement strategy aligns with the demonstrated clinical utility and cost-effectiveness of our tests, as well as with value-based care trends. We have validated the clinical utility of our tests through peer-reviewed publications and real-world data.

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 (starting in 2025)
- Employee benefits health plans
- Individual patients, who represent a small amount of our revenue

Commercial 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.

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 which CMS has a pricing rate of $759 per test. For other proprietary tests, we use PLA codes, including our carrier panel which CMS has a pricing rate of approximately $1,825 per test. We have also obtained PLA codes for our Northstar Select and Northstar Response tests, which CMS has pricing rates of approximately $2,920 per test and $1,644 per test, respectively. 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 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 section titled “Risk factors – Risks related to our reimbursements” included elsewhere in this prospectus.

As a result of these challenges and rates negotiated with contracted payors, our overall realized 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.

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 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 margins 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 laboratory-developed tests (LDTs) use instruments and reagents labeled as RUO.

Laboratory-developed tests. The FDA considers LDTs to be tests that are designed, developed, validated and used within a single laboratory. The FDA historically has taken the position that it has the authority to regulate such tests as medical devices under the FDC Act but had historically exercised enforcement discretion and did not require clearance, de novo classification, or approval of most LDTs prior to marketing.

In May 2024, the FDA published a final rule amending the definition of an IVD device to include LDTs and classifying LDTs as medical devices subject to FDA regulation. Under the final rule, all LDTs, unless subject to a specific exemption, would have been subject to premarket authorization requirements (510(k), de novo classification, or PMA), and laboratories performing LDTs would have needed to comply with post-market registration and listing, medical device reporting, correction, removal and recall, complaint handling, labeling, investigational device, and quality system requirements. The FDA intended to phase in these requirements beginning in May 2025. The final rule stated that certain categories of LDTs would be subject to enforcement discretion with respect to some or all of these requirements. For example, FDA intended to apply enforcement discretion to currently marketed LDTs that were first offered prior to May 6, 2024, with respect to most quality system requirements and the requirement for premarket authorization if they are not modified or modified in only limited ways, but such LDTs would have remained subject to the other requirements discussed above. The FDA intended to similarly exercise enforcement discretion with respect to premarket authorization for LDTs approved by the New York State Clinical Laboratory Evaluation Program. Under the final rule, most, but not all, of our LDTs may have been eligible for enforcement discretion.

On March 31, 2025, the U.S. District Court for the Eastern District of Texas vacated the final rule in its entirety, holding that the FDA’s attempt to regulate professional laboratory testing services as medical devices exceeds the authority granted to the FDA. It is unclear whether the FDA will appeal this decision and the ultimate outcome on this litigation is uncertain or if congress would enact legislation aimed at preventing FDA from regulating LDTs.

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 in 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 in 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) in 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 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.



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.



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. Our core values are:

- **Patient-Centered**. We place patients at the forefront of everything we do. We expect all team members to make business decisions guided by the best interest of patients, the company and the highest ethical standards.
- **Creative and Innovative**. We create a workplace where all team members are enabled and encouraged to bring new ideas and new ways of thinking to solve significant problems.
- **Profoundly Impactful**. We seek to revolutionize the molecular diagnostics industry by empowering patients with timely knowledge.
- **Internally Motivated and Passionate**. We seek to revolutionize the molecular diagnostics industry by empowering patients with timely knowledge.
- **Kindly Inquisitive and Collaborative**. We value an environment where employees are empowered to explore new ideas and work together constructively despite our differences.
- **Rational and Deliberate**. We expect all team members to make business decisions with thought and purpose. The choices we make should be guided by the best interests of our company, our patients, and the highest ethical standards.

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, 2024, we had 547 employees, all of which were full-time employees. Of these employees, 94 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.

Laboratory and R&D Facilities

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 December 31, 2026, and expiring in October 2042, with an option to extend for an additional seven years. We expect the new facility to nearly triple our current testing capacity We also have commercial leases for patient service centers in various cities, for an aggregate of approximately 6,500 square feet as of June 5, 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.

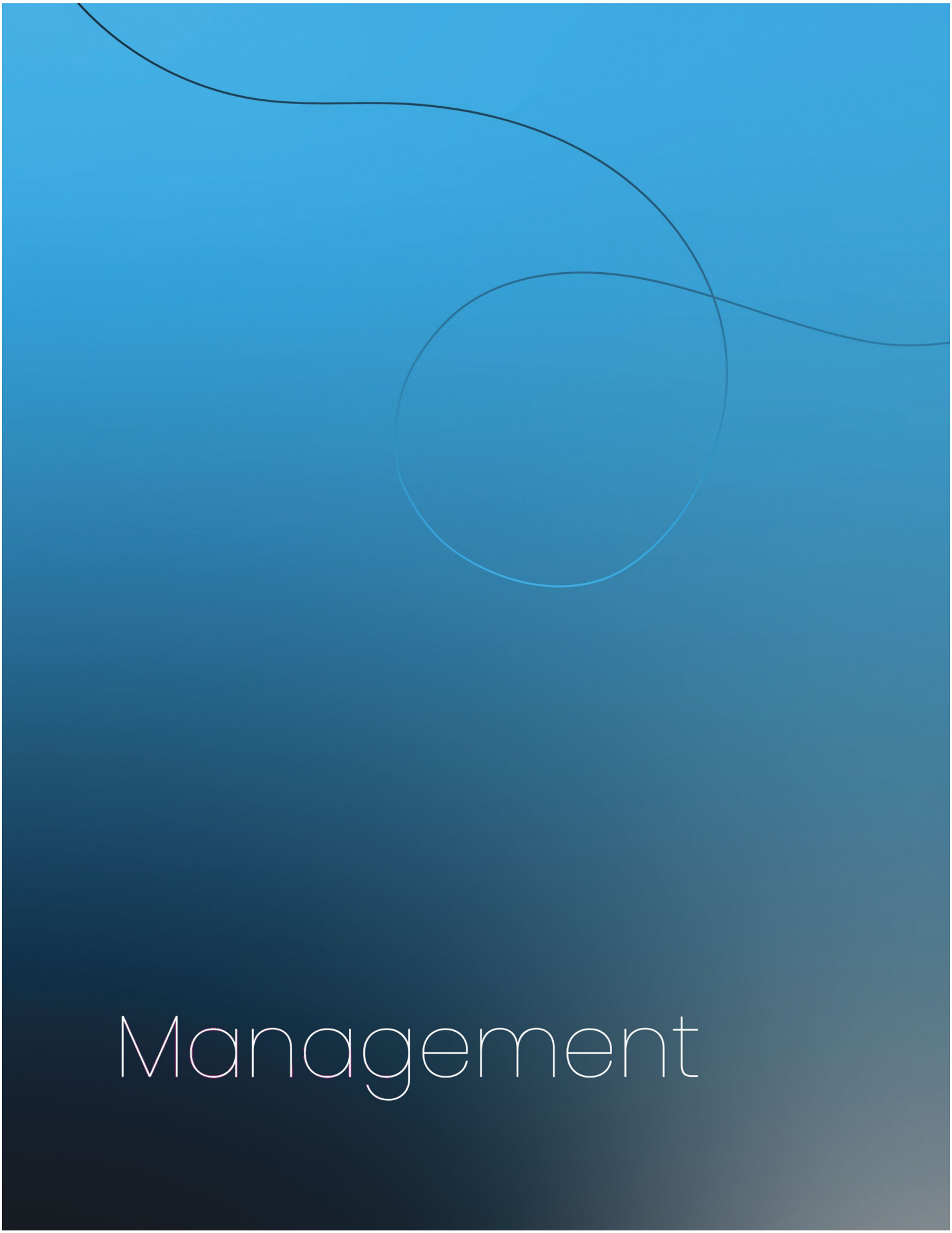
Legal Proceedings

From time to time, we are involved in legal claims, regulatory investigations, inquiries, proceedings and other legal matters arising from the normal course of business and typical for our industry. Although no formal legal proceeding has been instituted, from time to time, we receive requests from governmental agencies, or third

parties working on their behalf, for documents and information related to our products. We do not view any of the legal claims, regulatory investigations, inquiries, proceedings and other legal matters that we are currently subject to as being material to our business; however, it is difficult to assess the outcome of these matters, and we may not prevail in any current or future proceedings or litigation.

Litigation or any other legal, regulatory or administrative proceedings, regardless of the outcome, can result in substantial cost and diversion of our resources, including our management's time and attention, and there can be no assurances that favorable final outcomes will be obtained. For additional information on risks relating to legal proceedings, see the section titled "Risk Factors—Risks Related to Our Business and Strategy—We 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."

Table of Contents



Management

Executive officers and directors

The following table sets forth certain information with respect to our executive officers and directors, including their ages as of May 31, 2025:

Name	Age	Position(s)
Executive officers and employee directors		
Oguzhan Atay, PhD	36	Chief Executive Officer and Chair of the Board
David Tsao, PhD	36	President, Chief Technology Officer and Director
Ross Taylor	61	Chief Financial Officer
Shan Riku Sakakibara	41	Chief Product Officer
Thomas Lynch	58	General Counsel, Chief Compliance Officer and Secretary
Nancy Johnson	62	Senior Vice President of Sales and Commercial Operations
John ten Bosch, PhD	50	Senior Vice President of Laboratory Operations
Non-employee directors		
Thomas Bremner(2)	43	Director
Firat Ileri(2)	38	Director
Krishna Swaroop Kolluri(2)	61	Director
Akshay Rai	41	Director

(1) Member of the audit committee immediately after the effectiveness of the registration statement of which this prospectus forms a part.

(2) Member of the compensation committee.

(3) Member of the nominating and corporate governance committee immediately after the effectiveness of the registration statement of which this prospectus forms a part.

Executive officers and employee directors

Oguzhan Atay is our Chief Executive Officer and Co-Founder, having led the Company since its inception in 2016, and also serves as the Chair of our Board of Directors. Dr. Atay received his PhD in Biology from Stanford University, where his work was published on the cover of Cell Systems. He graduated summa cum laude and Phi Beta Kappa from Princeton University with a bachelor's in molecular biology and minors in physics, computer science, and applied mathematics. We believe that Dr. Atay is qualified to serve on our Board of Directors because of his experience as our co-founder and Chief Executive Officer, his co-development of our molecular counting platform, and his extensive knowledge of the precision diagnostics industry.

David Tsao is our President, Chief Technology Officer and Co-Founder, having been with the Company since its inception in 2016, and also serves as a member of our Board of Directors. Dr. Tsao oversees all technology developments at BillionToOne. He received a PhD in bioengineering from Rice University, where he was awarded a nanobiology training fellowship. He graduated cum laude from Princeton University with a bachelor's in physics and minors in biophysics and engineering management systems. While at Princeton, he was twice awarded the Shenstone Prize in physics. We believe that Dr. Tsao is qualified to serve on our Board of

Directors because of his co-development of our molecular counting platform, extensive technical expertise in molecular biology, and deep knowledge of the precision diagnostics industry.

Ross Taylor has served as our Chief Financial Officer since January 2024, bringing three decades of financial leadership to the Company. Prior to joining BillionToOne, Mr. Taylor was Chief Financial Officer for Codexis, Inc., a publicly traded enzyme engineering company, from 2019 to February 2023. Previously, he served as Chief Financial Officer of Abaxis, Inc., a publicly traded medical technology company, acquired by Zoetis for $2.0 billion. At Abaxis, he first held the role of Vice President of Business Development & Investor Relations from 2014 to 2015, before being appointed CFO from August 2015 through the company's successful acquisition in July 2018. Early in his career, Mr. Taylor spent more than a decade as an equity research analyst at leading Wall Street firms including CL King & Associates, UBS, Smith Barney, and CJ Lawrence, providing deep expertise in capital markets and strategic financial planning. Mr. Taylor holds an MBA from Columbia Business School and a B.A. in economics from Duke University.

Shan Riku Sakakibara joined BillionToOne in 2019 as one of our first employees and currently serves as our Chief Product Officer. Prior to her role as Chief Product Officer, Ms. Riku Sakakibara served in other executive positions, most recently as Senior Vice President of Product. Ms. Riku Sakakibara oversees both clinical and software product management, marketing, translational research, and clinical and medical affairs at BillionToOne. Ms. Riku Sakakibara has over 15 years of experience in launching and managing a wide range of products from software products to precision diagnostics clinical assays. Previously, Ms. Riku Sakakibara served as a Senior Product Manager and Portfolio Strategy Manager at Natera, Inc. from 2015 to 2017. Ms. Riku Sakakibara started her career at McKinsey & Co., where she worked with Fortune 100 companies. Ms. Riku Sakakibara graduated with a B.S. in chemistry from Massachusetts Institute of Technology, holds an MBA from Stanford University, and an MPA/ID from Harvard University.

Thomas Lynch joined BillionToOne as our General Counsel in October 2022. Mr. Lynch brings over two decades of experience leading legal teams. Prior to joining us, he served as Chief Compliance Officer, Advanced Healthcare Solutions at Fortive Corporation, a publicly traded provider of connected workflow solutions technologies, from April 2021 to October 2022. From 2018 to April 2021, Mr. Lynch served as the Chief Legal Officer at Nuwellis, a publicly traded medical device company. From 2015 to 2018, Mr. Lynch served as the Chief Administrative Officer and General Counsel at Orexigen Therapeutics, a publicly traded biotechnology company, which filed a voluntary petition for Chapter 11 bankruptcy in March 2018. In June 2018, Mr. Lynch was appointed as president of Orexigen Therapeutics to manage its restructuring. Mr. Lynch also held various senior legal and compliance positions at Boston Scientific Corporation and Novartis Pharma, earlier in his career. Mr. Lynch began his legal career at Dorsey & Whitney LLP. Mr. Lynch earned a B.A. in history from Stanford University, a JD from Boston College Law School and an MA in teaching from the University of St. Thomas, where he serves as an Adjunct Professor of Law.

Nancy Johnson joined BillionToOne in April 2019, even prior to the initial commercialization of our products, and has built both our prenatal and oncology commercial organizations as our Senior Vice President of Sales and Commercial Operations. Ms. Johnson brings more than 20 years of diagnostic sales leadership experience in both start-up and large-scale sales organizations. Most recently, Ms. Johnson played a key role in commercial strategy and execution at Foundation Medicine, a publicly traded molecular information company, that was acquired by Roche during her tenure. Prior to Foundation Medicine, she held several commercial leadership positions at various molecular diagnostic companies. Ms. Johnson started her career as a board-certified Medical Technologist and earned a B.S. in medical technology from Creighton University.

John ten Bosch joined BillionToOne in September 2020 as our Laboratory Director and has since been promoted multiple times, most recently to the role of Senior Vice President of Laboratory Operations. Dr. ten Bosch brings over 15 years of experience leading high-complexity CLIA laboratories, with expertise in regulatory oversight,

clinical laboratory operations, and test development. Prior to joining BillionToOne, he worked at Kaiser Permanente from 2012 to 2020, where he served as both Laboratory Director and Director of Quality for the Molecular Pathology and Cytogenetics laboratories. Dr. ten Bosch graduated magna cum laude from the University of California, Davis with a B.S. in Genetics. He earned his Ph.D. in Molecular and Cell Biology from the University of California, Berkeley, and completed postdoctoral fellowships at Stanford and UCLA.

Non-employee directors

Thomas Bremner has been a member of our Board of Directors since March 2022. Mr. Bremner is currently a partner of the Growth Equity team of Adams Street Partners, LLC, a global private equity investment management firm, and has been employed by Adams Street since 2013. Mr. Bremner's experience with the growth and development of healthcare companies provides our Board of Directors with a unique perspective on our long-term strategy. Mr. Bremner holds a B.S. in finance from the University of Dayton and an MBA from University of Chicago Booth School of Business. We believe that Mr. Bremner is qualified to serve on our Board of Directors because of his years of experience as an advisor to a wide range of healthcare companies.

Krishna Swaroop Kolluri has been a member of our Board of Directors since 2019. Mr. Kolluri has over 30 years of experience as a successful serial entrepreneur, CEO, senior operating executive, and venture capitalist Mr. Kolluri is a founding partner of Neotribe Ventures, an investment firm founded in 2017 that invests in breakthrough technology companies. Prior founding Neotribe, Mr. Kolluri was the General Partner of New Enterprise Associates from 2006 to 2016, focusing on venture financing with early stage companies. Mr. Kolluri received a B.Tech. in Mechanical Engineering from the Indian Institute of Technology Madras, India, and his Masters in Industrial Engineering from the University at Buffalo. We believe that Mr. Kolluri is qualified to serve on our Board of Directors because of his extensive executive management and venture capital experience.

Firat Ileri has been a member of our Board of Directors since 2019. Mr. Ileri is currently the managing partner of Hummingbird Ventures a global venture capital firm with over $1 billion in assets under management, which he joined in 2012. Mr. Ileri earned his B.S. in electrical engineering and computer science and in management science, and a Masters of Engineering in electrical engineering and computer science, all from Massachusetts Institute of Technology. We believe that Mr. Ileri is qualified to serve on our Board of Directors because of his venture capital experience in the biopharmaceutical and technology industries.

Akshay Rai has been a member of our Board of Directors since May 2024. Mr. Rai is a professional investor with over 18 years of experience investing in public and private equities, with a focus on healthcare and life sciences. He currently leads U.S. healthcare investments for Premji Invest, investing in growth stage private companies. Mr. Rai has been with Premji Invest since July 2010 and helped establish the U.S. healthcare investments practice for the firm, which includes investments in companies like Moderna, Devoted Health and Iora Health, among others. Prior to joining Premji Invest, Mr. Rai was part of the equity research team at Citigroup in India. Mr. Rai holds a bachelor of engineering degree from National Institute of Technology Karnataka and an MBA from the Indian Institute of Management Bangalore. We believe that Mr. Rai is qualified to serve on our Board of Directors because of his investment experience with both private and public healthcare companies.

Family relationships

There are no family relationships among any of our executive officers or directors.

Board composition

After the completion of this offering, the number of directors will be fixed by our Board of Directors, subject to the terms of our Post-IPO Certificate of Incorporation and Post-IPO Bylaws as each are in effect after this

offering. Each of our current directors will continue to serve as a director until the election and qualification of his or her successor, or until his or her earlier death, resignation, or removal. In accordance with the terms of our Post-IPO Certificate of Incorporation and Post-IPO Bylaws that will be effective immediately prior to the completion of this offering, our Board will be divided into three classes, Class I, Class II, and Class III, with members of each class serving staggered three-year terms. Effective immediately prior to the completion of this offering, our Board will be divided into the following classes:

- Class I, which will consist of , whose terms will expire at our first annual meeting of stockholders to be held after the completion of this offering;
- Class II, which will consist of , whose terms will expire at our second annual meeting of stockholders to be held after the completion of this offering; and
- Class III, which will consist of , whose terms will expire at our third annual meeting of stockholders to be held after the completion of this offering.

At each annual meeting of stockholders to be held after the initial classification, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following their election and until their successors are duly elected and qualified. The authorized size of our Board is currently six members and may be changed only by resolution by a majority of the Board. We expect that additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. This classification of the Board may have the effect of delaying or preventing changes in our control or management. Our directors may be removed for cause by the affirmative vote of two-thirds of the voting power of our then-outstanding capital stock.

Our directors were elected to and currently serve on the Board of Directors pursuant to the Voting Agreement. See the section titled “Certain relationships and related party transactions—Voting agreement.” This agreement will terminate upon the completion of this offering, after which there will be no further contractual obligations regarding the election of our directors.

Director independence

Our Board of Directors has undertaken a review of the independence of the directors and considered whether any director has a material relationship with us that could compromise his or her ability to exercise independent judgment in carrying out his or her responsibilities. Based upon information requested from and provided by each director concerning such director’s background, employment and affiliations, including family relationships, our Board of Directors determined that , representing of our directors, are “independent directors” as defined under current rules and regulations of the SEC and the listing standards of the Nasdaq Global Market (Nasdaq) . In making these determinations, our Board considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances that our Board deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director and the transactions involving them described in “Certain relationships and related party transactions.”

Board leadership structure

Our Board of Directors is currently chaired by our Chief Executive Officer and Co-Founder, Dr. Atay. Our Board of Directors does not have a policy that requires the roles of Chief Executive Officer and Chairman of the Board to be separate. The Board believes that Mr. Atay’s service as both Chief Executive Officer and Chairman of the Board is in the best interest of us and our stockholders.

Our corporate governance guidelines, which will be in effect upon the effectiveness of the registration statement of which this prospectus forms a part, provide that, if the chairperson of our Board of Directors is not an independent director, the Board will appoint an independent director as a lead independent director. currently serves as our lead independent director. The lead independent director's responsibilities include: facilitating communication between management, the independent directors, and the Chairman of the Board; actively participating in setting agendas for Board meetings; presiding at executive sessions of the Board; and performing such other duties as specified by the Board. Our corporate governance guidelines further provide that the Board periodically reviews its leadership structure and may separate or combine the roles of the Chairman of the Board and Chief Executive Officer when and if it deems it advisable and in the best interests of the Company and its stockholders to do so.

Role of the board in risk oversight

One of the key functions of our Board of Directors is informed oversight of our risk management process. In particular, our Board of Directors is responsible for monitoring and assessing strategic risk exposure. Our executive officers are responsible for the day-to-day management of the material risks we face. Our Board of Directors administers its oversight function directly as a whole. Our Board of Directors will also administer its oversight through various standing committees that address risks inherent in their respective areas of oversight. For example, our audit committee, which will be constituted prior to the completion of this offering, will be responsible for overseeing the management of risks associated with our financial reporting, accounting and auditing matters; our compensation committee oversees the management of risks associated with our compensation policies and programs; and our nominating and corporate governance committee, which will be constituted prior to the completion of this offering, will oversee the management of risks associated with director independence, conflicts of interest, composition and organization of our Board of Directors and director succession planning.

Board committees

Our Board of Directors has established a compensation committee, and intends to establish an audit committee and a nominating and corporate governance committee in connection with this offering, each of which is expected to have the composition and responsibilities described below upon the effectiveness of the registration statement of which this prospectus forms a part. From time to time, our Board may establish other committees to facilitate the management of our business.

Audit committee

Upon the effectiveness of the registration statement of which this prospectus forms a part, our audit committee will consist of , , and , with serving as the chairperson, and each of whom our Board of Directors will determine meets the independence requirements for audit committee members under the listing standards of Nasdaq and Rule 10A-3 of the Exchange Act, and the financial literacy requirements under the rules and regulations of Nasdaq and the SEC. In addition, our Board of Directors has determined that is an audit committee "financial expert" as defined by Item 407(d) of Regulation S-K under the Securities Act. Our audit committee will, among other things:

- select and oversee the independent registered public accounting firm;
- review and resolve any disagreements arising between management and the independent registered public accounting firm;

- review and approve audit and any non-audit services provided by the independent registered public accounting firm;
- help oversee our internal controls and disclosure controls and procedures;
- review and oversee the internal audit function, if applicable;
- develop procedures for employees to anonymously submit accounting or audit concerns;
- review policies on risk assessment and risk management; and
- review related party transactions.

Our audit committee will operate under a written charter that satisfies the applicable rules of the SEC and the listing standards of Nasdaq.

Compensation committee

Our compensation committee consists of Tom Bremner, Krishna Swaroop Kolluri and Firat Ileri, with Mr. Kolluri serving as the chairperson, and each of whom our Board of Directors will determine is a non-employee member of our Board of Directors as defined in Rule 16b-3 under the Exchange Act. The composition of our compensation committee will meet the requirements for independence under the current listing standards of Nasdaq and current SEC rules and regulations. Our compensation committee will, among other things:

- review and approve (or recommend to independent members of our Board of Directors) executive officer compensatory arrangements and succession plans, and ensure compliance with all legal and regulatory requirements;
- review and recommend to our Board of Directors the compensation to be paid to non-employee members of the Board of Directors;
- review, approve, and administer our employee benefit and equity incentive plans;
- administer our policy for the recovery of erroneously awarded compensation;
- review and establish general compensation and benefits policies, as well as our overall compensation philosophy; and
- retain compensation consultants and other advisors.

Our compensation committee will operate under a written charter that satisfies the applicable rules of the SEC and the listing standards of Nasdaq.

Nominating and corporate governance committee

Upon effectiveness of the registration statement of which this prospectus forms a part, our nominating and corporate governance committee will consist of , , and , with serving as the chairperson. The composition of our nominating and governance committee will meet the requirements for independence under the current listing standards of Nasdaq and current SEC rules and regulations. Our nominating and corporate governance committee will, among other things:

- identify and evaluate candidates to serve on our Board of Directors and its committees;
- facilitate the annual performance review of our Board of Directors and its committees;

- make recommendations regarding our Board of Directors and committee composition;
- review and evaluate any stockholder nominees for director submitted in accordance with Company policies and procedures;
- periodically review our code of conduct;
- review developments and evaluate the adequacy of our corporate governance practices and reporting; and
- make recommendations regarding corporate governance matters to our Board of Directors.

Our nominating and corporate governance committee will operate under a written charter that satisfies the applicable rules of the SEC and the listing standards of Nasdaq.

Code of conduct

Concurrently with this offering, we intend to adopt an amended and restated Code of Conduct applicable to all of our employees, executive officers, and directors. Following the completion of this offering, the Code of Conduct will be available on our website at https://billiontoone.com/. We expect that any amendments to the Code of Conduct, or any waivers of its requirements for directors and officers, will be disclosed on our website as required by applicable law or the listing standards of Nasdaq. The inclusion of our website address in this prospectus does not include or incorporate by reference into this prospectus the information on or accessible through our website.

Compensation committee interlocks and insider participation

None of our executive officers currently serves, or in the past year has served, as a member of the Board of Directors or compensation committee of any entity that has one or more executive officers serving on our Board of Directors or compensation committee. None of the members of our compensation committee is an officer or employee of our company, nor have they ever been an officer or employee of our company.

Director compensation

Drs. Atay and Tsao serve as our directors as well as our Chief Executive Officer and Chief Technology Officer, respectively. Neither of them has received any compensation for their service as directors for the year ended December 31, 2024. The compensation received by each of Drs. Atay and Tsao as employees is set forth in the section titled “Executive compensation—Summary compensation table.”

During the year ended December 31, 2024, we did not pay any fees to, make any equity awards or non-equity awards to, or pay any other compensation to the non-employee members of our Board of Directors, other than reimbursement of direct expenses incurred in connection with attending meetings of our Board of Directors or its committees.

Non-employee director compensation policy

We intend to adopt a non-employee director compensation policy, pursuant to which our non-employee directors will be eligible to receive compensation for service on our Board of Directors and committees of our Board of Directors, to be effective following the completion of this offering.

Executive compensation

Our named executive officers, which consist of our principal executive officer and our two other most highly compensated officers for our fiscal year ended December 31, 2024, are:

- Oguzhan Atay, PhD, Chief Executive Officer;
- Ross Taylor, Chief Financial Officer; and
- Nancy Johnson, Senior Vice President of Sales and Commercial Operations.

Summary compensation table

The following table shows information regarding the compensation of our named executive officers for the fiscal year ended December 31, 2024.

Name and principal position	Year	Salary ($)	Bonus ($)[1]	Option awards ($)[2]	Non-equity incentive plan compensation ($)[3]	All other compensation ($)[4]	Total ($)
Oguzhan Atay, PhD *Chief Executive Officer*	2024	303,739	55,722	—	—	11,603	371,064
Ross Taylor *Chief Financial Officer*	2024	296,969	148,899	1,611,750	—	4,829	2,063,447
Nancy Johnson *Senior Vice President of Sales and Commercial Operations*	2024	256,764	—	234,400	129,383	20,603	641,150

(1) The amount in this column reported for Dr. Atay represents a cash incentive bonus earned with respect to fiscal year 2024 that was paid in 2025. The amount in this column reported for Mr. Taylor represents (i) $100,000 in a sign-on bonus paid to Mr. Taylor in connection with commencement of employment with us and (ii) a cash incentive bonus of $48,899 earned with respect to fiscal year 2024 that was paid in 2025.

(2) The amounts in this column represent the aggregate grant date fair value of option awards granted to the named executive officer, computed in accordance with FASB ASC Topic No. 718. See Note 10 of the notes to our audited financial statements included elsewhere in this prospectus for a discussion of the assumptions made by us in determining the grant date fair value of our equity awards.

(3) This amount relates to commissions earned under a sales commission arrangement established for Ms. Johnson. Pursuant to this arrangement, Ms. Johnson was eligible to earn commissions for each fiscal quarter based upon her percentage achievement of specific sales targets established for each fiscal quarter.

(4) The amounts in this column reported for Dr. Atay and Mr. Taylor represent matching contributions under our 401(k) plan. The amount in this column reported for Ms. Johnson represents: (i) $9,000 in car allowance for use of her personal vehicle and (ii) $11,602 in matching contributions under our 401(k) plan.

Narrative explanation of compensation arrangements with our named executive officers

Base salaries and annual incentive opportunities

We pay each of our executives, including our named executive officers, a base salary to compensate them for services rendered to our company. As of December 31, 2024, our named executive officers base salaries were as follows: $306,000 for Dr. Atay, $306,000 for Mr. Taylor, and $270,300 for Ms. Johnson. Effective from July 1, 2024, each of Dr. Atay and Mr. Taylor became eligible to be considered for a discretionary annual incentive bonus, subject to their continued employment through the date that bonuses are paid.

Equity compensation

Historically, the equity compensation granted to our named executive officers has consisted of stock options. For a description of the stock options granted to our named executive officers in fiscal year 2024, please see the “Outstanding equity awards at 2024 fiscal year-end” table below.

Employee benefits and perquisites

Our named executive officers are eligible to participate in our health and welfare plans to the same extent as are full-time employees generally. We generally do not provide our named executive officers with perquisites or other personal benefits.

Retirement benefits

We have established a 401(k) tax-deferred savings plan, which permits participants, including our named executive officers, to make contributions by salary deduction pursuant to Section 401(k) of the Internal Revenue Code. Our named executive officers are eligible to participate in the 401(k) plan on the same terms as other full-time employees, including a 100% company matching contribution of the first 3% of an employee's contribution, and then 50% of the next 2% of an employee's contribution.

Employment arrangements with named executive officers

Our named executive officers have not previously entered into written employment agreements with us. We intend to enter into confirmatory employment letters with each of our named executive officers which will become effective upon the completion of this offering and will set forth the continuing terms of their employment. We intend that the written employment agreements with each of our named executive officers will cross-reference our Executive Severance and Change in Control Plan, pursuant to which they will each be eligible to receive certain severance and change in control benefits, as described in "Severance and Change in Control Benefits" below.

Outstanding equity awards at 2024 fiscal year-end

The following table sets forth information regarding each unexercised option held by each of our named executive officers as of December 31, 2024.

The vesting schedule applicable to each outstanding award is described in the footnotes to the table below.

Unless otherwise noted, all of the outstanding equity awards reported in the following table were granted under our 2018 Plan.

Name	Number of securities underlying unexercised options exercisable (#)	Number of securities underlying unexercised options unexercisable (#)	Option exercise price ($)	Option expiration date
Oguzhan Atay, PhD	640,000	—	2.80	06/07/2031
Ross Taylor	—	175,000(1)	11.55	01/13/2034
Nancy Johnson	833	19,167(2)	17.12	10/16/2034
	11,666	28,334(3)	11.55	10/17/2033
	20,312	4,688(4)	2.80	10/14/2031
	25,000	—	2.80	06/07/2031
	125,000	—	0.45	08/20/2029

(1) Option vests and becomes exercisable with respect to 1/4 of the shares on the one-year anniversary of January 8, 2024, and vests and becomes exercisable with respect to 1/48th of the shares in equal monthly installments thereafter, subject to the named executive officer's continued service to the Company through the applicable vesting date.

(2) Option vests and becomes exercisable in 48 equal monthly installments beginning with October 6, 2024, subject to the named executive officer's continued service to the Company through the applicable vesting date.

(3) Option vests and becomes exercisable in 48 equal monthly installments beginning with October 1, 2023, subject to the named executive officer's continued service to the Company through the applicable vesting date.

(4) Option vests and becomes exercisable in 48 equal monthly installments beginning with September 1, 2021, subject to the named executive officer's continued service to the Company through the applicable vesting date.

Severance and change in control benefits

Pursuant to their employment letter agreements, which will become effective upon the completion of this offering, we expect that each of Dr. Atay, Mr. Taylor and Ms. Johnson will be eligible to participate in our Executive Severance and Change in Control Plan. Pursuant to the Executive Severance and Change in Control Plan, we expect that each of our named executive officers will be eligible to receive the following severance benefits in the event that their employment is terminated by us without Cause (as defined below) or if they resign for Good Reason (as defined below) (either of which, a Qualifying Termination):

- An amount equal to months of base salary;
- Reimbursement for continued benefit coverage pursuant to COBRA, equal in length for up to the number of months of the officer's severance benefit; and
- If such termination is months prior to or within months after a change in control then the vesting of all then-unvested option shares shall be accelerated.

Equity plans

2025 equity incentive plan

Our Board of Directors intends to adopt and approve our 2025 Equity Incentive Plan (the 2025 Plan), prior to this offering and it will be submitted to our stockholders for approval. We expect that the 2025 Plan will become effective upon the effectiveness of the registration statement of which this prospectus is a part. Our 2025 Plan is intended to replace our 2018 Plan. However, awards outstanding under the 2018 Plan will continue to be governed by their existing terms. It is expected that our 2025 Plan will have the features described below.

Share reserve

The number of shares of our Class A common stock available for issuance under our 2025 Plan will equal the sum of shares plus up to shares remaining available for issuance under, or issued pursuant to or subject to awards granted under, our 2018 Plan. The number of shares reserved for issuance under our 2025 Plan will be increased automatically on the first business day of each of our fiscal years, commencing in 2025 and ending in 2035, by a number equal to the lesser of:

- % of the shares of Class A common stock outstanding on the last business day of the prior fiscal year; or
- the number of shares determined by our Board of Directors.

In general, to the extent that any awards under our 2025 Plan are forfeited, terminate, expire or lapse without the issuance of shares, or if we repurchase the shares subject to awards granted under our 2025 Plan, those shares will again become available for issuance under our 2025 Plan, as will shares applied to pay the exercise or purchase price of an award or to satisfy tax withholding obligations related to any award.

Administration

The compensation committee of our Board of Directors will administer our 2025 Plan. The compensation committee will have complete discretion to make all decisions relating to our 2025 Plan and outstanding awards, including repricing outstanding options and modifying outstanding awards in other ways.

Eligibility

Employees, non-employee directors, consultants and advisors will be eligible to participate in our 2025 Plan.

Under our 2025 Plan, the aggregate grant date fair value of awards granted to our non-employee directors may not exceed $ in any one fiscal year, except that the grant date fair value of awards granted to newly appointed non-employee directors may not exceed $ in the fiscal year in which such non-employee director is initially appointed to our Board of Directors.

Types of awards

Our 2025 Plan provides for the following types of awards:

- incentive and nonstatutory stock options;
- stock appreciation rights;
- restricted shares; and
- restricted stock units.

Options and stock appreciation rights

The exercise price for options granted under our 2025 Plan may not be less than 100% of the fair market value of our Class A common stock on the grant date. Optionees will be permitted to pay the exercise price in cash or, with the consent of the compensation committee:

- with shares of Class A common stock that the optionee already owns;
- by an immediate sale of shares through a broker approved by us;
- by instructing us to withhold a number of shares having an aggregate fair market value that does not exceed the exercise price; or
- by other methods permitted by applicable law.

An optionee who exercises a stock appreciation right receives the increase in value of our Class A common stock over the base price. The base price for stock appreciation rights may not be less than 100% of the fair market value of our Class A common stock on the grant date. The settlement value of a stock appreciation right may be paid in cash, shares of our common stock or a combination.

Options and stock appreciation rights vest as determined by the compensation committee. In general, they will vest over a four-year period following the date of grant. Options and stock appreciation rights expire at the time determined by the compensation committee but in no event more than ten years after they are granted. These awards generally expire earlier if the participant's service terminates earlier.

Restricted shares and restricted stock units

Restricted shares and restricted stock units may be awarded under our 2025 Plan in return for any lawful consideration, and participants who receive restricted shares or stock units generally are not required to pay cash for their awards. In general, these awards will be subject to vesting. Vesting may be based on length of service, the attainment of performance-based milestones or a combination of both, as determined by the compensation committee.

Corporate transactions

In the event we are a party to a merger, consolidation or certain change in control transactions, outstanding awards granted under our 2025 Plan, and all shares acquired under our 2025 Plan, will be subject to the terms of the definitive transaction agreement (or, if there is no such agreement, as determined by our compensation committee). Unless an award agreement provides otherwise, such treatment may include any of the following with respect to each outstanding award:

- the continuation, assumption or substitution of an award by a surviving entity or its parent;
- the cancellation of an award without payment of any consideration;
- the cancellation of the vested portion of an award (and any portion that becomes vested as of the effective time of the transaction) in exchange for a payment equal to the excess, if any, of the value that the holder of each share of our Class A common stock receives in the transaction over (if applicable) the exercise price otherwise payable in connection with the award; or
- the assignment of any reacquisition or repurchase rights held by us in respect of an award of restricted shares to the surviving entity or its parent (with proportionate adjustments made to the price per share to be paid upon exercise of such rights).

The compensation committee is not required to treat all awards, or portions thereof, in the same manner.

The vesting of an outstanding award may be accelerated by the administrator upon the occurrence of a change in control, whether or not the award is to be assumed or replaced in the transaction, or in connection with a termination of service following a change in control transaction. A change in control includes:

- any person acquiring beneficial ownership of more than 50% of our total voting power;
- the sale or other disposition of all or substantially all of our assets; or
- our merger or consolidation after which our voting securities represent 50% or less of the total voting power of the surviving or acquiring entity.

Changes in capitalization

In the event of certain changes in our capital structure without our receipt of consideration, such as a stock split, reverse stock split or dividend paid in Class A common stock, proportionate adjustments will automatically be made to:

- the maximum number and kind of shares available for issuance under our 2025 Plan, including the maximum number and kind of shares that may be issued upon the exercise of incentive stock options;
- the maximum number and kind of shares covered by, and exercise price, base price or purchase price, if any, applicable to each outstanding stock award; and
- the maximum number and kind of shares by which the share reserve may increase automatically each year.

In the event that there is a declaration of an extraordinary dividend payable in a form other than our Class A common stock in an amount that has a material effect on the price of our Class A common stock, a recapitalization, a spin-off or a similar occurrence, the compensation committee may make such adjustments to any of the foregoing as it deems appropriate, in its sole discretion.

Amendments or termination

Our Board of Directors may amend, suspend or terminate our 2025 Plan at any time. If our Board of Directors amends our 2025 Plan, it does not need stockholder approval of the amendment unless required by applicable law, regulation or rules. Our 2025 Plan will terminate automatically 10 years after the later of the date when our Board of Directors adopted our 2025 Plan or approved the latest share increase that was also approved by our stockholders.

2018 stock plan

Our Board of Directors adopted and our stockholders approved our 2018 Plan in December 2018. After completion of this offering, no further awards will be made under the 2018 Plan and the outstanding awards will continue to be governed by their existing terms, except that our Class A common stock will be the class of stock underlying the outstanding awards. In addition, we will make adjustments to the number of shares and the exercise price per share underlying outstanding awards to reflect changes made to our capital structure in connection with this offering. This summary, however, is not intended to be a complete description of the 2018 Plan and is qualified in its entirety by reference to the complete text of the 2018 Plan, which is filed as an exhibit to the registration statement of which this prospectus is a part. To the extent there is a conflict between the terms of this summary and the 2018 Plan, the terms of the 2018 Plan will control.

Types of awards

The 2018 Plan provides for the grant of incentive stock options, or ISOs, nonstatutory stock options, or NSOs, and awards of restricted stock (collectively, stock awards). ISOs may be granted only to our employees, but not employees of our affiliates. All other awards may be granted to our employees, our non-employee directors and consultants and the employees and consultants of our affiliates.

Share reserve

As of December 31, 2024, we have reserved 10,904,372 shares of our common stock for issuance under the 2018 Plan, all of which may be issued as incentive stock options. Unissued shares subject to awards that expire or become unexercisable without being exercised in full or are surrendered pursuant to an option exchange program and shares that are forfeited, cancelled, reacquired by us or withheld in payment of the purchase price or exercise price of an award or in satisfaction of withholding taxes will again become available for issuance under the 2018 Plan or, following completion of this offering, under the 2025 Plan.

Administration

Our Board of Directors, or a committee thereof, has administered the 2018 Plan since its adoption; however, following this offering, the compensation committee of our Board of Directors will generally administer the 2018 Plan. The administrator has complete discretion to make all decisions relating to the 2018 Plan and outstanding awards.

Eligibility

Our employees, non-employee members of our Board of Directors and consultants, including those of our affiliates, are eligible to participate in the 2018 Plan. However, only our direct employees are eligible to receive incentive stock options.

Options

The exercise price for options granted under the 2018 Plan is determined by the administrator, but, in the case of ISOs, may not be less than 100% of the fair market value of our common stock on the grant date. Optionees may pay the exercise price in cash or cash equivalents or by one, or any combination of, the following forms of payment, as permitted by the administrator in its sole discretion:

- Delivery of a promissory note, with the recourse, interest, security and redemption provisions determined by the administrator to the extent permitted under and in accordance with applicable law;
- Cancellation of indebtedness;
- Surrender of shares of common stock that the optionee already owns; or
- If our shares of common stock are publicly traded, through a sale of shares subject to the option through a securities broker; or Other methods permitted under applicable laws.

Options vest as determined by the administrator. In general, we have granted options that vest over a four-year period. Options expire at the time determined by the administrator, but in no event more than ten years after they are granted, and generally expire earlier if the optionee's service terminates.

Restricted shares

Restricted shares may be awarded or sold under the 2018 Plan in return for cash or cash equivalents or, as permitted by the administrator in its sole discretion, in exchange for services rendered to us, or through any other means permitted by applicable law. Restricted shares vest as determined by the administrator. The plan administrator determines the terms and conditions of restricted shares, including vesting and forfeiture terms. If a participant's service relationship with us ceases for any reason, we may receive any or all of the shares of common stock held by the participant that have not vested as of the date the participant terminates service with us through a forfeiture condition or a repurchase right.

Corporate transactions

In the event that we are a party to a merger, consolidation or the capital reorganization or business combination transaction, including any transaction or series of transaction in which any person becomes the beneficial owner of more than 50% of our then outstanding capital stock, or in the event of a sale of all or substantially all of our assets, awards granted under the 2018 Plan will be treated in the manner determined by the administrator. Such treatment may include, without limitation, one or more of the following with respect to outstanding awards:

- The continuation, assumption or substitution of an award by the surviving entity or its parent;
- Cancellation of the award in exchange for a payment equal to the excess, if any, of the value of the shares subject to the award over any exercise price per share applicable to the award; or
- Cancellation of the award without payment of any consideration.

The administrator is not obligated to treat all awards in the same manner.

Changes in capitalization

In the event of certain specified changes in the capital structure of our common stock, such as a stock split, reverse stock split, stock dividend, combination, consolidation, or reclassification or our shares of common

stock, proportionate adjustments will automatically be made in (i) each of the number and kind of shares available for future grants under the 2018 Plan, (ii) the number and kind of shares covered by each outstanding option and all restricted shares, (iii) the exercise price per share subject to each outstanding option and (iv) any repurchase price applicable to shares granted under the 2018 Plan. In the event of any increase or decrease in the number of issued shares without the receipt of consideration by the Company, an extraordinary cash dividend that has a material effect on the fair market value of our common stock, a recapitalization, a rights offering, a reorganization, merger, spin-off, split-up, change in corporate structure or other similar occurrence, the administrator shall make adjustments, in its sole discretion, to one or more of the items described above.

Transferability

A participant generally may not transfer stock awards under our 2018 Plan other than by will, the laws of descent and distribution, or as otherwise provided under our 2018 Plan.

Amendments or termination

Our Board of Directors may amend or terminate our 2018 Plan at any time, but no amendment or termination shall be made that would materially and adversely affect the rights of any participant under any outstanding stock award without the participant's consent. The Company shall obtain stockholder approval of any amendment to the 2018 Plan to the extent necessary to comply with appliable laws. The 2018 Plan provides that it will terminate automatically ten years after adoption, provided, however, it will terminate earlier upon the completion of this offering, but as noted above, awards outstanding under the 2018 Plan will remain outstanding and will continue to be governed by their existing terms.

Employee stock purchase plan

General

Our ESPP was adopted by our Board of Directors on , 2025, approved by our stockholders on , 2025 and will become effective upon the effectiveness of the registration statement of which this prospectus forms a part.

The ESPP is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423 of the Code.

Share reserve

shares of our Class A common stock have been reserved for issuance under our ESPP. The number of shares reserved for issuance under our ESPP will automatically be increased on the first business day of each of our fiscal years, commencing in 2026 and ending in 2036, by a number equal to the least of:

- shares;
- % of the shares of Class A common stock outstanding on the last business day of the prior fiscal year; or
- the number of shares determined by our Board of Directors.

The number of shares reserved under our ESPP will automatically be adjusted in the event of a stock split, stock dividend or a reverse stock split (including an adjustment to the per-purchase period share limit).

Administration

The compensation committee of our Board of Directors will administer our ESPP.

Eligibility

All of our employees will be eligible to participate if we employ them for more than 20 hours per week and for five or more months per year. Eligible employees may begin participating in our ESPP at the start of any offering period.

Offering periods

Each offering period will last a number of months determined by the compensation committee, not to exceed 27 months. A new offering period will begin periodically, as determined by the compensation committee. Offering periods may overlap or may be consecutive. Unless otherwise determined by the compensation committee, two offering periods of six months' duration will begin in each year on and . Unless otherwise determined by the administrator, the first offering period will begin on the effective date of the registration statement related to this offering and will end on , with the first purchase date occurring on .

Amount of contributions

Our ESPP will permit each eligible employee to purchase Class A common stock through payroll deductions. Each employee's payroll deductions may not exceed 15% of the employee's cash compensation. Each participant may purchase up to the number of shares determined by our Board of Directors on any purchase date, not to exceed 1,500 shares. The value of the shares purchased in any calendar year may not exceed $25,000. Participants may withdraw their contributions at any time before stock is purchased.

Purchase price

The price of each share of Class A common stock purchased under our 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, in the case of the first offering period, the price at which one share of Class A common stock is offered to the public in this offering) or the fair market value per share of Class A common stock on the purchase date.

Other provisions

Employees may end their participation in our ESPP at any time. Participation ends automatically upon termination of employment with us. If we experience a change in control, our ESPP will end and shares will be purchased with the payroll deductions accumulated to date by participating employees. Our Board of Directors or our compensation committee may amend or terminate our ESPP at any time.

Certain relationships and related party transactions

The following is a description of transactions since January 1, 2022, or currently proposed, to which we have been or will be a participant, in which the amount involved exceeded $120,000 and in which any of our executive officers, directors or beneficial holders of more than 5% of our capital stock (or any immediate family member of, or person sharing the household with, any of these individuals or entities), which we collectively refer to as a related party, had or will have a direct or indirect material interest, other than compensation arrangements for our directors and executive officers, which are disclosed elsewhere in this prospectus.

Series D redeemable convertible preferred stock financing

In May 2024, we issued and sold an aggregate of 4,656,233 shares of our Series D redeemable convertible preferred stock at a cash purchase price of $28.0204 per share for an aggregate purchase price of $130.5 million (the Series D Financing). Each share of Series D redeemable convertible preferred stock will convert automatically into shares of our Class A common stock immediately prior to the completion of this offering.

The following table summarizes purchases of our Series D redeemable convertible preferred stock by entities affiliated with certain of our directors and holders of more than 5% of our capital stock.

	Series D redeemable convertible preferred stock	
Purchaser	**Number of shares**	**Aggregate purchase price**
Entities affiliated with Adams Street Partners(1)	535,321	$ 14,999,908
Hummingbird Ventures(2)	446,103	$ 12,499,984
Libertus Capital I(3)	249,817	$ 6,999,972
Entities and individuals affiliated with Premji Invest(4)	1,802,255	$ 50,499,906

(1) Entities affiliated with Adams Street Partners that purchased shares of our Series D redeemable convertible preferred stock include: (i) Adams Street 2019 Direct Growth Equity Fund LP, (ii) Adams Street 2020 Direct Growth Equity Fund LP, (iii) Adams Street 2021 Direct Growth Equity Fund LP, (iv) Adams Street 2022 Direct Growth Equity Fund LP, (v) Adams Street Global Private Markets Fund LP, (vi) Adams Street Growth Equity Fund VII LP, and (vii) FCPR GF—Lumyna Private Equity World Fund. Thomas Bremner, a member of our Board of Directors, is a partner at Adams Street Partners.

(2) Entities affiliated with Hummingbird Ventures that purchased shares of Series C redeemable convertible preferred stock include Hummingbird Dragons CommV. Firat Ileri, a member of our Board of Directors, is the managing partner of Hummingbird Ventures.

(3) Entities affiliated with Libertus Capital that purchased shares of our Series C redeemable convertible preferred stock include: (i) Libertus Capital I, and (ii) Libertus Capital II. Libertus holds greater than 5% of our capital stock.

(4) Entities and individuals affiliated with Premji Invest that purchased shares of our Series D redeemable convertible preferred stock include: (i) Akshay Rai, (ii) Directed Trust Company FBO Eric Tong Roth IRA, (iii) Eric Aisi Tong, (iv) Andrew Chang, (v) Wipro Enterprises Private Limited, (vi) T.K. Kurien, (vii) Sandesh Kaveripatnam, and (viii) Vedant Agrawal. Akshay Rai, a member of our Board of Directors, is Vice President of Healthcare & Biotechnology Investments at Premji Invest.

2022 convertible note financing

In September 2022, we entered into convertible promissory note agreements whereby we sold and issued convertible promissory notes in an aggregate principal amount of $30.0 million (the 2022 Note Financing). Each convertible promissory note had an interest rate of 8% per annum. The aggregate principal and accrued interest converted into 1,726,823 shares of our Series C-1 redeemable convertible preferred stock at a conversion price of $19.6143 per share upon the closing of our Series D financing in May 2024, and the rights and obligations under the convertible promissory note agreements were terminated and canceled. Each share of Series C-1 redeemable convertible preferred stock will convert automatically into shares of our Class A common stock immediately prior to the completion of this offering.

The following table summarizes purchases of our convertible promissory notes in the 2022 Note Financing by entities affiliated with certain of our directors and holders of more than 5% of our capital stock.

Purchaser	Aggregate principal amount of convertible promissory notes
Entities affiliated with Adams Street Partners(1)	$ 3,000,000
Entities affiliated with Libertus Capital(2)	$ 15,000,000

(1) Entities affiliated with Adams Street Partners that purchased convertible promissory notes in our 2022 Note Financing include: (i) Adams Street 2019 Direct Growth Equity Fund LP, (ii) Adams Street 2020 Direct Growth Equity Fund LP, (iii) Adams Street 2021 Direct Growth Equity Fund LP, (iv) Adams Street 2022 Direct Growth Equity Fund LP, (v) Adams Street Global Private Markets Fund LP, (vi) Adams Street Growth Equity Fund VII LP, and (vii) FCPR GF—Lumyna Private Equity World Fund. Thomas Bremner, a member of our Board of Directors, is a partner at Adams Street Partners.

(2) Libertus Capital holds greater than 5% of our capital stock. Entities affiliated with Libertus Capital that purchased convertible promissory notes in our 2022 Note Financing include: (i) Libertus Capital I and (ii) Libertus Capital II.

Series C redeemable convertible preferred stock financing

From March through September 2022, we issued and sold an aggregate of 5,628,825 shares of our Series C redeemable convertible preferred stock at a cash purchase price of $25.4937 per share for an aggregate purchase price of approximately $143.5 million. Each share of Series C redeemable convertible preferred stock will convert automatically into shares of our Class A common stock immediately prior to the completion of this offering.

The following table summarizes purchases of our Series C redeemable convertible preferred stock by entities affiliated with certain of our directors and holders of more than 5% of our capital stock.

	Series C redeemable convertible preferred stock	
Purchaser	Number of shares	Aggregate purchase price
Entities affiliated with Adams Street Partners(1)	1,176,761	$ 29,999,991.94
Hummingbird Ventures(2)	1,706,303	$ 43,499,976.80
Entities affiliated with Libertus Capital(3)	784,505	$ 19,999,935.13
Entities affiliated with Neotribe Ventures(4)	242,216	$ 6,174,982.04

(1) Entities affiliated with Adams Street Partners that purchased shares of our Series C redeemable convertible preferred stock include: (i) Adams Street 2019 Direct Growth Equity Fund LP, (ii) Adams Street 2020 Direct Growth Equity Fund LP, (iii) Adams Street 2021 Direct Growth Equity Fund LP, (iv) Adams Street 2022 Direct Growth Equity Fund LP, (v) Adams Street Global Private Markets Fund LP, (vi) Adams Street Growth Equity Fund VII LP, and (vii) FCPR GF—Lumyna Private Equity World Fund. Thomas Bremner, a member of our Board of Directors, is a partner at Adams Street Partners.

(2) Entities affiliated with Hummingbird Ventures that purchased shares of Series C redeemable convertible preferred stock include: (i) Hummingbird Dragons CommV, and (ii) Hummingbird Opportunity Fund II CommV. Firat Ileri, a member of our Board of Directors, is the managing partner of Hummingbird Ventures.

(3) Entities affiliated with Libertus Capital that purchase shares of Series C redeemable convertible preferred stock include: (i) Libertus Capital I and (ii) Libertus Capital II. Libertus Capital holds greater than 5% of our capital stock.

(4) Entities affiliated with Neotribe Ventures that purchased shares of our Series C redeemable convertible preferred stock include Neotribe SPV I BTO, LLC. Krishna Swaroop Kolluri, a member of our Board of Directors, is a managing director at Neotribe Ventures.

Secondary sales

Pursuant to our 2018 Plan and the ROFR (as defined below), which is described below, certain holders of our capital stock and we or our assignees have a right of first refusal to purchase shares of our capital stock proposed to be sold by certain of our stockholders to other parties. These rights will terminate upon completion of this offering. We waived or allowed to expire our right of first refusal in connection with the following transactions involving directors, officers and holders of more than 5% of our capital stock:

In April 2022, Dr. Tsao entered into stock purchase agreements with us and certain affiliates of Libertus Capital, which holds more than 5% of our capital stock. Pursuant to these agreements, Dr. Tsao sold an aggregate of 196,126 shares of common stock for aggregate cash proceeds of $4,999,977.43 at a price per share of $25.4937.

In April 2022, Dr. Atay entered into stock purchase agreements with us and certain affiliates of Libertus Capital. Pursuant to these agreements, Dr. Atay sold an aggregate of 196,126 shares of our common stock for $4,999,977.41 aggregate cash proceeds at a price of $25.4937 per share.

In November 2022, entities affiliated with Libertus Capital, which holds more than 5% of our capital stock, purchased an aggregate of 87,700 shares of our common stock for $1,788,641.00 aggregate cash proceeds at a price of $20.395 per share, which included 30,000 shares purchased from Shan Riku Sakakibara, our Chief Product Officer.

In June 2024, entities affiliated with Libertus Capital, which holds more than 5% of our capital stock, purchased an aggregate of 52,750 shares of our common stock for $1,182,655.00 aggregate cash proceeds at a price of $22.42 per share, which included 9,500 shares purchased from John ten Bosch, our Senior Vice President of Laboratory Operations.

Directed share program

At our request, the underwriters have reserved up to approximately shares of Class A common stock being offered by this prospectus for sale, at the initial public offering price, to our officers, directors and employees through a directed share program. The directed share program will not limit the ability of our directors, officers or holders of more than 5% of our capital stock, to purchase more than $120,000 in value of our Class A common stock. We do not currently know the extent to which these related persons will participate in our directed share program, if at all, or the extent to which they will purchase more than $120,000 in value of our Class A common stock.

Investors' rights agreement

We have entered into an Amended and Restated Investors' Rights Agreement, dated May 14, 2024, by and among the Company and the investors listed on schedule A thereto (the IRA), including entities with which certain of our directors are affiliated. These stockholders are entitled to rights with respect to the registration of their shares following this offering. For a description of these registration rights, see the section titled "Description of capital stock—Registration rights." Other than these registration rights, all other terms of the IRA will terminate in connection with this offering.

Voting agreement

We have entered into an Amended and Restated Voting Agreement by and between the Company and certain holders of our redeemable convertible preferred stock, dated May 14, 2024 (the Voting Agreement), including entities with which certain of our directors are affiliated. Under the Voting Agreement, certain holders of our capital stock have agreed as to the manner in which they will vote their shares of our capital stock on certain matters, including with respect to the election of directors. The Voting Agreement will terminate upon the completion of this offering, at which time there will be no further contractual obligations regarding the manner in which shares are voted with respect to the election of our directors.

Right of first refusal and co-sale agreement

We have entered into an Amended and Restated Right of First Refusal and Co-Sale Agreement by and between the Company and certain holders of our redeemable convertible preferred stock, dated May 14, 2024 (the

ROFR), including entities with which certain of our directors are affiliated. Under the ROFR, certain holders of our capital stock have the right of first refusal and co-sale relating to the shares of our common stock held by the parties to the agreement. Upon the completion of this offering, the ROFR will terminate.

Indemnification agreements

Our amended and restated Post-IPO Certificate of Incorporation will contain provisions limiting the liability of directors and officers, and our Post-IPO Bylaws will provide that we will indemnify each of our directors and executive officers to the fullest extent permitted under Delaware law. Our Post-IPO Certificate of Incorporation and Post-IPO Bylaws will also provide our Board of Directors with discretion to indemnify our employees and other agents when determined appropriate by the Board of Directors. In addition, we have entered into or intend to enter into an indemnification agreement with each of our directors, which will require us to indemnify them. For more information regarding these agreements, see the section titled "—Limitations on liability and indemnification of directors and officers."

Other transactions

To facilitate the Class B Stock Exchange, we will enter into exchange agreements with our Co-Founders, effective as of immediately prior to effectiveness of the filing of our Post-IPO Certificate of Incorporation, pursuant to which shares of our Class A common stock held by our Co-Founders, or entities controlled by our Co-Founders, will automatically be exchanged for an equivalent number of shares of Class B common stock immediately prior to the completion of this offering.

Limitations on liability and indemnification of directors and officers

Our Post-IPO Certificate of Incorporation will contain provisions that limit the liability of our current and former directors for monetary damages to the fullest extent permitted by Delaware law. The Post-IPO Certificate of Incorporation will provide that our directors will not be personally liable to us or our stockholders for monetary damages for any breach of fiduciary duty as a director, except for liability:

- for any breach of the director's duty of loyalty to us or our stockholders;
- for acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- in respect of unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the DGCL;
- an officer in any action by or in the right of the Company; or
- for any transaction from which the director derives any improper personal benefit.

Such limitation of liability does not apply to liabilities arising under federal securities laws and does not affect the availability of equitable remedies such as injunctive relief or rescission.

Our Post-IPO Certificate of Incorporation will provide that if Delaware law is amended to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of our directors will be eliminated or limited to the fullest extent permitted by Delaware law. Our Post-IPO Certificate of Incorporation and our bylaws will provide that we are required to indemnify our executive officers and directors to the fullest extent permitted by Delaware law. Our Post-IPO Bylaws will also provide that, on satisfaction of certain conditions, we will advance the expenses incurred by a director or officer in advance of the final disposition of

an action or proceeding, and permit us to secure insurance on behalf of any director, officer, employee, or other enterprise agent for any liability arising out of his or her action in that capacity, whether or not Delaware law would otherwise permit indemnification.

We have entered into, and expect to continue to enter into, indemnification agreements with each of our directors and executive officers and certain other key employees. With certain exceptions, these agreements will provide for indemnification for related expenses including attorneys' fees, judgments, fines, and settlement amounts incurred by any of these individuals in connection with any action, proceeding, or investigation. We believe that these provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers. We also currently carry and intend to continue to carry liability insurance for our directors and officers.

The limitation of liability and indemnification provisions in our Post-IPO Certificate of Incorporation and our Post-IPO Bylaws may discourage stockholders from bringing a lawsuit against our directors for breach of their fiduciary duty. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and other stockholders. Furthermore, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damage awards against directors and officers as required by these indemnification provisions. At present, there is no pending litigation or proceeding involving any of our directors, officers, or employees for which indemnification is sought, and we are not aware of any threatened litigation that may result in claims for indemnification.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted for directors, executive officers, or persons controlling us, we have been informed that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Related party transaction policy

Our Board of Directors has adopted a formal written policy providing that we are not permitted to enter into any transaction that exceeds $120,000 in any given year and in which any related party has a direct or indirect material interest without the consent of our audit committee. Our audit committee will have the primary responsibility for reviewing and approving or disapproving such "related party transactions." The charter of our audit committee will provide that our audit committee shall review and approve in advance any related party transaction. In approving or rejecting any such transaction, our audit committee is to consider the relevant facts and circumstances available and deemed relevant to our audit committee, including whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances and the extent of the related party's interest in the transaction.

All of the transactions described in this section were entered into prior to the adoption of this policy. Although we have not had a written policy for the review and approval of transactions with related parties, our Board of Directors has historically reviewed and approved any transaction where a director or officer had a financial interest, including the transactions described above. Prior to approving such a transaction, the material facts as to the relationship or interest of the relevant director, officer or holder of five percent or more of any class of our voting securities in the agreement or transaction was disclosed to our Board of Directors. Our Board of Directors took this information into account when evaluating the transaction and in determining whether such transaction was fair to us and in the best interest of all our stockholders.

Principal stockholders

The following table sets forth the beneficial ownership of our capital stock as of , 2025, and as adjusted to reflect the sale of Class A common stock offered by us in this offering, for:

- each person, or group of affiliated persons, who is known by us to beneficially own more than 5% of our common stock;
- each of our named executive officers;
- each of our directors; and
- all of our current executive officers and directors as a group.

We have determined beneficial ownership in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting or investment power with respect to those securities. The information contained in the following table is not necessarily indicative of beneficial ownership for any other purpose, and the inclusion of any shares in the table does not constitute an admission of beneficial ownership of those shares. Unless otherwise indicated by the footnotes below, we believe, based on the information furnished to us, that the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to applicable community property laws.

The percentage ownership information shown in the table prior to this offering is based upon shares of Class A common stock and shares of Class B common stock outstanding as of , 2025, assuming (i) the Preferred Stock Conversion, (ii) the Reclassification, and (iii) the Class B Stock Exchange. The percentage ownership information shown in the table after this offering is based upon shares of Class A common stock and shares of Class B common stock outstanding immediately after the closing of the offering, assuming no exercise of the underwriters' option to purchase additional shares of Class A common stock. We have deemed shares of our Class A common stock subject to stock options that are currently exercisable or exercisable within 60 days of , 2025 to be outstanding and to be beneficially owned by the person holding the stock option for the purpose of computing the percentage ownership of that person. We did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person.

In addition, the table below excludes any potential purchases in this offering by the beneficial owners identified in the table below, including in the directed share program.

Except as otherwise noted below, the address for persons listed in the table is c/o BillionToOne, Inc., 1035 O'Brien Drive, Menlo Park, CA 94025.

Name of beneficial owner	Class A shares beneficially owned before this offering Number	%	Class B shares beneficially owned before this offering Number	%	% total voting power before this offering	Class A shares beneficially owned after this offering Number	%	Class B shares beneficially owned after this offering Number	%	% total voting power after this offering
Named executive officers and directors:										
Oguzhan Atay[1]										
David Tsao[2]										
Nancy Johnson[3]										
Dean Ross Taylor[4]										
Thomas Bremner[5]										
Firat Ileri[6]										
Krishna Swaroop Kolluri[7]										
Akshay Rai[8]										
All current executive officers and directors as a group (11 persons)[9]										
5% Stockholders										
Entities affiliated with Hummingbird Ventures[10]										
Entities affiliated with Libertus Capital[11]										
Pamir Gelenbe[12]										
Entities affiliated with Neotribe Ventures[13]										

(*) Represents beneficial ownership of less than 1%

(1) Consists of (i) shares of Class B common stock held by Dr. Atay and (ii) shares of Class A common stock issuable to Dr. Atay upon exercise of stock options within 60 days of , 2025. Also consists of shares of Class A common stock held by Dr. Atay's spouse. Dr. Atay disclaims beneficial ownership of the shares held by his spouse.

(2) Consists of (i) shares of Class B common stock held by Dr. Tsao; and (ii) shares of Class A common stock issuable to Dr. Tsao upon exercise of stock options within 60 days of , 2025.

(3) Consists of (i) shares of Class A common stock held by Ms. Johnson; and (ii) shares of Class A common stock issuable to Ms. Johnson upon exercise of stock options within 60 days of , 2025.

(4) Consists of shares of Class A common stock issuable to Mr. Taylor upon exercise of stock options within 60 days of , 2025.

(5) Consists of (i) shares of Class A common stock held by Adams Street 2019 Direct Growth Equity Fund LP; (ii) shares of Class A common stock held by Adams Street 2020 Direct Growth Equity Fund LP; (iii) shares of Class A common stock held by Adams Street 2021 Direct Growth Equity Fund LP; (iv) shares of Class A common stock held by Adams Street 2022 Direct Growth Equity Fund LP; (v) shares of Class A common stock held by Adams Street Global Private Markets Fund LP; (vi) shares of Class A common stock held by Adams Street Growth Equity Fund VII LP; and (vi) shares of Class A common stock held by FCPR GF—Lumyna Private Equity World Fund. Adams Street Partners, LLC is the managing member of the general partner of each of Adams Street 2019 Direct Growth Equity Fund LP, Adams Street 2020 Direct Growth Equity Fund LP, Adams Street 2021 Direct Growth Equity Fund LP, Adams Street 2022 Direct Growth Equity Fund LP, Adams Street Growth Equity Fund VII LP, and Adams Street Private Equity Navigator Fund LLC (f/k/a Adams Street Global Private Markets Fund LP) (collectively, the U.S. Funds) and, as a result, may be deemed to beneficially own the shares held by the U.S. Funds. Furthermore, Adams Street Partners, LLC, the Sous- Délégataire Financier of the Délégataire Financier of the management company of FCPR GF—Lumyna Private Equity World Fund (Lumyna and together with the U.S. Funds, the Funds) and, as a result, may be deemed to beneficially own the shares held by Lumyna. Thomas S. Bremner, Jeffrey T. Diehl, Brian Dudley, Elisha P. Gould, Robin Murray and Fred Wang, each of whom is a partner of Adams Street Partners, LLC (or a subsidiary thereof), may be deemed to have shared voting and investment power over the shares held by the Funds. The address for each entity referenced above is 1 North Wacker Drive, Suite 2200, Chicago, IL 60606-2807.

(6) Consists of (i) the shares of Class A common stock referenced in footnote 10 and (ii) shares of Class A common stock held directly by Mr. Ileri.

(7) Consists of the shares of Class A common stock referenced in footnote 13.

(8) Consists of (i) shares of Class A common stock held directly by Mr. Rai and (ii) shares of Class A common stock held by Wipro Enterprises Private Limited (Wipro), of which Mr. Rai is the nominee/investor director appointed by Wipro Enterprises Limited. Mr. Rai will not have voting or dispositive control of the securities described in clause (ii) of the prior sentence while such securities are held by Wipro and thus disclaims beneficial ownership of such securities The address for each of the entities and individuals listed in this footnote is 2180 Sand Hill Road, Ste. 100, Menlo Park, California 94025.

(9) Includes shares of Class A common stock issuable upon exercise of stock options within 60 days of , 2025.

(10) Consists of (i) shares of Class A common stock held by Hummingbird Opportunity Fund II CommV; (ii) shares of Class A common stock held by Hummingbird Ventures III CommV; (iii) shares of Class A common stock held by Hummingbird Dragons CommV; (iv) shares of Class A common stock held by Hummingbird Collective CommV; and (v) shares of Class A common stock held by HB&Q NV (HB&Q COMPARTMENT III). Humming Bird Ventures Management NV is the managing member of Hummingbird Opportunity Fund II CommV, Hummingbird Ventures III CommV, Hummingbird Dragons CommV, Hummingbird Collective CommV, and HB&Q NV (HB&Q COMPARTMENT III) (the Hummingbird Funds) and, as a result, may be deemed to beneficially own shares held by the Hummingbird Funds. Mr. Ileri, Barend Van den Brande, and Lukas Decoster are partners of Hummingbird Ventures Management NV and may be deemed to have shared voting and investment power over the shares held by the Hummingbird Funds. The address for each of the entities and individuals listed in this footnote is Chau. de la Hulpe 185, 1170 Watermael-Boitsfort, Belgium.

(11) Consists of (i) shares of Class A common stock held by Libertus Capital I; (ii) shares of Class A common stock held by Libertus Capital I (HV); and (iii) shares of Class A common stock held by Libertus Capital II. Libertus Capital S.A.R.L. is the general partner of Libertus Capital I, Libertus Capital I (HV) and Libertus Capital II (the Libertus Funds) and, as a result, may be deemed to beneficially own shares held by the Libertus Funds. Pamir Gelenbe, Johannes Dercksen and Pierre Ribeiro are members of the board of directors of Libertus Capital S.A.R.L. and may be deemed to have shared voting and investment power over the shares held by the Libertus Funds. The address for each of the entities and individuals listed in this footnote is 31 rue de Hollerich, L-1741, Luxembourg.

(12) Consists of (i) shares of Class A common stock held directly by Mr. Gelenbe; (ii) shares of Class A common stock held by GOPAE Turquoise Strategies Pte. Ltd.; (iii) shares of Class A common stock held by Libertus Capital I; (iv) shares of Class A common stock held by Libertus Capital I (HV); and (v) shares of Class A common stock held by Libertus Capital II. Mr. Gelenbe and Gulnar Hasnain are the controlling shareholders of GOPAE Turquoise Strategies Pte. Ltd., and as a result, they may be deemed to beneficially own shares held by GOPAE Turquoise Strategies Pte. Ltd. Mr. Gelenbe and Ms. Hasnain are also the controlling shareholders of PG Consulting Services LTD, which is the sole shareholder of Libertus Capital S.A.R.L., the general partner of the Libertus Funds and, as a result they may be deemed to beneficially own shares held by the Libertus Funds. The address for each of the entities and individuals listed in this footnote is 31 rue de Hollerich, L-1741, Luxembourg.

(13) Consists of (i) shares of Class A common stock held by Neotribe Ignite Fund I, L.P.; (ii) shares of Class A common stock held by Neotribe SPV I BTO, LLC; and (iii) shares of Class A common stock held by NeoTribe Ventures I, L.P., for itself and as nominee for NeoTribe Associates I, L.P. Krishna Swaroop Kolluri is the general partner for each of Neotribe Ignite Fund I, L.P. and NeoTribe Ventures I, L.P. and NeoTribe Associates I, L.P., and the managing member of Neotribe SPV I BTO, LLC and may be deemed to have beneficial ownership of the shares held by each of them. The address for each of the entities and individuals listed in this footnote is 1300 El Camino Real, Suite 100, Menlo Park, California 94025.

Description of capital stock

The following is a summary of our capital stock, certain provisions of our Post-IPO Certificate of Incorporation and Post-IPO Bylaws as each will be in effect upon the completion of this offering, our IRA, and relevant provisions of Delaware law. Because it is only a summary, it does not contain all the information that may be important to you. These descriptions are qualified in their entirety by our Post-IPO Certificate of Incorporation, our Post-IPO Bylaws, and our IRA, which are each filed as exhibits to our registration statement of which this prospectus is a part, as well as the relevant provisions of the DGCL.

General

Immediately prior to the completion of this offering, our Post-IPO Certificate of Incorporation will provide for two classes of common stock. In addition, our Post-IPO Certificate of Incorporation will authorize shares of undesignated preferred stock, the rights, preferences, and privileges of which may be designated from time to time by our Board of Directors.

Immediately prior to the completion of this offering, our authorized capital stock will consist of shares, all with a par value of $ per share, of which:

- shares are designated as Class A common stock;
- shares are designated as Class B common stock; and
- shares are designated as preferred stock.

Common stock

Upon completion of this offering, we will have two classes of authorized common stock: Class A common stock and Class B common stock. The rights of the holders of our Class A common stock and our Class B common stock are identical, except with respect to voting, conversion and transfer rights.

As of June 30, 2025, after giving effect to (i) the Preferred Stock Conversion, (ii) the Reclassification, (iii) the Class B Stock Exchange, as if each event had occurred on June 30, 2025, we had outstanding shares of Class A common stock and shares of Class B common stock.

Dividend rights

Subject to preferences that may apply to shares of preferred stock outstanding at the time, the holders of outstanding shares of our Class A common stock and Class B common stock are entitled to receive dividends out of funds legally available if our Board of Directors, in its discretion, determines to issue dividends and only then at the times and in the amounts that our Board of Directors may determine. See the section titled “Dividend policy” for more information.

Voting rights

Holders of our Class A common stock will be entitled to one vote and holders of our Class B common stock will be entitled to 10 votes for each share held on all matters submitted to a vote of stockholders. The holders of our Class A common stock and Class B common stock will vote together as a single class, unless otherwise required by law or our Post-IPO Certificate of Incorporation. Delaware law could require either holders of our Class A common stock or Class B common stock to vote separately as a single class in the following circumstances:

- if we were to seek to amend our Post-IPO Certificate of Incorporation to increase or decrease the par value of a class of our capital stock, then that class would be required to vote separately to approve the proposed amendment; and

- if we were to seek to amend our Post-IPO Certificate of Incorporation in a manner that alters or changes the powers, preferences, or special rights of a class of our capital stock in a manner that affected its holders adversely, then that class would be required to vote separately to approve the proposed amendment.

The holders of our Class A common stock and our Class B common stock will not have cumulative voting rights in the election of directors.

Conversion rights

Holders of our Class A common stock will have no conversion rights.

Each outstanding share of our Class B common stock will be convertible at any time at the option of the holder into one share of our Class A common stock. In addition, each share of our Class B common stock will convert automatically into one share of our Class A common stock upon any transfer, whether or not for value, which occurs after the completion of this offering, except for certain permitted transfers set forth in our Post-IPO Certificate of Incorporation, including . Once converted into our Class A common stock, such Class B common stock will not be reissued.

In addition, each share of Class B common stock held by a Founder and such 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 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 Founder is no longer serving as an officer or director of the Company.

All of the outstanding shares of our Class B common stock will convert automatically on a one-for-one basis into shares of our Class A common stock upon the earliest of (i) seven 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. Following the conversion of all outstanding shares of our Class B common stock into Class A common stock, no further shares of our Class B common stock will be issued.

Right to receive liquidation distributions

Upon our dissolution, liquidation or winding-up, the assets legally available for distribution to our stockholders are distributable ratably among the holders of our Class A common stock and our Class B common stock, subject to prior satisfaction of all outstanding debt and liabilities and the preferential rights and payment of liquidation preferences, if any, on any outstanding shares of preferred stock.

No preemptive or similar rights

Our shares of common stock are not entitled to preemptive rights and are not subject to conversion, redemption or sinking fund provisions (except, in respect of our Class B common stock, for the conversion rights noted above). The rights, preferences, and privileges of the holders of our common stock will be subject to and may be adversely affected by the rights of the holders of shares of any series of our preferred stock that we may designate in the future.

Preferred stock

As of , there were shares of our redeemable convertible preferred stock outstanding. Immediately prior to the completion of this offering, each outstanding share of redeemable convertible preferred stock will convert into one share of our common stock pursuant to the Preferred Stock Conversion.

Upon the filing and effectiveness of our Post-IPO Certificate of Incorporation, our Board of Directors may, without further action by our stockholders, fix the rights, preferences, privileges, and restrictions of up to an aggregate of shares of preferred stock in one or more series and authorize their issuance. These rights, preferences, and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms, and the number of shares constituting any series or the designation of such series, any or all of which may be greater than the rights of our common stock. The issuance of our preferred stock could adversely affect the voting power of holders of our common stock, and the likelihood that such holders will receive dividend payments and payments upon liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring, or preventing a change of control or other corporate action. Upon the completion of this offering, no shares of preferred stock will be outstanding, and we have no present plan to issue any shares of preferred stock.

Stock options

As of June 30, 2025, options to purchase an aggregate of shares of common stock were outstanding at a weighted-average exercise price of approximately $ per share. For additional information regarding the terms of our stock options outstanding under our 2018 Plan, see the section titled “Executive compensation—Equity plans.”

Warrants

As of December 31, 2024, we had outstanding warrants to purchase (i) an aggregate of up to 80,357 shares of our common stock with an exercise price of $2.80 per share (the 2021 Common Warrant), (ii) an aggregate of up to 41,209 shares of our common stock with an exercise price of $10.92 per share (the 2022 Common Warrant and together with the 2021 Common Warrant, the Common Warrants) and (iii) an aggregate of up to 9,660 shares of our Series A-6 redeemable convertible preferred stock with an exercise price of $2.5879 per share (the A-6 Warrant). In connection with this offering, the 2021 Common Warrant, the 2022 Common Warrant and the A-6 Warrant will become exercisable for an aggregate of shares, shares and shares, respectively, of our Class A common stock at an exercise price of $ per share for the 2021 Common Warrant, $ per share for the 2022 Common Warrant, and $ per share for the A-6 Warrant.

Registration rights

After the completion of this offering, holders of shares of our Class A common stock (including, following the Class B Stock Exchange, shares of our Class A common stock issuable upon the conversion of shares of Class B common stock) will be entitled to certain rights with respect to registration of such shares under the Securities Act pursuant to the terms of the IRA between us and the holders of these shares, which was entered into in connection with our redeemable convertible preferred stock financings. These shares are referred to as registrable securities.

The IRA includes demand, piggyback and Form S-3 registration rights as described more fully below.

Demand registration rights

At any time beginning six months after this offering, the holders of registrable securities have the right to make up to two demands that we file a registration statement under the Securities Act with having an aggregate offering price, net of selling expenses, of at least $20 million, subject to specified exceptions.

Piggyback registration rights

If we register any of its securities for public sale solely for cash (other than a registration pursuant to the demand registration rights described above, a registration for a direct listing, a registration relating solely to our equity incentive plans, a registration relating to a reorganization transaction under Rule 145, a registration on any form that does not include substantially the same information as would be required to be included in a registration statement covering the registrable securities, or a registration statement where the only common stock being registered is common stock issuable upon conversion of debt securities that are also being registered), the holders of our registrable securities then outstanding will each be entitled to notice of the registration and will have the right to include their shares in the registration statement.

These piggyback registration rights are subject to specified conditions and limitations, including the right of the underwriters of any underwritten offering to limit the aggregate value of registrable securities to be included in the registration statement, but not below 25% of the total value of securities included in such registration.

We expect that the requisite stockholders who are party to our IRA will waive their rights with respect to the notice of this offering and to the inclusion of their registrable shares in this offering.

Registration on Form S-3

If we are eligible to file a registration statement on Form S-3, the holders of at least 30% of the registrable securities then outstanding have the right to demand that we file registration statements on Form S-3; provided, that the aggregate offering price, net of selling expenses, of the securities to be sold under the registration statement is at least $10 million. The right to have such shares registered on Form S-3 is further subject to other specified conditions and limitations.

Termination of registration rights

The registration rights will survive this offering and will terminate after the earlier of either five years following the completion of this offering and a liquidation event, and, with respect to any particular stockholder, when such stockholder can sell all its shares in compliance with Rule 144(b)(i) or if such stockholder holds 1% or less of the outstanding common stock and is able to sell all of its registrable securities during a three month period in compliance with Rule 144 under the Securities Act.

Anti-takeover provisions

Some provisions of Delaware law, our Post-IPO Certificate of Incorporation, and our Post-IPO Bylaws contain or will contain provisions that could make the following transactions more difficult: an acquisition of us by means of a tender offer; an acquisition of us by means of a proxy contest or otherwise; or the removal of our incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interest or in our best interests, including transactions which provide for payment of a premium over the market price for our shares. These provisions may also have the effect of preventing changes in the composition of our Board of Directors and management. These provisions, summarized below, are intended to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our Board of Directors. We believe that the benefits of the increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

Anti-takeover statute

We are subject to Section 203 of the DGCL, which prohibits persons deemed to be "interested stockholders" from engaging in a "business combination" with a publicly held Delaware corporation for three years following the date these persons become interested stockholders unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. Generally, an "interested stockholder" is a person who, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation's voting stock. Generally, a "business combination" includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. The existence of this provision may have an anti-takeover effect with respect to transactions not approved in advance by our Board of Directors.

Preferred stock

Our Board of Directors will have the authority, without further action by our stockholders, to issue up to shares of undesignated preferred stock with rights and preferences, including voting rights, designated from time to time by our Board of Directors. The existence of authorized but unissued shares of preferred stock would enable our Board of Directors to render more difficult or to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest, or other means.

Stockholder meetings

Our Post-IPO Bylaws will provide that, once our Class B common stock no longer represents a majority of voting power of our outstanding capital stock, a special meeting of stockholders may be called only by our chairman of the Board of Directors, chief executive officer or president (in the absence of a chief executive officer), or by a resolution adopted by a majority of our Board of Directors.

Requirements for advance notice of stockholder nominations and proposals

Our Post-IPO Bylaws will establish advance notice procedures with respect to stockholders seeking to bring business before our annual meeting of stockholders, or to nominate candidates for election as directors, other than nominations made by or at the direction of the Board of Directors, or a committee thereof. Our Post-IPO Bylaws will also specify certain requirements regarding the form and content of a stockholder's notice. These provisions may preclude our stockholders from bringing matters before our annual meeting of stockholders or from making nominations for directors at our meetings of stockholders.

Stockholder action

Our Post-IPO Certificate of Incorporation and Post-IPO Bylaws will provide that, once our Class B common stock no longer represents a majority of voting power of our outstanding capital stock, stockholders will not be able to take action by written consent, and will only be able to take action at annual or special meetings of our stockholders.

Classified board

Our Board of Directors will be divided into three classes. The directors in each class will serve for a three-year term, one class being elected each year by our stockholders. For more information on the classified board, see the section titled "Management—Board composition." This system of electing and removing directors may tend

to discourage a third party from making a tender offer or otherwise attempting to obtain control of us, because it generally makes it more difficult for stockholders to replace a majority of the directors.

Removal of directors

Our Post-IPO Certificate of Incorporation will provide that, once our Class B common stock no longer represents a majority of voting power of our outstanding capital stock, no member of our Board of Directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the affirmative vote of two-thirds of the voting power of our then-outstanding capital stock.

Stockholders not entitled to cumulative voting

Our Post-IPO Certificate of Incorporation will not permit stockholders to cumulate their votes in the election of directors.

Choice of forum

Upon the completion of this offering, our Post-IPO Certificate of Incorporation will provide that the Court of Chancery of the State of Delaware will be 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 Post-IPO Certificate of Incorporation or our Post-IPO Bylaws or any action asserting a claim against us that is governed by the internal affairs doctrine. Our Post-IPO Certificate of Incorporation will also provide 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.

Some companies that adopted a similar federal district court forum selection provision were subject to a suit in the Chancery Court of Delaware by stockholders who asserted that the provision is not enforceable. While the Delaware Supreme Court held that such federal district court forum selection provision was in fact valid, there can be no assurance that federal courts or other state courts will follow the holding of the Delaware Supreme Court or determine that the our federal district court forum selection provision should be enforced in a particular case.

These choice of forum provisions do not apply to actions brought to enforce a duty or liability created by the Exchange Act. We intend for the choice of forum provision regarding claims arising under the Securities Act to apply despite the fact that Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all actions brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. There is uncertainty as to whether a court would enforce such provision with respect to claims under the Securities Act, and our stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

These exclusive forum provisions may limit the ability of our stockholders to bring a claim in a judicial forum that such stockholders find favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees. Alternatively, if a court were to find such provisions contained in our certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could materially adversely affect our business, financial condition and operating results.

Amendment of charter provisions

Once our Class B common stock no longer represents a majority of voting power of our outstanding capital stock, the amendment of any of the above provisions, except for the provision making it possible for our Board of Directors to issue preferred stock, would require approval of two-thirds of the voting power of our then-outstanding capital stock.

Transfer agent and registrar

Upon the completion of this offering, the transfer agent and registrar for our Class A common stock and Class B common stock will be . The transfer agent's address is .

Nasdaq Global Market listing

We intend to apply for listing of our Class A common stock on the Nasdaq Global Market under the trading symbol "BLLN," and this offering is contingent upon obtaining approval of such listing.

Shares eligible for future sale

Prior to this offering, no public market existed for our Class A common stock, and although we expect that our Class A common stock will be approved for listing on Nasdaq, we cannot assure investors that there will be an active public market for our Class A common stock following this offering. We cannot predict what effect, if any, sales of our shares in the public market or the availability of shares for sale will have on the market price of our Class A common stock. Future sales of substantial amounts of common stock in the public market, or the possibility of these sales or issuances occurring, could adversely affect the prevailing market price of our Class A common stock or impair our ability to raise equity capital.

Upon the completion of this offering, based on the number of our shares outstanding as of June 30, 2025 and after giving effect to the Preferred Stock Conversion, the Reclassification and the Class B Stock Exchange, as if each event had occurred on June 30, 2025, we will have an aggregate of shares of our Class A common stock (or shares of our Class A common stock if the underwriters exercise in full their option to purchase additional shares) and an aggregate of shares of our Class B common stock outstanding. This includes all shares of Class A common stock that we are selling in this offering, which shares may be resold in the public market immediately unless purchased by our affiliates, and assumes no additional exercise of outstanding options or warrants other than as described elsewhere in this prospectus.

The remaining shares of our Class A common stock and all of the shares of our Class B common stock will be “restricted securities,” as that term is defined in Rule 144. Restricted securities are eligible for public sale only if they are registered under the Securities Act or if they qualify for an exemption from registration under Rules 144 or 701 under the Securities Act, which are summarized below. Substantially all of these shares will be subject to a lock-up period under the lock-up agreements and market stand-off agreements described below.

As a result of these lock-up and market stand-off agreements, and subject to the provisions of Rules 144 or 701, shares of our Class A common stock will be available for sale in the public market as follows (assuming no exercise of outstanding stock options subsequent to June 30, 2025):

- beginning on the date of this prospectus, all shares of our Class A common stock sold in this offering will be eligible for immediate sale in the public market, unless purchased by our affiliates; and
- beginning 180 days after the date of this prospectus, additional shares of Class A common stock and shares of Class A common stock issuable upon the conversion of outstanding Class B common stock will become eligible for sale in the public market, of which shares will be held by affiliates and subject to the volume, manner of sale, and other restrictions of Rule 144, as described below.

In addition, after this offering, up to shares of Class A common stock may be issued upon exercise of outstanding stock options as of June 30, 2025, and shares of Class A common stock are available for future issuance under our 2018 Plan.

Rule 144

In general, under Rule 144 as currently in effect, once we have been subject to public company reporting requirements of Section 13 or Section 15(d) of the Exchange Act for at least 90 days, an eligible stockholder is entitled to sell such shares without complying with the manner of sale, volume limitation, or notice provisions of Rule 144, subject to compliance with the public information requirements of Rule 144. To be an eligible stockholder under Rule 144, such stockholder must not be deemed to have been one of our affiliates for purposes of the Securities Act at any time during the 90 days preceding a sale and must have beneficially

owned the shares proposed to be sold for at least six months, including the holding period of any prior owner other than our affiliates. If such a person has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than our affiliates, then such person is entitled to sell such shares without complying with any of the requirements of Rule 144, subject to the expiration of the lock-up agreements and/or market stand-off arrangements described below, which prevent the sale of shares.

In general, under Rule 144, as currently in effect, our affiliates or persons selling shares on behalf of our affiliates are entitled to sell shares on expiration of the lock-up agreements and/or market standoff arrangements described below, subject, in the case of restricted securities, to such shares having been beneficially owned for at least six months. Beginning 90 days after the date of this prospectus, within any three-month period, such stockholders may sell a number of shares that does not exceed the greater of:

- 1% of the number of shares of common stock then outstanding, which will equal shares immediately after this offering, assuming no exercise of the underwriters' option to purchase additional shares of common stock from us; or
- the average weekly trading volume of our common stock during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Sales under Rule 144 by our affiliates or persons selling shares on behalf of our affiliates are also subject to certain manner of sale provisions and notice requirements and to the availability of current public information about us.

Rule 701

Rule 701 under the Securities Act, or Rule 701, generally allows a stockholder who was issued shares under a written compensatory plan or contract and who is not deemed to have been an affiliate of our company during the immediately preceding 90 days, to sell these shares in reliance on Rule 144, but without being required to comply with the public information, holding period, manner of sale limitations, volume limitation, or notice provisions of Rule 144. Rule 701 also permits affiliates of our company to sell their Rule 701 shares under Rule 144 without complying with the holding period requirements of Rule 144. All holders of Rule 701 shares, however, are required by that rule to wait until 90 days after the date of this prospectus before selling those shares under Rule 701, subject to the expiration of the lock-up agreements and market stand-off arrangements described below.

Form S-8 registration statements

We intend to file one or more registration statements on Form S-8 under the Securities Act with the SEC as soon as practicable after the time at which the registration statement of which this prospectus forms a part becomes effective to register the offer and sale of shares of our Class A common stock that are subject to outstanding stock options and Class A common stock issued or issuable under our employee benefit plans as defined in Form S-8. These registration statements will become effective immediately on filing. Shares covered by these registration statements will then be eligible for sale in the public markets, subject to vesting restrictions, any applicable lock-up agreements and/or market stand-off arrangements described below and Rule 144 limitations applicable to affiliates.

Lock-up agreements and market stand-off arrangements

We will agree that we will not, subject to certain exceptions, (i) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right, or warrant to

purchase, hedge, lend, or otherwise transfer or dispose of, directly or indirectly, or submit to, or file with the SEC a registration statement under the Securities Act relating to any shares of our Class A common stock or securities convertible into or exchangeable or exercisable for any shares of our Class A common stock, or (ii) enter into any swap, hedging or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of any shares of Class A common stock or any such other securities, or publicly disclose the intention to undertake any of the foregoing (regardless of whether any of these transactions are to be settled by the delivery of shares of Class A common stock or such other securities, in cash or otherwise), in each case without the prior written consent of J.P. Morgan Securities LLC for a period of 180 days after the date of this prospectus, other than the shares of our Class A common stock to be sold in this offering and certain other exceptions.

Our directors and executive officers, and substantially all of our securityholders (such persons, the lock-up parties) have entered, or will enter, into lock-up agreements with the underwriters or are subject to market stand-off arrangements prior to the commencement of this offering pursuant to which each lock-up party, with limited exceptions, for a period of 180 days after the date of this prospectus (such period, the restricted period), may not and may not cause any of their direct or indirect affiliates to, without the prior written consent of J.P. Morgan Securities LLC, (i) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of our common stock or any securities convertible into or exercisable or exchangeable for our common stock (including without limitation, our common stock or such other securities which may be deemed to be beneficially owned by the lock-up party in accordance with the rules and regulations of the SEC and securities which may be issued upon exercise of a stock option or warrant) (collectively with the common stock, the lock-up securities) or (ii) enter into any hedging, swap or other agreement or transactions that transfers, in whole or in part, any of the economic consequences of ownership of the lock-up securities, whether any such transaction described in clause (i) or (ii) above is to be settled by delivery of the lock-up securities, in cash or otherwise, (iii) make any demand for or exercise any right with respect to the registration of any lock-up securities, or (iv) publicly disclose the intention to do any of the foregoing.

Registration rights

Upon the completion of this offering, the holders of shares of our Class A common stock or their permitted transferees (including, following the Class B Stock Exchange, shares of our Class A common stock issuable upon the conversion of shares of Class B common stock), will be entitled to certain rights with respect to the registration of the offer and sale of their shares under the Securities Act. All such shares are covered by lock-up agreements or market stand-off arrangements. Following the expiration of the lock-up and market stand-off period, registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act immediately on the effectiveness of the registration. See the section titled “Description of capital stock—Registration rights” for additional information.

Rule 10b5-1 plans

After this offering, certain of our employees, including our executive officers, and/or directors may enter into written trading plans that are intended to comply with Rule 10b5-1 under the Exchange Act. Sales under these trading plans would not be permitted until the expiration of the lock-up agreements or market stand-off arrangements relating to the offering described above.

Material U.S. federal income tax consequences to non-U.S. holders of our Class A common stock

The following is a general discussion of the material U.S. federal income tax considerations applicable to non-U.S. holders (as defined below) with respect to their ownership and disposition of shares of our Class A common stock issued pursuant to this offering. All prospective non-U.S. holders of our Class A common stock should consult their tax advisors with respect to the U.S. federal, state, local and non-U.S. tax consequences of the purchase, ownership and disposition of our Class A common stock. For purposes of this discussion, a non-U.S. holder means a beneficial owner of our Class A common stock (other than an entity or arrangement that is treated as a partnership or pass-through entity for U.S. federal income tax purposes) that is not, for U.S. federal income tax purposes, any of the following:

- an individual citizen or resident of the United States;
- a corporation (or other entity treated as a corporation for U.S. federal income tax purposes) created or organized in the United States or under the laws of the United States, any state thereof or the District of Columbia;
- an estate, the income of which is includable in gross income for U.S. federal income tax purposes regardless of its source; or
- a trust if (1) a court within the United States is able to exercise primary supervision over the administration of the trust and one or more "U.S. persons," as defined under the Code (as defined below), have the authority to control all substantial decisions of the trust or (2) such trust has made a valid election to be treated as a U.S. person for U.S. federal income tax purposes.

This discussion is based on current provisions of the Internal Revenue Code of 1986, as amended (the Code), existing, temporary and proposed U.S. treasury regulations promulgated thereunder (Treasury Regulations), judicial opinions, published positions of the Internal Revenue Service (the IRS), and other applicable authorities, all of which are subject to change or to differing interpretation, possibly with retroactive effect. Any change could alter the tax consequences to non-U.S. holders described in this prospectus. This discussion assumes that a non-U.S. holder holds shares of our Class A common stock as a capital asset (generally, property held for investment) for U.S. federal income tax purposes. This discussion does not address all aspects of U.S. federal income taxation that may be important to a particular non-U.S. holder in light of that non-U.S. holder's individual circumstances, nor does it address any aspects of the unearned income Medicare contribution tax pursuant to the Health Care and Education Reconciliation Act of 2010, any U.S. federal tax consequences (such as gift or estate taxes) other than income taxes, any U.S. alternative minimum taxes, the impact of special tax accounting rules under Section 451(b) of the Internal Revenue Code of 1986, as amended (the Code), or any state, local or non-U.S. taxes. This discussion may not apply, in whole or in part, to particular non-U.S. holders in light of their individual circumstances or to holders subject to special treatment under the U.S. federal income tax laws (such as taxpayers that have elected mark-to-market accounting, insurance companies, tax-exempt organizations, government organizations, tax-qualified retirement plans, financial institutions, brokers or dealers in securities, pension plans, "controlled foreign corporations," "passive foreign investment companies," corporations that accumulate earnings to avoid U.S. federal income tax, corporations organized outside of the United States, any state thereof or the District of Columbia that are nonetheless treated as U.S. taxpayers for U.S. federal income tax purposes, non-U.S. holders that hold our Class A common stock as part of a straddle, hedge, conversion transaction, synthetic security or other integrated investment, holders who own, actually or constructively, more than 5% of our Class A common stock, certain former U.S. citizens or long-term residents, and persons who acquire our Class A common stock through the exercise of an option or otherwise as compensation).

If a partnership (or other entity or arrangement treated as a partnership for U.S. federal income tax purposes) holds our Class A common stock, the tax treatment of a partner (or equivalent) therein will generally depend on the status of the partner and the activities of the partnership. Partners of a partnership holding our Class A common stock should consult their tax advisor as to the particular U.S. federal income tax consequences applicable to them.

We have not sought and will not seek any ruling from the IRS with respect to the statements made and the conclusions reached in the following discussion. There can be no assurance that the IRS will not challenge one or more of the tax consequences described herein, or that any such challenge would not be sustained by a court.

THIS SUMMARY IS FOR GENERAL INFORMATION ONLY AND IS NOT INTENDED TO CONSTITUTE A COMPLETE DESCRIPTION OF ALL TAX CONSEQUENCES FOR NON-U.S. HOLDERS RELATING TO THE OWNERSHIP AND DISPOSITION OF OUR CLASS A COMMON STOCK. PROSPECTIVE HOLDERS OF OUR CLASS A COMMON STOCK SHOULD CONSULT WITH THEIR TAX ADVISORS REGARDING THE TAX CONSEQUENCES TO THEM (INCLUDING THE APPLICATION AND EFFECT OF ANY FEDERAL, STATE, LOCAL, AND NON-U.S. TAX LAWS) OF THE OWNERSHIP AND DISPOSITION OF OUR CLASS A COMMON STOCK.

Dividends

As discussed in the section titled “Dividend policy,” we do not expect to declare or make any distributions on our Class A common stock in the foreseeable future. If we do pay dividends on shares of our Class A common stock, however, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Distributions in excess of our current and accumulated earnings and profits will constitute a return of capital that is applied against and reduces, but not below zero, a non-U.S. holder’s adjusted tax basis in shares of our Class A common stock. Any excess will be treated as capital gain and such gain will be subject to the treatment described below under the section titled “—Gain on sale or other disposition of Class A common stock.” Any such distributions will also be subject to the discussion below under the section titled “—Backup withholding and information reporting” and “—Foreign account tax compliance act.”

Any dividend paid to a non-U.S. holder on our Class A common stock that is not effectively connected with a non-U.S. holder’s conduct of a trade or business in the United States will generally be subject to U.S. withholding tax at a 30% rate. The withholding tax might apply at a reduced rate, however, under the terms of an applicable income tax treaty between the United States and the non-U.S. holder’s country of residence. You should consult your own tax advisors regarding your entitlement to benefits under a relevant income tax treaty. Generally, in order for the applicable withholding agent to withhold tax at a lower treaty rate, a non-U.S. holder must certify its entitlement to treaty benefits. A non-U.S. holder generally can meet this certification requirement by providing an IRS Form W-8BEN, W-8BEN-E or other appropriate IRS W-8 form (or any successor or substitute form thereof) to the applicable withholding agent. If the non-U.S. holder holds the stock through a financial institution or other agent acting on the holder’s behalf, the holder will be required to provide appropriate documentation to the holder’s agent. The holder’s agent will then be required to provide certification to the applicable withholding agent, either directly or through other intermediaries. Any such certifications provided to an applicable withholding agent or intermediary must be updated periodically. If you are eligible for a reduced rate of U.S. federal withholding tax under an income tax treaty, you may generally obtain a refund or credit of any excess amounts withheld by filing an appropriate claim for a refund with the IRS in a timely manner.

Dividends received by a non-U.S. holder that are effectively connected with a U.S. trade or business conducted by the non-U.S. holder, and if required by an applicable income tax treaty between the United States and the

non-U.S. holder's country of residence, are attributable to a permanent establishment or fixed base maintained by the non-U.S. holder in the United States, are not subject to U.S. withholding tax. To obtain this exemption, a non-U.S. holder must provide the applicable withholding agent with an IRS Form W-8ECI (or any successor or substitute form thereof) properly certifying such exemption, and periodically update such certification. Such effectively connected dividends, although not subject to withholding tax, are taxed at the same U.S. federal income tax rates applicable to U.S. persons, net of certain deductions and credits. In addition to being taxed at U.S. federal income tax rates, dividends received by a corporate non-U.S. holder that are effectively connected with a U.S. trade or business of the corporate non-U.S. holder may also be subject to a branch profits tax at a rate of 30% or such lower rate as may be specified by an applicable tax treaty.

Gain on sale or other disposition of Class A common stock

Subject to the discussion below under the section titled "—Backup withholding and information reporting" and "—Foreign Account Tax Compliance Act," non-U.S. holders will generally not be subject to U.S. federal income tax on any gains realized on the sale, exchange or other disposition of our Class A common stock unless:

- the gain (1) is effectively connected with the conduct by the non-U.S. holder of a U.S. trade or business and (2) if required by an applicable income tax treaty between the United States and the non-U.S. holder's country of residence, is attributable to a permanent establishment or fixed base maintained by the non-U.S. holder in the United States (in which case the special rules described below apply);
- the non-U.S. holder is an individual who is present in the United States for 183 days or more in the taxable year of the sale, exchange or other disposition of our Class A common stock, and certain other requirements are met (in which case the gain would be subject to a flat 30% tax, or such reduced rate as may be specified by an applicable income tax treaty, which may be offset by U.S. source capital losses, even though the individual is not considered a resident of the United States), provided that the non-U.S. Holder has timely filed U.S. federal income tax returns with respect to such losses; or
- the rules of the Foreign Investment in Real Property Tax Act (FIRPTA), treat the gain as effectively connected with a U.S. trade or business.

The FIRPTA rules may apply to a sale, exchange or other disposition of our Class A common stock if we are, or were within the shorter of the five-year period preceding the disposition and the non-U.S. holder's holding period, a U.S. real property holding corporation, or USRPHC. In general, we would be a USRPHC if interests in U.S. real property comprised at least half of the value of our worldwide real property and our other assets held for use in a trade or business. Although there can be no assurances, we believe that we are not currently and will not become a USRPHC for U.S. federal income tax purposes, and the remainder of this discussion so assumes. However, because the determination of whether we are a USRPHC depends on the fair market value of our U.S. real property interests relative to the fair market value of our U.S. and worldwide real property interests plus our other assets used or held for use in a trade or business, there can be no assurance that we will not become a USRPHC in the future. Even if we are or were to become a USRPHC gain arising from the sale or other taxable disposition by a non-U.S. holder will not be subject to U.S. federal income tax if our Class A common stock is "regularly traded," as defined by applicable Treasury Regulations, on an established securities market, and such non-U.S. holder owned, actually and constructively, 5% or less of our Class A common stock throughout the shorter of the five-year period ending on the date of the sale or other taxable disposition or the non-U.S. holder's holding period. If the foregoing exception does not apply, and we are a USRPHC, a Non-U.S. Holder's proceeds received on the disposition of our Class A common stock will generally be subject to withholding at a rate of 15%. No assurances can be provided that our Class A common stock will be regularly traded on an established securities market for the purposes of the rule described above.

If any gain from the sale, exchange or other disposition of our Class A common stock, (1) is effectively connected with a U.S. trade or business conducted by a non-U.S. holder and (2) if required by an applicable income tax treaty between the United States and the non-U.S. holder's country of residence, is attributable to a permanent establishment or fixed maintained by such non-U.S. holder in the United States, then the gain generally will be subject to U.S. federal income tax at the same rates applicable to U.S. persons, net of certain deductions and credits. If the non-U.S. holder is a corporation, under certain circumstances, that portion of its earnings and profits that is effectively connected with its U.S. trade or business, subject to certain adjustments, generally would be subject also to a "branch profits tax" at a rate of 30% or such lower rate as may be specified by an applicable income tax treaty.

Backup withholding and information reporting

The applicable withholding agent must report annually to the IRS and to each non-U.S. holder the amount of dividends paid to, and the tax withheld with respect to, each non-U.S. holder. These reporting requirements apply regardless of whether withholding was reduced or eliminated by an applicable tax treaty. Copies of this information reporting may also be made available under the provisions of a specific tax treaty or agreement with the tax authorities in the country in which the non-U.S. holder resides or is established. Dividends paid to non-U.S. holders subject to withholding of U.S. federal income tax, as described above under the section titled "—Dividends," will generally be exempt from U.S. backup withholding.

A non-U.S. holder will generally be subject to backup withholding for dividends on our Class A common stock paid to such holder unless such holder certifies under penalties of perjury that, among other things, it is a non-U.S. holder (and the payer does not have actual knowledge or reason to know that such holder is a U.S. person), generally on a properly executed IRS Form W-8BEN or W-8BEN-E or other appropriate IRS Form W-8 (or any successor or substitute form thereof), or otherwise establishes an exemption.

Information reporting and backup withholding generally are not required with respect to the amount of any proceeds from the sale or other disposition of our Class A common stock by a non-U.S. holder outside the United States through a foreign office of a foreign broker that does not have certain specified connections to the United States. However, if a non-U.S. holder sells or otherwise disposes of its shares of Class A common stock through a U.S. broker or the U.S. offices of a foreign broker, the broker will generally be required to report the amount of proceeds paid to the non-U.S. holder to the IRS and impose backup withholding on that amount unless such non-U.S. holder provides appropriate certification to the broker of its status as a non-U.S. holder (and the payer does not have actual knowledge or reason to know that such holder is a U.S. person) or otherwise establishes an exemption.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules from a payment to a non-U.S. holder generally can be credited against the non-U.S. holder's U.S. federal income tax liability, if any, or refunded, provided that the required information is furnished to the IRS in a timely manner. Non-U.S. holders should consult their tax advisors regarding the application of the information reporting and backup withholding rules to them.

Foreign account tax compliance act

Under the Foreign Account Tax Compliance Act (FATCA), a withholding tax of 30% applies to certain payments to foreign financial institutions, including investment funds, and certain other non-U.S. entities that fail to comply with certain information reporting and certification requirements pertaining to their direct and indirect U.S. securityholders and/or U.S. accountholders and do not otherwise qualify for an exemption. Under applicable Treasury Regulations and IRS guidance, this withholding currently applies to payments of dividends,

if any, on, and, subject to the proposed Treasury Regulations discussed below, gross proceeds from the sale or other disposition of our Class A common stock. An intergovernmental agreement between the United States and a foreign country may modify the requirements described in this paragraph.

While, beginning on January 1, 2019, withholding under FATCA would have applied also to payments of gross proceeds from the sale or other disposition of our Class A common stock, proposed Treasury Regulations eliminate FATCA withholding on payments of gross proceeds entirely. Taxpayers (including applicable withholding agents) generally may rely on these proposed Treasury Regulations until final Treasury Regulations are issued.

If withholding under FATCA is required on any payment related to our Class A common stock, investors not otherwise subject to withholding (or that otherwise would be entitled to a reduced rate of withholding) on such payment may be required to seek a refund or credit from the IRS.

Prospective investors are encouraged to consult with their own tax advisors regarding the possible implications of FATCA on their investment in our Class A common stock.

THE PRECEDING DISCUSSION OF U.S. FEDERAL TAX CONSIDERATIONS IS FOR GENERAL INFORMATION PURPOSES ONLY. IT IS NOT LEGAL OR TAX ADVICE. EACH PROSPECTIVE INVESTOR SHOULD CONSULT ITS OWN TAX ADVISOR REGARDING THE PARTICULAR U.S. FEDERAL, STATE, LOCAL, AND NON-U.S. TAX CONSEQUENCES OF PURCHASING, HOLDING, AND DISPOSING OF OUR COMMON STOCK, INCLUDING THE CONSEQUENCES OF ANY PROPOSED CHANGE IN APPLICABLE LAWS.

Underwriting

We are offering the shares of Class A common stock described in this prospectus through a number of underwriters. J.P. Morgan Securities LLC, Piper Sandler & Co., Jefferies LLC and William Blair & Company, L.L.C. are acting as joint book-running managers of the offering and as representatives of the underwriters. We have entered into an underwriting agreement with the underwriters. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to the underwriters, and each underwriter has severally agreed to purchase, at the public offering price less the underwriting discounts and commissions set forth on the cover page of this prospectus, the number of shares of Class A common stock listed next to its name in the following table:

Name	Number of shares
J.P. Morgan Securities LLC	
Piper Sandler & Co.	
Jefferies LLC	
William Blair & Company, L.L.C.	
Stifel, Nicolaus & Company, Incorporated	
Wells Fargo Securities, LLC	
BTIG, LLC	
Total	

The underwriters are committed to purchase all the shares of Class A common stock offered by us if they purchase any shares. The underwriting agreement also provides that if an underwriter defaults, the purchase commitments of non-defaulting underwriters may also be increased or the offering may be terminated.

The underwriters propose to offer the shares of Class A common stock directly to the public at the initial public offering price set forth on the cover page of this prospectus and to certain dealers at that price less a concession not in excess of $ per share. After the initial offering of the shares to the public, if all of the shares of Class A common stock are not sold at the initial public offering price, the underwriters may change the offering price and the other selling terms. Sales of any shares made outside of the United States may be made by affiliates of the underwriters.

The underwriters have an option to buy up to additional shares of Class A common stock from us to cover sales of shares by the underwriters which exceed the number of shares specified in the table above. The underwriters have 30 days from the date of this prospectus to exercise this option to purchase additional shares. If any shares are purchased with this option to purchase additional shares, the underwriters will purchase shares in approximately the same proportion as shown in the table above. If any additional shares of Class A common stock are purchased, the underwriters will offer the additional shares on the same terms as those on which the shares are being offered.

The underwriting fee is equal to the public offering price per share of Class A common stock less the amount paid by the underwriters to us per share of Class A common stock. The underwriting fee is $ per share. The following table shows the per share and total underwriting discounts and commissions to be paid to the

underwriters assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

	Without option to purchase additional shares exercise	With full option to purchase additional shares exercise
Per share	$	$
Total	$	$

We estimate that the total expenses of this offering, including registration, filing and listing fees, printing fees and legal and accounting expenses, but excluding the underwriting discounts and commissions, will be approximately $. We have agreed to reimburse the underwriters for expenses relating to the clearance of this offering with the Financial Industry Regulatory Authority, Inc. (FINRA) in an amount up to $.

A prospectus in electronic format may be made available on the web sites maintained by one or more underwriters, or selling group members, if any, participating in the offering. The underwriters may agree to allocate a number of shares to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives to underwriters and selling group members that may make Internet distributions on the same basis as other allocations.

We will agree that we will not, subject to certain exceptions, (i) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, hedge, lend, or otherwise transfer or dispose of, directly or indirectly, or submit to, or file with, the SEC a registration statement under the Securities Act relating to any shares of our Class A common stock or securities convertible into or exchangeable or exercisable for any shares of our Class A common stock, or (ii) enter into any swap, hedging or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of any shares of Class A common stock or any such other securities, or publicly disclose the intention to undertake any of the foregoing (regardless of whether any of these transactions are to be settled by the delivery of shares of Class A common stock or such other securities, in cash or otherwise), in each case without the prior written consent of J.P. Morgan Securities LLC for a period of 180 days after the date of this prospectus, other than the shares of our Class A common stock to be sold in this offering.

The restrictions on our actions, as described above, do not apply to certain transactions, including (i) the issuance of shares of common stock or securities convertible into or exercisable for shares of our common stock pursuant to the conversion or exchange of convertible or exchangeable securities or the exercise of warrants or options (including net exercise) or the settlement of restricted stock units (RSUs) (including net settlement), in each case outstanding on the date of the underwriting agreement and described in this prospectus; (ii) grants of stock options, stock awards, restricted stock, RSUs, or other equity awards and the issuance of shares of our common stock or securities convertible into or exercisable or exchangeable for shares of our common stock (whether upon the exercise of stock options or otherwise) to our employees, officers, directors, advisors, or consultants pursuant to the terms of an equity compensation plan in effect as of the closing date of this offering and described in this prospectus, provided that such recipients enter into a lock-up agreement with the underwriters; (iii) the issuance of up to 5% of the outstanding shares of our common stock, or securities convertible into, exercisable for, or which are otherwise exchangeable for, our common stock, immediately following the closing date of this offering, in acquisitions or other similar strategic transactions, provided that such recipients enter into a lock-up agreement with the underwriters; or (iv) the filing of any registration statement on Form S-8 relating to securities granted or to be granted pursuant to any plan in effect on the date of the underwriting agreement and described in this prospectus or any assumed benefit plan pursuant to an acquisition or similar strategic transaction.

Our directors and executive officers, and substantially all of our securityholders (such persons, the lock-up parties) have entered, or will enter, into lock-up agreements or are subject to market stand-off arrangements with the underwriters prior to the commencement of this offering pursuant to which each lock-up party, with limited exceptions, for a period of 180 days after the date of this prospectus (such period, the restricted period), may not and may not cause any of their direct or indirect affiliates to, without the prior written consent of J.P. Morgan Securities LLC, (i) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of our common stock or any securities convertible into or exercisable or exchangeable for our common stock (including without limitation, our common stock or such other securities which may be deemed to be beneficially owned by the lock-up party in accordance with the rules and regulations of the SEC and securities which may be issued upon exercise of a stock option or warrant) (collectively with the common stock, the lock-up securities), (ii) enter into any hedging, swap or other agreement or transaction that transfers, in whole or in part, any of the economic consequences of ownership of the lock-up securities, whether any such transaction described in clause (i) or (ii) above is to be settled by delivery of the lock-up securities, in cash or otherwise, (iii) make any demand for or exercise any right with respect to the registration of any lock-up securities, or (iv) publicly disclose the intention to do any of the foregoing.

Such persons or entities have further acknowledged that these undertakings preclude them from engaging in any hedging or other transactions or arrangements (including, without limitation, any short sale or the purchase or sale of, or entry into, any put or call option, or combination thereof, forward, swap or any other derivative transaction or instrument, however described or defined) designed or intended, or which could reasonably be expected to lead to or result in, a sale or disposition or transfer (whether by the lock-up party or any other person) of any economic consequences of ownership, in whole or in part, directly or indirectly, of any lock-up securities, whether any such transaction or arrangement (or instrument provided for thereunder) would be settled by delivery of lock-up securities, in cash or otherwise.

The restrictions described in the immediately preceding paragraph and contained in the lock-up agreements between the underwriters and the lock-up parties do not apply, subject in certain cases to various conditions, to certain transactions, including (a) transfers of lock-up securities: (i) as a bona fide gift or gifts, or for bona fide estate planning purposes, (ii) by will or intestacy, (iii) to any trust for the direct or indirect benefit of the lock-up party or the immediate family of the lock-up party, or if the lock-up party is a trust, to a trustor or beneficiary of the trust or to the estate of a beneficiary of such trust, (iv) to a partnership, limited liability company or other entity of which the lock-up party and its immediate family are the legal and beneficial owner of all of the outstanding equity securities or similar interests, (v) to a nominee or custodian of a person or entity to whom a disposition or transfer would be permissible under clauses (i) through (iv), (vi) in the case of a corporation, partnership, limited liability company, trust or other business entity, (A) to another corporation, partnership, limited liability company, trust or other business entity that is an affiliate of the lock-up party, or to any investment fund or other entity controlling, controlled by, managing or managed by or under common control with the lock-up party or its affiliates (including, for the avoidance of doubt, where the lock-up party is a partnership, to its general partner or a successor partnership or fund, or any other funds managed by such partnership), or (B) as part of a distribution to members or stockholders of the lock-up party; (vii) by operation of law, such as pursuant to a qualified domestic order, divorce settlement, divorce decree or separation agreement, (viii) to us from an employee upon death, disability or termination of employment, in each case, of such employee, (ix) as part of a sale of lock-up securities acquired (A) from underwriters in this offering or (B) in open market transactions after the completion of this offering, (x) to us in connection with the vesting, settlement, or exercise of restricted stock units, options, warrants or other rights to purchase shares of our common stock (including, in each case, by way of “net” or “cashless” exercise), including for the payment of exercise price, tax or remittance payments due as a result of the vesting, settlement, or exercise of such

restricted stock units, options, warrants or rights, provided that any such shares of our common stock received upon such exercise, vesting or settlement shall be subject to the terms of such lock-up agreement, and provided further that any such restricted stock units, options, warrants or rights are held by the lock-up party pursuant to an agreement or equity awards granted under a stock incentive plan or other equity award plan, each such agreement or plan which is described in this prospectus, (xi) in "sell to cover" or similar open market transactions by an employee of the Company (who is not a Section 16 officer or director of the Company) of up to $10 million of shares of common stock (in the aggregate for all employees) during the restricted period to satisfy tax withholding obligations as a result of the exercise, vesting and/or settlement of equity awards (including options) held by the lock-up party and issued pursuant to a plan or arrangement described in this prospectus, or (xii) pursuant to a bona fide third-party tender offer, merger, consolidation or other similar transaction approved by our Board of Directors and made to all holders of our capital stock involving a change of control (the transfer (whether by tender offer, merger, consolidation or other similar transaction), in one transaction or a series of related transactions, to a person or group of affiliated persons, of shares of capital stock if, after such transfer, such person or group of affiliated persons would hold more than 90% of our outstanding voting securities (or the surviving entity)), provided that in the event that such tender offer, merger, consolidation or other similar transaction is not completed, all such lock-up securities shall remain subject to the restrictions in the immediately preceding paragraph; (b) the exercise of outstanding options, settlement of restricted stock units or other equity awards or exercise of warrants pursuant to plans described in this prospectus, provided that any lock-up securities received upon such exercise, vesting or settlement would be subject to restrictions similar to those in the immediately preceding paragraph; (c) the conversion, exchange or reclassification of outstanding equity securities into shares of our common stock or warrants to acquire shares of our common stock, provided that any such shares of our common stock or warrants received upon such conversion would be subject to restrictions similar to those in the immediately preceding paragraph; and (d) the establishment by lock-up parties of trading plans pursuant to Rule 10b5-1 under the Exchange Act for the transfer of shares of the lock-up securities, provided that (1) such plans do not provide for the transfer of lock-up securities during the restricted period, and (2) any required public announcement or filing under the Exchange Act made by any person regarding the establishment of such plan during the restricted period shall include a statement that the undersigned is not permitted to transfer, sell or otherwise dispose of securities under such plan during the restricted period in contravention of restrictions similar to those in the immediately preceding paragraph and no public filing, report or announcement by any party shall be made voluntarily in connection with such trading plan.

J.P. Morgan Securities LLC, in its sole discretion, may release the securities subject to any of the lock-up agreements with the underwriters described above, in whole or in part at any time.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act.

We intend to apply to have our Class A common stock approved for listing on the Nasdaq Global Market under the trading symbol "BLLN," and this offering is contingent upon obtaining such approval.

In connection with this offering, the underwriters may engage in stabilizing transactions, which involves making bids for, purchasing and selling shares of Class A common stock in the open market for the purpose of preventing or retarding a decline in the market price of the Class A common stock while this offering is in progress. These stabilizing transactions may include making short sales of Class A common stock, which involves the sale by the underwriters of a greater number of shares of Class A common stock than they are required to purchase in this offering, and purchasing shares of Class A common stock on the open market to cover positions created by short sales. Short sales may be "covered" shorts, which are short positions in an amount not greater than the underwriters' option to purchase additional shares referred to above, or may be "naked" shorts, which are short positions in excess of that amount.

The underwriters may close out any covered short position either by exercising their option to purchase additional shares, in whole or in part, or by purchasing shares in the open market. In making this determination, the underwriters will consider, among other things, the price of shares available for purchase in the open market compared to the price at which the underwriters may purchase shares through the option to purchase additional shares. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the Class A common stock in the open market that could adversely affect investors who purchase in this offering. To the extent that the underwriters create a naked short position, they will purchase shares in the open market to cover the position.

The underwriters have advised us that, pursuant to Regulation M of the Securities Act, they may also engage in other activities that stabilize, maintain or otherwise affect the price of the Class A common stock, including the imposition of penalty bids. This means that if the representatives of the underwriters purchase Class A common stock in the open market in stabilizing transactions or to cover short sales, the representatives can require the underwriters that sold those shares as part of this offering to repay the underwriting discount received by them.

These activities may have the effect of raising or maintaining the market price of the Class A common stock or preventing or retarding a decline in the market price of the Class A common stock, and, as a result, the price of the Class A common stock may be higher than the price that otherwise might exist in the open market. If the underwriters commence these activities, they may discontinue them at any time. The underwriters may carry out these transactions on , in the over-the-counter market or otherwise.

Prior to this offering, there has been no public market for our Class A common stock. The initial public offering price will be determined by negotiations between us and the representatives of the underwriters. In determining the initial public offering price, we and the representatives of the underwriters expect to consider a number of factors including:

- the information set forth in this prospectus and otherwise available to the representatives;
- our prospects and the history and prospects for the industry in which we compete;
- an assessment of our management;
- our prospects for future earnings;
- the general condition of the securities markets at the time of this offering;
- the recent market prices of, and demand for, publicly traded common stock of generally comparable companies; and
- other factors deemed relevant by the underwriters and us.

Neither we nor the underwriters can assure investors that an active trading market will develop for shares of our Class A common stock, or that the shares will trade in the public market at or above the initial public offering price.

Other relationships

Certain of the underwriters and their affiliates have provided in the past to us and our affiliates and may provide from time to time in the future certain commercial banking, financial advisory, investment banking and other services for us and such affiliates in the ordinary course of their business, for which they have received and may continue to receive customary fees and commissions. In addition, from time to time, certain of the

underwriters and their affiliates may effect transactions for their own account or the account of customers, and hold on behalf of themselves or their customers, long or short positions in our debt or equity securities or loans, and may do so in the future.

Directed share program

At our request, the underwriters have reserved up to 5% of the shares of Class A common stock being offered by this prospectus for sale, at the initial public offering price, to our officers, directors and employees through a directed share program. Shares purchased through the directed share program will not be subject to a lock-up restriction, except in the case of shares purchased by any of our directors or officers. We do not know if these parties will choose to purchase all or any portion of these reserved shares, but the number of shares of our Class A common stock available for sale to the general public will be reduced to the extent these individuals or entities purchase such reserved shares. Any reserved shares that are not so purchased will be offered by the underwriters to the general public on the same terms as the other shares offered by this prospectus. J.P. Morgan Securities LLC will administer our directed share program. We will agree to indemnify the underwriters against certain liabilities and expenses, including liabilities under the Securities Act, in connection with sales of the shares reserved for the directed share program.

Selling restrictions

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

Notice to prospective investors in the European Economic Area

In relation to each Member State of the European Economic Area (each a Relevant State), no shares have been offered or will be offered pursuant to the offering to the public in that Relevant State prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Relevant State or, where appropriate, approved in another Relevant State and notified to the competent authority in that Relevant State, all in accordance with the Prospectus Regulation, except that offers of shares may be made to the public in that Relevant State at any time under the following exemptions under the Prospectus Regulation:

(i) to any legal entity which is a qualified investor as defined under Article 2 of the Prospectus Regulation;

(ii) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the Prospectus Regulation), subject to obtaining the prior consent of the underwriters; or

(iii) in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of shares shall require us or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus

Regulation. and each person who initially acquires any shares or to whom any offer is made will be deemed to have represented, acknowledged and agreed to and with each of the underwriters and to us that it is a "qualified investor" within the meaning of Article 2(e) of the Prospectus Regulation. In the case of any shares being offered to a financial intermediary as that term is used in the Prospectus Regulation, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the shares acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer of any shares to the public other than their offer or resale in a Relevant State to qualified investors as so defined or in circumstances in which the prior consent of the underwriters have been obtained to each such proposed offer or resale.

For the purposes of this provision, the expression an "offer to the public" in relation to shares in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares, and the expression "Prospectus Regulation" means Regulation (EU) 2017/1129.

Notice to prospective investors in the United Kingdom

No shares have been offered or will be offered pursuant to the offering to the public in the United Kingdom prior to the publication of a prospectus in relation to the shares which (i) has been approved by the Financial Conduct Authority or (ii) is to be treated as if it had been approved by the Financial Conduct Authority in accordance with the transitional provisions in Article 74 (transitional provisions) of the Prospectus Amendment etc (EU Exit) Regulations 2019/1234, except that the shares may be offered to the public in the United Kingdom at any time:

(i) to any legal entity which is a qualified investor as defined under Article 2 of the UK Prospectus Regulation;

(ii) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the UK Prospectus Regulation), subject to obtaining the prior consent of underwriters for any such offer; or

(iii) in any other circumstances falling within Section 86 of the FSMA,

provided that no such offer of the shares shall require the Issuer or any Manager to publish a prospectus pursuant to Section 85 of the FSMA or supplement a prospectus pursuant to Article 23 of the UK Prospectus Regulation. For the purposes of this provision, the expression an "offer to the public" in relation to the shares in the United Kingdom means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares and the expression "UK Prospectus Regulation" means Regulation (EU) 2017/1129 as it forms part of domestic law by virtue of the European Union (Withdrawal) Act 2018.

In addition, in the United Kingdom, this document is being distributed only to, and is directed only at, and any offer subsequently made may only be directed at persons who are "qualified investors" (as defined in the Prospectus Regulation) (i) who have professional experience in matters relating to investments falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the Order) and/or (ii) who are high net worth companies (or persons to whom it may otherwise be lawfully communicated) falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as relevant persons) or otherwise in circumstances which have not resulted and will not result in an offer to the public of the shares in the United Kingdom within the meaning of the Financial Services and Markets Act 2000.

Any person in the United Kingdom that is not a relevant person should not act or rely on the information included in this document or use it as basis for taking any action. In the United Kingdom, any investment or investment activity that this document relates to may be made or taken exclusively by relevant persons.

Notice to prospective investors in Canada

The shares may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the shares must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

Notice to prospective investors in Switzerland

This prospectus does not constitute an offer to the public or a solicitation to purchase or invest in any shares. No shares have been offered or will be offered to the public in Switzerland, except that offers of shares may be made to the public in Switzerland at any time under the following exemptions under the Swiss Financial Services Act (FinSA):

(i) to any person which is a professional client as defined under the FinSA;

(ii) to fewer than 500 persons (other than professional clients as defined under the FinSA), subject to obtaining the prior consent of the representatives of the underwriters for any such offer; or

(iii) in any other circumstances falling within Article 36 FinSA in connection with Article 44 of the Swiss Financial Services Ordinance, provided that no such offer of shares shall require the Company or any investment bank to publish a prospectus pursuant to Article 35 FinSA.

The shares have not been and will not be listed or admitted to trading on a trading venue in Switzerland.

Neither this document nor any other offering or marketing material relating to the shares constitutes a prospectus as such term is understood pursuant to the FinSA and neither this document nor any other offering or marketing material relating to the shares may be publicly distributed or otherwise made publicly available in Switzerland.

Notice to prospective investors in the Dubai International Financial Centre

This document relates to an Exempt Offer in accordance with the Markets Law, DIFC Law No. 1 of 2012, as amended. This document is intended for distribution only to persons of a type specified in the Markets Law,

DIFC Law No. 1 of 2012, as amended. It must not be delivered to, or relied on by, any other person. The Dubai Financial Services Authority (DFSA) has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus supplement nor taken steps to verify the information set forth herein and has no responsibility for this document. The securities to which this document relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the securities offered should conduct their own due diligence on the securities. If you do not understand the contents of this document you should consult an authorized financial advisor.

In relation to its use in the DIFC, this document is strictly private and confidential and is being distributed to a limited number of investors and must not be provided to any person other than the original recipient, and may not be reproduced or used for any other purpose. The interests in the securities may not be offered or sold directly or indirectly to the public in the DIFC.

Notice to prospective investors in the United Arab Emirates

The shares have not been, and are not being, publicly offered, sold, promoted or advertised in the United Arab Emirates (including the Dubai International Financial Centre) other than in compliance with the laws of the United Arab Emirates (and the Dubai International Financial Centre) governing the issue, offering and sale of securities. Further, this prospectus does not constitute a public offer of securities in the United Arab Emirates (including the Dubai International Financial Centre) and is not intended to be a public offer. This prospectus has not been approved by or filed with the Central Bank of the United Arab Emirates, the Securities and Commodities Authority, Financial Services Regulatory Authority (FSRA) or the Dubai Financial Services Authority (DFSA).

Notice to prospective investors in Australia

This prospectus:

- does not constitute a disclosure document or a prospectus under Chapter 6D.2 of the Corporations Act 2001 (Cth) (the Corporations Act);
- has not been, and will not be, lodged with the Australian Securities and Investments Commission (ASIC), as a disclosure document for the purposes of the Corporations Act and does not purport to include the information required of a disclosure document for the purposes of the Corporations Act; and
- may only be provided in Australia to select investors who are able to demonstrate that they fall within one or more of the categories of investors, available under section 708 of the Corporations Act (Exempt Investors).

The shares may not be directly or indirectly offered for subscription or purchased or sold, and no invitations to subscribe for or buy the shares may be issued, and no draft or definitive offering memorandum, advertisement or other offering material relating to any shares may be distributed in Australia, except where disclosure to investors is not required under Chapter 6D of the Corporations Act or is otherwise in compliance with all applicable Australian laws and regulations. By submitting an application for the shares, you represent and warrant to us that you are an Exempt Investor.

As any offer of shares of our Class A common stock under this prospectus will be made without disclosure in Australia under Chapter 6D.2 of the Corporations Act, the offer of those securities for resale in Australia within 12 months may, under section 707 of the Corporations Act, require disclosure to investors under Chapter 6D.2 if none of the exemptions in section 708 applies to that resale. By applying for the shares of our Class A common stock you undertake to us that you will not, for a period of 12 months from the date of issue of the shares, offer,

transfer, assign or otherwise alienate those shares of our Class A common stock to investors in Australia except in circumstances where disclosure to investors is not required under Chapter 6D.2 of the Corporations Act or where a compliant disclosure document is prepared and lodged with ASIC.

Notice to prospective investors in Japan

The shares have not been and will not be registered pursuant to Article 4, Paragraph 1 of the Financial Instruments and Exchange Act. Accordingly, none of the shares nor any interest therein may be offered or sold, directly or indirectly, in Japan or to, or for the benefit of, any "resident" of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to or for the benefit of a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the Financial Instruments and Exchange Act and any other applicable laws, regulations and ministerial guidelines of Japan in effect at the relevant time.

Notice to prospective investors in Hong Kong

The shares have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (a) to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong) (the SFO) of Hong Kong and any rules made thereunder; or (b) in other circumstances which do not result in the document being a "prospectus" as defined in the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32) of Hong Kong) (the CO) or which do not constitute an offer to the public within the meaning of the CO. No advertisement, invitation or document relating to the shares has been or may be issued or has been or may be in the possession of any person for the purposes of issue, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" as defined in the SFO and any rules made thereunder.

Notice to prospective investors in Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, no shares have been or will be offered or sold and no shares have been or will be made the subject of an invitation for subscription or purchase, and no prospectus or any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares, has been or will be circulated or distributed, whether directly or indirectly, to any person in Singapore other than (i) to an institutional investor (as defined in Section 4A of the Securities and Futures Act 2001 of Singapore, as modified or amended from time to time (the SFA)) pursuant to Section 274 of the SFA, (ii) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions specified in Section 275 of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Singapore SFA Product Classification — In connection with Section 309B of the SFA and the CMP Regulations 2018, unless otherwise specified before an offer of shares of our Class A common stock, we have determined, and hereby notify all relevant persons (as defined in Section 309A(1) of the SFA), that the shares of Class A common stock are "prescribed capital markets products" (as defined in the CMP Regulations 2018) and Excluded Investment Products (as defined in MAS Notice SFA 04-N12: Notice on the Sale of Investment Products and MAS Notice FAA-N16: Notice on Recommendations on Investment Products).

Notice to prospective investors in Bermuda

Shares may be offered or sold in Bermuda only in compliance with the provisions of the Investment Business Act of 2003 of Bermuda which regulates the sale of securities in Bermuda. Additionally, non-Bermudian persons (including companies) may not carry on or engage in any trade or business in Bermuda unless such persons are permitted to do so under applicable Bermuda legislation.

Notice to prospective investors in Saudi Arabia

This document may not be distributed in the Kingdom of Saudi Arabia except to such persons as are permitted under the Rules on the Offer of Securities and Continuing Obligations Regulations as issued by the board of the Saudi Arabian Capital Market Authority (CMA) pursuant to resolution number 3-123-2017 dated 27 December 2017, as amended (the CMA Regulations). The CMA does not make any representation as to the accuracy or completeness of this document and expressly disclaims any liability whatsoever for any loss arising from, or incurred in reliance upon, any part of this document. Prospective purchasers of the securities offered hereby should conduct their own due diligence on the accuracy of the information relating to the securities. If you do not understand the contents of this document, you should consult an authorized financial adviser.

Notice to prospective investors in the British Virgin Islands

The shares are not being, and may not be offered to the public or to any person in the British Virgin Islands for purchase or subscription by or on behalf of us. The shares may be offered to companies incorporated under the BVI Business Companies Act, 2004 (British Virgin Islands) (BVI Companies), but only where the offer will be made to, and received by, the relevant BVI Company entirely outside of the British Virgin Islands.

Notice to prospective investors in China

This prospectus will not be circulated or distributed in the PRC and the shares will not be offered or sold, and will not be offered or sold to any person for re-offering or resale directly or indirectly to any residents of the PRC (for such purposes, not including the Hong Kong and Macau Special Administrative Regions or Taiwan), except pursuant to any applicable laws and regulations of the PRC. Neither this prospectus nor any advertisement or other offering material may be distributed or published in the PRC, except under circumstances that will result in compliance with applicable laws and regulations.

Notice to prospective investors in Korea

The shares have not been and will not be registered under the Financial Investments Services and Capital Markets Act of Korea and the decrees and regulations thereunder (the FSCMA), and the shares have been and will be offered in Korea as a private placement under the FSCMA. None of the shares may be offered, sold or delivered directly or indirectly, or offered or sold to any person for re-offering or resale, directly or indirectly, in Korea or to any resident of Korea except pursuant to the applicable laws and regulations of Korea, including the FSCMA and the Foreign Exchange Transaction Law of Korea and the decrees and regulations thereunder (the FETL). Furthermore, the purchaser of the shares shall comply with all applicable regulatory requirements (including but not limited to requirements under the FETL) in connection with the purchase of the shares. By the purchase of the shares, the relevant holder thereof will be deemed to represent and warrant that if it is in Korea or is a resident of Korea, it purchased the shares pursuant to the applicable laws and regulations of Korea.

Notice to prospective investors in Malaysia

No prospectus or other offering material or document in connection with the offer and sale of the shares has been or will be registered with the Securities Commission of Malaysia (Commission) for the Commission's approval pursuant to the Capital Markets and Services Act 2007. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Malaysia other than (i) a closed end fund approved by the Commission; (ii) a holder of a Capital Markets Services Licence; (iii) a person who acquires the shares, as principal, if the offer is on terms that the shares may only be acquired at a consideration of not less than RM250,000 (or its equivalent in foreign currencies) for each transaction; (iv) an individual whose total net personal assets or total net joint assets with his or her spouse exceeds RM3 million (or its equivalent in foreign currencies), excluding the value of the primary residence of the individual; (v) an individual who has a gross annual income exceeding RM300,000 (or its equivalent in foreign currencies) per annum in the preceding twelve months; (vi) an individual who, jointly with his or her spouse, has a gross annual income of RM400,000 (or its equivalent in foreign currencies), per annum in the preceding twelve months; (vii) a corporation with total net assets exceeding RM10 million (or its equivalent in a foreign currencies) based on the last audited accounts; (viii) a partnership with total net assets exceeding RM10 million (or its equivalent in foreign currencies); (ix) a bank licensee or insurance licensee as defined in the Labuan Financial Services and Securities Act 2010; (x) an Islamic bank licensee or takaful licensee as defined in the Labuan Financial Services and Securities Act 2010; and (xi) any other person as may be specified by the Commission; provided that, in the each of the preceding categories (i) to (xi), the distribution of the shares is made by a holder of a Capital Markets Services License who carries on the business of dealing in securities. The distribution in Malaysia of this prospectus is subject to Malaysian laws. This prospectus does not constitute and may not be used for the purpose of public offering or an issue, offer for subscription or purchase, invitation to subscribe for or purchase any securities requiring the registration of a prospectus with the Commission under the Capital Markets and Services Act 2007.

Notice to prospective investors in Taiwan

The shares have not been and will not be registered with the Financial Supervisory Commission of Taiwan pursuant to relevant securities laws and regulations and may not be sold, issued or offered within Taiwan through a public offering or in circumstances which constitutes an offer within the meaning of the Securities and Exchange Act of Taiwan that requires a registration or approval of the Financial Supervisory Commission of Taiwan. No person or entity in Taiwan has been authorized to offer, sell, give advice regarding or otherwise intermediate the offering and sale of the shares in Taiwan.

Notice to prospective investors in South Africa

Due to restrictions under the securities laws of South Africa, no "*offer to the public*" (as such term is defined in the South African Companies Act, No. 71 of 2008 (as amended or re-enacted) (the South African Companies Act) is being made in connection with the issue of the shares in South Africa. Accordingly, this document does not, nor is it intended to, constitute a "*registered prospectus*" (as that term is defined in the South African Companies Act) prepared and registered under the South African Companies Act and has not been approved by, and/or filed with, the South African Companies and Intellectual Property Commission or any other regulatory authority in South Africa. The shares are not offered, and the offer shall not be transferred, sold, renounced or

delivered, in South Africa or to a person with an address in South Africa, unless one or other of the following exemptions stipulated in section 96 (1) applies:

Section 96 (1) (a)	the offer, transfer, sale, renunciation or delivery is to: (i) persons whose ordinary business, or part of whose ordinary business, is to deal in securities, as principal or agent; (ii) the South African Public Investment Corporation; (iii) persons or entities regulated by the Reserve Bank of South Africa; (iv) authorized financial service providers under South African law; (v) financial institutions recognised as such under South African law; (vi) a wholly-owned subsidiary of any person or entity contemplated in (c), (d) or (e), acting as agent in the capacity of an authorized portfolio manager for a pension fund, or as manager for a collective investment scheme (in each case duly registered as such under South African law); or (vii) any combination of the persons in (i) to (vi); or
Section 96 (1) (b)	the total contemplated acquisition cost of the securities, for any single addressee acting as principal is equal to or greater than ZAR1,000,000 or such higher amount as may be promulgated by notice in the Government Gazette of South Africa pursuant to section 96(2)(a) of the South African Companies Act.

Information made available in this prospectus should not be considered as "*advice*" as defined in the South African Financial Advisory and Intermediary Services Act, 2002.

Notice to prospective investors in Israel

This prospectus does not constitute a prospectus under the Israeli Securities Law, 5728-1968, or the Israeli Securities Law, and has not been filed with or approved by the Israel Securities Authority. In Israel, this prospectus is being distributed only to, and is directed only at, and any offer of the shares is directed only at, (i) a limited number of persons in accordance with the Israeli Securities Law and (ii) investors listed in the first addendum, or the Addendum, to the Israeli Securities Law, consisting primarily of joint investment in trust funds, provident funds, insurance companies, banks, portfolio managers, investment advisors, members of the Tel Aviv Stock Exchange, underwriters, venture capital funds, entities with equity in excess of NIS 50 million and "qualified individuals," each as defined in the Addendum (as it may be amended from time to time), or, collectively referred to as qualified investors (in each case, purchasing for their own account or, where permitted under the Addendum, for the accounts of their clients who are investors listed in the Addendum). Qualified investors are required to submit written confirmation that they fall within the scope of the Addendum, are aware of the meaning of the same and agree to it.

Notice to prospective investors in Mexico

The shares have not been and will not be registered with the Mexican National Securities Registry (Registro Nacional de Valores, or the RNV) maintained by the Mexican National Banking and Securities Commission (Comisión Nacional Bancaria y de Valores, or the CNBV), and therefore, may not be offered or sold publicly in Mexico or otherwise be subject to intermediation activities in Mexico, however, the shares may only be offered

and sold in Mexico on a private placement basis to investors that qualify as institutional or qualified investors pursuant to the private placement exemption set forth in Article 8 of the Mexican Securities Market Law (Ley del Mercado de Valores) and regulations thereunder. The information contained in this prospectus is solely our responsibility and has not been reviewed or authorized by the CNBV and may not be publicly distributed in Mexico. In making an investment decision, all investors, including any Mexican investor, who may acquire the shares from time to time, must rely on their own examination of the Company and the terms of this offering and the notes, including the merits and risks involved.

Notice to prospective investors in India

This prospectus has not been and will not be registered as a prospectus with any registrar of companies in India. This prospectus has not been and will not be reviewed or approved by any statutory or regulatory authority in India, including the Securities and Exchange Board of India, Reserve Bank of India, any registrar of companies in India or any stock exchange in India. This prospectus and this offering of ordinary shares are not and should not be construed as an invitation, offer or sale of any securities to the public in India. Other than in compliance with the private placement exemptions under applicable laws and regulations in India, including the Companies Act, 2013, as amended, our ordinary shares have not been, and will not be, offered or sold to the public or any member of the public in India. This prospectus is strictly personal to the recipient and neither this prospectus nor the offering of our ordinary shares is calculated to result, directly or indirectly, in our ordinary shares becoming available for subscription or purchase by persons other than those receiving the invitation or offer. Each investor is deemed to have acknowledged, represented and agreed that it is eligible to invest in us and our ordinary shares under applicable laws, rules and regulations in India, without the requirement to obtain any prior approval, and that it is not prohibited or prevented under any law, rule or regulation in India from acquiring, owning or selling our ordinary shares.

Legal matters

The validity of the shares of Class A common stock being offered by this prospectus will be passed upon for us by Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP, San Francisco, California. Cooley LLP, San Francisco, California, is representing the underwriters in connection with this offering.

Experts

The financial statements as of December 31, 2024 and 2023 and for the years then ended included in this prospectus have been so included in reliance on the report of PricewaterhouseCoopers LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

Where you can find additional information

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of Class A common stock being offered by this prospectus, which constitutes a part of the registration statement. This prospectus does not contain all of the information in the registration statement and its exhibits. For further information with respect to us and the Class A common stock offered by this prospectus, we refer you to the registration statement and its exhibits. Statements contained in this prospectus as to the contents of any contract or any other document referred to are not necessarily complete, and in each instance, we refer you to the copy of the contract or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference.

Upon the completion of this offering, we will be subject to the information reporting requirements of the Exchange Act, and we will file reports, proxy statements, and other information with the SEC. The SEC maintains a website that contains reports, proxy and information statements, and other information regarding registrants that file electronically with the SEC. The address of the website is www.sec.gov. We also maintain a website at https://billiontoone.com, at which you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. However, the information contained in or accessible through our website is not part of this prospectus or the registration statement of which this prospectus forms a part.

Index to financial statements

BILLIONTOONE, INC. AUDITED FINANCIAL STATEMENTS AS OF AND FOR THE YEARS ENDED DECEMBER 31, 2024 AND 2023

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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 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, 2024 and 2023, and the related statements of operations and comprehensive loss, of redeemable convertible preferred stock and stockholders' deficit and of cash flows for the years then ended, 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, 2024 and 2023, and the results of its operations and its cash flows for the years then ended 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 and in accordance with auditing standards generally accepted in the United States of America. 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
San Jose, California
June 20, 2025

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

BILLIONTOONE, INC.
Balance Sheets
(in thousands, except share amounts)

	December 31, 2023	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 97,268	$ 191,477
Accounts receivable	9,090	24,709
Inventories	7,198	8,733
Prepaid expenses and other current assets	1,941	2,898
Total current assets	115,497	227,817
Property and equipment, net	17,479	17,111
Operating lease right-of-use assets, net	56,387	51,739
Other non-current assets	2,314	5,392
Total assets	$ 191,677	$ 302,059
Liabilities, redeemable convertible preferred stock, and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 3,211	$ 4,304
Accrued expenses and other current liabilities	2,411	3,882
Accrued commissions	1,851	2,756
Accrued compensation and employee benefits	2,561	8,419
Deferred revenue, current	3,024	2,806
Operating lease liabilities, current	3,771	4,393
Financing lease liabilities, current	2,288	1,826
Convertible notes	47,686	-
Total current liabilities	66,803	28,386
Operating lease liabilities, non-current portion	55,195	50,802
Financing lease liabilities, non-current portion	2,406	874
Long-term debt	35,000	51,481
Other non-current liabilities	1,799	2,763
Total liabilities	161,203	134,306
Commitments and contingencies (Note 7)		
Redeemable convertible preferred stock, $0.00001 par value; 23,161,933 and 29,544,989 shares authorized as of December 31, 2023 and 2024, respectively; 22,701,179 and 29,084,235 shares issued and outstanding as of December 31, 2023 and 2024, respectively; aggregate liquidation preference of $232,025 and $422,458 as of December 31, 2023 and 2024, respectively	249,527	419,409
Stockholders' deficit:		
Common stock, $0.00001 par value; 42,176,761 and 51,100,000 shares authorized as of December 31, 2023 and 2024, respectively; 10,572,061 and 10,925,950 shares issued and outstanding as of December 31, 2023 and 2024, respectively	-	-
Additional paid-in capital	21,578	30,545
Accumulated deficit	(240,631)	(282,201)
Total stockholders' deficit	(219,053)	(251,656)
Total liabilities, redeemable convertible preferred stock, and stockholders' deficit	$ 191,677	$ 302,059

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

BILLIONTOONE, INC.
Statements of Operations and Comprehensive Loss
(in thousands, except per share amounts)

	Year Ended December 31,	
	2023	2024
Revenue	$ 71,729	$ 152,582
Cost of revenue	54,421	71,667
Gross profit	17,308	80,915
Operating expenses:		
Research and development	22,414	36,596
Selling, general and administrative	64,389	91,465
Total operating expenses	86,803	128,061
Loss from operations	(69,495)	(47,146)
Other income (expense):		
Interest income	3,456	5,819
Interest expense	(3,272)	(2,386)
Net gain on extinguishment of debt	-	7,289
Change in fair value of term loan	-	(3,137)
Change in fair value of convertible notes	(12,921)	(835)
Other expense, net	(442)	(1,145)
Total other income (expense)	(13,179)	5,605
Loss before provision for income taxes	(82,674)	(41,541)
Provision for income taxes	9	29
Net loss and comprehensive loss	$ (82,683)	$ (41,570)
Net loss per share:		
Basic and diluted	$ (8.45)	$ (4.12)
Weighted-average shares used in calculating net loss per share:		
Basic and diluted	9,783	10,080

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

BILLIONTOONE, INC.
Statements of Redeemable Convertible Preferred Stock and Stockholders' Deficit
(in thousands, except share data)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' 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)

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

BILLIONTOONE, INC.
Statement of Cash Flows
(in thousands)

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

BILLIONTOONE, INC.
Statement of Cash Flows—Continued
(in thousands)

	Year Ended December 31, 2023	Year Ended December 31, 2024
Cash flows from financing activities:		
Proceeds from issuance of debt, net	15,000	49,775
Repayment of debt upon extinguishment	-	(35,000)
Payment of exit fee and prepayment payable upon debt extinguishment	-	(1,688)
Principal payments on finance lease liabilities	(2,090)	(2,376)
Repurchase of common stock outstanding	-	(546)
Payment of debt issuance costs on term loan	-	(228)
Proceeds from exercise of stock options, net of repurchases	444	1,084
Proceeds from partial repayment of promissory note by executive	51	-
Proceeds from issuance of Series D redeemable convertible preferred stock, net of issuance costs	-	129,996
Net cash provided by financing activities	13,405	141,017
Net increase in cash and cash equivalents	42,571	94,209
Cash and cash equivalents at beginning of year	54,697	97,268
Cash and cash equivalents at end of year	$ 97,268	$ 191,477
Supplemental cash flow disclosure:		
Cash payments for interest	$ 2,584	$ 3,915
Cash paid for income taxes	$ -	$ 9
Supplemental non-cash investing and financing activities:		
Right-of-use assets obtained in exchange for new finance lease liabilities	$ 2,795	$ 395
Purchases of property and equipment in accounts payable and accrued expenses and other current liabilities	$ -	$ 1,001
Issuance of Series C-1 redeemable convertible preferred stock upon settlement of convertible notes	$ -	$ 39,886
Exercise of stock options for which cash has not been received	$ 102	$ 173

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

(2) Summary of Significant Accounting Policies

Basis of Presentation

The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP"). Prior to April 2024, the financial statements also included the Company's wholly owned subsidiary SeqIndia Labs Private Limited which had immaterial activities and was not material to these financial statements and was divested in April 2024. Accordingly, in 2023, the financial statements were consolidated while in 2024 they were not. All intercompany transactions and balances have been eliminated upon consolidation.

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: the fair value of common stock, stock-based compensation, deferred tax assets and liabilities, useful lives of long-lived assets, the incremental borrowing rate applied to operating and finance leases, determination of revenue recognition and accounts receivable, the valuation of warrants for common stock and warrants for redeemable convertible preferred stock, and valuation of debt and convertible notes. These estimates are inherently subject to judgment and actual results could differ from those estimates.

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

To date, the Company's available liquidity and operations have been financed primarily through the issuance of convertible notes, redeemable convertible preferred stock and debt. The Company has incurred losses through the year ended December 31, 2024. The Company used $53.7 million and $41.4 million in operating activities for the years ended December 31, 2023 and 2024, respectively, and had an accumulated deficit of $240.6 million and $282.2 million as of December 31, 2023 and 2024, respectively. The Company continues to invest in the

development and commercialization of its existing and future products and, consequently, it 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 after the financial statements are available for issuance.

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 clinical development or in preclinical development. If the Company is unable to advance its product candidates through clinical development, obtain regulatory approval 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 preclinical studies and clinical trials, the regulatory approval process is expensive, time-consuming and uncertain and may prevent the Company from obtaining clinical trial and marketing approvals for the commercialization of some or all of its product candidates. As a result, the Company cannot predict when, or if, and in which territories, it will obtain marketing approval 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 fund policies require the weighted average maturity of the fund's securities holdings not to exceed 90 days.

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.

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

Fair Value of Financial Instruments

The Company records certain of its financial assets and liabilities at fair value, including money market funds, which are measured at fair value using quoted prices in active markets (Level 1 inputs). The carrying amounts of the Company's other financial instruments, which include cash, accounts receivable, and accounts payable approximate their fair values due to their 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 liability, either directly or indirectly.
Level 3 input	Unobservable inputs for the assets or liability. 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.

The Company's money market funds 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's convertible notes and term loan, which the Company elected the fair value option for, and warrant liabilities are classified as Level 3 of the fair value hierarchy and are recorded at fair value on a recurring basis.

During the years ended December 31, 2023 and 2024, there was no change in the fair value of the convertible notes or loan agreement that was 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, 2023 and 2024. Account balances are written off against the allowance after all means of collection have been exhausted without success. During the years ended December 31, 2023 and 2024, 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 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 products 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 loss. During the years ended December 31, 2023 and 2024, inventory write-downs totaled approximately $0.1 million and $0.1 million, respectively, and were related to expired and unusable products.

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, 2023 and 2024.

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

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Company generally bills an insurance carrier, Medicaid or a patient or a combination of both upon delivery of test results.

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

The Company uses the expected value method of estimating variable consideration. The total consideration the Company expects to collect in exchange for the Company's products is an estimate and is largely variable in nature. Consideration includes reimbursement from both patients and insurance carriers. 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 update 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 under which the Company is licensing the Company's proprietary knowledge, performing clinical trial support services including developing a clinical study assay, and other testing services to support a clinical trial for the counterparty. The Company concluded that the agreement with Johnson & Johnson was within the scope of ASC 606 because the counterparty in the agreement meets the definition of a customer. The Company evaluated the terms of the agreement for revenue recognition, including whether the services are capable of being distinct and considered distinct within the context of the contract. The Company concluded that the licensing of the know how is not distinct from the other promises within the agreement and, as a result, was treated as a single performance obligation. Under this contract the Company receives payments upon the achievement of milestones, including (i) receipt of approval of the trial, which was achieved in 2023, (ii) various patient enrollment milestones, and (iii) subsequent full trial completion, as well as reimbursement for testing services. In making assessment of whether variable consideration should be included in the transaction price, the Company considers the degree of complexity and uncertainty associated with each milestone and related testing services, and whether achievement of the milestones and testing services are dependent on parties other than the Company. The Company recognizes revenue for the single performance obligation over time as the related services are provided. The Company utilizes an input method to measure progress to depict the transfer of services as the Company believes it provides a faithful depiction of the transfer of services over the contract. In accordance with ASC 606, the Company applies the constraint on variable consideration and includes 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.

As of December 31, 2024, the Company's further performance obligations beyond one year were $6.3 million. The Company expects to recognize substantially all of the remaining performance obligations as revenue over the 12 months following December 31, 2024.

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Disaggregation of revenue

The following table presents disaggregation of revenue by Oncology, Prenatal and Clinical trial support services:

	Year ended December 31,	
	2023	2024
	(in thousands)	
Prenatal	$ 68,803	$ 145,901
Oncology	-	2,944
Clinical trial support services	2,926	3,737
Total revenues	$ 71,729	$ 152,582

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

Deferred revenue

Deferred revenue, which is a contract liability, consists of billings or cash received for services in advance of revenue recognition and is recognized as revenue when all the Company's revenue recognition criteria are met. As of December 31, 2023 and 2024, the deferred revenue balance was $3.0 million and $2.8 million, respectively, all of which is considered short-term. For the years ended December 31, 2023 and 2024, revenue recognized from deferred revenue at the beginning of the period was $0 and $3.0 million, respectively. The decrease in deferred revenue balances as of December 31, 2024 as compared to December 31, 2023 is attributed to the timing of contractual payments for testing and consulting services and timing of delivery of the clinical test results and services.

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 loss and amounted to approximately $0.4 million and $1.3 million for the years ended December 31, 2023 and 2024, 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 Loss

During the years ended December 31, 2023 and 2024, the Company did not have any other comprehensive income (loss) and, therefore, the net loss and comprehensive 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.

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 income (expense) in the statements of operations and comprehensive loss.

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Notes to Financial Statements

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 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 income (expense) in the statements of operations and comprehensive 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.

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 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 loss.

Segment revenues are derived from prenatal and oncology testing results, leveraging the Company's diagnostic technology platform, which are delivered to patients, who are the Company's customer. The Company's customers are predominantly located in the United States. Substantially all of the Company's long-lived assets are located in the United States. The Company's technology platform is applied similarly in both the prenatal and oncology settings.

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

Recently Adopted Accounting Pronouncements

In November 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*, which expands segment disclosures by requiring disclosure of significant segment expenses that are regularly provided

to the CODM and included within each reported measure of segment profit and loss, an amount and description of its composition for other segment items, and interim disclosures of a reportable segment's profit or loss and assets. This guidance also requires disclosures of the title and position of the CODM, and an explanation of how the CODM uses the reported measures of segment profit or loss in assessing segment performance and deciding how to allocate resources. The Company adopted this ASU for its year ended December 31, 2024, and the adoption did not have a material impact on the Company's financial statements or disclosures.

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 disclosures.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* ("ASU 2023-09"), which expands income tax disclosure requirements to include additional information related to the rate reconciliation of effective tax rates to statutory rates, as well as additional disaggregation of taxes paid. This ASU also removed disclosure related to certain unrecognized tax benefits and deferred taxes. ASU 2023-09 is effective for fiscal years beginning after December 15, 2024. This ASU may be applied prospectively or retrospectively, and early adoption is permitted. The Company is currently evaluating the impact of the adoption of this standard on the Company's financial statement disclosures.

In November 2024 and January 2025, 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.

(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, 2023 (in thousands):

	Level 1	Level 2	Level 3	Total
Redeemable convertible preferred stock warrants	$ -	$ -	$ 146	$ 146
Common stock warrants	-	-	1,653	1,653
Convertible notes	-	-	47,686	47,686
Total liabilities	$ -	$ -	$ 49,485	$ 49,485

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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
Current liabilities:				
Redeemable convertible preferred stock warrants	$ -	$ -	$ 230	$ 230
Common stock warrants	-	-	2,533	2,533
Term Loan	-	-	51,481	51,481
Total liabilities	$ -	$ -	$ 54,244	$ 54,244

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

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

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

	December 31,	
	2023	2024
Stock price	$ 13.41	$ 20.32
Exercise price	$2.80 – $10.92	$2.80 – $10.92
Volatility	60.0%	84.0%
Expected term (years)	1.5	2.3
Risk-free rate	4.50%	4.14%
Dividend yield	-%	-%

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

	December 31,	
	2023	2024
Stock price	$ 17.45	$ 25.83
Exercise price	$ 2.59	$ 2.59
Volatility	60.0%	84.0%
Expected term (years)	1.5	2.3
Risk-free rate	4.50%	4.14%
Dividend yield	-%	-%

The fair value of the convertible notes is measured based on the present value of the notes based on the fair market yield to maturity and an estimate of the probability of the notes' conversion features. The fair market yield was estimated based on publicly traded debt securities with similar maturities and risk. During the 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).

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The significant assumptions used in preparing discounted cash flow for valuing the convertible notes as of December 31, 2023 and right before the conversion date May 15, 2024 are as follows:

	December 31, 2023	May 15, 2024
Principal outstanding (in $'000s)	30,000	30,000
Expected term (years)	0.7	-
Risk-free rate	5.26%	5.46%
Interest rate	8.00%	8.00%

During the year ended December 31, 2024, the Company entered into a new term loan agreement for which the Company elected to account for using the fair value option. As such, the fair value of the debt is calculated by using the probability weighting of the present value of settlement scenarios (See Note 10).

The significant assumptions used in preparing the income approach model for valuing the new term loan as of August 2, 2024 and December 31, 2024 are as follows:

	August 2, 2024	December 31, 2024
Discount rate	10.02%	9.37%
Annual interest rate	8.00%	8.00%
Expected term (years) – Scenario 1	5.73	5.32
Expected term (years) – Scenario 2	7.10	6.69

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

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, 2023	$ 1,261	$ 98	$ 34,765	$ -
Additions	-	-	-	-
Adjustment to fair value	392	48	12,921	-
Balance at December 31, 2023	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

For the years ended December 31, 2023 and 2024, the Company recognized losses related to the change in the fair value of the common stock warrant liability and redeemable convertible preferred stock warrant liability in other expense, net in the statements of operations and comprehensive loss. The Company will continue to recognize changes in the fair value of the common stock warrant liability and redeemable convertible preferred stock warrant liability until the warrants are exercised, expire, or qualify for equity classification.

For the years ended December 31, 2023 and 2024, the Company recognized losses related to the change in the fair value of convertible notes in change in fair value of convertible notes in the statements of operations and comprehensive 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 loss upon the conversion date (See Note 9).

For the year ended December 31, 2024, the Company recognized a loss related to the change in fair value of the term loan in change in fair value of term loan in the statements of operations and comprehensive loss.

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

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 years ended December 31, 2023 and 2024, the Company had no transfers of financial assets or liabilities between Level 1 and Level 2 or between Level 2 and Level 3 of the fair value hierarchy.

(4) Property and Equipment, Net

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

	2023	2024
Machinery and equipment	$ 10,616	$ 14,585
Equipment under finance lease	11,829	11,210
Furniture and fixtures	3,337	3,391
Automobiles	40	40
Computer hardware	1,154	1,770
Computer software	200	227
Construction in progress	497	2,747
Leasehold improvements	222	290
Property and equipment, gross	27,895	34,260
Less: Accumulated depreciation and amortization	(10,416)	(17,149)
Property and equipment, net	$ 17,479	$ 17,111

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

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

BILLIONTOONE, INC.
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(5) Accrued Expenses and Other Current Liabilities

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

	2023	2024
Accrued professional services	$ 322	$ 898
Accrued inventory purchases	290	443
Accrued property and other taxes	228	443
Accrued information technology purchases	136	250
Accrued legal expenses	87	191
Accrued phlebotomy expenses	64	171
Accrued insurance expenses	136	159
Accrued rent	604	160
Accrued interest	256	-
Accrued clinical expenses	40	98
Other	249	1,069
Accrued expenses and other current liabilities	$ 2,411	$ 3,882

(6) Redeemable Convertible Preferred Stock

As of December 31, 2023, 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
Total	23,161,933	22,701,179	$ 249,527	$ 232,025

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

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

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Notes to Financial Statements

The rights, preferences and privileges of the Company's redeemable convertible preferred stock are 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, 2024.

(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. For the year ended December 31, 2023 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, 2023 and 2024.

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(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 2022, 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 loss.

In October 2023, the Company signed a lease amendment for the Union City, CA lease to increase the lease's tenant improvement allowance by approximately $0.6 million. The increase in the allowance is amortized into the lease payments, resulting in a corresponding increase in total lease payments of $0.6 million. The lease amendment was considered a lease modification under ASC 842 and the ROU asset and lease liability were remeasured at the modification date. The remeasurement of the lease resulted in an increase in both the operating ROU asset and the operating lease liability of approximately $0.6 million.

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 December 31, 2026 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 sheet for the year ended December 31, 2024

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

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

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

As of December 31, 2023 and 2024, the weighted average remaining operating lease term was 8.8 years and 7.8 years, respectively.

As of December 31, 2023 and 2024, the weighted average discount rate used to estimate operating lease liabilities was 8.4% and 8.4%, respectively.

As of December 31, 2024, future lease payments under operating leases were as follows (in thousands):

Year ending December 31:	
2025	$ 8,810
2026	9,115
2027	9,430
2028	9,757
2029	10,094
Thereafter	29,382
Total lease payments	$ 76,588
Less: imputed interest	(21,393)
Present value of operating lease liabilities	$ 55,195

Financing Leases

As of December 31, 2023 and 2024, the weighted average remaining financing lease term was 2.3 years and 1.8 years, respectively.

As of December 31, 2023 and 2024, the weighted average interest rate for the Company's financing leases was 6.5% and 6.5%, respectively.

As of December 31, 2024, future lease payments under financing leases were as follows (in thousands):

Year ending December 31:	
2025	$ 1,931
2026	536
2027	377
Total lease payments	$ 2,844
Less: interest expense	(144)
Present value of financing lease liabilities	$ 2,700

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

	2023	2024
Amortization of right-of-use assets:	$ 3,085	$ 3,436
Operating cash flows from financing leases (interest paid):	361	243
Total finance lease cost	$ 3,446	$ 2,619

(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.

Holders of the Notes could have converted their notes into shares of common stock at or after an initial public offering at a conversion price dependent on the initial price per share offered in connection with the initial public offering; or 70% of the price per share payable to common stockholders in connection with another liquidation event.

Upon the Company's next equity financing, the Notes could have automatically converted into the equity issued in that financing (which was expected to be Series D redeemable convertible preferred stock) at a conversion price equal to the lower of 70% of the next equity price per share and an amount calculated by dividing a valuation cap of $1 billion by the fully diluted number of shares.

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 income (expense) in the Company's statements of operations and comprehensive loss. Changes in fair value attributable to credit risk are immaterial to the financial statements as of December 31, 2023 and 2024. Inputs for fair value were determined by evaluating the probability of various conversion scenarios and applicable market interest rates.

The estimated fair value of the Notes was determined by using a scenario-based analysis that estimated the fair value of the Notes based on the probability-weighted present value of expected future investment returns, considering possible outcomes available to the noteholder, including conversions to common stock and maturity. The estimated fair value of the Notes was $47.7 million as of December 31, 2023.

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 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 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 of December 31, 2023, the Company had $35.0 million of outstanding debt with WAB. The first payment due on the debt was in August 2025 and the last payment was in July 2027. 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

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 is 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, which was 3.25% at December 31, 2021. 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 its October 2021 loan and security agreement 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"). The advanced principal will accrue interest based on the floating prime rate per annum, which was 8.5% at December 31, 2023.

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 have 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 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.

Oberland Note Purchase Agreement

In August 2024, the Company entered into a note purchase agreement (the "2024 Notes") with BWCB SA LLC (an entity affiliated with Oberland Capital Management, LLC ("Oberland Capital")), which provided the Company with up to four tranches of capital advances totaling up to $140.0 million. The advanced principal accrues interest at a rate of 8.0% per annum. The first tranche of $50.0 million was advanced on August 5, 2024, with a Maturity Date on the seventh anniversary of the first purchase date (August 31, 2031). The first tranche requires interest-only payments through August 31, 2031 and a lump sum payment due on August 31, 2031.

The second tranche of up to $35.0 million in principal is available at the Company's option at any time prior to September 30, 2025 provided that the trailing six-month worldwide net revenue of the Company is at least $80.0 million. The third tranche of up to $30.0 million in principal is available at the Company's option at any time prior to March 31, 2026, provided that the trailing six-month Gross Margin of the Company is at least 45%.

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Gross Margin is defined as (I) net revenue minus cost of goods sold divided by (II) net revenue, expressed as a percentage. The fourth tranche of up to $25.0 million in principal will be made available to the Company at the mutual agreement of the parties at any time prior to March 31, 2026.

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

The Company is required to maintain trailing six-month net revenue based on a schedule that gradually increases up to $120.0 million after the year ending December 31, 2026. In addition, the Company is required to maintain a trailing six-month Gross Margin of not less than 30%.The agreement also contains a revenue participation agreement, under which, for any fiscal quarter, 0.01% of net revenue for such fiscal quarter (up to $100.0 million of net revenue for each fiscal year) per each $1.0 million principal amount of the notes will be payable to Oberland Capital. Amounts owed under the revenue participation agreement at December 31, 2024 are solely comprised of interest payments on the debt.

The term loan advances are secured by a lien on the Company's assets.

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 loss. The Company also elected to present interest incurred on the 2024 Notes in the change in fair value of the term loan; interest expense under the Oberland Capital arrangement was $1.6 million for the year ended December 31, 2024.

The Company's total indebtedness as of December 31, 2023 and 2024 is as follows (in thousands):

As of December 31:	2023	2024
Long-term debt	$ 35,000	$ 51,481
Plus: accreted exit fee	441	-
Less: unamortized debt discount	(441)	—
Long-term debt, net	35,000	51,481
Less: current portion	-	-
Long-term debt, noncurrent portion	$ 35,000	$ 51,481

Future principal payments of the Company's long-term debt as of December 31, 2024 of $50.0 million is due during the year ending December 31, 2031.

Redeemable Convertible Preferred Stock Warrants

The Company has issued Comerica Bank a warrant to purchase 9,660 Series A-6 redeemable convertible preferred shares at an exercise price of $2.59 per share in connection with a former loan and security agreement

entered into in March 2020. The warrants are exercisable until March 15, 2030. The warrants are classified as liabilities on the Company's balance sheet.

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 become exercisable as the Company makes additional draws on the 2022 LSA Amendment. As of December 31, 2023 all of the warrants were exercisable. The warrants will expire if unexercised on July 22, 2032. Upon the occurrence of an acquisition of the Company, if the acquiror shall not have assumed the warrants, WAB shall have the right to put the warrants back to the Company for cash equal to the greater of (x) $412,500 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 income (expense) in the statements of operations and comprehensive loss (See Note 3).

The issuance date fair value of the warrants was determined using the option pricing model, with the following assumptions:

	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	$ 169,592	$ 311,685

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.

(11) Common Stock

As of December 31, 2023 and 2024, the Company's Certificate of Incorporation, as amended, authorized the Company to issue 42,176,761 and 51,100,000 shares of common stock with a par value of $0.00001, respectively. Total common stock outstanding as of December 31, 2023 and 2024 was 10,572,061 and 10,925,950, respectively. Each share of common stock is entitled to one vote. The holders of common stock are also entitled to receive dividends whenever funds are legally available and when and if declared by the Board of Directors, subject to the prior rights of holders of all classes of stock outstanding. As of December 31, 2024, no dividends had been declared or paid.

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

The amount of such shares of the Company's common stock reserved for these purposes at December 31, 2024, is as follows:

Series A-1 Redeemable Convertible Preferred Stock	1,349,650
Series A-2 Redeemable Convertible Preferred Stock	1,137,210
Series A-3 Redeemable Convertible Preferred Stock	899,730
Series A-4 Redeemable Convertible Preferred Stock	25,761
Series A-5 Redeemable Convertible Preferred Stock	114,613
Series A-6 Redeemable Convertible Preferred Stock	5,796,201
Series B-1 Redeemable Convertible Preferred Stock	5,182,287
Series B-2 Redeemable Convertible Preferred Stock	2,566,902
Series C Redeemable Convertible Preferred Stock	5,628,825
Series C-1 Redeemable Convertible Preferred Stock	1,726,823
Series D Redeemable Convertible Preferred Stock	4,656,233
Redeemable Convertible Preferred stock warrants	9,660
Common stock warrants	121,566
Options to purchase common stock	6,849,412
Stock options available for future grants	1,659,634
Total common stock reserved	37,724,507

Stock Plan

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

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

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

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*. The Board of Directors considers 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 include, but are 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.
- *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 2018 Plan during the years ended December 31, 2023 and 2024 were as follows:

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

BILLIONTOONE, INC.
Notes to Financial Statements

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, 2023	4,633,430	$ 3.33	8.4	$ 25,974
Granted	2,096,500	9.72		
Exercised	(147,352)	3.49		
Forfeited or expired	(389,342)	4.86		
Outstanding as of December 31, 2023	6,193,236	$ 5.39	8.0	$ 49,467
Granted	1,366,595	15.23		
Exercised	(380,639)	3.04		
Forfeited or expired	(329,780)	9.78		
Outstanding as of December 31, 2024	6,849,412	$ 7.28	7.5	$ 73,992
Vested and exercisable as of December 31, 2024	4,198,202	$ 4.22	6.7	$ 58,168
Vested and expected to vest as of December 31, 2024	6,849,933	$ 7.28	7.5	$ 74,000

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, 2023 and 2024 was $1.2 million and $4.7 million, respectively.

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. 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. The 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, 2024 there was approximately $22.2 million of total unrecognized compensation cost related to unvested options, which is expected to be recognized over the weighted average period of 2.6 years.

Restricted Stock Award Activity

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

	Awards	Weighted-Average Grant Date Fair Value (per share)
Nonvested as of January 1, 2023	14,584	$ 0.35
Issued	-	-
Vested	(14,584)	0.35
Forfeited	-	-
Nonvested as of December 31, 2023	-	-

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

BILLIONTOONE, INC.
Notes to Financial Statements

Stock-Based Compensation Expense

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

	2023	2024
Cost of revenue	$ 683	$ 1,183
Research and development	1,450	2,341
Selling, general and administrative	2,721	4,838
Total stock-based compensation	$ 4,854	$ 8,362

Options Subject to Early Exercise

At the discretion of the Company's Board of Directors, certain options may be exercisable immediately at the date of grant but are subject to a repurchase right, under which 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. 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, 2023 and 2024, the liability was not material and included in accrued expenses and other current liabilities on the accompanying balance sheets related to 3,542 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.

Repurchase of Common Stock

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

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. As of December 31, 2024, the loans were still outstanding. The terms of the loan require the loans to be repaid prior to termination or public offering.

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 year ended December 31, 2023 and 2024 are as follows (in thousands):

	2023	2024
Current:		
Federal	$ -	$ -
State	9	29
Foreign	-	-
	9	29
Deferred:		
Federal	-	-
State	-	-
Foreign	-	-
	-	-
Total provision for income taxes	$ 9	$ 29

BILLIONTOONE, INC.
Notes to Financial Statements

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, 2023 and 2024 are as follows (in thousands):

	2023	2024
Deferred tax assets:		
Net operating loss carryforwards	$ 35,228	$ 36,725
Capitalized R&D expenditure	6,186	11,477
Accruals and reserves	944	2,322
R&D credits	2,424	3,768
Lease Liability	13,994	13,126
Stock-based compensation	-	859
Other	486	21
Total deferred tax asset	59,262	68,298
Deferred tax liabilities:		
Depreciation and amortization	(386)	(320)
Right of Use Asset	(13,382)	(12,304)
Total deferred tax liabilities	(13,768)	(12,624)
Less: valuation allowance	(45,494)	(55,674)
Net deferred tax assets	$ -	$ -

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 periods presented (in thousands):

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

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, 2023 and 2024 primarily due to state income taxes, nondeductible expenses, research and development tax credits, change in fair value of term loan, and the change in valuation allowance.

As of December 31, 2023 and 2024, the Company had a net operating loss carryforwards of $148.7 million and $154.9 million for federal purposes, and $73.8 million and $78.6 million for state and city purposes, respectively. If not utilized, these carryforwards will begin to expire in 2036 for federal, and 2026 for state and city purposes.

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 to 80% of U.S. federal taxable income. Some but not all states conform to the federal treatment of net operating losses.

As of December 31, 2023, the Company had research and development tax credit carryforwards for federal tax purposes of $2.6 million and state research and development tax credit carryforwards of $1.4 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 has not performed a Section 382 analysis.

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, 2023 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 increased by approximately $16.1 million and $10.1 million during the years ended December 31, 2023 and 2024, respectively.

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 $1.4 million and $2.2 million as of December 31, 2023 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):

	2023	2024
Unrecognized tax benefits - beginning of period	$ 818	$ 1,410
Increases related to current year's tax positions	629	774
Decreases related to prior years' tax positions	(37)	-
Unrecognized tax benefits - end of period	$ 1,410	$ 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, 2023 and 2024, the Company recognized no interest and penalties associated with unrecognized tax benefits. There are no tax positions for which it is reasonably possible that the total amounts of unrecognized tax benefits will significantly increase or decrease within 12 months of the reporting date.

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.

(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, 2023 and 2024, the Company contributed $1.7 million and $2.4 million to this plan, respectively.

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Notes to Financial Statements

(14) Related Party Transactions

During the year ended December 31, 2023, the Company's former CFO left the Company. Upon his departure, the Company's Board of Directors approved the extension of the exercise period to ten years from the date of grant for all of his common stock options that were fully vested at the time of his departure. The impact on the financial statements resulting from the extension of the exercise term was not material. In February 2024, the Company also repurchased 26,750 shares of common stock that were held by the former CFO. Please refer to Note 11 for additional information on this transaction.

There were no other material related party transactions during the year ended December 31, 2023 and 2024.

(15) Net Loss Per Share Attributable to Shareholders

The Company applies the two-class method when computing net 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 (loss) 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 loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period, less shares subject to repurchase. Diluted net loss per share is computed by including all potentially dilutive securities outstanding for the period using the treasury stock method or the if-converted method, as applicable. For periods in which the Company reports net losses, diluted net loss per common share is the same as basic net loss per common share as all potentially dilutive securities are anti-dilutive.

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

	2023	2024
Numerator:		
Net loss	$ (82,683)	$ (41,570)
Denominator:		
Weighted-average shares used in calculating net loss per share, basic and diluted	9,783	10,080
Net loss per share, basic and diluted	$ (8.45)	$ (4.12)

Since the Company was in a loss position for the period presented, basic net loss per share is the same as diluted net loss per share as the inclusion of all potential common shares outstanding would have been anti-dilutive.

BILLIONTOONE, INC.
Notes to Financial Statements

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, 2023 and 2024:

	2023	2024
Redeemable convertible preferred stock	22,701,179	29,084,235
Outstanding stock options	6,193,236	6,849,412
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

(16) Subsequent Events

Management evaluates events occurring subsequent to the date of the financial statements in determining the accounting for and disclosure of transactions and events that affect the financial statements. Subsequent events have been evaluated through June 20, 2025, which is the date that the financial statements were available to be issued.

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Class A common stock

Preliminary prospectus

J.P. Morgan	**Piper Sandler**	**Jefferies**	**William Blair**
Stifel	**Wells Fargo Securities**		**BTIG**

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Part II

Information not required in prospectus

Item 13. Other expenses of issuance and distribution

The following table sets forth all costs and expenses, other than underwriting discounts and commissions, payable by us in connection with the sale of the Class A common stock being registered. All amounts shown are estimates except for the Securities and Exchange Commission (SEC), registration fee, the Financial Industry Regulatory Authority (FINRA), filing fee and the Nasdaq listing fee.

Item	Amount paid or to be paid
SEC registration fee	*
FINRA filing fee	*
Nasdaq listing fee	*
Printing and engraving expenses	*
Legal fees and expenses	*
Accounting fees and expenses	*
Blue sky qualification fees and expenses	*
Transfer Agent fees and expenses	*
Miscellaneous expenses	*
Total	$ *

* To be completed by amendment

Item 14. Indemnification of directors and officers

Section 145 of the DGCL authorizes a court to award, or a corporation's Board of Directors to grant, indemnity to directors and officers under certain circumstances and subject to certain limitations. The terms of Section 145 of the DGCL are sufficiently broad to permit indemnification under certain circumstances for liabilities, including reimbursement of expenses incurred, arising under the Securities Act.

As permitted by the DGCL, our Post-IPO Certificate of Incorporation and Post-IPO Bylaws, as each will be in effect immediately prior to the completion of this offering, contain provisions relating to the limitation of liability and indemnification of our directors and officers. The Post-IPO Certificate of Incorporation will provide that our directors will not be personally liable to us or our stockholders for monetary damages for any breach of fiduciary duty as a director, except for liability:

- for any breach of the director's duty of loyalty to us or our stockholders;
- for acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- in respect of unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the DGCL;
- an officer in any action by or in the right of the Company; or
- for any transaction from which the director derives any improper personal benefit.

Our Post-IPO Certificate of Incorporation also will provide that if Delaware law is amended after the approval by our stockholders of the Post-IPO Certificate of Incorporation, to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of our directors will be eliminated or limited to the fullest extent permitted by Delaware law.

Our Post-IPO Bylaws will provide that we will indemnify our directors and officers to the fullest extent permitted by Delaware law, as it now exists or may in the future be amended, against all expenses and liabilities reasonably incurred in connection with their service for or on our behalf. Our Post-IPO Bylaws will provide that we shall advance the expenses incurred by a director or officer in advance of the final disposition of an action or proceeding, and permit us to secure insurance on behalf of any director, officer, employee, or other agent for any liability arising out of his or her action in that capacity, whether or not Delaware law would otherwise permit indemnification.

We have entered into indemnification agreements with each of our directors and executive officers and certain other key employees, a form of which is attached as Exhibit 10.1. The form of agreement provides that we will indemnify each of our directors, executive officers and such other key employees against any and all expenses incurred by that director, executive officer, or other key employee because of his or her status as one of our directors, executive officers, or other key employees, to the fullest extent permitted by Delaware law, our Post-IPO Certificate of Incorporation and our Post-IPO Bylaws. In addition, the form agreement provides that, to the fullest extent permitted by Delaware law, we will advance all expenses incurred by our directors, executive officers and other key employees in connection with a legal proceeding.

Reference is made to the underwriting agreement contained in Exhibit 1.1 to this registration statement, indemnifying our directors and officers against limited liabilities. In addition, Section 2.8 of our IRA contained in Exhibit 4.1 to this registration statement provides for indemnification of certain of our stockholders against liabilities described therein.

We currently carry and intend to continue to carry liability insurance for our directors and officers.

Item 15. Recent sales of unregistered securities

The following list sets forth information regarding all unregistered securities issued by us since January 1, 2022:

Convertible promissory notes

- In September 2022, we issued convertible promissory notes with an approximate principal value of $30.0 million to seventeen accredited investors (the Convertible Promissory Notes). Each Convertible Promissory Note had an interest rate of 8% per annum. In May 2024, such Convertible Promissory 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.

Note Purchase Agreement

We entered into a debt facility with availability of up to $140.0 million, issuable in four separate tranches, pursuant a Note Purchase Agreement, dated as of August 2, 2024, by and among us, the purchasers party thereto, and BWCB SA LLC (an entity affiliated with Oberland Capital), as purchaser's agent (the Note Purchase Agreement). As of June 30, 2025, we have drawn $ million under the debt facility. The advanced principal accrues interest at a rate of 8.0% per annum. We have the option, but not the obligation, to issue and sell an additional three separate tranches of notes in the amounts of $35.0 million, $30.0 million and $25.0 million, respectively, under the Note Purchase Agreement, subject to the terms and conditions set forth in such Agreement.

Redeemable convertible preferred stock

- Between March 2022 and September 2022, we issued an aggregate of 5,628,825 shares of Series C redeemable convertible preferred stock at a cash purchase price of $25.4937 per share to for an aggregate purchase price of approximately $143.5 million to thirty-nine accredited investors.

- In May 2024, we issued an aggregate of 4,656,233 shares of Series D redeemable convertible preferred stock at a cash purchase price of $28.0204 per share for an aggregate purchase price of approximately $130.5 million to thirty-five accredited investors.

Options

- We have granted options to purchase 6,849,412 shares of common stock to employees, directors and other service providers pursuant to our 2018 Stock Plan, with per share exercise prices ranging from $0.06 to $17.12 as of December 31, 2024. Since January 1, 2022, 725,989 shares of common stock have been issued upon the exercise of stock options pursuant to the 2018 Stock Plan.

Warrants

- In July 2022, we issued a warrant to purchase up to 41,209 shares of common stock with an exercise price of $10.92 per share to one accredited investor; 30,907 warrants were exercisable upon execution of the agreement; the remaining warrants became exercisable as we made additional draws on the Western Alliance Bank debt. As of December 31, 2023 all of the warrants were exercisable.

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.

Item 16. Exhibits and financial statement schedules

(a) Exhibits

Exhibit No.	Description
1.1**	Form of Underwriting Agreement
3.1**	Amended and Restated Certificate of Incorporation of the Registrant, as currently in effect.
3.2**	Form of Post-IPO Certificate of Incorporation of the Registrant, to be effective upon completion of this offering.
3.3**	Amended and Restated Bylaws of Registrant, as currently in effect.
3.4**	Form of Post-IPO Bylaws of Registrant, to be effective upon completion of this offering.
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.
4.2**	Warrant to Purchase Stock, issued to Comerica Bank, dated March 16, 2020.
4.3**	Warrant to Purchase Stock, issued to Western Alliance Bank, dated October 12, 2021.
4.4**	Warrant to Purchase Stock, issued to Western Alliance Bank, dated July 22, 2022.
5.1**	Opinion of Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP.

Exhibit No.	Description
10.1**	Note Purchase Agreement, dated as of 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.
10.2**	Lease Agreement for Union City facility, dated April 10, 2022.
10.3**	Amendment No. 1 to Lease Agreement for Union City facility, dated October 11, 2023.
10.4**	Lease Agreement for Menlo Park facility, dated May 21, 2020.
10.5**	Amendment No. 1 to Lease Agreement for Menlo Park facility, dated August 7, 2021.
10.6**	Collaboration Agreement, by and between the Registrant and Janssen Research & Development, dated January 6, 2023.
10.7**	Amendment No. 1 to Collaboration Agreement with Janssen Research & Development, dated July 14, 2023.
10.8**	Amendment No. 2 to Collaboration Agreement with Janssen Research & Development, dated August 11, 2023.
10.9**+	Form of Indemnification Agreement by and between the Registrant and each of its directors and executive officers.
10.10**+	2018 Stock Plan, as amended, and forms of agreements thereunder.
10.11**+	2025 Equity Incentive Plan, and forms of agreements thereunder.
10.12**+	2025 Employee Stock Purchase Plan.
23.1**	Consent of PricewaterhouseCoopers LLP, independent registered public accounting firm.
23.2**	Consent of Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP (contained in Exhibit 5.1).
24.1**	Power of Attorney (included on signature page of the original filing of this registration statement).

* Filed herewith

** To be filed by amendment.

\+ Indicates management contract or compensatory plan.

(b) Financial statement schedules

No financial statement schedules are provided because the information called for is not required or is shown either in the financial statements or related notes, which are incorporated herein by reference.

Item 17. Undertakings

Insofar as indemnification by the registrant for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this Registration Statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this Registration Statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

Signatures

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of , State of , on , 2025.

BillionToOne, Inc.

By: _____
Oguzhan Atay
Chief Executive Officer

KNOW ALL BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Oguzhan Atay and Ross Taylor, and each of them, his or her true and lawful agent, proxy, and attorney-in-fact, 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 (1) act on, sign and file with the Securities and Exchange Commission any and all amendments (including post-effective amendments) to this registration statement together with all schedules and exhibits thereto and any subsequent registration statement filed pursuant to Rule 462(b) under the Securities Act of 1933, as amended, together with all schedules and exhibits thereto, (2) act on, sign, and file such certificates, instruments, agreements and other documents as may be necessary or appropriate in connection therewith, (3) act on and file any supplement to any prospectus included in this registration statement or any such amendment or any subsequent registration statement filed pursuant to Rule 462(b) under the Securities Act of 1933, as amended, and (4) take any and all actions which may be necessary or appropriate to be done, as fully for all intents and purposes as he or she might or could do in person, hereby approving, ratifying and confirming all that such agent, proxy and attorney-in-fact or any of his substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
Oguzhan Atay	Chief Executive Officer and Director (*Principal Executive Officer*)	
Ross Taylor	Chief Financial Officer (*Principal Financial and Accounting Officer*)	
David Tsao	Chief Technology Officer and Director	
Thomas Bremner	Director	
Firat Ileri	Director	
Krishna Swaroop Kolluri	Director	
Akshay Rai	Director	