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

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2024

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from _____ to _____

Commission file number 001-39482

GeneDx Holdings Corp.

(Exact name of registrant as specified in its charter)

Delaware	**85-1966622**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

333 Ludlow Street, North Tower, 6th Floor
Stamford, Connecticut 06902
(Address of Principal Executive Offices) (Zip Code)

Registrant's telephone number, including area code: **(888) 729-1206**

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

Title of each class	Trading Symbol	Name of each exchange on which registered
Class A common stock, par value $0.0001 per share	WGS	The Nasdaq Stock Market LLC
Warrants to purchase one share of Class A common stock, each at an exercise price of $379.50 per share	WGSWW	The Nasdaq Stock Market LLC

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

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

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

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

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

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

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

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7252(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

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

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

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

The aggregate market value of voting common stock held by non-affiliates of the registrant (assuming for purposes of this calculation, without conceding, that all executive officers and directors are "affiliates") was approximately $432 million as of June 28, 2024 (the last business day of the registrant's most recently completed second fiscal quarter), based on the closing sale price of such stock as reported on the Nasdaq Global Select Market.

The registrant had outstanding 28,068,274 shares of Class A common stock as of February 14, 2025.

DOCUMENTS INCORPORATED BY REFERENCE

Part III incorporates information by reference from the registrant's definitive proxy statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A, not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, in connection with the registrant's 2025 Annual Meeting of Stockholders (the "2025 Proxy Statement").

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Certain matters discussed in this report, including matters discussed under the caption "Management's Discussion and Analysis of Financial Condition and Results of Operations," may constitute forward-looking statements for purposes of the Securities Act of 1933, as amended (the "Securities Act"), and the Securities Exchange Act of 1934, as amended, (the "Exchange Act"), and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from the future results, performance or achievements expressed or implied by such forward-looking statements. The words "anticipate," "believe," "estimate," "may," "expect" and similar expressions are generally intended to identify forward-looking statements. Our actual results may differ materially from the results anticipated in these forward-looking statements due to a variety of factors, including, without limitation, those discussed under the captions "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this report, as well as other factors which may be identified from time to time in our other filings with the Securities and Exchange Commission (the "SEC"), or in the documents where such forward-looking statements appear. All written or oral forward-looking statements attributable to us are expressly qualified in their entirety by these cautionary statements. Such forward-looking statements include, but are not limited to, statements about:

- our estimates of the sufficiency of our existing capital resources combined with future anticipated cash flows and future capital requirements to finance our operating requirements, and capital expenditures;
- our expectations for generating revenue, incurring losses, and becoming profitable on a sustained basis;
- unforeseen circumstances or other disruptions to normal business operations arising from general economic and political conditions such as recessions, fluctuating inflation, interest rates and tariff rates, supply chain interruptions and manufacturing constraints, public health emergencies, natural disasters, acts of terrorism or other uncontrollable events;
- our expectations regarding our ability to scale to profitability, our plans to pursue a new strategic direction, and the cost savings and impact on our gross margins from exiting our reproductive and women's business and our somatic tumor testing business;
- our ability to successfully implement our business strategy;
- our expectations or ability to enter into service, collaboration and other partnership agreements;
- our expectations or ability to build our own commercial infrastructure to scale, market and sell our products;
- actions or authorizations by the U.S. Food and Drug Administration ("FDA"), or other regulatory authorities;
- risks related to governmental regulation and other legal obligations, including privacy, data protection, information security, consumer protection, and anti-corruption and anti-bribery;
- our ability to obtain and maintain intellectual property protection for our product candidates;
- our ability to compete against existing and emerging technologies;
- third-party payor reimbursement and coverage decisions, negotiations and settlements;
- our reliance on third-party service providers for our data programs;
- our accounting estimates and judgments, including our expectations regarding the adequacy of our reserves for third party payor claims;
- our stock price and its volatility; and
- our ability to attract and retain key personnel.

The forward-looking statements contained in this report reflect our views and assumptions only as of the date that this report is signed. Except as required by law, we assume no responsibility for updating any forward-looking statements.

We qualify all of our forward-looking statements by these cautionary statements. In addition, with respect to all of our forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

Part I

Item 1. Business

Unless otherwise stated in this Annual Report or the context otherwise requires, references to:

- "GeneDx Holdings" refer to GeneDx Holdings Corp., a Delaware corporation;
- "Legacy GeneDx" refer to GeneDx, LLC, a Delaware limited liability company, which we acquired on April 29, 2022 (the "Acquisition");
- "Legacy Sema4" refer to Sema4 OpCo Inc., a Delaware corporation, which consummated the business combination with CM Life Sciences, Inc. ("CMLS") on July 22, 2021 (the "Business Combination"); and
- "we," "us" and "our," the "Company" and "GeneDx" refer, as the context requires, to GeneDx Holdings and its consolidated subsidiaries.

The Company's Class A common stock and public warrants are listed on the Nasdaq Global Select Market under the symbols "WGS" and "WGSWW," respectively.

Purpose

At GeneDx, we believe that everyone deserves personalized, targeted medical care—and that it all begins with a genetic diagnosis. Fueled by one of the world's largest rare disease data sets, our industry-leading exome and genome tests translate complex genomic data into clinical answers that unlock personalized health plans, accelerate drug discovery, and improve health system efficiencies. We operate with conviction that what is best for patients must be embedded in every aspect of our work. In support of these beliefs, we value equitability, simplicity and transparency.

Overview

GeneDx was founded in 2000 by scientists from the National Institutes of Health whose mission was making genetic testing accessible for patients with rare diseases. The company quickly became a leader in genomics, creating the foundation for how to provide genomic information at scale and pioneering exome and genome sequencing for rare and ultra-rare genetic pediatric disorders. 25 years later, we have amassed one of the world's largest rare disease datasets and remain a leader in genomics.

Today, we are powered by our industry-leading genomic interpretation platform, and we believe exome and genome testing will become the standard for diagnosis of genetic disease, with the potential to transform healthcare and improve patients' quality of life.

Industry Background

Targeted genetic tests and panel testing make up the vast majority of diagnostics tests ordered today. While panel testing can be useful, it has an increasing limitation as we move towards genetic-based healthcare. Panels only allow you to test for insights that physicians predefine based on symptoms, which can lead to inconclusive results and an inefficient process. It is hypothesis-based medicine based on symptoms that may overlap across diseases. We firmly believe that an affordable, scalable and actionable genome is the future of medicine. The barrier to having actionable information from a genomic sequence is significant—and not just due to costs, which are coming down. The less-discussed barrier to having actionable information lies in the ability to process a genome's worth of information—quickly and scalably—and to deliver both a result that a clinician can easily act upon to help a patient and a robust dataset that enables clinicians to drive precise diagnosis and personalized health plans, and researchers to develop and advance therapeutics.

Most companies in today's genetics industry are taking a test-by-test approach to cross the chasm from genetics early adopters to genome-guided healthcare in the mainstream market. We believe that driving clinician and patient awareness and influencing policy decisions may facilitate uptake within the industry. In addition, making genetics part of mainstream medicine requires advancing the technology to provide personalized and actionable health insights. It also requires having a robust, well-characterized dataset that can maximize answers and minimize unknowns to drive a new era of discovery.

Exome and whole genome sequencing provide the broadest view into the genomic variant—we are looking comprehensively into over 20,000 genes, while panels look at anywhere from two to a few hundred genes. While most of the industry has focused on panels, we have focused on exome and whole genome developing structured gene-disease knowledge curated by our team of experts to power automated interpretation and reporting.

One Test

The genome is composed of 3 billion "letters", or base pairs, of DNA. The exome is a portion of the genome that encodes proteins, which are involved in many different types of cellular functions. Changes in a genome or exome can change the way proteins are formed or utilized by the cell, potentially causing disease.

When patients present with complex issues, a genetic diagnosis may be available, but a traditional genetic panel test may be too narrow to identify the cause. Some genetic disorders present with very specific symptoms, so tests that read the "letters" of a single gene or a small panel of genes, may make sense for physicians to use in diagnosis. But for many other genetic diseases, patients can present with overlapping symptoms so finding the correct diagnosis is not always straightforward and may require multiple tests, costly evaluations, invasive procedures, and long hospital stays. Exome and genome sequencing can find different genetic alterations, or variants, that more targeted tests miss and are especially useful when the timing is critical to directing or altering medical management.

With 25 years of operation, GeneDx has a proven track record of expertise in genetic testing. We launched the industry's first commercially available next generation sequencing panels in 2008, pioneered exome sequencing in 2012 and have sequenced over 750,000 exomes and genomes to date. We have performed over one million genetic tests and worked tirelessly to develop:

- A curated database of disease-associated genomic variants;
- Proprietary bioinformatics and variant interpretation pipelines; and
- Rapid exome and whole genome sequencing testing options.

The status quo of genetic testing requires repeated and fragmented testing which, in many cases, is conducted too late for physicians to use in treatment of patients. Targeted genetic tests and panels have been largely commoditized leaving physicians, healthcare partners and patients searching for deeper answers and enhanced utility. The scalable exome and whole genome interpretation that we can deliver at speed do not require a long, complex, expensive, expert-guided search and may make most other genetic tests obsolete. In addition, using whole genome testing is incredibly simple: it's designed to be Just One Test.

Advanced Technology with a Human Touch

Our team includes over 200 genetic counselors, physicians, scientists, and clinical and molecular genomics specialists. We believe we are one of the industry's leading genetic testing experts. We share the same goal as healthcare providers, patients, and families: to provide personalized and actionable health insights.

Our years of exome and genome sequencing experience have provided us with a substantial dataset, including over 6 million structured phenotypes with approximately 60% of all exomes/genomes to date processed as parent-child trios. We have invested resources over time to annotate the phenotypes and sequence the parents of patients, because their genetic sequences can often provide additional diagnostic information, potentially improving the precision of genetic analysis. Importantly, we have served the Medicaid population for nearly a decade ahead of the first state to enact health coverage for exome/genome and as such, our data set is highly diversified matching the demographic dispersion of the United States. In addition, the data from more families allows us to continually improve interpretation of genetic code and variants that may cause disease. We believe we have more expertly annotated disease-causing variants than the largest public archive.

Internally developed with over one million sequenced specimens, our database is designed to lead to increasingly reliable diagnostic test results. The structured gene-disease knowledge curated by our team of experts is powering automated interpretation and reporting built to handle genomic data at scale. Combined with our proprietary, state-of-the-art variant identification software, our ability to deliver highly accurate test results makes finding definitive diagnoses, even in complex cases, possible. Implemented with expert oversight, our advanced interpretation methods incorporate automation, bioinformatics, and cloud-based machine learning, enabling efficient discovery of genetic differences at previously undetectable levels.

As the number of new patients we test grows, so does our database, and the new data increases the potential for greater insights. As we capture more genomic and phenotypic data, we hope to fuel a positive feedback cycle of discovery that continuously delivers more value for patients, providers and healthcare partners.

Market Opportunity

Our primary growth engine in the short term will be expanding our current market-leading exome and genome sequencing capabilities in the outpatient setting, including geneticists, pediatric development specialists, and other pediatric specialists, as well as the neonatal in-patient setting, also referred to as Neonatal Intensive Care Units ("NICU"). Over time we fully expect more and more use cases and reimbursement pathways for exome and genome to open up across a wide spectrum of pediatric and adult diseases, conditions and disorders. As we plan for longer-term growth, we aim to bring whole genome newborn screening to

the market, supported with the launch of a new customer experience platform for non-geneticists, patients and caregivers, and evidence generation to establish the clinical and economic benefits of screening. Also, as we plan for longer-term growth, we believe there is a large data partnership opportunity with biopharmaceutical ("biopharma") companies, international testing opportunities, as well as a market to provide interpretation and information services for customers that sequence locally but look to GeneDx for analysis and interpretation.

We believe we are particularly well-suited for helping rare disease and pediatric developmental disorder patients, their care teams and biopharma companies today. This is a large market with immense unmet medical need. There are over 7,000 individual diseases affecting nearly 10% of the total population in the United States, of which 50% are children. As a result, there are over 700 medicines in development for these diseases, with a regulatory pathway facilitated by the Orphan Drug Act of 1983. By providing the precise genetic diagnosis of patients with rare disease, our expertise and technology may provide researchers and biopharma companies with the information needed to develop and commercialize a new treatment for the disease.

By unlocking the value of the products, our knowledge base, network of relationships, and expertise, our team is well positioned to lead what we believe is a nearly a $25 billion global market opportunity in pediatric and rare disease and a nearly $20 billion global market opportunity for adult disease and disorders.

Our Strategy

We believe that the span and depth of our experience and dataset allows us to return more positive findings and thus clinical utility, both immediately and over time through reanalysis, than other sources. Importantly, we believe that we return fewer uncertain findings compared to public datasets, which makes our analysis easier to interpret outside of the medical genetics community.

At the same time, we have improved quality and speed to delivery of exome and genome tests and have significantly lowered the associated sequencing costs since initial launch in 2013. Much of this decline was driven by reduced sequencing costs shared across the industry; however, we have reduced wet labor and processing costs and in the interpretation layer through accumulating data and experience, and we expect further decline in costs going forward.

Leveraging these capabilities, we aim to be the global market leader in the development and delivery of reliable, actionable, scalable exome and genome sequencing and interpretation and information services. Our strategy focuses on the following objectives:

- Expand the utilization of exome and genome sequencing as the first- or second-tier test over most other genetically targeted tests by leveraging decades of earned trust amongst expert geneticists; and
- Expand the utilization of industry-leading exome and genome sequencing beyond the genetic experts into the non-expert setting, potentially creating a new standard of care which enables faster diagnoses, reduces suffering, and helps healthcare systems save money. In the near term, our principal target markets will be settings with the most vulnerable patients who can benefit the most including, but not limited to, NICU and patients with pediatric developmental disorders ("Pediatric Developmental Disorders").

To achieve these objectives, we:

- Deploy our team of approximately 70 field-based sales representatives and medical science liaisons, and plan to construct an industry-leading brand, product, marketing, communications and market access platform by leveraging decades of earned trust across the genetics community.
- Partner with leaders across health systems, manufacturers, commercial and governmental payors and advocacy groups. We aim to collaborate on programs to establish definitive clinical and economic case for broad use of genomic-guided medicine. Such programs will focus on:
    - support for rapid whole genome sequencing in the NICU and Pediatric Developmental Disorder settings;
    - diagnosis of disease and prevention of chronic conditions in adults; and
    - use of rapid whole genome sequencing for broad newborn screening.
- Plan to open new markets and geographies and unlock the value of our dataset with independently scalable cloud-based interpretation and information service offerings. This will enable healthcare partners to incorporate genetics into clinical care by accessing our analysis and interpretation capabilities remotely while sequencing locally to reduce complexity, logistics cost and wait times, and align to local restrictions where applicable.
- Plan to launch a new provider and patient experience with the eventual goal of providing lifelong access and portability of genomic information. At initial sequence, rapid results provide clinicians simple, actionable, easy to understand results for non-geneticists and tailored resources for patients and caregivers. On an ongoing basis, reanalysis unlocks a renewable source of insight, replacing any future germline screening. We will sequence once, and analyze for life.

- Plan to optimize our services to become a solutions provider of choice for biopharma companies. Such solutions will focus on value-added services such as:
  - Finding rare disease patients for clinical trial recruitment and/or delivery of targeted therapeutics.
  - Supporting research and development for targeted therapies with analytic reports leveraging clinicogenomics data across multiple therapeutic areas with an initial emphasis in rare disease.
  - Providing a therapeutic area agnostic platform to access to data, patients and insights for real world evidence and data to support end-to-end drug discovery pipeline.

Research and Development

Our research and development activities include information technology, product development, customer experience, medical affairs, collaborations and research, including health economic and outcomes research ("HEOR"). These activities are principally focused on our efforts to develop and improve the software we use to analyze data, process genomic test orders, deliver reports, and improve customer experience.

We are also participating in certain collaborative studies aimed to provide evidence of the clinical and economic benefit for exome and whole genome sequencing. Two such studies currently underway include the SeqFirst study—in collaboration with Seattle Children's Hospital and University of Washington—which is designed to demonstrate the broad utility of rapid whole genome sequencing for critically ill newborns and, the Genomic Uniform-Screening Against Rare Diseases In All Newborns ("GUARDIAN") study—in collaboration with New York-Presbyterian, Columbia University, New York State Department of Health and Illumina, Inc.—which is designed to assess whole genome sequencing to screen newborns for more conditions than those currently included in standard newborn screening in the United States. The goals of these studies are to drive earlier diagnosis and treatment to improve the health of the newborns who participate in such studies, generate evidence to support the expansion of newborn screening through genomic sequencing, and characterize the prevalence and natural history of rare genetic conditions.

Competition

Our competitors include companies that offer molecular genetic testing and consulting services, including specialty and reference laboratories that offer traditional single- and multi-gene tests and biopharma companies. In addition, there are a large number of new entrants into the market for genetic information ranging from informatics and analysis pipeline developers to focused, integrated providers of genetic tools and services for health and wellness, including Illumina, Inc., which is also one of our suppliers. In addition to the companies that currently offer traditional genetic testing services and research centers, other established and emerging healthcare, information technology and service companies may commercialize competitive products including informatics, analysis, integrated genetic tools and services for health and wellness. Principal competitors include companies such as Baylor Genetics, Exact Sciences Corp. (via Prevention), Rady Children's Hospital and Tempus (via Ambry Genetics) as well as other commercial and academic labs.

Customers and Seasonality

We receive payment for our products and services from third-party payors, patients, business-to-business clients, and from other healthcare partners. Substantially all of our revenue for the year ended December 31, 2024 has been primarily derived from diagnostic test reports and we expect this trend to continue in the near-term. We expect over time to achieve a mix of revenue from diagnostic tests, data and information solutions, newborn screening products and information and interpretation services.

Approximately 2% of our revenues today are derived from referral sources outside of the United States. We expect over time to increase rest of world revenue as knowledge and understanding of the benefits of exome and whole genome sequencing continue to expand.

We typically experience higher revenue in our fourth quarter and lower revenue in the first quarter due in part to seasonal demand of our tests from patients who have met their annual insurance deductible. However, changes in our product and payor mix might cause these seasonal patterns to be different than future patterns of our revenue or financial performance.

For information regarding our customer concentration in relation to certain of the Company's third-party payors, see Note 2, "*Summary of Significant Accounting Policies*" in the notes to our consolidated financial statements.

Raw Materials and Suppliers

We rely on a limited number of suppliers, including Illumina, Inc., Integrated DNA Technologies Incorporated, Agilent Technologies, Roche Holdings Ltd., QIAGEN, Inc. and Twist Biosciences, for certain laboratory reagents, as well as sequencers and other equipment and materials, which we use in our laboratory operations. Our operations could be interrupted if we

encounter delays or difficulties in securing reagents, sequencers or other equipment or materials, and if we cannot obtain an acceptable substitute. Any such interruption could significantly affect our business, financial condition, results of operations and reputation. We believe that there are only a few other manufacturers that are currently capable of supplying and servicing the equipment necessary for our operations, including sequencers and various associated reagents and enzymes. The use of equipment or materials provided by these replacement suppliers would require us to alter our operations. Transitioning to a new supplier would be time consuming and expensive, may result in interruptions in operations, could affect the performance specifications of our laboratory operations or could require that we revalidate our tests. We cannot be certain that we will be able to secure alternative equipment, reagents and other materials, or bring such equipment, reagents and materials online and revalidate them without experiencing interruptions in our workflow. If we encounter delays or difficulties in securing, reconfiguring or revalidating equipment and materials, our business and reputation could be adversely affected.

Intellectual Property

We rely on a combination of intellectual property rights, including trade secrets, copyrights, trademarks, customary contractual protections to protect our core technology and intellectual property.

Patents

The fields of genomic and health information analysis present limited opportunities for patent protection, based on current legal precedents. Our patent protection strategy has focused on seeking protection for certain of our non-gene specific technology and our specific biomarkers. In this regard, we have three pending U.S. non-provisional utility patent applications and seven U.S. provisional patent applications. The utility patent applications include a U.S. patent application related to generating a cancer determination from electronic health records using a cancer determination analysis system, a U.S. patent application related to providing a homologous recombination DNA repair deficiency score for a cancer patient, and a U.S. patent application related to therapeutic treatment for subjects having certain polymorphic markers associated with specific human leukocyte antigen alleles. If patents are issued from the currently pending applications, the earliest patents will begin expiring in the early 2040s, subject to potential extensions of the patent term that will be calculated based on the length of the patent examination process. The claim scope of any potentially issued patents stemming from the present applications may be narrower than included in the initial filings due to any amendments that may arise throughout their prosecution.

We do not presently have any patents directed to the sequences of specific genes or variants of such genes, nor do we currently rely on any in-licensed gene patent rights of any third party. We may, in time, seek additional patent protection to protect technology that is not gene-specific and that provides us with a potential competitive advantage as we focus on making comprehensive genetic information less expensive and more broadly available to our customers.

Trade Secrets

We rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain and develop our competitive position. We have a trade secrecy program to prevent disclosure of our trade secrets to others, except under stringent conditions of confidentiality when disclosure is critical to our business. We protect trade secrets and know-how by establishing confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors, and collaborators. These agreements also provide that all inventions resulting from work performed for us or relating to our business and conceived or completed during the period of employment or assignment, as applicable, will be our exclusive property. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary information by third parties.

Our valuable trade secrets relate to proprietary bioinformatic tools such as:

- custom data processing methods and analytical pipelines for NGS, aCGH, MLPA, Sanger, and other genomic data, optimized and validated to the highest performance standards;
- a novel detection method to uncover notoriously difficult to detect sequence variants called mobile element insertions and partial-exon deletions; and
- custom variant analysis platforms built from the ground up for exome and genome-scale data interpretation.

Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, these steps may be circumvented, or third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. Accordingly, we may not be able to meaningfully protect our trade secrets.

Trademarks

We own or are applying for various trademarks, service marks, trade names, and product service names in the U.S and other commercially important markets. We intend to invest significant resources in the growth and protection of our reputation and trademarks. Our trademark portfolio is designed to protect the brands for our products and services, both current and in the pipeline.

Human Capital Resources

We aim to recruit, develop, and retain diverse, high-quality talent and are committed to creating a workplace that supports the success of its people by investing in their personal development and career growth. Our team of nearly 1,000 individuals are champions of not only our organization, but our patients, providers and partners.

We are committed to developing our workforce. Our talent development programs provide employees with the resources they need to achieve their career goals, build management skills and lead their teams. Managers coach and hold conversations with employees' regarding their career and development plans, thereby staying true to our belief in accountability and openness.

Total Rewards

We offer competitive compensation to attract and retain high quality talent, and we care for our people so they can focus on our mission. Our employees' total compensation package includes competitive salary, bonuses or sales incentives, equity through our equity incentive plans, 401(K) plan with matching opportunities, and the opportunity to participate in our employee stock purchase plan. Equity participation is provided for certain positions because ownership in the company drives commitment to our long-term success. We provide programs including healthcare and insurance benefits, health savings and flexible spending accounts, paid time off, family leave, flexible work schedules, fertility, adoption and surrogacy assistance, employee assistance and wellness support, among many others.

Government Regulation

Our business and the services (both current and in the pipeline) we provide are subject to and impacted by extensive and frequently changing laws and regulations in the United States (at both the federal and state levels) and internationally. Failure to comply with the applicable laws and regulations can subject us to repayment of amounts previously paid to us, significant civil and criminal penalties, loss of licensure, certification, or accreditation, or exclusion from state and federal health care programs. The significant areas of regulation are summarized below:

Clinical Laboratory Improvement Amendments of 1988 and State Regulation

Our clinical laboratories must hold certain federal, state and local licenses, certifications and permits to conduct our business. Laboratories in the United States that perform testing on human specimens for the purpose of providing information for the diagnosis, prevention, or treatment of disease or impairment, or the assessment of health are subject to the Clinical Laboratory Improvement Amendments of 1988, as amended, and its implementing regulations ("CLIA"). CLIA requires such laboratories to be certified by the federal government and mandates compliance with various operational, personnel, facilities administration, inspections, quality control, quality assessment and proficiency testing requirements intended to ensure that testing services are accurate, reliable and timely. CLIA certification also is 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 laboratory located in Gaithersburg, Maryland is CLIA certified to perform high complexity tests. Laboratories performing high complexity testing are required to meet more stringent requirements than laboratories performing less complex tests. The regulatory and compliance standards applicable to the testing we perform may change over time, and any such changes could have a material effect on our business.

As a condition of CLIA certification, our laboratory is subject to survey and inspection every two years to assess compliance with program standards, in addition to being subject to additional random inspections. The biennial survey is conducted by the Centers for Medicare & Medicaid Services ("CMS"), a CMS agent (typically a state agency), or a CMS-approved accreditation organization. Our Gaithersburg laboratory has been accredited by the College of American Pathologists ("CAP"), which means that our laboratory has been certified as following CAP guidelines in operating the laboratory and in performing tests that ensure the quality of our results. Because our laboratory is accredited by CAP, which is a CMS-approved accreditation organization, CMS does not perform these biennial surveys and inspections and relies on our CAP surveys and inspections. We may also be subject to additional unannounced inspections.

CLIA provides that a state may adopt laboratory regulations consistent with those under federal law, and a number of states have implemented their own (sometimes more stringent) laboratory regulatory requirements. CLIA does not preempt state laws that have established laboratory quality standards that are at least as stringent as the federal law requirements under CLIA. State laws

may require that nonresident laboratories, or out-of-state laboratories, maintain a laboratory license to perform tests on samples from patients who reside in that state. As a condition of state licensure, these state laws may require that laboratory personnel meet certain qualifications, specify certain quality control procedures or facility requirements, or prescribe record maintenance requirements. We maintain state laboratory licenses for our Gaithersburg facility in Maryland and in New York, California, Pennsylvania and Rhode Island. In addition to having a laboratory license in New York, our laboratory is also required to obtain approval on a test-specific basis for the tests it runs as laboratory developed tests ("LDTs") by the New York Department of Health before specific testing is performed on samples from New York. If any states currently have or adopt similar licensure requirements in the future, we may be required to modify, delay or stop our operations in those states.

If a laboratory is out of compliance with state laws or regulations governing licensed laboratories or with CLIA, penalties may include suspension, limitation or revocation of the license or CLIA certificate, assessment of civil monetary penalties or fines, civil injunctive suit or criminal penalties. Failure to comply with CLIA could also result in a directed plan of correction and state on-site monitoring. Loss of a laboratory's CLIA certificate or state license may also result in the inability to receive payments from state and federal health care programs as well as private third-party payors. We believe that we are in material compliance with CLIA and all applicable licensing laws and regulations.

CLIA and state laws and regulations, operating together, sometimes limit the ability of laboratories to offer consumer-initiated testing (also known as "direct access testing"). CLIA certified laboratories are permitted to perform testing only upon the order of an "authorized person," defined as an individual authorized under state law to order tests or receive test results, or both. Many states do not permit persons other than licensed healthcare providers to order tests. We currently do not offer direct access testing and our CLIA tests may only be ordered by authorized healthcare providers.

Diagnostic Products and FDA Oversight of Laboratory Developed Tests

FDA Oversight of Laboratory Developed Tests

We currently offer an LDT version of certain tests. Historically, the FDA has exercised a policy of enforcement discretion with respect to most LDTs, whereby the FDA did not actively enforce its medical device regulatory requirements for such tests. However, at various points in recent years, FDA has indicated that it intends to end enforcement discretion for many tests offered as LDTs, and to require such tests to comply with certain FDA regulatory requirements. Agency officials have previously expressed significant concerns regarding performance disparities between some LDTs and in vitro diagnostics that have been reviewed, cleared, authorized or approved by the FDA.

Most recently, on April 29, 2024, the FDA published a final rule on LDTs, in which FDA outlines its plans to end enforcement discretion for many LDTs in five stages over a four-year period. In Phase 1 (effective May 6, 2025), clinical laboratories would be required to comply with medical device (adverse event) reporting, correction/removal reporting, and certain quality systems complaint handling requirements. In Phase 2 (effective May 6, 2026), clinical laboratories would be required to comply with all other device requirements (e.g., registration/listing, labeling, investigational use), except for remaining quality systems requirements and premarket review. In Phase 3 (effective May 6, 2027), clinical laboratories would be required to comply with all remaining applicable quality systems requirements. In Phase 4 (effective November 6, 2027), clinical laboratories would be required to comply with premarket submission requirements for high-risk tests (i.e., tests subject to premarket approval (PMA) requirement). Finally, in Phase 5 (effective May 6, 2028), clinical laboratories would be required comply with premarket submission requirements for moderate- and low-risk tests (i.e., tests subject to de novo or 510(k) requirement). The final rule potentially extends enforcement discretion for certain tests – e.g., LDTs approved by the New York State Department of Health, and LDTs first marketed prior to May 6, 2024 which are not modified or are modified in certain limited ways – from certain FDA regulatory requirements, provided certain important limitations have been met. We are actively reviewing the final rule to evaluate its applicability to our operations, and the extent to which we may be required to modify our operations to comply with its requirements.

Multiple lawsuits have been filed challenging the FDA's authority to regulate LDTs as medical devices under the Federal Food, Drug, and Cosmetic Act.

Legislative proposals addressing the FDA's oversight of LDTs have also been introduced in previous Congresses, and we expect that new legislative proposals will be introduced from time-to-time. For example, versions of the Verifying Accurate Leading-edge IVCT Development Act (the "VALID Act") have been introduced in Congress several times in recent years, but the VALID Act has not been enacted. The VALID Act, as most recently proposed, would create a new category of medical products separate from medical devices called "in vitro clinical tests," or IVCTs. As most recently proposed, the VALID Act would modify the Federal Food, Drug, and Cosmetic Act (the "FDCA") and establish a risk-based approach to imposing requirements related to premarket review, quality systems, and labeling requirements on all IVCTs, including LDTs, but a grandfathering provision would create exemptions from certain requirements for certain LDTs (e.g., LDTs first offered for clinical use not later than May

6, 2024). The likelihood that Congress will pass such legislation and the extent to which such legislation may affect the FDA's plans to regulate certain LDTs as medical devices is difficult to predict at this time.

If the FDA ultimately regulates certain LDTs as medical devices, whether via final guidance, final regulation, or as instructed by Congress, our tests may be subject to certain additional regulatory requirements. Complying with the FDA's requirements for medical devices can be expensive, time-consuming, and subject us to significant or unanticipated delays. Insofar as we may be required to obtain premarket clearance or approval to perform or continue performing an LDT, we cannot be sure that we will be able to obtain such authorization. Even if we obtain regulatory clearance or approval where required, such authorization may not be for the intended uses that we believe are commercially attractive or are critical to the commercial success of our tests. As a result, the application of the FDA's oversight to our tests could materially and adversely affect our business, financial condition, and results of operations.

We will continue to monitor changes to all LDT regulatory policy so as to ensure compliance with the current regulatory scheme. The FDA in the course of enforcing the FDCA may subject a company to various sanctions for violating FDA regulations or provisions of the FDCA, including requiring recalls, issuing Warning Letters, seeking to impose civil money penalties, seizing devices that the agency believes are non-compliant, seeking to enjoin distribution of a specific device, seeking to revoke a clearance or approval, seeking disgorgement of profits and/or seeking to criminally prosecute a company and its officers and other responsible parties.

Additionally, certain of our diagnostic products in development may be subject to regulation by the FDA and similar international health authorities. For these products, we would have an obligation to adhere to the FDA's current Good Manufacturing Practices and diagnostic product regulations, including providing for an establishment and product listing with the FDA. Additionally, we would be subject to periodic FDA inspections, quality control procedures, and other detailed validation procedures. If the FDA finds deficiencies in the validation of our manufacturing and quality control practices, it may impose restrictions on marketing specific products until corrected. Regulation by governmental authorities in the United States and other countries may be a significant factor in how we develop, test, produce and market our diagnostic test products.

Corporate Practice of Medicine

Numerous states prohibit business organizations from practicing medicine or employing or engaging physicians to practice medicine, which prohibitions are generally referred to as the prohibition against the corporate practice of medicine. These laws are intended to prevent interference in the medical decision-making process by anyone who is not a licensed physician. For example, California's Medical Board has indicated that determining what diagnostic tests are appropriate for a particular condition and taking responsibility for the ultimate overall care of the patient, including providing treatment options available to the patient, would constitute the unlicensed practice of medicine if performed by an unlicensed person. Violation of these corporate practice of medicine prohibitions may result in civil or criminal fines, as well as sanctions imposed against us and/or the professional through licensure proceedings.

Other Regulatory Requirements

We are subject to laws and regulations related to the protection of the environment, the health and safety of employees and the handling, transportation and disposal of regulated medical waste, hazardous waste and biohazardous waste, including chemical, biological agents and compounds, blood and bone marrow samples and other human tissue, and radioactive materials. For example, the U.S. Occupational Safety and Health Administration has established extensive requirements relating specifically to workplace safety for healthcare employers in the United States. For purposes of transportation, some biological materials and laboratory supplies are classified as hazardous materials and are subject to regulation by one or more of the following: the U.S. Department of Transportation, the U.S. Public Health Service, the U.S. Postal Service, the Office of Foreign Assets Control and the International Air Transport Association. We generally use third-party vendors to dispose of regulated medical waste, hazardous waste and radioactive materials and contractually require them to comply with applicable laws and regulations. These vendors are licensed or otherwise qualified to handle and dispose of such wastes.

Federal and State Healthcare Fraud & Abuse Laws

Federal and State Physician Self-Referral Prohibitions

We are subject to the federal physician self-referral prohibitions, commonly known as the Stark Law. These restrictions generally prohibit a physician who has (or whose immediate family member has) a financial relationship, such as an ownership or investment interest in or compensation arrangement with us, from making referrals for "designated health services", including clinical laboratory services, if payment for the services may be made under Medicare. If such a financial relationship exists, referrals are prohibited unless a statutory or regulatory exception applies. The Stark Law also prohibits us from billing for any such prohibited referral. 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. Several Stark Law exceptions are relevant to many common financial relationships involving clinical laboratories and referring physicians and may be relied upon if all of the elements of the applicable exception are satisfied. Penalties for violating the Stark Law include the return of funds received for all prohibited referrals, fines, civil monetary penalties and possible exclusion from federal health care programs. In addition, violations of the Stark Law may also serve as the basis for liability under the federal False Claims Act (the "FCA"), which can result in additional civil and criminal penalties. Several states have enacted comparable self-referral laws which may be broader in scope and apply regardless of payor.

Federal and State Anti-Kickback Laws

The federal Anti-Kickback Statute (the "AKS"), makes it a felony for a person or entity, including a clinical laboratory, to, among other things, knowingly and willfully offer, pay, solicit or receive any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in order to induce or reward 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. The government may also assert that a claim that includes items or services resulting from a violation of the AKS constitutes a false or fraudulent claim under the FCA, which is discussed in greater detail below. Additionally, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. 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 all payors or to state program payors. Penalties for violations of such laws include imprisonment and significant monetary fines and, in the case of the AKS, exclusion from federal health care programs. Federal and state law enforcement authorities scrutinize arrangements between health care providers and potential referral sources to ensure that the arrangements are not designed as a mechanism to induce patient care referrals or induce the purchase or prescribing of particular products or services. 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 provide for a number of safe harbors. If an arrangement meets the conditions of an applicable exception or safe harbor, it is deemed not to violate the AKS. An arrangement must fully meet each condition of an applicable exception or safe harbor in order to qualify for protection. Failure to meet the conditions of a safe harbor, however, does not render an arrangement illegal. Rather, the government may evaluate such arrangements on a case-by-case basis, taking into account all facts and circumstances.

In addition, the federal Eliminating Kickbacks in Recovery Act of 2018 (the "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 and certain other entities or in exchange for an individual using the services of such entities. The EKRA applies to all payors including commercial payors and government payors, and EKRA violations result in significant fines and/or up to 10 years in jail, separate and apart from existing AKS liability. Several EKRA exceptions are relevant to many common financial relationships involving clinical laboratories and may be relied upon if all of the elements of the applicable exception are satisfied. Failure to meet the requirements of an exception, however, does not render an arrangement illegal. Rather, the government may evaluate such arrangements on a case-by-case basis, taking into account all facts and circumstances.

Other Federal and State Fraud & Abuse Healthcare Laws

In addition to the requirements discussed above, several other health care fraud and abuse laws could have an effect on our business.

The 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 in order to secure payment or retaining an overpayment by the federal government. Under the FCA, a person acts knowingly if he or she has actual knowledge of the information or acts in deliberate ignorance or in reckless disregard of the truth or falsity of the information. Specific intent to defraud is not required. FCA violations can result in penalties of up to three times the actual damages sustained by the government, plus civil penalties for each false claim. 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. Several states have enacted comparable false claims laws which may be broader in scope and apply regardless of payor.

The Social Security Act includes civil monetary penalty provisions that impose 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 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. Several states have enacted comparable laws which may be broader in scope and apply regardless of payor. In addition, a person who offers or provides to a Medicare or Medicaid beneficiary any remuneration, including waivers of co-payments and deductible amounts (or any part thereof), 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 under the civil monetary penalties law. Moreover, in certain cases, providers who routinely waive copayments and deductibles for Medicare and Medicaid beneficiaries, can also be held liable under the civil monetary penalty provisions and certain other laws, such as the AKS and FCA. One of the statutory exceptions to the civil monetary penalty prohibition is non-routine, unadvertised waivers of copayments or deductible amounts based on individualized determinations of financial need or exhaustion of reasonable collection efforts. The Office of Inspector General of the U.S. Department of Health and Human Services ("HHS"), emphasizes, however, that this exception should only be used occasionally to address special financial needs of a particular patient. States may have similar prohibitions.

Other Federal and State Healthcare Laws

In addition to the fraud and abuse laws discussed above, our business potentially is subject to the following additional healthcare regulatory laws:

Laws Governing Genetic Counseling Services

Our genetic counseling partner may provide services via electronic means that could subject it to various federal, state and local certification and licensing laws, regulations and approvals, relating to, among other things, the adequacy of health care, the practice of medicine and other health professions (including the provision of remote care and cross-coverage practice), equipment, personnel, operating policies and procedures and the prerequisites for ordering laboratory tests. Some states have enacted regulations specific to providing services to patients via telehealth. Such regulations include, among other things, informed consent requirements that some states require providers to obtain from their patients before providing telehealth services. Health professionals who provide professional services using telehealth modalities must, in most instances, hold a valid license to practice the applicable health profession in the state in which the patient is located. In addition, certain states require a physician providing telehealth to be physically located in the same state as the patient. Any failure to comply with these laws and regulations could result in civil or criminal penalties against telehealth providers.

Clinical and Human Subjects Research Regulations

We may collaborate or support ongoing clinical or other human subjects research that could subject us to a number of laws and regulations pertaining to such research, including, but not limited to the Federal Policy for Protection of Human Subjects (as set forth in the implementing regulations of any signatory federal department or agency), the FDCA and its applicable implementing regulations at 21 C.F.R. Parts 11, 50, 54, 56, 58 and 812 and all equivalent legal requirements in other jurisdictions.

Privacy and Security Laws

Health Insurance Portability and Accountability Act

Under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), HHS has issued regulations to protect the privacy and provide for the security of protected health information ("PHI") used or disclosed by covered entities, including most health care providers and their respective business associates, as well as the business associates' subcontractors. HIPAA also regulates standardization of data content, codes, and formats used in certain health care transactions and standardization of identifiers for health plans and providers. Four principal regulations with which we are required to comply have been issued in final form under HIPAA and HITECH: privacy regulations, security regulations, breach notification regulations, and standards for electronic transactions, which establish standards for common healthcare transactions.

The privacy regulations cover the use and disclosure of PHI by covered entities as well as business associates, which are persons or entities that perform certain functions for or on behalf of a covered entity that involve the creation, receipt, maintenance, or transmission of PHI. Business associates are defined to include a subcontractor to whom a business associate delegates a function, activity, or service, other than in the capacity of the business associate's workforce. As a general rule, a covered entity or business associate may not use or disclose PHI except as permitted or required under the privacy regulations. The privacy regulations also set forth certain rights that an individual has with respect to his or her PHI maintained by a covered entity or business associate, including the right to access or amend certain records containing his, her or their PHI, request restrictions on the use or disclosure of his, her or their PHI, or request an accounting of disclosures of his or her PHI.

Covered entities and business associates also must comply with the security regulations, which establish requirements for safeguarding the confidentiality, integrity, and availability of PHI that is electronically transmitted or electronically stored. In addition, HITECH, among other things, established certain PHI breach notification requirements with which covered entities and business associates must comply. In particular, a covered entity must notify any individual whose unsecured PHI is breached according to the specifications set forth in the breach notification rule. A covered entity must also notify the Secretary of HHS and, under certain circumstances, the media of a breach of unsecured PHI.

The HIPAA privacy, security, and breach notification regulations establish a uniform federal "floor" and do not preempt state laws that are more stringent or provide individuals with greater rights with respect to the privacy or security of, and access to, their records containing PHI or insofar as such state laws apply to personal information that is broader in scope than PHI. In addition, individuals (or their personal representatives, as applicable) generally have the right to access test reports directly from laboratories and to direct that copies of those reports be transmitted to persons or entities designated by the individual.

HIPAA authorizes state attorneys general to file suit on behalf of their residents for violations. Courts are able to award damages, costs, and attorneys' fees related to violations of HIPAA in such cases. While HIPAA does not create a private right of action allowing individuals to file suit against us in civil court for violations of HIPAA, its standards have been used as the basis for duty of care cases in state civil suits such as those for negligence or recklessness in the misuse or breach of PHI. In addition, violations of HIPAA could result in significant penalties imposed by the HHS's Office for Civil Rights. HIPAA also mandates that the Secretary of HHS conduct periodic compliance audits of HIPAA covered entities, such as us, and their business associates for compliance with the HIPAA privacy and security standards. It also tasks HHS with establishing a methodology whereby harmed individuals who were the victims of breaches of unsecured PHI may receive a percentage of the civil monetary penalty paid by the violator.

HHS announced on December 27, 2024, and published in the Federal Register on January 6, 2025, a Notice of Proposed Rulemaking proposing extensive modifications to the HIPAA security regulations. If finalized, these modifications and could entail significant additional compliance obligations and costs for HIPAA-regulated covered entities and business associates.

Further, there are a number of state laws regarding the privacy and security of health information and personal data that are applicable to our clinical laboratories. We believe that we have taken the steps required of us to comply with health information privacy and security statutes and regulations in all jurisdictions, both state and federal, and we intend to continue to comprehensively protect all personal information and to comply with all applicable laws regarding the protection of such information. However, these laws constantly change, and we may not be able to maintain compliance in all jurisdictions where we do business. Failure to maintain compliance, including in connection with changes in state or federal laws regarding privacy or security, could result in civil and/or criminal penalties as well as significant reputational damage and could also have a material adverse effect on our business.

California and Other State Consumer Privacy Laws

The California Consumer Privacy Act, as amended by the California Privacy Rights Act (together with the California Consumer Privacy Act, the "CCPA"), confers to California consumers, among other things, the right to receive notice of the categories of personal information that will be collected by a business, how the business will use and share the personal information, and the categories of third parties who will receive the personal information. The CCPA also confers rights to access, delete, correct, or request a portable dataset, the right to limit processing of "sensitive personal information," and the right to receive equal service and pricing from a business after exercising a consumer right granted by the CCPA. In addition, the CCPA allows California consumers the right to opt out of the "sale" of their personal information, which the CCPA defines broadly as any disclosure of personal information to a third party in exchange for monetary or other valuable consideration. The CCPA also allows California consumers to opt out of the "sharing" of information, which restricts a company's use of personal information for cross-context behavioral advertising. The CCPA requires a business to implement reasonable security procedures to safeguard personal information against unauthorized access, use, or disclosure and imposes purpose limitation, data minimization, data retention and other security compliance obligations on regulated businesses. The CCPA requires businesses to include specific provisions in contracts with third parties that process data on a business's behalf regarding the third party's processing and management of such data.

The CCPA does not apply to personal information that is PHI under HIPAA and that is collected by a business associate or covered entity under HIPAA. The CCPA also exempts patient information that is processed by a covered entity and maintained in the same manner as PHI. Accordingly, the CCPA will not apply to much of the genetic testing and patient information we collect and process. However, we are required to comply with the CCPA insofar as we collect other categories of California consumers' personal information, such as information about California-based employees, contractors, business contacts and website visitors.

The CCPA is enforceable through administrative fines of up to $2,500 for each violation, or $7,500 for intentional violations or where the violator has actual knowledge that the personal information relates to an individual under 16 years of age.

In addition to the CCPA, by the end of 2024, there were eight other states that had consumer privacy laws come into effect, including Colorado, Connecticut, Florida, Montana, Oregon, Texas, Utah, and Virginia. Eight more states will have comprehensive consumer data privacy laws that come into effect in 2025, and many other states have introduced or enacted similar consumer privacy laws. These new state privacy laws and any potential federal consumer privacy law will and would impose additional data protection obligations on covered businesses, including additional consumer rights, limitations on data uses, new audit requirements for higher risk data and opt outs for certain uses of sensitive data. The new and proposed privacy laws may result in further uncertainty and may require us to incur additional expenditures to comply. These regulations and legislative developments have potentially far-reaching consequences and may require us to modify our data management and data use practices and incur substantial compliance expense. Our failure to comply with applicable laws and regulations or other obligations to which we may be subject relating to personal data, or to protect personal data from unauthorized access, use, or other processing, could result in enforcement actions and regulatory investigations against us, claims for damages by customers and other affected individuals, fines, damage to our reputation, and loss of goodwill, any of which could have a material adverse effect on our operations, financial performance, and business.

Genetic Privacy and Testing Laws

We are subject to myriad laws that require us to establish safeguards for the conduct of genomic testing and analysis and to protect against the misuse of genetic information and human biological specimens ("samples") from which genetic information can be derived. These laws vary in their scope and in the nature of their requirements and restrictions. For example, certain genetic privacy laws prohibit the retention of samples after performing a genomic analysis and prohibit the collection, use or disclosure of genetic information or samples for certain purposes, such as research, without appropriate informed consent from the individual or unless the genetic information or samples are appropriately de-identified. Other laws may impose additional requirements, including requirements regarding institutional review board review and approval for certain research uses of genetic information or samples or requirements to implement certain security controls in connection with the transfer of genetic information. We must comply with such genetic privacy and testing laws in our collection, use, disclosure and retention of genetic information and samples.

Other Data Protection Laws

There are a growing number of jurisdictions around the globe that have privacy and data protection laws that may apply to us as we enter or expand our business in jurisdictions outside of the United States. These laws are typically triggered by a company's establishment or physical location in the jurisdiction, data processing activities that take place in the jurisdiction, and/or the processing of personal information about individuals located in that jurisdiction that are targeted, for example, by an offer of goods or services. Certain data protection laws, such as those in the European Union, (the "EU") and United Kingdom (the "UK"), are comprehensive in nature and include significant requirements around the processing of personal information, while other jurisdictions may have laws less restrictive or prescriptive than those in the United States. Enforcement of these laws varies from jurisdiction to jurisdiction, with a variety of consequences, including civil or criminal penalties, litigation private rights of action, or damage to our reputation.

For example, the EU's General Data Protection Regulation ("GDPR"), including as implemented and amended through the UK Data Protection Act 2018 ("UK GDPR"), applies to any data collection, use and sharing in the context of an establishment in the EU or UK as well as extraterritorially to any entity outside the EU and UK when they process personal information related to an offer of goods or services to, or monitoring the behavior of, individuals who are located in the EU or UK. The GDPR and UK GDPR impose requirements on controllers and processors of personal data, including when personal information is transferred outside of the EU or the UK to another country and enhanced protections for "special categories" of personal data, which include sensitive information such as health and genetic information of data subjects. The GDPR and UK GDPR also grant individuals various rights in relation to their personal data including the rights of access, rectification, objection to certain processing and deletion. The GDPR and UK GDPR provide an individual with an express right to seek legal remedies if the individual believes his or her rights have been violated. Failure to comply with the requirements of the GDPR or the related national data protection laws of the member states of the EU, which may deviate from or be more restrictive than the GDPR, or a failure to comply with the UK GDPR may result in significant administrative fines issued by EU or UK regulators.

Information Blocking Prohibition

On May 1, 2020, the Office of the National Coordinator for Health Information Technology ("ONC") promulgated final regulations under the authority of the 21st Century Cures Act to impose new conditions to obtain and maintain certification of certified health information technology and prohibit certain covered actors, including developers of certified health information

technology, health information networks/health information exchanges, and health care providers, from engaging in activities that are likely to interfere with the access, exchange, or use of electronic health information (information blocking). The final regulations further defined exceptions for activities that are permissible, even though they may have the effect of interfering with the access, exchange, or use of electronic health information. The information blocking regulations compliance date was April 5, 2021 and the HHS subsequently issued a final rule called the HTI-1 Rule that, among other things, revised the information blocking regulations, effective March 11, 2024. Since then, ONC has published in the Federal Register several proposed and final rules that, among other things, propose to or further revise the information blocking regulations. Under the 21st Century Cures Act, health care providers that violate the information blocking prohibition will be subject to appropriate disincentives. On July 1, 2024, the HHS published in the Federal Register a final rule to establish such disincentives, effective July 31, 2024. Developers of certified information technology and health information networks/health information exchanges may be subject to civil monetary penalties of up to $1 million per violation (adjusted for inflation). The HHS Office of Inspector General has the authority to impose such penalties and on July 3, 2023, published a final rule in the Federal Register codifying new authority in regulation, which became effective September 1, 2023. On July 29, 2024, HHS published a statement in the Federal Register that, among other things, announced a reorganization of certain roles and functions and renamed ONC the Assistant Secretary for Technology Policy and Office of the National Coordinator for Health Information Technology, or ASTP/ONC.

Federal and State Consumer Protection Laws

The Federal Trade Commission (the "FTC") is an independent U.S. law enforcement agency charged with protecting consumers and enhancing competition across broad sectors of the economy. The FTC's primary legal authority with respect to data privacy and security comes from Section 5 ("Section 5") of the Federal Trade Commission Act (the "FTC Act"), which prohibits unfair or deceptive acts or practices in the marketplace. The FTC has increasingly used this broad authority to police data privacy and security, using its powers to investigate and bring lawsuits. Where appropriate, the FTC can seek a variety of remedies, such as but not limited to requiring the implementation of comprehensive privacy and security programs, biennial assessments by independent experts, monetary redress to consumers, and provision of robust notice and choice mechanisms to consumers. In addition to its enforcement mechanisms, the FTC uses a variety of tools to protect consumers' privacy and personal information, including pursuing enforcement actions to stop violations of law, conducting studies and issuing reports, hosting public workshops, developing educational materials and testifying before the U.S. Congress on issues that affect consumer privacy. Recently, the FTC has issued guidance emphasizing that their authority to prevent unfair or deceptive acts or practices extends to advertising and marketing claims for health care and health-related products.

The majority of data privacy cases brought by the FTC fall under the "deceptive" acts prong of Section 5. These cases often involve a failure on the part of a company to adhere to its own privacy and data protection principles set forth in its policies or other statements made to consumers. To avoid Section 5 violations, the FTC encourages companies to build privacy protections and safeguards into relevant portions of their business, and to consider privacy and data protection as the company grows and evolves. In addition, privacy notices should clearly and accurately disclose the type(s) of personal information the company collects, how the company uses and shares that information, and the security measures used by the company to protect that information.

In recent years, the FTC's enforcement under Section 5 related to data security has included alleged violations of the "unfairness" prong. Many of these cases have alleged that companies were unfair to consumers because they failed to take reasonable and necessary measures to protect consumer data. The FTC has not provided bright line rules defining what constitutes "reasonable and necessary measures" for implementing a cybersecurity program, but it has provided guidance, tips and advice for companies. The FTC has also published past complaints and consent orders, which it urges companies use as guidance to help avoid an FTC enforcement action, even if a data breach or loss occurs.

In addition to the FTC Act, most U.S. states have unfair and deceptive acts and practices statutes, known as Unfair Deceptive Acts and Practices ("UDAP") statutes, that substantially mirror the FTC Act and have been applied in the privacy and data security context. These vary in substance and strength from state to state. Many have broad prohibitions against unfair and deceptive acts and practices. These statutes generally allow for private rights of action and are enforced by the states' Attorneys General.

Reimbursement and Billing

In April 2014, Congress passed the Protecting Access to Medicare Act of 2014 ("PAMA"), which included substantial changes to the way in which clinical laboratory services are paid under Medicare. Under PAMA (as amended) and its implementing regulations, laboratories that realize at least $12,500 in Medicare Clinical Laboratory Fee Schedule ("CLFS") revenues during the six month reporting period and that receive the majority of their Medicare revenue from payments made under the CLFS or the Physician Fee Schedule must report, beginning in 2017, and then in 2026 and every three years thereafter (or annually for "advanced diagnostic laboratory tests"), private payor payment rates and volumes for their tests. None of our tests meet the current definition of advanced diagnostic laboratory tests, and therefore we believe we are required to report private payor rates

for our tests on an every-three-years basis, starting next in 2026. The Centers for Medicare & Medicaid Services ("CMS") use the rates and volumes reported by laboratories to develop Medicare payment rates for the tests equal to the volume-weighted median of the private payor payment rates for the tests. Laboratories that fail to report the required payment information may be subject to substantial civil money penalties.

As set forth under the regulations implementing PAMA, for tests furnished on or after January 1, 2018, Medicare payments for clinical diagnostic laboratory tests are paid based upon these reported private payor rates. For clinical diagnostic laboratory tests that are assigned a new or substantially revised code, initial payment rates for clinical diagnostic laboratory tests that are not advanced diagnostic laboratory tests will be assigned by the crosswalk or gap-fill methodology, as under prior law. Initial payment rates for new advanced diagnostic laboratory tests will be based on the actual list charge for the laboratory test.

The payment rates calculated under PAMA went into effect starting January 1, 2018. Where applicable, reductions to payment rates resulting from the new methodology were limited to 10% per test per year in each of the years 2018 through 2020. Rates were held at 2020 levels during 2021 through 2024 and will continue to be held at such levels in 2025. Then, where applicable based upon median private payor rates reported in 2017 or 2026, reduced by up to 15% per test per year in each of 2026 through 2028 (with a second round of private payor rate reporting in 2026 to establish rates for 2027 through 2029).

PAMA codified Medicare coverage rules for laboratory tests by requiring any local coverage determination to be made following the local coverage determination process. PAMA also authorizes CMS to consolidate coverage policies for clinical laboratory tests among one to four laboratory-specific Medicare Administrative Contractors. These same contractors may also be designated to process claims if CMS determines that such a model is appropriate. It is unclear whether CMS will proceed with contractor consolidation under this authorization.

PAMA also authorized the adoption of new, temporary billing codes and/or unique test identifiers for FDA-cleared or approved tests as well as advanced diagnostic laboratory tests. The American Medical Association has created a section of billing codes, Proprietary Laboratory Analyses ("PLA"), to facilitate implementation of this section of PAMA. These codes may apply to one or more of our tests if we apply for PLA coding.

Reimbursement and billing for diagnostic services is highly complex, and errors in billing potentially can result in denied claims and/or in substantial obligations to repay overpayments to payors. Laboratories must bill various payors, such as private third-party payors, including managed care organizations ("MCO"), and state and federal health care programs, such as Medicare and Medicaid, and each may have different billing requirements. Additionally, the audit requirements we must meet to ensure compliance with applicable laws and regulations, as well as our internal compliance policies and procedures, add further complexity to the billing process. Other factors that complicate billing include:

- variability in coverage and information requirements among various payors;
- patient financial assistance programs;
- missing, incomplete or inaccurate billing information provided by ordering physicians;
- billings to payors with whom we do not have contracts;
- disputes with payors as to which party is responsible for payment; and
- disputes with payors as to the appropriate level of reimbursement.

Depending on the reimbursement arrangement and applicable law, the party that reimburses us for our services may be:

- a third party who provides coverage to the patient, such as an insurance company or MCO;
- a state or federal healthcare program; or
- the patient.

Available Information

We make our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to these reports, as well as our other SEC filings, available on our website, free of charge, as soon as reasonably practicable after they are electronically filed with or furnished to the SEC. Our website address is www.genedx.com. The information contained on our website is not incorporated by reference in this document.

We have used, and intend to continue to use, our website, investor relations website (accessible via our website), and social media accounts, including our X, formerly Twitter, feed @GeneDx, our LinkedIn page and our Facebook page, as a means of disclosing material non-public information and for complying with our disclosure obligations under Regulation FD.

Item 1A. Risk Factors

You should carefully review and consider the following risk factors and the other information contained in this Annual Report on Form 10-K as well as in our other filings with the SEC before deciding whether to invest in our securities. We cannot assure you that any of the events discussed below will not occur. These events could have a material and adverse impact on our business, financial condition, results of operations and prospects. Unless otherwise indicated, references to our business being harmed in these risk factors will include harm to our business, reputation, financial condition, results of operations, net revenue and future prospects. In such event, the trading price of our securities could decline, and you could lose all or part of your investment. This discussion does not address all of the risks that we face, and we may face additional risks and uncertainties that are not presently known to us, or that we currently deem immaterial, which may also impair our business or financial condition. The following discussion should be read in conjunction with the consolidated financial statements and notes thereto included herein.

Risk Factors Summary

Our business is subject to a number of risks and uncertainties, including those risks discussed at length below. These risks include, among others, the following:

- We need to scale our infrastructure in advance of demand for our products and services, and our failure to generate sufficient demand for our products and services would have a negative impact on our business and our ability to attain profitability.
- We face intense competition. If we do not continue to innovate and provide products and services that are useful to customers, including providers and patients, and partners, we may not remain competitive, which could harm our business and operating results.
- If third-party payors, including managed care organizations, private health insurers and government health plans, do not provide adequate reimbursement for our tests, or seek to amend or renegotiate their fee reimbursement schedules, or if we are unable to comply with their requirements for reimbursement, our commercial success could be negatively affected.
- We may need to raise additional capital to fund our existing operations, develop additional products and services, commercialize new products and services or expand our operations.
- If we fail to comply with federal and state laboratory licensing requirements or standards, we could lose the ability to perform our tests or experience disruptions to our business.
- We rely on highly skilled personnel in a broad array of disciplines and, if we are unable to hire, retain or motivate these individuals, or maintain our corporate culture, we may not be able to maintain the quality of our services or grow effectively.
- We rely on a limited number of suppliers or, in some cases, single suppliers, for some of our laboratory instruments and materials and may not be able to find replacements or immediately transition to alternative suppliers or service providers.
- We rely on a limited number of product and service providers for data infrastructure and analytics capabilities, and any disruption of, or interference with, our use of data and workflow services could adversely affect our business, financial condition, and results of operations, and we may not be able to find replacements or immediately transition to alternative products or service providers.
- Our projections are subject to significant risks, assumptions, estimates and uncertainties, including assumptions regarding adoption of our products and services. As a result, our projected revenues, market share, expenses and profitability may differ materially from our expectations in any given quarter or fiscal year.
- Uncertainty in the development and commercialization of our enhanced or new tests or services could materially adversely affect our business, financial condition and results of operations.
- We currently use, and in the future expect to increase our use of, information and rights from customers, strategic partners, and collaborators for several aspects of our operations, and if we cannot maintain current and enter new relationships with these parties with adequate access and authorization to such information, our business will suffer.
- Our operating results could be subject to significant fluctuation, which could increase the volatility of our stock and warrant prices and cause losses to our stockholders.
- We may be unable to realize the level of the anticipated benefits that we expect from exiting businesses and restructuring our operations, which may adversely impact our business and results of operations.
- Changes in FDA enforcement discretion for LDTs could subject our operations to much more significant regulatory requirements.
- Compliance with the HIPAA security, privacy and breach notification regulations may increase our costs.
- We face uncertainty related to healthcare reform, pricing, coverage and reimbursement, which could reduce our revenue.
- Our inability to effectively protect our proprietary products, processes, and technologies, including the confidentiality of our trade secrets, could harm our competitive position.

- Security breaches, privacy issues, loss of data and other incidents could compromise sensitive, protected, or personal information related to our business, could prevent it from accessing critical information, and could expose it to regulatory liability, which could adversely affect our business.

Risks Related to Our Business, Industry and Operations

We need to scale our infrastructure in advance of demand for our tests, and our failure to generate sufficient demand for our tests would have a negative impact on our business and our ability to attain profitability.

Our success depends in large part on our ability to extend our market position, to provide customers with high-quality test reports quickly and at a lower price than our competitors, and to achieve sufficient test volume to realize economies of scale. In addition, we regularly evaluate and refine our testing process, often significantly updating our workflows, including with respect to exome sequencing and whole genome sequencing. In order to execute our business model, we intend to continue to invest heavily in order to significantly scale our infrastructure, including our testing capacity, particularly with respect to exome sequencing and whole genome sequencing to supplement our panel testing capabilities and information systems, expand our commercial operations, customer service, billing and systems processes and enhance our internal quality assurance program. We expect that much of this growth will be in advance of demand for our tests. Our current and future expense levels are to a large extent fixed and are largely based on investment plans and estimates of future revenue. Because the timing and amount of revenue from our tests is difficult to forecast, when revenue does not meet expectations, we may not be able to adjust our spending promptly or reduce spending to levels commensurate with our revenue. Even if we successfully scale our infrastructure and operations, there can be no assurance that tests will increase at levels consistent with the growth of our infrastructure. If we fail to generate demand commensurate with this growth or if we fail to scale our infrastructure sufficiently in advance of demand to successfully meet such demand, our business, prospects, financial condition and results of operations could be adversely affected.

If we are not able to continue to generate substantial demand for our tests, our commercial success will be negatively affected.

Our business model assumes that we will be able to generate significant test volume, particularly with respect to exome sequencing and whole genome sequencing in addition to our panel testing offerings, and we may not succeed in continuing to drive adoption of our tests to achieve sufficient volumes. Inasmuch as detailed genetic data from exome and whole genome sequencing has only recently become available at relatively affordable prices, the continued pace and degree of clinical acceptance of the utility of such testing is uncertain. Specifically, it is uncertain how much genetic data will be accepted as necessary or useful, as well as how detailed that data should be, particularly since medical practitioners may have become accustomed to genetic testing that is specific to one or a few genes and may not embrace the utility of exome sequencing and whole genome sequencing. Given the substantial amount of additional information available from a broad-based testing panel such as ours, there may be distrust as to the reliability of such information when compared with more limited and focused genetic tests. To generate further demand for our tests, we will need to continue to make clinicians aware of the benefits of our tests, including the price, the breadth of our testing options, and the benefits of having additional genetic data available from which to make treatment decisions. A lack of or delay in clinical acceptance of our exome sequencing and whole genome sequencing testing, or our legacy broad-based panels testing, would negatively impact sales and market acceptance of our tests and limit our revenue growth and potential profitability. Genetic testing is expensive, and many potential customers may be sensitive to pricing. In addition, potential customers may not adopt our tests if adequate reimbursement is not available, or if we are not able to maintain low prices relative to our competitors.

If we are not able to generate demand for our tests at sufficient volume, or if it takes significantly more time to generate this demand than we anticipate, our business, prospects, financial condition and results of operations could be materially harmed.

If our laboratories become inoperable due to disasters, health epidemics or for any other reasons, we will be unable to perform tests and our business will be harmed.

We perform all of our exome sequencing and whole genome sequencing tests at our production facilities in Gaithersburg, Maryland. Our laboratories and the equipment we use to perform our tests would be costly to replace and could require substantial lead time to replace and qualify for use. Our laboratories may be harmed or rendered inoperable by natural or man-made disasters, including flooding, fire and power outages, or by health epidemics, which may render it difficult or impossible for us to perform our tests for some period of time. The inability to perform our tests or the backlog that could develop if our laboratories are inoperable for even a short period of time may result in the loss of customers or harm our reputation. Although we maintain insurance for damage to our property and the disruption of our business, this insurance may not be sufficient to cover all potential losses and may not continue to be available to us on acceptable terms, if at all.

Other companies or institutions may develop and market novel or improved technologies, which may make our technologies less competitive or obsolete.

We operate in a rapidly evolving and highly competitive industry. There are a number of private and public companies that offer products or services or have announced that they are developing products or services that compete, or may one day compete, with our products or services. Some of our current and potential competitors possess greater brand recognition, financial and other resources and development capabilities than we do. As the fields of exome and genome analysis and health information become more widely known to the public, we anticipate that competition will further increase. We expect to compete with a broad range of organizations in the U.S. and other countries that are engaged in the development, production and commercialization of genetic testing and screening products, including exome and whole genome sequencing products, health information services, and analytics, and data science services, and other diagnostic products. These competitors include:

- companies that offer clinical, research and data clinical services, molecular genetic testing and other clinical diagnostics, life science research and drug discovery services, data services and healthcare analytics, and consumer genetics products;
- academic and scientific institutions;
- governmental agencies; and
- public and private research organizations.

We may be unable to compete effectively against our competitors either because their products and services are superior or because they may have more expertise, experience, financial resources, or stronger business relationships. These competitors may have broader product lines and greater name recognition than we do. Furthermore, we must compete successfully in our existing markets, including exome and whole genome sequencing, but also in any new markets we expand into. Even if we successfully develop new marketable products or services, our current and future competitors may develop products and services that are more commercially attractive than ours, and they may bring those products and services to market earlier or more effectively than we are able to. If we are unable to compete successfully against current or future competitors, we may be unable to increase market acceptance for and sales of our tests and services, which could prevent us from increasing or sustaining our revenues or achieving sustained profitability.

We face intense competition. If we do not continue to innovate and provide products and services that are useful to customers, including providers and patients, and partners, we may not remain competitive, which could harm our business and operating results.

Our business environment is rapidly evolving and intensely competitive. Our businesses face changing technologies, shifting provider and patient needs, and frequent introductions of rival products and services. To compete successfully, we must accurately anticipate technology developments and deliver innovative, relevant and useful products, services, and technologies in a timely manner. As our businesses evolve, the competitive pressure to innovate will encompass a wider range of products and services. We must continue to invest significant resources in research and development, including through acquisitions and collaborations, joint ventures and partnerships, in order to enhance our current diagnostics and health information and data science technologies, and existing and new products and services based off these technologies.

We have many competitors in different industries. Our current and potential domestic and international competitors range from large and established companies to emerging start-ups in addition to academic and scientific institutions, and public and private research organizations. Some competitors have longer operating histories than our Company in various sectors. They can use their experience and resources in ways that could affect our competitive position, including by making acquisitions, continuing to invest heavily in research and development and in talent, initiating intellectual property claims (whether or not meritorious), and continuing to compete aggressively for our customers and partners in the market for genetic testing and screening, health information and data science products and services. Our competitors may be able to innovate and provide products and services faster than we can or may foresee the need for products and services before we do.

Our operating results may also suffer if our products and services are not responsive to the needs of our customers and partners. As technologies continue to develop, our competitors may be able to offer products and services that are, or that are seen to be, substantially similar to or better than our current products and services. This may force us to compete in different ways and expend significant resources in order to remain competitive. If our competitors are more successful than us in developing compelling products and services for or in attracting and retaining customers or partners in the market for genetic testing and screening, health information and data science products and services, our operating results could be harmed.

If third-party payors, including managed care organizations, private health insurers and government health plans, do not provide adequate reimbursement for our tests, or seek to amend or renegotiate their fee reimbursement schedules, or if we are unable to comply with their requirements for reimbursement, our commercial success could be negatively affected.

Our ability to increase the number of billable tests and our revenue therefrom will depend on our success in achieving reimbursement for our tests from third-party payors. Reimbursement by a payor may depend on a number of factors, including a payor's determination that a test is appropriate, medically necessary, cost-effective, correctly billed, and has received prior authorization. The commercial success of our current and future products, if approved, will depend on the extent to which our customers receive coverage and adequate reimbursement from third-party payors, including managed care organizations and government payors (e.g., Medicare and Medicaid).

Since each payor makes its own decision as to whether to establish a policy or enter into a contract to cover our tests, as well as the amount it will reimburse for a test, seeking these approvals is a time-consuming and costly process. In addition, the determination by a payor to cover and the amount it will reimburse for our tests will likely be made on an indication-by-indication basis and may consider our billing practices and reimbursements from other payors and from our patient billing programs. To date, we have obtained policy-level reimbursement approval or contractual reimbursement for some indications for our tests from most of the large commercial third-party payors in the U.S., and the Centers for Medicare & Medicaid Services ("CMS"). We believe that establishing adequate reimbursement from Medicare is an important factor in gaining adoption from healthcare providers. Our claims for reimbursement from third-party payors may be denied upon submission, and we must appeal the claims. The appeals process is time consuming and expensive and may not result in payment. In cases where there is not a contracted rate for reimbursement, there is typically a greater coinsurance or copayment requirement from the patient, which may result in further delay or decreased likelihood of collection.

A significant portion of the payments for our tests are paid or reimbursed under insurance programs with third-party payors. Billing and reimbursement for diagnostic tests is highly complex and closely scrutinized by payors. In particular, billing and reimbursement for multi-gene panel tests and other complex diagnostic tests continues to pose a particular risk of payor audit and potential overpayment obligations. Accurate billing requires sophisticated internal procedures and systems controls and ongoing oversight to ensure compliance with payor requirements.

To contain reimbursement and utilization rates, third-party payors often attempt to, or do in fact, amend or renegotiate their fee reimbursement schedules. Loss of revenue caused by third-party payor cost containment efforts or an inability to negotiate satisfactory reimbursement rates could have a material adverse effect on our revenue and results of operations.

Furthermore, in cases where we or our partners have established reimbursement rates with third-party payors, we face additional challenges in complying with their procedural requirements for reimbursement. These requirements often vary from payor to payor and are reassessed by third-party payors on a regular basis, and we have needed additional time and resources to comply with them. We have also experienced, and may continue to experience, delays in or denials of coverage if we do not adequately comply with these requirements. Our third-party payors have also requested, and in the future may request, audits of the amounts paid to us. In the past, we have been required to repay certain amounts to payors as a result of such audits. For more information regarding this matter, see Note 3, "*Revenue Recognition*" to our consolidated financial statements included within this Annual Report. In addition to potential repayment obligations, failure to comply with payor reimbursement policies could result in government enforcement actions and, potentially, exclusion from certain payor programs, which could have a material adverse effect on our business.

We expect to continue to focus our resources on increasing adoption of, and expanding coverage and reimbursement for, our current tests and any future tests we may develop or acquire. If we fail to expand and maintain broad adoption of, and coverage and reimbursement for, our tests, our ability to generate revenue could be harmed and our future prospects and our business could suffer.

We use artificial intelligence in our business, and challenges with properly managing its use could result in reputational harm, competitive harm, and legal liability, and adversely affect our results of operations.

We currently incorporate artificial intelligence ("AI") solutions into our workflows and these applications may become important in our operations over time. Further, we are in the process of enhancing and broadening our offerings with AI technologies, and we are exploring potential third-party partnerships to help us offer more robust solutions for providers and patients. Our competitors or other third parties may incorporate AI into their products and offerings more quickly or more successfully than us, which could impair our ability to compete effectively and adversely affect our results of operations. Additionally, if the content, analyses, or recommendations that AI applications assist in producing are or are alleged to be inaccurate, deficient, or biased, our business, financial condition and results of operations may be adversely affected. The use of AI applications has resulted in, and may in the future result in, cybersecurity incidents that implicate the personal medical and genetic data of patients analyzed within

such applications. Any such cybersecurity incidents related to our use of AI applications to analyze personal data could adversely affect our reputation and results of operations. AI also presents emerging ethical issues and if our use of AI becomes controversial, we may experience brand or reputational harm, competitive harm, or legal liability. The rapid evolution of AI, including potential government regulation of AI and its various uses, may require significant resources to develop, test and maintain offerings, services, and features to help us implement AI ethically in order to minimize unintended, harmful impact.

We may need to raise additional capital to fund our existing operations, develop additional products and services, commercialize new products and services or expand our operations.

We have incurred net losses and negative cash flows from operations since our inception, with an accumulated deficit of $1.4 billion as of December 31, 2024.

We may seek to sell common or preferred equity or convertible debt securities, enter into credit facilities or other forms of third-party funding or debt financing, or dispose of assets or businesses. For example, we have an effective shelf registration statement that we filed with the SEC in August of 2022, registering $300 million of shares of our Class A common stock and other securities. As of December 31, 2024, approximately $102 million of securities remained available under this registration statement. Further, we have entered into a sales agreement (the "Sales Agreement") with TD Securities (USA) LLC ("TD Cowen") pursuant to which we may, but are not obligated to, offer and sell, from time to time, shares of our Class A common stock with an aggregate offering price up to $75.0 million through TD Cowen, as sales agent, subject to the terms and conditions described in the Sales Agreement and SEC rules and regulations (our "ATM offering"). As of December 31, 2024, approximately $26.8 million of capacity remained available under this ATM offering.

We may also consider raising additional capital in the future to expand our business, to pursue strategic investments, to take advantage of financing opportunities or for other reasons, including to:

- increase our sales and marketing efforts to drive market adoption of our current and future products and services;
- fund development efforts for our current and future products and services;
- expand our products and services into other disease indications and clinical applications;
- acquire, license or invest in technologies;
- acquire or invest in complementary businesses or assets; and
- finance capital expenditures and general and administrative expenses.

Our present and future funding requirements will depend on many factors, including:

- our ability to achieve revenue growth;
- our rate of progress in establishing payor coverage and reimbursement arrangements with commercial third-party payors and government payors;
- the cost of expanding our laboratory operations and offerings, including our sales and marketing efforts;
- our rate of progress in, and cost of the sales and marketing activities associated with, establishing adoption of our services for biopharma partners;
- our rate of progress in, and cost of research and development activities associated with, products and services in research and early development;
- the effect of competing technological, product and market developments;
- costs related to international expansion; and
- the potential cost of and delays in product development as a result of any regulatory oversight applicable to our products and services.

The various ways we could raise additional capital carry potential risks. If we raise funds by issuing equity securities, dilution to our stockholders could result. Any preferred equity securities issued also could provide for rights, preferences or privileges senior to those of holders of our Class A common stock. If we raise funds by issuing debt securities, those debt securities would have rights, preferences and privileges senior to those of holders of our Class A common stock. The terms of debt securities issued or borrowings pursuant to a credit agreement could impose significant restrictions on our operations. If we raise funds through collaborations and licensing arrangements, we might be required to relinquish significant rights to our technologies or products and services or grant licenses on terms that are not favorable to us.

Our credit agreement contains operating and financial restrictions that may limit our business and financing activities.

Our credit agreement with Perceptive Credit Holdings IV, LP ("Perceptive") contains operating and financial restrictions that may limit our business and financing activities. In particular, our credit agreement includes customary affirmative and negative covenants and events of default, including negative covenants that restrict, among other things, our ability to incur indebtedness and liens, dispose of property and make investments. In addition, the credit agreement requires us to maintain aggregate

unrestricted cash of not less than $5.0 million and minimum levels of quarterly core revenue through the third quarter of 2028. The operating and financial restrictions in the credit agreement, as well as any other financing arrangements that we may enter into, may limit our ability to finance our operations, or engage in, expand, or otherwise pursue our business activities and strategies. Our ability to comply with these or other covenants may be affected by events beyond our control, and future breaches of these or other covenants could result in a default under the credit agreement or any other financing arrangement. If not waived, future defaults could cause all of the outstanding indebtedness under our credit agreement or other financing arrangement to become immediately due and payable and terminate all commitments to extend further credit, if any. Furthermore, if we were unable to repay our credit agreement or other indebtedness then due and payable, secured lenders could proceed against the assets, if any, securing such indebtedness. A default would also likely significantly diminish the market price of our securities.

If we do not have or are unable to generate sufficient cash to repay our debt obligations when they become due and payable, either upon maturity or in the event of a default, we may not be able to obtain additional debt or equity financing on favorable terms, if at all, which may negatively impact our ability to operate and continue our business as a going concern.

Ethical, legal and social concerns related to the use of genomic medicine and health information analysis could reduce demand for our tests.

Genomic medicine and health information analysis has raised ethical, legal and social issues regarding privacy rights and the appropriate uses of the resulting information. Domestic and international governmental and regulatory authorities could, for social or other purposes, such as data privacy, limit or regulate the use of health information or health information testing or prohibit testing for specific information derived from health information testing, including, for example, data on genetic predisposition to certain conditions, particularly for those that have no known cure. Similarly, these concerns may lead patients to refuse to use, or clinicians to be reluctant to order, genomic tests as part of health information assessment even if permissible, or lead patients to withhold or withdraw consent for our use of their data. These and other ethical, legal and social concerns may limit market acceptance of our tests or services or reduce the potential markets for our tests, or services, either of which could have an adverse effect on our business, research, financial condition or results of operations.

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

We are subject to Clinical Laboratory Improvement Amendments of 1988 (“CLIA”), a federal law that regulates clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. CLIA regulations establish specific standards with respect to personnel qualifications, facility administration, proficiency testing, quality control, quality assurance and inspections. CLIA certification is also required in order for us to be eligible to bill state and federal healthcare programs, as well as many private third-party payors, for our tests. We have current CLIA, College of American Pathologists (“CAP”), and other certifications to conduct our tests at our laboratory in Maryland. To renew these certifications, we are subject to survey and inspection on a regular basis and at the request of the certifying bodies. Moreover, CLIA inspectors may make random inspections of our clinical reference laboratory.

We would also be required to maintain in-state licenses if we were to conduct testing in other states. Several states require the licensure of out-of-state laboratories that accept specimens from certain states.

In addition to having a laboratory license in New York, our clinical reference laboratory is approved on test-specific bases for the tests it runs as laboratory-developed tests (“LDTs”), by the New York State Department of Health (“NYDOH”). Other states may adopt similar licensure requirements in the future, which may require us to modify, delay or stop our operations in such jurisdictions. We may also be subject to regulation in foreign jurisdictions as we seek to expand international utilization of our tests or such jurisdictions adopt new licensure requirements, which may require review of our tests in order to offer them or may have other limitations such as restrictions on the transport of samples necessary for us to perform our tests that may limit our ability to make our tests available outside of the U.S. Complying with licensure requirements in new jurisdictions may be expensive, time-consuming, and subject us to significant and unanticipated delays.

Failure to comply with applicable clinical laboratory licensure requirements or standards may result in a range of enforcement actions, including license suspension, limitation, or revocation, directed plan of action, onsite monitoring, civil monetary penalties, criminal sanctions, and cancellation of the laboratory’s approval to receive Medicare and Medicaid payment for our services, as well as significant adverse publicity. Any sanction imposed under CLIA, its implementing regulations, or state or foreign laws or regulations governing clinical laboratory licensure, or our failure to renew our CLIA certifications, a state or foreign license, or accreditation, could have a material adverse effect on our business, financial condition and results of operations. Even if we were able to bring our laboratory back into compliance, we could incur significant expenses and potentially lose revenue in doing so.

The CAP maintains a clinical laboratory accreditation program. CAP asserts that its program is "designed to go well beyond regulatory compliance" and helps laboratories achieve the highest standards of excellence to positively impact patient care. 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 U.S. require CAP accreditation as a condition to permitting clinical laboratories to test samples taken from their citizens. We have a CAP accreditations for our laboratory. Failure to maintain CAP accreditation could have a material adverse effect on the sales of our tests and the results of our operations.

Risks Related to Our Business Model

We rely on highly skilled personnel in a broad array of disciplines and, if we are unable to hire, retain or motivate these individuals, or maintain our corporate culture, we may not be able to maintain the quality of our services or grow effectively.

Our performance, including our research and development programs and laboratory operations, largely depends on our continuing ability to identify, hire, develop, motivate and retain highly skilled personnel for all areas of our organization, including software developers, geneticists, biostatisticians, bioinformaticians, data scientists, certified laboratory directors and technicians and other scientific and technical personnel to process and interpret our tests and related data. In addition, we may need to continue to expand our sales force with qualified and experienced personnel. Competition in our industry for qualified employees is intense, and we may not be able to attract or retain qualified personnel in the future due to the competition for qualified personnel among life science and technology businesses as well as universities and public and private research institutions, particularly in the geographies in which we operate. Further, we may be unable to obtain the necessary visas for foreign personnel to work in the U.S. In addition, our compensation arrangements, such as our equity award programs, may not always be successful in attracting new employees and retaining and motivating our existing employees. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that could adversely affect our ability to scale our business, support our research and development efforts and our clinical laboratories. We believe that our corporate culture fosters innovation, creativity and teamwork. However, as our organization grows, we may find it increasingly difficult to maintain the beneficial aspects of our corporate culture. This could negatively impact our ability to retain and attract employees and our future success.

The loss of any member or change in structure of our senior management team could adversely affect our business.

Our success depends in large part upon the skills, experience and performance of key members of our executive management team and others in key leadership positions. The efforts of these persons will be critical to us as we continue to develop our technologies and test processes and focus on scaling our business. If we were to lose one or more key executives, we may experience difficulties in competing effectively, developing our tests and technologies and implementing our business strategy. Only certain of our executives have employment contracts, and the majority of our employees are at-will, which means that either we or any employee may terminate their employment at any time or in the notice period set forth in an executive's contract. In addition, we do not have long-term retention agreements in place with our executive officers. Furthermore, we compete against other leading companies in the diagnostics, health information, and data sciences markets for top talent. If such competitors offer better compensation or opportunities, there is no guarantee that we would be able to retain our key executives.

We may not be able to manage our future growth effectively, which could make it difficult to execute our business strategy.

Our expected future growth could create a strain on our organizational, administrative and operational infrastructure, including data and laboratory operations, quality control, customer service, marketing and sales, and management. We may not be able to maintain the quality of or expected turnaround times for our products or services or satisfy customer demand as it grows. We may need to continue expanding our sales force to facilitate our growth, and we may have difficulties locating, recruiting, training and retaining sales personnel. Our ability to manage our growth effectively will require us to continue to improve our operational, financial and management controls, as well as our reporting systems and procedures. As we grow, any failure of our controls or interruption of our facilities or systems could have a negative impact on our business and financial operations.

International expansion of our business could expose us to business, regulatory, political, operational, financial and economic risks associated with doing business outside of the U.S.

When cleared, authorized or approved, we and our collaborators may market, sell, and distribute our products and services outside of the U.S., and our business would be subject to risks associated with doing business outside of the U.S., including an increase in

our expenses and diversion of our management's attention from the development of future products and services. Accordingly, our business and financial results in the future could be adversely affected due to a variety of factors, including:

- multiple, conflicting and changing laws and regulations such as privacy, security and data use regulations, tax laws, export and import restrictions, economic sanctions and embargoes, employment laws, anticorruption laws, regulatory requirements, reimbursement or payor regimes and other governmental approvals, permits and licenses;
- failure by us, our collaborators or our distributors to obtain regulatory clearance, authorization or approval for the use of our products and services in various countries;
- additional potentially relevant third-party patent rights;
- complexities and difficulties in obtaining intellectual property protection and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations, including repatriating foreign earned profits;
- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems;
- difficulties in negotiating favorable reimbursement negotiations with governmental authorities;
- logistics and regulations associated with shipping samples, including infrastructure conditions and transportation delays;
- limits in our ability to penetrate international markets if we are not able to conduct our clinical diagnostic services locally;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products and services and exposure to foreign currency exchange rate fluctuations;
- international regulations and license requirements that may restrict foreign investment in and operation of the internet, IT infrastructure, data centers and other sectors, and international transfers of data;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, and outbreak of disease;
- boycotts, curtailment of trade and other business restrictions; and
- regulatory and compliance risks that relate to maintaining accurate information and control over sales and distributors' activities that may fall within the purview of the Foreign Corrupt Practices Act of 1977 (the "FCPA"), its books and records provisions, or its anti-bribery provisions, Canada's Corruption of Foreign Public Officials Act, or laws similar to the FCPA in other jurisdictions in which we may in the future operate, such as the United Kingdom's Bribery Act of 2010 and anti-bribery requirements of member states in the European Union (the "EU").

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

Unfavorable U.S. or global economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and financial markets. A severe or prolonged economic downturn or increase in inflation and interest rates could result in a variety of risks to our business, including weakened demand for our products and services, increased costs and expenses and a reduced ability to raise additional capital when needed on favorable terms, if at all. A weak declining or inflationary economy could also strain our collaborators and suppliers, resulting in supply disruption, or cause delays in their payments to us. For example, we have experienced and may continue to experience interruptions in the supply of the diagnostic testing materials necessary for our testing products and material and shipping cost increases. We also have significant supply contracts that are short-term and, as we enter into the renewal cycles for these contracts, we may face material price increases upon renewal.

In particular, challenging macroeconomic conditions, including cost inflation, decreases in per capita income and levels of disposable income, increased and/or prolonged unemployment or a decline in consumer confidence, as well as limited or significantly reduced points of access of our tests, could have a material adverse effect on the demand for our tests. Under difficult economic conditions, consumers may seek to reduce discretionary spending by forgoing our tests. Decreased demand for our tests, could negatively affect our overall financial performance.

Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business, financial condition, or results of operations.

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

We have sourced and will continue to source components of our diagnostic testing workflow, including sequencers and other laboratory equipment, reagents, lab supplies and other laboratory services and materials and related services, from third parties.

Our failure to maintain a continued supply of our sequencers and other laboratory equipment, reagents, lab supplies and other laboratory services and materials, along with the right to use certain hardware and software and related services, would adversely impact our business, financial condition, and results of operations. In particular, while we are seeking to validate our tests on additional sequencing platforms, we have not, to date, validated a viable alternative sequencing platform on which our testing could be run in a commercially viable manner. These efforts will require significant resources, expenditures and time and attention of management, and there is no guarantee that we will be successful in implementing any such sequencing platforms in a commercially sustainable way. We also cannot guarantee that we will appropriately prioritize or select alternative sequencing platforms on which to focus our efforts, in particular given our limited product and research and development resources and various business initiatives, which could result in increased costs and delayed timelines or otherwise adversely impact our business and results of operations.

Because we rely on third-party manufacturers, we do not control the manufacture of these components, including whether such components will meet our quality control requirements, nor the ability of our suppliers to comply with applicable legal and regulatory requirements. In many cases, our suppliers are not contractually required to supply these components to the quality or performance standards that we require. If the supply of components we receive does not meet our quality control or performance standards, we may not be able to use the components, or if we use them not knowing that they are of inadequate quality, which occasionally occurs with respect to certain reagents, our tests may not work properly or at all, or may provide erroneous results, and we may be subject to significant delays caused by interruption in production or manufacturing or to lost revenue from such interruption or from spoiled tests. In addition, any natural or other disaster, acts of war or terrorism, shipping embargoes, labor unrest, political instability, outbreak of disease or similar events at our third-party manufacturers' facilities that cause a loss of manufacturing capacity would heighten the risks that we face.

In the event of any adverse developments with our sole suppliers, or if any of our sole suppliers modifies any of the components they supply to us, our ability to supply our products may be interrupted, and obtaining substitute components could be difficult or require us to re-design or re-validate our products. Our failure to maintain a continued supply of components, a supply that meets our quality control requirements, or changes to or termination of our agreements or inability to renew our agreements with these parties or enter into new agreements with other suppliers could result in the loss of access to important components of our tests and impact our test performance or affect our ability to perform our tests in a timely manner or at all, which could impair, delay or suspend our commercialization activities. In the event that we transition to a new supplier from any of our sole suppliers, doing so could be time-consuming and expensive, may result in interruptions in our ability to supply our products to the market, could affect the performance of our tests or could require that we re-validate our affected tests using replacement equipment and supplies, which could delay the performance of our tests, impact diagnostic solutions and heath information derived from such tests, and result in increased costs. Any of these occurrences could have a material adverse effect on our business, financial condition and results of operations.

We rely on a limited number of product and service providers for data infrastructure and analytics capabilities, and any disruption of, or interference with, our use of data and workflow services could adversely affect our business, financial condition, and results of operations, and we may not be able to find replacements or immediately transition to alternative products or service providers.

We currently rely upon third-party services for data storage and workflow management, including cloud storage solution providers, such as Microsoft Azure ("Azure"), Amazon Web Services ("AWS"), and Oracle Cloud Infrastructure ("OCI"). We rely on each of these providers to complete several vital workflows in our health information and data science service delivery. To varying degrees some of those services are proprietary to how each platform performs in connection with our current usage of the services.

Nearly all of our data storage and analytics are conducted on, and the data and content we generate on our platforms are processed through, servers hosted by these providers, particularly Azure, AWS and OCI. We also rely on email service providers, bandwidth providers, internet service providers and mobile networks to deliver communications to patients, physicians and partners and to allow patients, physicians and our partners to access various offerings from our platforms. If our third-party vendors are unable or unwilling to provide the services necessary to support our business, or if our agreements with such vendors are terminated, our operations could be significantly disrupted. Some of our vendor agreements may be unilaterally terminated by the licensor for convenience, including with respect to Azure, AWS or OCI, and if such agreements are terminated, we may not be able to enter into similar relationships in the future on reasonable terms or at all.

Any damage to, or failure of, our systems or the systems of our third-party data centers or our other third-party providers could result in interruptions to the availability or functionality of database and platforms. As a result, we could lose health information data and miss opportunities to acquire and retain patients, physicians and partners including health systems and pharmaceutical and biotech companies, which could result in decreased revenue. If for any reason our arrangements with our data centers or third-party providers are terminated or interrupted, such termination or interruption could adversely affect our business, financial

condition and results of operations. We exercise little control over these providers, which increases our vulnerability to problems with the services they provide. We could incur additional expense in arranging for new or redesigned facilities, technology, services and support. In addition, the failure of our third-party data centers or any other third-party providers to meet our capacity needs or any system failure as a result of reliance on third parties, including network, software or hardware failure, which causes a delay or interruption in our services and products, including our ability to handle existing or increased processing of data on our platforms, could have a material adverse effect on our business, revenues, operating results and financial condition.

Our current and future products and services may never achieve significant commercial market acceptance.

Our success depends on the market's confidence that we can provide data-driven research and diagnostic products and services that improve clinical outcomes, lower healthcare costs and enable better product development by biopharma companies. Failure of our products and services, or those jointly developed with our collaborators, to perform as expected or to be updated to meet market demands could significantly impair our operating results and our reputation. We believe patients, health systems, clinicians, academic institutions and biopharma companies are likely to be particularly sensitive to defects, errors, inaccuracies and delays with our products and services. Furthermore, inadequate performance of these products or services may result in lower confidence in our services in general.

We and our collaborators may not succeed in achieving significant commercial market acceptance for our current or future products and services due to a number of factors, including:

- our ability to demonstrate the utility of our platforms and related products and services and their potential advantages over existing clinical AI technology, life sciences research, clinical diagnostic and drug discovery technologies to academic institutions, biopharma companies and the medical community;
- our ability, and that of our collaborators, to perform clinical trials or other research to gather adequate evidence and/or to secure and maintain FDA and other regulatory clearance authorization or approval for our products or products developed based off our platform;
- the agreement by third-party payors to reimburse our products or services, the scope and extent of which will affect patients' willingness or ability to pay for our products or services and will likely heavily influence physicians' decisions to recommend our products or services;
- the rate of adoption of our platforms and related products and services by academic institutions, clinicians, patients, key opinion leaders, advocacy groups and biopharma companies; and
- the impact of our investments in product and services, and technological innovation and commercial growth.

Additionally, our customers and collaborators may decide to decrease or discontinue their use of our products and services due to changes in their research and development plans, failures in their clinical trials, financial constraints, the regulatory environment, negative publicity about our products and services, competing products or the reimbursement landscape, all of which are circumstances outside of our control. We may not be successful in addressing these or other factors that might affect the market acceptance of our products, services and technologies. Failure to achieve widespread market acceptance of our platform and related products and services would materially harm our business, financial condition and results of operations.

Our projections are subject to significant risks, assumptions, estimates and uncertainties, including assumptions regarding the adoption of our products and services. As a result, our projected revenues, market share, expenses and profitability may differ materially from our expectations in any given fiscal quarter or year.

We operate in rapidly changing and competitive industries and our projections are subject to the risks and assumptions made by our management with respect to these industries. Operating results are difficult to forecast, as they generally depend on our assessment of the timing of adoption of our current and future products and services, which is uncertain. Furthermore, as we invest in the continued development of new businesses that have yet to achieve significant commercial success, whether because of competition or otherwise, we may not recover the often substantial up-front costs of developing and marketing those products and services or recover the opportunity cost of diverting management and financial resources away from other products or services. Additionally, our business may be affected by reductions in customer or partner demand as a result of a number of factors, which may be difficult to predict. Similarly, our assumptions and expectations with respect to margins and the pricing of our products and services may not prove to be accurate as a result of competitive pressures, customer or partner demands. This may result in decreased revenue, and we may be unable to adopt measures in a timely manner to compensate for any unexpected shortfall in revenue. This inability could cause our operating results in a given fiscal quarter or year to be higher or lower than expected. Any failure to achieve our projected operating results could harm the trading price of our securities and our financial position.

We have estimated the global market opportunity for our current and future products and services, and these markets may be smaller than we estimate.

Our estimates of the global market opportunity for our current products and services and those under development are based on a number of internal and third-party estimates, including, the market opportunity for rare disease and pediatric developmental disorders, adult disorders and newborn screening. The estimates also depend on whether we or our collaborators are able to engage, diagnose or treat patients through or using our products and services, the number of potential clinical tests utilized per treatment course per patient, the ongoing engagement by patients, physicians and health systems on our platforms, and the assumed prices at which we can sell our current and future products and services for markets that have not been established. 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 addressable market for our current or future products and services may prove to be incorrect. If the actual number of patients who would benefit from our products or services, the price at which we can sell future products and services or the annual addressable market for our products or services is smaller than we have estimated, it may impair our sales growth and have an adverse impact on our business.

Uncertainty in the development and commercialization of our enhanced or new tests or services could materially adversely affect our business, financial condition and results of operations.

Our success will depend in part on our ability to effectively introduce enhanced or new offerings, with a focus on expanding the clinical utility and application of exome and whole genome sequencing and developing solutions our health information platform can provide to partners. The development and launch of enhanced or new tests requires the completion of certain clinical development and commercialization activities that are complex, costly, time-intensive and uncertain, and requires us to accurately anticipate patients', clinicians', payors' and other counterparties' attitudes and needs as well as emerging technology and industry trends. This process is conducted in various stages, and each stage presents the risk that we will not achieve our goals.

We have relatively limited experience developing and commercializing products and services outside of the diagnostics business, and we may not be successful in our current or future efforts to do so. We also have limited experience forecasting our future financial performance from our new products and services, and our actual results may fall below our financial guidance or other projections, or the expectations of analysts or investors, which could cause the price of our Class A common stock and warrants to decline. We may experience research and development, regulatory, marketing and other difficulties that could delay or prevent our introduction of enhanced or new tests and result in increased costs and the diversion of management's attention and resources from other business matters, such as from our current product and service offerings, which currently represent the significant majority of our current revenues. For example, any tests that we may enhance or develop may not prove to be clinically effective in clinical trials or commercially, or may not meet our desired target product profile, be offered at acceptable cost and with the sensitivity, specificity and other test performance metrics necessary to address the relevant clinical need or commercial opportunity, our test performance in commercial experience may be inconsistent with our validation or other clinical data, we may not be successful in achieving market awareness and demand, whether through our own sales and marketing operations or through collaborative arrangements, healthcare providers may not order or use, or third-party payors may not reimburse for, any tests that we may enhance or develop, or we may otherwise have to abandon a test or service in which we have invested substantial resources.

We cannot provide assurance that we can successfully complete the development of any new or enhanced product, or that we can establish or maintain the collaborative relationships that may be essential to our collaborators' goals, including clinical development or commercialization efforts. For example, the publication of clinical data in peer-reviewed journals is a crucial step in commercializing and obtaining reimbursement for certain diagnostic solutions such as the ones offered by us, and our inability to control when, if ever, results are published may delay or limit our ability to derive sufficient revenues from any diagnostic solution that is the subject of or component in a study. Peer-reviewed publications regarding our products may be limited by many factors, including delays in the completion of, poor design of, or lack of compelling data from, clinical studies, as well as delays in the review, acceptance and publication process. If our diagnostic solutions or the technology underlying our current and future diagnostic solutions do not receive sufficient favorable exposure in peer-reviewed publications, the rate of clinician adoption of our diagnostic solutions and positive reimbursement coverage determinations for our diagnostic solutions could be negatively affected.

These and other factors beyond our control could result in delays or other difficulties in the research and development, approval, production, launch, marketing or distribution of enhanced or new tests and could adversely affect our competitive position and results of operations.

We currently use, and in the future expect to increase our use of, information and rights from customers, strategic partners, and collaborators for several aspects of our operations, and if we cannot maintain current and enter new relationships with these parties with adequate access and authorization to such information, our business will suffer.

Accessing, combining, curating, and analyzing health information, including longitudinal patient medical history data and genetic data, are core features of our heath information platform. The regulatory landscape around the storage, processing and deidentification of genetic data is evolving globally and greatly impacts the ability of us, our strategic partners and collaborators to process and use the data in connection with our products and services.

We have limited resources to conduct our health information services, data analysis, life sciences research, clinical diagnostics and drug discovery operations and have not yet fully established infrastructure for sales, marketing or distribution in connection with our products and services. Our future success depends in part on our ability to maintain and grow our existing relationships and to establish new relationships. Many factors may impact the success of such collaborations, including our ability to perform our obligations, our collaborators' satisfaction with our products and services, our collaborators' performance of their obligations to us, our collaborators' internal priorities, resource allocation decisions and competitive opportunities, the ability to obtain regulatory approvals, disagreements with collaborators, the costs required of either party to the collaboration and related financing needs, and operating, legal and other risks in any relevant jurisdiction. Our ability to support such collaborations may also depend on factors outside of our control including the willingness of patients to engage with us and share their data, societal perspectives on privacy, and the willingness of health systems to establish collaborations, relationships and programs utilizing their data, all of which may impact the utility of these databases and the insights we will be able to generate from expanding datasets. In addition to reducing our revenue or delaying the development of our future products and services, the loss of one or more of these relationships may reduce our access to research, longitudinal patient health data, clinical trials or computing technologies that facilitate the collection and incorporation of new information into the databases we manage and to which we have access. All of the risks relating to product and service development, regulatory clearance, authorization or approval and commercialization described herein apply to us derivatively through the activities of our collaborators. We engage in conversations with companies regarding potential collaborations on an ongoing basis. These conversations may not result in a commercial agreement. Even if an agreement is reached, the resulting relationship may not be successful, and any products and services developed as part of the collaboration may not produce successful outcomes. Speculation in the industry about our existing or potential collaborations can be a catalyst for adverse speculation about us, or our products or services, which can adversely affect our reputation and our business.

If our products and services do not perform as expected, we may not realize the expected benefits of such products and services.

The success of our products depends on the market's confidence that we can provide reliable products and services that enable high quality diagnostic testing and health information services with high sensitivity and specificity and short turnaround times. There is no guarantee that the accuracy and reproducibility we have demonstrated to date will continue as our product deliveries increase and our product and service portfolio expands.

Our products and services use a number of complex and sophisticated biochemical and bioinformatics processes, many of which are highly sensitive to external factors. An operational, technological or other failure in one of these complex processes or fluctuations in external variables may result in sensitivity or specificity rates that are lower than we anticipate or result in longer than expected turnaround times. In addition, labs are required to validate their processes before using our products for clinical purposes. These validations are outside of our control. If our products do not perform, or are perceived to not have performed, as expected or favorably in it to competitive products, our operating results, reputation, and business will suffer, and we may also be subject to legal claims arising from product limitations, errors, or inaccuracies.

If our sales and development or other collaborations and commercial relationships are not successful and we are not able to offset the resulting impact through our own efforts or through agreements with new partners, our commercialization activities may be impaired, and our financial results could be adversely affected.

Part of our business strategy is to develop relationships with health systems, biopharma companies, and other partners to utilize our products and to provide access to data. Developing and commercializing products with third parties reduces our control over such development and commercialization efforts and subjects us to the various risks inherent in a joint effort with a third party, such as delays, operational issues, technical difficulties and other contingencies outside of our influence or control. The financial condition of these third parties could weaken, or they could terminate their relationship with us and/or stop sharing data or other information; reduce their marketing efforts relating to our products; develop and commercialize, or otherwise utilize competing products in addition to or in lieu of our tests; merge with or be acquired by a competitor of us or a company that chooses to de-prioritize the efforts to utilize our products or provide us with adequate data; or otherwise breach their agreements with us. Further, we must expend resources to operationalize our existing collaborations with our health system partners, which requires

substantial effort in areas such as integrations for testing workflow, electronic medical record, consents, marketing, and billing. To the extent we are not successful at operationalizing existing collaborations with health partners, we may not be able to further improve or pursue new agreements with additional partners. Furthermore, our partners may misappropriate our trade secrets or use our proprietary information in such a way as to expose us to litigation and potential liability, and our compliance risk may increase to the extent that we are responsible for our partners' activities. Disagreements or disputes with our health systems and other partners, including disagreements over customers, proprietary or other rights or our or their compliance with financial or other contractual obligations, might cause delays or impair the development or commercialization of our products, services, and technologies, lead to additional responsibilities for us with respect to new products, services and technologies, or result in litigation or arbitration, any of which would divert management attention and resources and be time-consuming and expensive.

If our relationships are not successful, our ability to develop and improve of products, services and technologies, and to successfully execute our commercial strategy regarding such products, services and technologies, could be compromised.

Our operating results could be subject to significant fluctuation, which could increase the volatility of our stock and warrant prices and cause losses to our stockholders.

Our operating results may fluctuate significantly, depending on a variety of factors, including the following:

- our success in marketing and selling, and changes in demand for, our tests, and the level of reimbursement and collection obtained for such tests;
- seasonal and environmental variations affecting healthcare provider recommendations for our tests and patient compliance with healthcare provider recommendations, including without limitation holidays, weather events, and circumstances such as the outbreak of coronavirus or influenza that may limit patient access to medical practices for diagnostic tests and preventive services;
- our success in collecting payments from third-party payors, patients and collaborative partners, variation in the timing of these payments and recognition of these payments as revenues;
- the pricing of our tests, including potential changes in CMS or other reimbursement rates;
- circumstances affecting our ability to provide our tests, including weather events, supply shortages, or regulatory or other circumstances that adversely affect our ability to manufacture our tests or process tests in our clinical laboratories;
- circumstances affecting our ability to provide health information and data science services to biopharma partners, including software or hardware failures, insufficient capacity, regulatory changes or other circumstances that adversely affect the ability of us to deliver these services;
- fluctuations in the amount and timing of our selling and marketing costs and our ability to manage costs and expenses and effectively implement our business;
- our research and development activities; and
- our ability to collect, use, and commercialize data in a changing regulatory environment at a time when the public is growing increasingly concerned about privacy.

Our revenue growth rate could decline over time, and it may experience downward pressure on our operating margins in the future.

Our revenue growth rate could decline over time as a result of a number of factors, including increasing competition and the continued expansion of our business into a variety of new fields. Changes in geographic mix and product and service mix and an increasing competition for tests may also affect our revenue growth rate. We may also experience a decline in our revenue growth rate as our revenues increase to higher levels, if there is a decrease in the rate of adoption of our products, services, and technologies, among other factors.

In addition to a decline in our revenue growth rate, we may also experience downward pressure on our gross operating margins resulting from a variety of factors, such as the continued expansion of our business into new fields, including new products and services, as well as significant investments in new areas, all of which may have margins lower than those that we generate from testing. We may also experience downward pressure on our gross operating margins from increasing competition and increased costs for many aspects of our business. We may also pay increased fees to our partners as well as increased acquisition costs. We may also face an increase in infrastructure costs, supporting other businesses. Additionally, our expenditures to promote new products and services or to distribute certain products and services or increased investment in our innovation efforts may affect our operating margins.

Due to these factors and the evolving nature of our business, our historical revenue growth rate and historical gross operating margins may not be indicative of our future performance.

Our ability to use our net operating loss carry forwards and certain other tax attributes may be limited.

As of December 31, 2024, our total gross deferred tax assets were approximately $318 million. Future realization of the tax benefits of existing temporary differences and carryforwards ultimately depends on the existence of sufficient taxable income within the carryforward period. As of December 31, 2024 and December 31, 2023, the Company performed an evaluation to determine whether a valuation allowance was needed. Based on the Company's analysis, which considered all available evidence, both positive and negative, the Company determined that it is more likely than not that a significant portion of its deferred tax assets will not be realized. Accordingly, the Company maintained a full valuation allowance as of December 31, 2024 and December 31, 2023.

Furthermore, under Section 382 of the Internal Revenue Code of 1986, as amended (the "Internal Revenue Code"), if a corporation undergoes an "ownership change," the corporation's ability to use its pre-change net operating loss carryforwards ("NOLs") and other pre-change tax attributes (such as research tax credits) to offset its future taxable income may be limited. In general, an "ownership change" occurs if there is a cumulative change in its ownership by "5% shareholders" that exceeds 50 percentage points over a rolling three-year period. Our existing NOLs and tax credit carryovers may be subject to limitations arising from previous ownership changes, and if we undergo one or more ownership changes in connection with completed acquisitions, including the Business Combination or the Acquisition, or future transactions in our stock, our ability to utilize NOLs and tax credit carryovers could be further limited by Section 382 of the Internal Revenue Code. As a result, if we earn future taxable income, our ability to use our pre-change net operating loss and tax credit carryforwards to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. In addition, the Tax Cuts and Jobs Act limits the deduction for NOLs to 80% of current year taxable income and eliminates NOL carrybacks. Further, there may also be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state liability.

Risks Related to Our Key Relationships

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

Our core business depends on our ability to quickly and reliably deliver test results to our customers. We typically receive blood and saliva samples for analysis at our laboratory facilities within days of collection from the patient. Disruptions and errors in these delivery service and accessioning errors and breaches, whether due to error by the delivery service, labor disruptions, bad weather, natural disaster, terrorist acts or threats, outbreaks of disease 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 operating results may be adversely affected.

Risks Related to Acquisitions and Other Strategic Transactions

We may seek to grow our business through additional acquisitions of complementary products or technologies and we may from time to time dispose of or discontinue businesses or assets, and the failure to manage these acquisitions or dispositions, or the failure to integrate acquired businesses with our existing business, could have a material adverse effect on our business, financial condition and operating results.

From time to time, we may consider additional opportunities to acquire other products or technologies that may enhance our product platform or technology, expand the breadth of our markets or customer base, or advance our business strategies. In addition, we exited both our reproductive and women's health testing business and our somatic tumor testing business, which involves the divestiture of these businesses, and we may consider disposing other assets or businesses in the future.

Potential acquisitions involve numerous risks, including:

- problems assimilating the acquired products or technologies;
- issues maintaining uniform standards, procedures, controls and policies;
- unanticipated costs associated with acquisitions;
- diversion of management's attention from our existing business;
- risks associated with entering new markets in which we have limited or no experience; and
- increased legal and accounting costs relating to the acquisitions or compliance with regulatory matters.

We do not know if we will be able to identify any other acquisitions we deem suitable, whether we will be able to successfully complete any acquisitions on favorable terms or at all, or whether we will be able to successfully integrate any acquired products

or technologies. Our potential inability to integrate any acquired products or technologies effectively may adversely affect our business, operating results and financial condition.

Dispositions may similarly involve risks associated with the potential disruption of our ongoing business and distraction of our management team, and the anticipated benefits and cost savings of these transactions may not be realized fully, or at all, or take longer to realize than anticipated. In addition, dispositions may involve our continued financial involvement in a divested business, such as through continuing equity ownership, transition service agreements, guarantees, indemnities or other current or contingent financial obligations. Under these arrangements, performance by the acquired or divested business, or other conditions outside our control, could affect our future financial results.

Risks Related to Legal, Regulatory and Compliance

We may be subject to increased compliance risks as a result of our rapid growth, including our dependence on our sales, marketing and billing efforts.

We have had to expand our training and compliance efforts in line with our increasing reliance on personnel in our sales, marketing and billing functions, and our expansion of these functions in line with the overall growth in our business. We continue to monitor our personnel, but we have in the past experienced, and may in the future experience, situations in which employees fail to strictly adhere to our policies. In addition, sales and marketing activities in the healthcare space are subject to various rules and regulations. Moreover, our billing and marketing messaging can be complex and nuanced, and there may be errors or misunderstandings in our employees communication of such messaging. Furthermore, we utilize text messaging, email, phone calls and other similar methods to communicate with patients who are existing or potential users of our products for various business purposes. These activities subject us to laws and regulations relating to communications with consumers, such as the CAN-SPAM Act and the Telephone Consumer Protection Act, violations of which could subject us to claims by consumers, who may seek actual or statutory damages, which could be material in the aggregate. As we continue to scale up our sales and marketing efforts in line with the growth in our business, in particular our increased pace of product launches as well as further geographical expansion, we face an increased need to continuously monitor and improve our policies, processes and procedures to maintain compliance with a growing number and variety of laws and regulations, including with respect to consumer marketing. To the extent that there is any violation, whether actual, perceived or alleged, of our policies or applicable laws and regulations, we may incur additional training and compliance costs, may receive inquiries from third-party payors or other third parties, or be held liable or otherwise responsible for such acts of non-compliance. Any of the foregoing could adversely affect our cash flow and financial condition.

If we use hazardous materials in a manner that causes injury, we could be liable for resulting damages.

Our activities currently require the use of hazardous chemicals and biological material. 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. Additionally, we are subject on an ongoing basis to federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. The cost of compliance with these laws and regulations may become significant, and our failure to comply may result in substantial fines or other consequences, and either could negatively affect our operating results.

Changes in FDA enforcement discretion for laboratory developed tests LDTs could subject our operations to much more significant regulatory requirements.

We currently offer an LDT version of certain tests. Historically, the FDA has exercised a policy of enforcement discretion with respect to most LDTs, whereby the FDA did not actively enforce its medical device regulatory requirements for such tests. However, at various points in recent years, FDA has indicated that it intends to end enforcement discretion for many tests offered as LDTs, and to require such tests to comply with certain FDA regulatory requirements. Agency officials have previously expressed significant concerns regarding performance disparities between some LDTs and in vitro diagnostics that have been reviewed, cleared, authorized or approved by the FDA.

Most recently, on April 29, 2024, the FDA published a final rule on LDTs, in which FDA outlines its plans to end enforcement discretion for many LDTs in five stages over a four-year period. In Phase 1 (effective May 6, 2025), clinical laboratories would be required to comply with medical device (adverse event) reporting, correction/removal reporting, and certain quality systems complaint handling requirements. In Phase 2 (effective May 6, 2026), clinical laboratories would be required to comply with all other device requirements (e.g., registration/listing, labeling, investigational use), except for remaining quality systems requirements and premarket review. In Phase 3 (effective May 6, 2027), clinical laboratories would be required to comply with all remaining applicable quality systems requirements. In Phase 4 (effective November 6, 2027), clinical laboratories would be

required to comply with premarket submission requirements for high-risk tests (i.e., tests subject to premarket approval (PMA) requirement). Finally, in Phase 5 (effective May 6, 2028), clinical laboratories would be required to comply with premarket submission requirements for moderate- and low-risk tests (i.e., tests subject to de novo or 510(k) requirement). The final rule potentially extends enforcement discretion for certain tests – e.g., LDTs approved by the New York State Department of Health, and LDTs first marketed prior to May 6, 2024 which are not modified or are modified in certain limited ways – from certain FDA regulatory requirements, provided certain important limitations have been met. We are actively reviewing the final rule to evaluate its applicability to our operations, and the extent to which we may be required to modify our operations to comply with its requirements.

Multiple lawsuits have been filed challenging the FDA's authority to regulate LDTs as medical devices under the Federal Food, Drug, and Cosmetic Act. The outcome of these lawsuits is uncertain at this time.

If the FDA were to determine that certain tests offered by us as LDTs are no longer eligible for enforcement discretion for any reason, including new rules, policies or guidance, or due to changes in statute, our tests may become subject to extensive FDA requirements or our business may otherwise be adversely affected. If the FDA were to actively regulate our LDTs, we could experience reduced revenue or increased costs, which could adversely affect our business, prospects, results of operations and financial condition. If required, the regulatory marketing authorization process required to bring our current or future LDTs into compliance may involve, among other things, successfully completing additional clinical validations and submitting to and obtaining clearance from the FDA for a premarket clearance (510(k)) submission or authorization for a de novo submission or approval of a premarket approval application. Furthermore, pending legislative proposals, if enacted, such as the VALID Act, could create new or different regulatory and compliance burdens on us and could have a negative effect on our ability to keep products on the market or develop new products, which could have a material effect on our business. In the event that the FDA requires marketing authorization of our LDTs in the future, the FDA may not ultimately grant any clearance, authorization or approval requested by us in a timely manner, may limit our indication in a way that is not commercially desirable, or refuse to provide such authorization at all. In addition, if the FDA inspects our laboratory in relation to the marketing of any FDA-authorized test, any enforcement action the FDA takes might not be limited to the FDA-authorized test carried by us and could encompass our other testing services.

Our business is subject to various complex laws and regulations applicable to clinical diagnostics. We could be subject to significant fines and penalties if we or our partners fail to comply with these laws and regulations.

As a provider of clinical diagnostic products and services, we and our partners are subject to extensive and frequently changing federal, state, local and foreign laws and regulations governing various aspects of our business.

In particular, the clinical laboratory and healthcare industry is subject to significant governmental certification and licensing regulations, as well as federal, state and foreign laws regarding:

- test ordering and billing practices;
- marketing, sales and pricing practices;
- health information privacy and security, including HIPAA and comparable state laws;
- insurance;
- anti-markup legislation;
- fraud and abuse; and
- consumer protection.

We are also required to comply with applicable FDA regulations, including with respect to our labeling and promotion activities. In addition, advertising and marketing of our clinical products are subject to regulation by the Federal Trade Commission (the "FTC"), and advertising of laboratory services is regulated by certain state laws. Violation of any FDA requirement could result in enforcement actions, such as seizures, injunctions, civil penalties and criminal prosecutions, and violation of any FTC or state law requirement could result in injunctions and other remedies, all of which could have a material adverse effect on our business. Most states also have similar regulatory and enforcement authority for devices. Additionally, most foreign countries have authorities comparable to the FDA and processes for obtaining marketing approvals. Obtaining and maintaining these approvals, and complying with all laws and regulations, may subject us to similar risks and delays as those we could experience under FDA, FTC and state regulation. We incur various costs in complying and overseeing compliance with these laws and regulations. The growth of our business and sales organization, the acquisition of additional businesses or products and services and our expansion outside of the U.S. may increase the potential of violating these laws, regulations or our internal policies and procedures.

Healthcare policy has been a subject of extensive discussion in the executive and legislative branches of the federal and many state governments, and healthcare laws and regulations are subject to change. Development of the existing commercialization strategy for our tests and planned development of products in our pipeline has been based on existing healthcare policies. We

cannot predict what additional changes, if any, will be proposed or adopted or the effect that such proposals or adoption may have on our business, financial condition and results of operations.

If we or our partners, fail to comply with these laws and regulations, it could incur significant fines and penalties and our reputation and prospects could suffer. Additionally, any such partners could be forced to cease offering our products and services in certain jurisdictions, which could materially disrupt our business. An adverse outcome could include us being required to pay treble damages, incur civil and criminal penalties, paying attorneys' fees, entering into a corporate integrity agreement, being excluded from participation in government healthcare programs, including Medicare and Medicaid, and other adverse actions that could materially and adversely affect our business, financial condition and results of operations.

Compliance with the HIPAA security, privacy and breach notification regulations may increase our costs.

The HIPAA privacy, security and breach notification regulations, which include requirements implemented under the HITECH Act, establish federal standards with respect to the uses and disclosures of protected health information ("PHI"), by health plans, healthcare providers and healthcare clearinghouses. The HIPAA regulations generally prohibit the use and disclosure of PHI without patient authorization, unless the use or disclosure is for payment, treatment or healthcare operations purposes. In setting standards to protect the confidentiality, integrity and security of PHI, the regulations establish a regulatory framework that addresses a variety of subjects, including:

- the circumstances under which uses and disclosures of PHI are permitted or required without a written authorization from the patient, including but not limited to treatment purposes, activities to obtain payments for our services, and our healthcare operations activities;
- a patient's rights to access, amend and receive an accounting of certain disclosures of PHI;
- requirements to notify individuals if there is a breach of their PHI;
- the contents of notices of privacy practices related to the use and disclosure of PHI;
- administrative, technical and physical safeguards required of entities that use or receive PHI;
- criteria related to the deidentification and aggregation of PHI; and
- the use and protection of electronic PHI.

We are also required to comply with applicable state privacy, security and breach notification laws and regulations, which may be more stringent than federal HIPAA requirements. In addition, for healthcare data transfers from other countries relating to citizens and/or residents of those countries, we are also required to comply with the laws of those countries. Furthermore, on December 1, 2022, the U.S. Department of Health and Human Services, Office for Civil Rights ("OCR") issued a Bulletin highlighting the obligations of HIPAA covered entities and business associates with respect to the use of online tracking technologies. OCR updated this Bulletin on March 18, 2024. To the extent that a covered entity or business associate permits a tracking technology vendor to collect PHI of its customers, the parties must enter into a business associate agreement. In addition, the PHI collected may only be used for treatment or health care operation purposes, in accordance with HIPAA. The PHI cannot be used for marketing purposes that are not connected with treatment or health care operations absent a HIPAA compliant authorization from each customer whose information is being shared.

Although HIPAA does not provide for private rights of action, HIPAA gives OCR and the Department of Justice the authority to assess significant fines and other penalties for wrongful use or disclosure of PHI, including potential civil and criminal fines and penalties. OCR may require an entity to enter into a settlement agreement which may include ongoing oversight and auditing of a company's HIPAA compliance program.

In addition, computer networks are always vulnerable to breach and unauthorized persons may in the future be able to exploit weaknesses in the security systems of our computer networks and gain access to PHI. Additionally, we share PHI with third-parties who are legally obligated to safeguard and maintain the confidentiality of PHI. Despite such protections, unauthorized persons may also be able to gain access to PHI stored in such third parties' computer networks. Any wrongful use or disclosure of PHI by us or such third-parties, including disclosure due to data theft or unauthorized access to us or such third-parties' computer networks, could subject us to fines or penalties that could adversely affect our business and results of operations. In addition, we distribute PHI to patients in physical form (e.g., test materials and/or test results), which introduces additional risk that human error will result in unauthorized disclosures of PHI. Although HIPAA does not expressly provide for a private right of action for damages, we could also be liable for damages under state privacy laws to private parties for the wrongful use or disclosure of confidential health information or other private personal information.

We have implemented practices intended to meet the requirements of the HIPAA privacy, security and breach notification regulations, as required by law, but cannot guarantee that such practices fully satisfy all applicable requirements under HIPAA. In addition, the Company has experienced a number of "security incidents" (as defined under HIPAA) that involved the unauthorized disclosure of PHI. A subset of these incidents was determined to be reportable breaches requiring disclosure to

OCR, as well as to the affected patients. Moreover, we cannot confirm that we have identified all previous incidents that could constitute reportable breaches, or that the mitigation steps undertaken in response to known breaches are adequate to satisfy applicable regulatory requirements and prevent any future unauthorized disclosures.

As noted above, in addition to HIPAA, we are subject to myriad federal, state, and local requirements pertaining to the collection, retention, and disclosure of genetic material. While we endeavor to remain current with such requirements, we can provide no assurance that we are, or will remain, in compliance with all applicable requirements. Failure to comply with privacy and data security requirements could result in a variety of consequences, including significant fines and penalties as well as damage to our reputation, any of which could have a material adverse effect on our business.

Some of our activities may subject the Company to risks under federal and state laws prohibiting 'kickbacks' and false or fraudulent claims.

In addition to FDA marketing and promotion restrictions, several other types of state and federal healthcare fraud and abuse laws have been applied in recent years to restrict certain marketing practices in the healthcare product and service industry and to regulate billing practices and financial relationships with healthcare providers, hospitals and other healthcare providers. These laws include, among others, a federal law commonly known as the federal Anti-Kickback Statute, the federal False Claims Act, the federal physician self-referral law, known as the Stark Law, and corollary state laws. These laws constrain, among other things, the sales, marketing and other promotional activities of manufacturers of medical devices and providers of laboratory services by limiting the kinds of financial arrangements, including sales programs, free goods and services, consulting arrangements, speaker programs, compensated service arrangements (including specimen collection and processing), and other non-monetary compensation (e.g., meals, gifts and other business courtesies), that may be used with hospitals, healthcare providers, laboratories and other potential purchasers or prescribers of medical devices and laboratory services. The federal and state fraud and abuse laws prescribe civil and, in some cases, criminal penalties (including fines) for noncompliance that can be substantial. In addition, various states have enacted false claim laws analogous to the federal laws that apply where a claim is submitted to any third-party payor and not only a governmental payor program. Moreover, any claim for reimbursement that is predicated on a violation of the Anti-Kickback Statute may constitute a "false claim" under the False Claims Act (discussed in further detail below).

In 2018, Congress passed the Eliminating Kickbacks in Recovery Act ("EKRA"), as part of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act. Similar to the Anti-Kickback Statute, EKRA imposes criminal penalties for knowing or willful payment or offer, or solicitation or receipt, of any remuneration, whether directly or indirectly, overtly or covertly, in cash or in kind, in exchange for the referral or inducement of laboratory testing (among other healthcare services) unless a specific exception applies. However, unlike the Anti-Kickback Statute, EKRA is not limited to services covered by federal or state healthcare programs but applies more broadly to services covered by "healthcare benefit programs," including commercial insurers. As currently drafted, EKRA potentially expands the universe of arrangements that could be subject to government enforcement under federal fraud and abuse laws. In addition, while the Anti-Kickback Statute, includes certain exceptions that are widely relied upon in the healthcare industry, including safe harbors applicable to certain employees and personal service contracts, and not all of those same exceptions apply under EKRA. EKRA expressly does not protect employee compensation that varies by the number of individuals referred to a laboratory, the number of tests performed by a laboratory, or the amount billed to or received from a health benefit program from individuals referred to a laboratory. Because EKRA is a relatively new law, there is no agency guidance and only two courts have addressed the application of EKRA and those courts reached opposite conclusions. One Court ruled that the commission-based compensation provisions of a laboratory employee's contract did not violate EKRA while the other court expressly disagreed. Given the conflicting opinions, we cannot be assured that courts in our jurisdiction will reach the same conclusion or that the decision will not be overturned if there is an appeal. We cannot assure you that our relationships with healthcare providers, hospitals, customers, our own sales representatives, or any other party will not be subject to scrutiny or will survive regulatory challenge under EKRA or other anti-kickback laws.

The False Claims Act prohibits, among other things, knowingly presenting (or causing the presentation of) a false claim for payment to the federal government. Violation of the False Claims Act can result in substantial penalties, including treble damages. Moreover, the False Claims Act permits enforcement by qui tam relators (i.e., whistleblowers), such as competitors, customers, or current/former employees, who will receive a portion of any settlement. As discussed above, violations of the Anti-Kickback statute can serve as the basis for enforcement under the False Claims Act. In addition, inaccurate or otherwise improper claims for reimbursement could constitute a false claim, meaning that we or our partners must carefully and accurately code claims for reimbursement, proactively monitor the accuracy and appropriateness of claims and payments received, diligently investigate any credible information indicating that we or our partners may have received an overpayment, and promptly return any overpayments. Medicare payments are subject to audit, including through the Comprehensive Error Rate Testing ("CERT"),

program, and payments may be recouped by CMS if it is determined that they were improperly made. Currently, a small percentage of our revenues are generated by payments from Medicare.

While we continually strive to comply with these complex requirements, interpretations of the applicability of these laws to marketing and billing practices are constantly evolving and even an unsuccessful challenge could cause adverse publicity and be costly to respond to, and thus could harm our business and prospects. In addition, while we have and will continue to enter into certain financial arrangements with referral sources, and we endeavor to ensure that such arrangements are designed to comply with applicable rules, laws and regulations, we can offer no assurance that such arrangements will not result in regulatory or enforcement scrutiny. Our failure to comply with applicable laws could result in various adverse consequences that could have a material adverse effect upon our business, including the exclusion of our products and services from government programs and the imposition of civil or criminal sanctions.

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, our implementing regulations or other state, federal and foreign laws and regulations affecting licensure or certification, or by future changes in these laws or regulations.

Federal law requires virtually all clinical laboratories to comply with CLIA, which generally involves becoming certified by the federal and state government for the testing that will be performed and complying with various operational, personnel, facilities administration, quality and proficiency testing requirements intended to ensure that testing services are accurate and reliable. CLIA certification is also a prerequisite to be eligible to bill state and federal healthcare programs, as well as many private third-party payors, for clinical diagnostic testing services. For example, as a condition of our CLIA certification, a laboratory may be subject to survey and inspection every other year, additional random inspections and surprise inspections based on complaints received by state or federal regulators. The biennial survey and inspection is conducted by CMS, a CMS agent or, if the laboratory holds a CLIA certificate of accreditation, a CMS-approved accreditation organization, such as CAP. Sanctions for failure to comply with CLIA requirements, including proficiency testing violations, may include suspension, revocation or limitation of a laboratory's CLIA certificate, which is necessary to conduct business, as well as the imposition of significant civil, administrative or criminal sanctions against the lab, its owners and other individuals. In addition, we are subject to regulation under certain state laws and regulations governing laboratory licensure. Some states have enacted laboratory licensure and compliance laws that are more stringent than CLIA. Changes in state licensure laws that affect our ability to offer and provide research and diagnostic products and 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.

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.

We may never obtain approval in the EU or in any other foreign country for any of our products or services and, even if we do, we or our partners and collaborators may never be able to commercialize them in another jurisdiction, which would limit our ability to realize their full market potential.

In order to eventually market any of our current or future products and services in any particular foreign jurisdiction, we must establish compliance with numerous and varying regulatory requirements on a jurisdiction-by-jurisdiction basis regarding quality, safety, performance, privacy and efficacy. In addition, clinical trials or clinical investigations conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory clearance, authorization or approval in one country does not guarantee regulatory clearance, authorization or approval in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods.

Seeking foreign regulatory clearance, authorization or approval could result in difficulties and costs for us and our collaborators and require additional preclinical studies, clinical trials or clinical investigations which could be costly and time-consuming. Regulatory requirements and ethical approval obligations can vary widely from country to country and could delay or prevent the introduction of our products and services in those countries. The foreign regulatory clearance, authorization or approval process involves all of the risks and uncertainties associated with FDA clearance, authorization or approval. We currently have limited experience in obtaining regulatory clearance, authorization or approval in international markets. If we or our collaborators fail to comply with regulatory requirements in international markets or to obtain and maintain required regulatory clearances, authorizations or approvals in international markets, or if those approvals are delayed, our target market will be reduced and our ability to realize the full market potential of our products and services will be unrealized.

Complying with numerous statutes and regulations pertaining to our business is an expensive and time-consuming process, and any failure to comply could result in substantial penalties.

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 currently include, among others:

- HIPAA, which establishes comprehensive federal standards with respect to the privacy and security of protected health information and requirements for the use of certain standardized electronic transactions;
- amendments to HIPAA under HITECH, which strengthen and expand HIPAA privacy and security compliance requirements, increase penalties for violators and expand vicarious liability, extend enforcement authority to state attorneys general, and impose requirements for breach notification;
- the General Data Protection Regulation ("GDPR") and UK Data Protection Act 2018 ("UK GDPR"), which imposes strict privacy and security requirements on controllers and processors of European and UK personal data, including enhanced protections for "special categories" of personal data, including sensitive information such as health and genetic information of data subjects;
- the CCPA , and similar consumer privacy laws in Colorado, Connecticut, Utah, and Virginia, which, among other things, regulate how subject businesses may collect, use, disclose and/or sell the personal information of consumers who reside in each state, affords rights to consumers that they may exercise against businesses that collect their information, and requires implementation of reasonable security measures to safeguard personal information of consumers;
- laws governing genetic counseling services, relating to, among other things, the adequacy of health care, the practice of medicine and other health professions (including the provision of remote care and cross-coverage practice), equipment, personnel, operating policies and procedures and the prerequisites for ordering laboratory tests. Some states have enacted regulations specific to providing services to patients via telehealth. Such regulations include, among other things, informed consent requirements that some states require providers to obtain from their patients before providing telehealth services. Health professionals who provide professional services using telehealth modalities must, in most instances, hold a valid license to practice the applicable health profession in the state in which the patient is located. In addition, certain states require a healthcare professional providing telehealth to be physically located in the same state as the patient. Any failure to comply with these laws and regulations could result in civil or criminal penalties against telehealth providers;
- clinical and human subjects research regulations, including but not limited to the federal Policy for Protection of Human Subjects (45 C.F.R. Part 46), the FDCA and its applicable implementing regulations at 21 C.F.R. Parts 11, 50, 54, 56, 58 and 812, and all equivalent legal requirements in other jurisdictions;
- the federal Anti-Kickback Statute, which prohibits knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for the referral of an individual, for the furnishing of or arrangement for the furnishing of any item or service for which payment may be made in whole or in part by a federal healthcare program, or the purchasing, leasing, ordering, arranging for, or recommend purchasing, leasing or ordering, any good, item or service for which payment may be made, in whole or in part, under a federal healthcare program;
- EKRA, which prohibits payments for referrals to recovery homes, clinical treatment facilities, and laboratories and reaches beyond federal health care programs, to include private insurance;
- the federal physician self-referral law, known as the Stark Law, which prohibits a physician from making a referral to an entity for certain designated health services covered by the Medicare program, including laboratory and pathology services, if the physician or an immediate family member has a financial relationship with the entity unless an exception applies, and prohibits an entity from billing for designated health services furnished pursuant to a prohibited referral;
- the federal False Claims Act, which imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment to the federal government;
- 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;
- the HIPAA fraud and abuse provisions, which create new federal criminal statutes that prohibit, among other things, defrauding health care benefit programs, willfully obstructing a criminal investigation of a healthcare offense and falsifying or concealing a material fact or making any materially false statements in connection with the payment for healthcare benefits, items or services;
- other federal and state fraud and abuse laws, such as anti-kickback laws, prohibitions on self-referral, fee-splitting restrictions, insurance fraud laws, anti-markup laws, prohibitions on the provision of tests at no or discounted cost to induce physician or patient adoption, and false claims acts, which may extend to services reimbursable by any third-party payor, including private insurers;
- the 21st Century Cures Act information blocking prohibition, which prohibits covered actors from engaging in certain practices that are likely to interfere with the access, exchange, or use of electronic health information;

- the Physician Payments Sunshine Act and similar state laws that require reporting of certain payments and other transfers of value made by applicable manufacturers, directly or indirectly, to or on behalf of covered recipients including physicians (defined to include doctors of medicine, osteopathy, dentists, optometrists, podiatrists and chiropractors), physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, anesthesiologist assistants, certified nurse midwives and teaching hospitals as well as ownership and investment interests held by physicians and their immediate family members;
- state laws that limit or prohibit the provision of certain payments and other transfers of value to certain covered healthcare providers;
- the prohibition on reassignment of Medicare claims, which, subject to certain exceptions, precludes the reassignment of Medicare claims to any other party;
- state laws that prohibit other specified practices, such as billing clinicians for testing that they order; waiving coinsurance, copayments, deductibles and other amounts owed by patients; billing a state Medicaid program at a price that is higher than what is charged to one or more other payors;
- similar foreign laws and regulations that may apply to us in the countries in which we operate or may operate in the future; and
- laws that relate to maintaining accurate information and control over activities that may fall within the purview of the U.S. Foreign Corrupt Practices Act, its books and records provisions, or anti-bribery provisions.

We have adopted policies and procedures designed to comply with these laws and regulations. While the Company continues to develop and improve its compliance program, we acknowledge that further development will be necessary to help mitigate enforcement risk. Our compliance may also be subject to governmental review and, in the event of a violation of certain legal requirements, any deficiencies in our policies, procedures, and controls may subject us to increased sanctions that could materially affect our business.

Furthermore, the U.S. Supreme Court recently reversed its longstanding approach under the Chevron doctrine, which provided for judicial deference to regulatory agencies. As a result of this decision, we cannot be sure whether there will be increased challenges to existing agency regulations or how lower courts will apply the decision in the context of other regulatory schemes without more specific guidance from the U.S. Supreme Court. For example, the U.S. Supreme Court's decision could significantly impact healthcare, privacy, AI and anti-corruption practices and other regulatory regimes with which we are required to comply. Any such regulatory developments could result in uncertainty about and changes in the ways such regulations apply to us, and may require additional resources to ensure our continued compliance.

In addition, the growth of our business and our expansion outside of the U.S. may increase the potential of violating these laws or our internal policies and procedures. The risk of us being found in violation of these or other laws and regulations is further increased by the fact that many have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. 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. If our operations are found to be in violation of any of these laws and regulations, we may be subject to any applicable penalty associated with the violation, including significant administrative, civil and criminal penalties, damages, fines, imprisonment, exclusion from participation in Federal healthcare programs, refunding of payments received by us and curtailment or cessation of our operations, which may impact existing contracts with key payors, collaborators, health systems, and commercial partners. Any of the foregoing consequences could seriously harm our business and our financial results.

We face uncertainty related to healthcare reform, pricing, coverage and reimbursement, which could reduce our revenue.

Healthcare reform laws, including the Patient Protection and Affordable Care Act ("ACA,") and the Protecting Access to Medicare Act of 2014 ("PAMA,") are significantly affecting the U.S. healthcare and medical services industry. Existing legislation, and possible future legal and regulatory changes, including potential repeal or modification of the ACA, elimination of penalties regarding the individual mandate for coverage, or approval of health plans that allow lower levels of coverage for preventive services, could materially change the structure and finances of the health insurance system and the methodology for reimbursing medical services, drugs and devices, including our current and future products and services. The ACA has also been the subject of various legal challenges, and if the plaintiffs in any case challenging the ACA are ultimately successful, insurance coverage for our tests could be materially and adversely affected. Any change in reimbursement policy could result in a change in patient cost-sharing, which could adversely affect a provider's willingness to prescribe and patient's willingness and ability to use our tests and any other product or service we may develop. Healthcare reforms, which may intend to reduce healthcare costs, may have the effect of discouraging third-party payors from covering certain kinds of medical products and services, particularly newly developed technologies, or other products or tests we may develop in the future. We cannot predict whether future healthcare reform initiatives will be implemented at the federal or state level or the effect any such future legislation or regulation will have on it. The taxes imposed by new legislation, cost reduction measures and the expansion in the government's role in the

U.S. healthcare industry may result in decreased profits to us, which may adversely affect our business, financial condition and results of operations.

PAMA presents significant uncertainty for future CMS reimbursement rates for our tests. Because Medicare currently covers a significant number of patients, any reduction in the CMS reimbursement rate for our tests would negatively affect our revenues and our business prospects. Under PAMA, unless delayed by an act of Congress, CMS reimbursement rates for clinical diagnostic laboratory tests are updated every three years, or annually for clinical laboratory tests that are considered "advanced diagnostic laboratory tests". The CMS reimbursement rates for clinical diagnostic laboratory tests are updated based on the volume-weighted median of private payor rates for each clinical diagnostic laboratory test based on data submitted by certain applicable laboratories. Further, laboratories that fail to report or erroneously report required payment information may be subject to substantial civil money penalties. There can be no assurance under PAMA that adequate CMS reimbursement rates will continue to be assigned to our tests. Congress could modify or repeal PAMA in the future or CMS could modify regulations under PAMA, and any such action could have the effect of reducing the CMS reimbursement rate for our tests. Further, it is possible that Medicare or other federal payors that provide reimbursement for our tests may suspend, revoke or discontinue coverage at any time, may require co-payments from patients, or may reduce the reimbursement rates payable to us. Any such action could have a negative impact on our revenues.

Product and professional liability suits against us could result in expensive and time-consuming litigation, payment of substantial damages and increases in our insurance rates.

The sale and use of our solutions, products and services could lead to product or professional liability claims, including class action lawsuits. We may also be subject to liability for errors in the test results including health information it provides to healthcare providers or patients or for a misunderstanding of, or inappropriate reliance upon, the information it provides. Claims could also arise out of clinical studies we may conduct or any of our other activities. A product or professional liability claim could result in substantial damages, be costly and time consuming to defend, and cause material harm to our business, reputation or financial condition. We cannot assure you that our liability insurance would protect our assets from the financial impact of defending a product or professional liability claim. Any claim brought against us, with or without merit, could increase our liability insurance rates or prevent it from securing insurance coverage in the future.

Errors, defects, or mistakes in our products or services, and operations could harm our reputation, decrease market acceptance of our products or services.

We are creating new products and services, many of which are initially based on largely untested technologies. As all of our products and services progress, we or others may determine that it made product or service-level scientific or technological mistakes. The diagnostic and testing processes utilize a number of complex and sophisticated molecular, biochemical, informatics, and mechanical processes, many of which are highly sensitive to external factors. An operational or technological failure in one of these complex processes or fluctuations in external factors may result in less efficient processing or variation between testing runs. Refinements to our processes may initially result in unanticipated issues that reduce the efficiency or increase variability. In particular, sequencing, which is a key component of these processes, could be inefficient with higher-than-expected variability thereby increasing total sequencing costs and reducing the number of samples we can process in a given time period. Therefore, inefficient or variable processes can cause variability in our operating results and damage our reputation.

In addition, our laboratory operations could result in any number of errors or defects. Our quality assurance system may fail to prevent it from inadvertent problems with samples, sample quality, lab processes including sequencing, software, data upload or analysis, raw materials, reagent manufacturing, assay quality or design, or other components or processes. In addition, our assays may have quality or design errors, and we may have inadequate procedures or instrumentation to process samples, assemble our proprietary primer mixes and commercial materials, upload and analyze data, or otherwise conduct our laboratory operations. If we provide products or services with undiscovered errors to our customers, our clinical diagnostics may falsely indicate a patient has a disease or genetic variant, fail to assess a patient's risk of getting a disease or having a child with a disease, or fail to detect disease or variant in a patient who requires or could benefit from treatment or intervention. We believe our customers are likely to be particularly sensitive to product and service defects, errors and delays, including if our products and services fail to indicate the presence of residual disease with high accuracy from clinical specimens or if we fail to list or inaccurately indicate the presence or absence of disease in our test report or analysis. In drug discovery, such errors may interfere with our collaborators' clinical studies or result in adverse safety or efficacy profiles for their products in development. This may harm our customers' businesses and may cause it to incur significant costs, divert the attention of key personnel, encourage regulatory enforcement action against it, create a significant customer relations problem for us and cause our reputation to suffer. We may also be subject to warranty and liability claims for damages related to errors or defects in our products or services. Any of these developments could harm our business and operating results.

We are subject to increasingly complex taxation rules and practices, which may affect how we conduct our business and our results of operations.

As our business grows, we are required to comply with increasingly complex taxation rules and practices. We are subject to tax in multiple U.S. tax jurisdictions and may be subject to foreign tax jurisdictions in the future. The development of our tax strategies requires additional expertise and may impact how we conduct our business. Our future effective tax rates could be unfavorably affected by changes in, or interpretations of, tax rules and regulations in the jurisdictions in which we do business or by changes in the valuation of our deferred tax assets and liabilities. Furthermore, we provide for certain tax liabilities that involve significant judgment. We are and may be subject to the examination of our tax returns by federal, state and foreign tax authorities. If our tax strategies are ineffective or it is not in compliance with domestic and international tax laws, as applicable, our financial position, operating results and cash flows could be adversely affected.

Risks Related to Our Intellectual Property

Our inability to effectively protect our proprietary products, processes, and technologies, could harm our competitive position.

We currently rely upon trade secret protection and copyright, as well as non-disclosure agreements and confidentiality and intellectual property ownership provisions in agreements with our consultants, collaborators, vendors and other third parties, confidentiality and proprietary rights agreements, including invention assignment provisions, with our employees, and, to a limited extent, patent protection, to protect our confidential and proprietary information. As our competitors have utilized and are expected to continue utilizing similar methods and have aggregated and are expected to continue to aggregate similar databases of genetic testing information, our success will depend upon our ability to develop proprietary methods and databases and to defend any advantages afforded by our methods and databases relative to our competitors. If we do not protect our intellectual property adequately, competitors may be able to use our methods and databases and thereby erode any competitive advantages we may have.

We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies are covered by valid and enforceable patents or are effectively maintained as trade secrets. In this regard, we have applied, and we intend to continue applying, for patents covering such aspects of our technologies as we deem appropriate. However, we expect that potential patent coverage we may obtain will not be sufficient to prevent substantial competition. In this regard, we believe it is probable that others will independently develop similar or alternative technologies or design around those technologies for which we may obtain patent protection. In addition, any patent applications we file may be rejected during examination and may not result in issued patents, or may be invalidated or narrowed in scope after they are issued. Questions as to inventorship or ownership may also arise. Any finding that our patents or applications are unenforceable could harm our ability to prevent others from practicing the related technology, and a finding that others have 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, if at all. It would be expensive, if we initiate lawsuits to protect or enforce our patents or trade secrets, or defend against third-party IP claims, and if we lose, we may lose some of our intellectual property rights. Furthermore, these lawsuits may divert the attention of our management and technical personnel.

We expect to continue relying substantially upon trade secrets and proprietary know-how protection for our confidential and proprietary information, and we have taken security measures to maintain such protection for this information. These measures, however, may not provide adequate protection for our trade secrets, know-how or other confidential information. Among other things, we seek to protect our trade secrets and confidential information by entering into confidentiality agreements with employees and consultants. There can be no assurance that any confidentiality agreements that we have with our employees and consultants will provide meaningful protection for our trade secrets and confidential information or will provide adequate remedies in the event of unauthorized use or disclosure of such information. Accordingly, there also can be no assurance that our trade secrets will not become known. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our competitive position could be harmed.

Any inability to effectively protect our proprietary technologies under certain jurisdictions and legal regimes could harm our competitive position.

Our success and ability to compete in certain jurisdictions and under certain legal regimes 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 U.S. and other countries; this becomes increasingly important as we expand our operations and enter into strategic collaborations with partners to develop and commercialize products outside of the U.S. The laws of some foreign countries do not protect proprietary

rights to the same extent as the laws of the U.S., and we may encounter difficulties in establishing and enforcing its proprietary rights in some jurisdictions. In addition, the proprietary positions of companies developing and commercializing tools for molecular diagnostics, including our own, 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 issues arising under patents and patent applications owned or controlled by our collaborators and licensors.

Any of these factors could adversely affect our ability to obtain commercially relevant or competitively advantageous patent protection for our products.

If patent regulations or standards are modified, such changes could have a negative impact on our business.

From time to time, the U.S. Supreme Court, other federal courts, the U.S. Congress or the U.S. Patent & Trademark Office ("USPTO") may change the standards of patentability and validity of patents within the screening and diagnostics space, and any such changes could have a negative impact on our business.

There have been several cases involving "gene patents" and diagnostic claims that have been considered by the U.S. Supreme Court. In March 2012, the Supreme Court *in Mayo Collaborative Services v. Prometheus Laboratories, Inc,* found a patented diagnostic method claim unpatentable because the relationship between a metabolite concentration and optimized dosage was a patent-ineligible "law of nature." In June 2013, the Supreme Court ruled in *ACLU v. Myriad Genetics, Inc,* that an isolated genomic DNA sequence is not patent eligible, but complementary DNA, or "cDNA," is eligible. The *Prometheus and Myriad* decisions, as well as subsequent case law, affect the legal concept of subject matter eligibility by seemingly narrowing the scope of the statute defining patentable inventions.

In December 2014 and again in 2019, the USPTO published revised guidelines for patent examiners to apply when examining process claims for patent eligibility in view of several recent Supreme Court decisions, including *Mayo, Association for Molecular Pathology v. Myriad Genetics, Inc.*, and *Alice Corporation Pty. Ltd. v. CLS Bank International*, and others. The guidance indicates that claims directed to a law of nature, a natural phenomenon, or an abstract idea that do not meet the eligibility requirements should be rejected as non-statutory, patent ineligible subject matter. While these guidelines may be subject to review and modification by the USPTO over time, we cannot assure you that our intellectual property strategy or patent portfolio will not be negatively impacted by the decisions described above, rulings in other cases or changes in guidance or procedures issued by the USPTO.

Additional substantive changes to patent law, whether new or associated with the America Invents Act which substantially revised the U.S. patent system, may affect our ability to obtain, enforce or defend our patents. Accordingly, it is not clear what, if any, impact these substantive changes will ultimately have on the cost of prosecuting our patent applications, our ability to obtain patents based on our discoveries and our ability to enforce or defend our issued patents, all of which could have a material adverse effect on our business.

If we are not able to adequately protect our trade secrets and other proprietary information, including the databases we manage and to which we have access, the value of our technology and products could be significantly diminished.

We rely on trade secret and proprietary know-how protection for our confidential and proprietary information and have taken security measures to protect this information. These measures, however, may not provide adequate protection. For example, we have a policy of requiring our consultants, advisors and collaborators, including, for example, our strategic collaborators with whom we seek to develop and commercialize products, to enter into non-disclosure agreements and our employees to enter into confidentiality and proprietary rights and, in certain cases non-compete agreements. However, breaches of our physical or electronic security systems, or breaches caused by our employees who failing to abide by their confidentiality obligations during or upon termination of their employment with us, could compromise these protection efforts. Any action we take to enforce our rights may be time-consuming, expensive, and possibly unsuccessful. Even if successful, the resulting remedy may not adequately compensate us for the harm caused by the breach. These risks are heightened in countries where laws or law enforcement practices may not protect proprietary rights as fully as in the U.S. or Europe. Any unauthorized use or disclosure of, or access to, our trade secrets, know-how or other proprietary information, whether accidentally or through willful misconduct, could have a material adverse effect on our programs and our strategy, and on our ability to compete effectively.

If our trademarks and trade names are not adequately protected, we may not be able to build name recognition in our markets of interest, and our business may be adversely affected.

Failure to maintain our trademark registrations, or to obtain new trademark registrations in the future, could limit our ability to protect our trademarks and impede our marketing efforts in the countries in which we operate. We may not be able to protect our rights to trademarks and trade names which we may need to build name recognition with potential partners or customers in our markets of interest. As a means to enforce our trademark rights and prevent infringement, we may be required to file trademark

claims against third parties or initiate trademark opposition proceedings. This can be expensive and time-consuming, and possibly unsuccessful. our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to infringe on other marks.

Our pending trademark applications in the U.S. and in other foreign jurisdictions where we may file may not be successful. Even if these applications result in registered trademarks, third parties may challenge these trademarks in the future. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected.

Litigation or other proceedings resulting from either third-party claims of patent infringement, or asserting infringement by third parties of our technology, could be costly, time-consuming, and could limit our ability to commercialize our products or services.

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 genetic diagnostics industry. Third parties, including our competitors, have asserted and may in the future assert that we are infringing their intellectual property rights. We may also become subject to and/or initiate future intellectual property litigation as our product portfolio and the level of competition in our industry grow.

Because the USPTO maintains patent applications in secrecy until a patent application publishes or the patent is issued, we have no way of knowing if others may have filed patent applications covering technologies used by it or our partners. Additionally, there may be third-party patents, and other intellectual property rights relevant to our technologies that may block us from commercializing our technologies. From time-to-time, we have received correspondence from third parties alleging to hold intellectual property rights that could block our development or commercialization of products. While none of these inquiries to date have had any material effect on us, we may receive inquiries in the future that could have a material effect on our business. Even if third-party claims are without merit, defending a lawsuit may result in substantial expense to us and may divert the attention of management and key personnel. In addition, we cannot provide assurance that we would prevail in any such suits to the extent necessary to conduct our business according to our strategic plan or that the damages or other remedies, if any, awarded against us would not be substantial. Claims of intellectual property infringement may require that we, or our strategic partners, enter into unsustainably high royalty or license agreements with third parties that may only be available on unacceptable terms, if at all. In addition, we could experience delays in product introductions or sales growth while we attempt to develop non-infringing alternatives. These claims could also result in injunctions against the further development and commercial sale of services or products containing our technologies, which would have a material adverse effect on our business, financial condition and results of operations.

We cannot predict whether, or offer any assurance that, the patent infringement claims may initiate in the future will be successful. We are and 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 it would be adequately compensated for the harm to our business. If we are unable to enjoin third-party infringement, our revenues 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.

Our use of open-source software could subject our business to possible litigation or cause us to subject our platform to unwanted open-source license conditions that could negatively impact our sales.

A limited but meaningful portion of our platforms and products incorporate open-source software, and we will incorporate open-source software into other offerings or products in the future. Such open-source software is generally licensed by its authors or other third parties under open-source licenses. There is little legal precedent governing the interpretation of certain terms of these licenses, and therefore the potential impact of these terms on our business is unknown and may result in unanticipated obligations regarding our products and technologies. 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 one or more of these licenses, we could be required to incur significant legal expenses defending against such allegations. In addition, if we combine our proprietary software with open-source software in a certain manner, under some open-source licenses, we could be required to release the source code of our proprietary software, which could substantially help our competitors develop products that are similar to or better than our products.

We rely on strategic collaborative and licensing arrangements with third parties to develop intellectual property. We may not be able to successfully establish and maintain such intellectual property.

The development and commercialization of our products and services rely, directly or indirectly, upon strategic collaborations and licensing agreements with third parties. Such arrangements provide us with intellectual property and other business rights crucial to our product development and commercialization. We have incorporated licensed technology into our tests. Our dependence on licensing, collaboration and other similar agreements with third parties may subject it to a number of risks. There can be no assurance that any current contractual arrangements between us and third parties or between our strategic partners and other third parties will be continued on materially similar terms and will not be breached or terminated early. Any failure to obtain or retain the rights to necessary technologies on acceptable commercial terms could require us to re-configure our products and services, which could negatively impact their commercial sale or increase the associated costs, either of which could materially harm our business and adversely affect our future revenues and ability to achieve sustained profitability.

We expect to continue and expand our reliance on collaborative and licensing arrangements. Establishing new strategic collaborations and licensing arrangements is difficult and time-consuming. Discussions with potential collaborators or licensors may not lead to the establishment of collaborations on favorable terms, if at all. To the extent we agree to work exclusively with one collaborator in a given area, our opportunities to collaborate with other entities could be limited. Potential collaborators or licensors may reject collaborations with it based upon their assessment of our financial, regulatory or intellectual property position or other factors. Even if we successfully establish new collaborations, these relationships may never result in the successful commercialization of any product or service. In addition, the success of the projects that require collaboration with third parties will be dependent on the continued success of such collaborators. There is no guarantee that our collaborators will continue to be successful and, as a result, we may expend considerable time and resources developing products or services that will not ultimately be commercialized.

Risks Related to Cybersecurity, Privacy and Information Technology

Interruption, interference with, or failure of our information technology and communications systems could hurt our ability to effectively provide our products and services, which could harm our reputation, financial condition, and operating results.

The availability of our products and services and fulfillment of our customer contracts depend on the continuing operation of our information technology and communications systems. Our systems are vulnerable to damage, interference, or interruption from terrorist attacks, natural disasters, the effects of climate change (such as sea level rise, drought, flooding, wildfires, and increased storm severity), power loss, telecommunications failures, computer viruses, ransomware attacks, computer denial of service attacks, phishing schemes, or other attempts to harm or access our systems. Some of our data centers are located in areas with a high risk of major earthquakes or other natural disasters. Our data centers are also subject to break-ins, sabotage, and intentional acts of vandalism, and, in some cases, to potential disruptions resulting from problems experienced by facility operators. Some of our systems are not fully redundant, and disaster recovery planning cannot account for all eventualities.

The occurrence of a natural disaster, closure of a facility, or other unanticipated problems at our data centers could result in lengthy interruptions in our service. In addition, our products and services are highly technical and complex and may contain errors or vulnerabilities, which could result in interruptions in or failure of our services or systems.

Security breaches, privacy issues, loss of data and other incidents could continue to compromise sensitive, protected, or personal information related to our business, could prevent it from accessing critical information, and could expose it to regulatory liability, which could adversely affect our business.

In the ordinary course of our business, our collection and storing of PHI also includes more sensitive data, such as genetic information, as well as personally identifiable information, genetic information, credit card information, financial information, intellectual property and proprietary business information owned or controlled by us or our customers, payors and other parties. We manage and maintain our applications and data utilizing a combination of on-site systems, managed data center systems and cloud-based systems. We also communicate PHI and other sensitive patient data through our various customer tools and platforms, and in physical form. In addition to storing and transmitting sensitive data that is subject to multiple legal protections, these applications and data encompass a wide variety of business-critical information including research and development information, commercial information, and business and financial information. We continue to face a number of risks relative to protecting this critical information, including loss of access risk, inappropriate disclosure, inappropriate modification, and the risk

of our being unable to adequately monitor and modify our controls over our critical information. Any technical problems that may arise in connection with the data that we access and our systems, including those that are hosted by third-party providers, could result in interruptions to our business and operations or exposure to security vulnerabilities. These types of problems may be caused by a variety of factors, including infrastructure changes, intentional or accidental human actions or omissions, software errors, malware, viruses, security attacks, fraud, spikes in customer usage and denial of service issues. From time to time, large third-party web hosting providers have experienced outages or other problems that have resulted in their systems being offline and inaccessible. Such outages could materially impact our business and operations.

Although we take what we believe to be reasonable and appropriate measures, including a formal, dedicated enterprise security program, to protect sensitive information from various compromises (including unauthorized access, disclosure, or modification or lack of availability), our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance, lost or stolen technology, or other disruptions. Any such breach or interruption could compromise our networks and the information stored therein could be accessed by unauthorized parties, altered, publicly disclosed, lost or stolen.

Further, some of our customer tools and platforms are currently accessible through a portal and there is no guarantee that we can protect our portal from a security breach. Unauthorized access, loss or dissemination could also disrupt our operations (including our ability to conduct our analyses, provide test results, bill payors or patients, process claims and appeals, provide customer assistance, conduct research and development activities, collect, process and prepare company financial information, provide information about our tests and other patient and physician education and outreach efforts through our website, and manage the administrative aspects of our business) and damage our reputation, any of which could adversely affect our business. In addition to data security risks, we also face privacy risks. For example, as noted above, pursuant to guidance recently issued by OCR, HIPAA covered entities and business associates who permit tracking technology vendors to collect PHI from their patients must enter into a HIPAA compliant business associate agreement with that vendor or obtain advance consent. We have utilized, and may continue to utilize, tracking technologies on one or more of our websites, and may not be able to do so in a manner that is consistent with what HIPAA requires. Should we actually violate, or be perceived to have violated, any privacy promises our business makes to patients or consumers, we could be subject to a complaint from an affected individual or interested privacy regulator, such as OCR, the FTC, a state Attorney General, an EU Member State Data Protection Authority, or a data protection authority in another international jurisdiction. This risk is heightened given the sensitivity of the data we collect.

Any security compromise that causes an apparent privacy violation could also result in legal claims or proceedings; liability under federal, state, foreign, or multinational laws that regulate the privacy, security, or breach of personal information, such as but not limited to the HIPAA, HITECH, state data security and data breach notification laws, the EU's GDPR, the UK Data Protection Act of 2018; and related regulatory penalties. Penalties for failure to comply with a requirement of HIPAA or HITECH vary significantly, and, depending on the knowledge and culpability of the HIPAA-regulated entity, may include civil monetary penalties of up to $1.5 million per calendar year for each provision of HIPAA that is violated. A person who knowingly obtains or discloses individually identifiable health information in violation of HIPAA may face a criminal penalty of up to $50,000 and up to one-year imprisonment. The criminal penalties increase if the wrongful conduct involves false pretenses or the intent to sell, transfer or use identifiable health information for commercial advantage, personal gain or malicious harm. Penalties for unfair or deceptive acts or practices under the FTC Act or state UDAP, statutes may also vary significantly.

There has been unprecedented activity in the development of data protection regulation around the world. As a result, the interpretation and application of consumer, health-related and data protection laws in the U.S., Europe and elsewhere are often uncertain, contradictory and in flux. The GDPR applies to any entity established in the EU as well as extraterritorially to any entity outside the EU that offers goods or services to, or monitors the behavior of, individuals who are located in the EU. The GDPR imposes strict requirements on controllers and processors of personal data, including enhanced protections for "special categories" of personal data, which includes sensitive information such as health and genetic information of data subjects. The GDPR also grants individuals various rights in relation to their personal data, including the rights of access, rectification, objection to certain processing and deletion. The GDPR provides an individual with an express right to seek legal remedies if the individual believes his or her rights have been violated. Failure to comply with the requirements of the GDPR or the related national data protection laws of the member states of the EU, which may deviate from or be more restrictive than the GDPR, may result in significant administrative fines issued by EU regulators. Maximum penalties for violations of the GDPR are capped at 20 million euros or 4% of an organization's annual global revenue, whichever is greater.

Additionally, the implementation of GDPR has led other jurisdictions to either amend or propose legislation to amend their existing data privacy and cybersecurity laws to resemble the requirements of GDPR. For example, on June 28, 2018, California adopted the CCPA. The CCPA regulates how certain for-profit businesses that meet one or more CCPA applicability thresholds collect, use, and disclose the personal information of consumers who reside in California. Among other things, the CCPA confers to California consumers the right to receive notice of the categories of personal information that will be collected by a business,

how the business will use and share the personal information, and the third parties who will receive the personal information; the CCPA also confers rights to access, delete, or transfer personal information; and the right to receive equal service and pricing from a business after exercising a consumer right granted by the CCPA. In addition, the CCPA allows California consumers the right to opt out of the "sale" of their personal information, which the CCPA defines broadly as any disclosure of personal information to a third party in exchange for monetary or other valuable consideration. The CCPA also requires a business to implement reasonable security procedures to safeguard personal information against unauthorized access, use, or disclosure. California amended the law in September 2018 to exempt all PHI collected by certain parties subject to HIPAA, and further amended the law in September 2020 to clarify that de-identified data as defined under HIPAA will also be exempt from the CCPA. The California Attorney General's final regulations implementing the CCPA took effect on August 14, 2020. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches resulting from a business's failure to implement and maintain reasonable data security procedures that is expected to increase data breach litigation. In addition, California voters recently approved the California Privacy Rights Act of 2020 ("CPRA,") that went into effect on January 1, 2023. The CPRA among other things, amends the CCPA to give California residents the ability to limit the use of their sensitive information provides for penalties for CPRA violations concerning California residents under the age of 16, and establishes a new California Privacy Protection Agency to implement and enforce the law. Other jurisdictions in the U.S. are beginning to propose and enact laws similar to the CCPA. Some observers have noted that the CCPA could mark the beginning of a trend toward more stringent privacy legislation, which could increase our potential liability and adversely affect our business, results of operations, and financial condition.

It is possible the GDPR, CCPA and other emerging U.S. and international data protection laws may be interpreted and applied in manner that is inconsistent with our practices. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. In addition, these privacy laws and regulations may differ from country to country and state to state, and our obligations under these laws and regulations vary based on the nature of our activities in the particular jurisdiction, such as whether we collect samples from individuals in the local jurisdiction, perform testing in the local jurisdiction, or process personal information regarding employees or other individuals in the local jurisdiction. In the U.S., the SEC has adopted rules for mandatory disclosure of cybersecurity incidents suffered by public companies, as well as cybersecurity governance and risk management. Complying with these various laws and regulations could cause us to incur substantial costs or require it to change our business practices and compliance procedures in a manner adverse to our business. Any failure or perceived failure by us to comply with these laws may also subject us to enforcement action or litigation, any of which could harm our business. We can provide no assurance that it is or will remain in compliance with diverse privacy and data security requirements in all of the jurisdictions in which we do business. Failure to comply with privacy and data security requirements could result in a variety of consequences, or damage to our reputation, any of which could have a material adverse effect on our business.

Data privacy and security concerns relating to our technology and our practices could damage our reputation, subject it to significant legal and financial exposure, and deter current and potential users or customers from using our products and services. Software bugs or defects, security breaches, and attacks on our systems could result in the improper disclosure and use of user data and interference with our users and customers' ability to use our products and services, harming our business operations and reputation.

Concerns about our practices with regard to the collection, use, disclosure, or security of personal information or other data-privacy-related matters, even if unfounded, could harm our reputation, financial condition, and operating results. Our policies and practices may change over time as expectations regarding privacy and data change.

Our products and services involve the storage and transmission of protected health information and other personal information, proprietary information, and bugs, theft, misuse, defects, vulnerabilities in our products and services, and security breaches expose us to a risk of loss of this information, improper use and disclosure of such information, litigation, and other potential liability. Systems and control failures, security breaches, failure to comply with our privacy policies, and/or inadvertent disclosure of user data could result in government and legal exposure, seriously harm our reputation and brand and, therefore, our business, and impair our ability to attract and retain users or customers. We expect to continue to expend significant resources to maintain security protections that shield against bugs, theft, misuse, or security vulnerabilities or breaches.

We experience cyber-attacks and other attempts to gain unauthorized access to our systems on a regular basis. We may experience future security issues, whether due to employee error or malfeasance or system errors or vulnerabilities in our or other parties' systems, which could result in significant legal and financial exposure. Government inquiries and enforcement actions, litigation, and adverse press coverage could harm our business. We may be unable to anticipate or detect attacks or vulnerabilities or implement adequate preventative measures. Attacks and security issues could also compromise trade secrets and other sensitive information, harming our business.

While we have dedicated significant resources to privacy and security incident response capabilities, including dedicated worldwide incident response teams, our response process may not be adequate, may fail to accurately assess the severity of an incident, may not respond quickly enough, or may fail to sufficiently remediate an incident. As a result, we may suffer significant legal, reputational, or financial exposure, which could harm our business, financial condition, and operating results.

We depend on our scientific computing and information technology and management systems and any failure of these systems could harm our business.

We depend on scientific computing and information technology and management systems, including third-party cloud computing infrastructure, operating systems and AI platforms, for significant elements of our operations, including our laboratory information management system, clinical database, analytical platform, laboratory workflow tools, customer and collaborator reporting and related functions. We also depend on our proprietary workflow software to support new product and service launches and regulatory compliance.

We use complex software processes and bioinformatic pipelines to manage samples and evaluate sequencing result data. These are subject to initial design or ongoing modifications which may result in unanticipated issues that could cause variability in patient results, leading to service disruptions or errors, resulting in liability.

We have installed, and expect to expand, a number of enterprise software systems that affect a broad range of business processes and functional areas, including systems laboratory operations, handling human resources, financial controls and reporting, contract management, regulatory compliance and other infrastructure operations, and patient consent and information management. In addition to these business systems, we have installed, and intend to extend, the capabilities of both our preventative and detective security controls by augmenting the monitoring and alerting functions, the network design and the automatic countermeasure operations of our technical systems. These information technology and telecommunications systems support a variety of functions, including laboratory operations, test validation, sample tracking, quality control, customer service support, billing and reimbursement, research and development activities, scientific and medical curation and general administrative activities. In addition, our third-party billing and collections provider depends upon technology and telecommunications systems provided by outside vendors.

Information technology and telecommunications systems are vulnerable to damage from a variety of sources, including telecommunications or network failures, malicious internal or external human acts and natural disasters. Moreover, despite network security and back-up measures, some of our servers are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptive problems. Despite the precautionary measures we have taken to prevent unanticipated problems that could affect our information technology and telecommunications systems, failures or significant downtime of these systems or those used by our collaborators or subcontractors could prevent it from conducting our comprehensive screening analysis, clinical diagnostics and drug discovery, preparing and providing reports to researchers, clinicians and our collaborators, billing payors, handling physician inquiries, conducting research and development activities and managing the administrative aspects of our business. Any disruption or loss of information technology or telecommunications systems on which critical aspects of our operations depend could have an adverse effect on our business and our reputation, and we may be unable to regain or repair our reputation in the future.

Our ability to transfer data stored outside of the U.S. could be limited by international regulations or other action by foreign governments, which could adversely affect our business.

Some of the data we process in the ordinary course of our business may be stored outside of the U.S. In order to process such data, we may need to transfer them to countries other than those where they are stored. Should a foreign government adopt a regulation restricting the international transfer of such data, we may not be able to process them, which could adversely impact our business.

Risks Related to Being a Public Company

We incur significant costs and demands on management as a result of compliance with laws and regulations applicable to public companies, which could harm our operating results.

As a public company, we incur significant legal, accounting and other expenses, including costs associated with public company reporting requirements. In addition, the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act") as well as rules implemented by the SEC and the Nasdaq Stock Market ("Nasdaq") impose a number of requirements on public companies, including with respect to corporate governance practices. The SEC and other regulators have continued to adopt new rules and regulations and make additional changes to existing regulations that require the company's compliance. In addition, the Dodd-Frank Wall Street Reform and Consumer Protection Act (the "Dodd-Frank Act"), enacted in 2010, includes significant corporate governance and executive-compensation-related provisions. Our management and other personnel will need to devote a substantial amount of time to these

compliance and disclosure obligations. If these requirements divert the attention of our management and personnel from other aspects of our business concerns, they could have a material adverse effect on our business, financial condition and results of operations. Moreover, these rules and regulations applicable to public companies substantially could increase our legal, accounting and financial compliance costs, require that we hire additional personnel and make some activities more time consuming and costly.

A market for our securities may not continue, which would adversely affect the liquidity and price of our securities.

The price of our securities may fluctuate significantly due to general market and economic conditions. An active trading market for our securities may not be sustained. In addition, the price of our securities can vary due to general economic conditions and forecasts, our general business condition and the release of our financial reports. You may be unable to sell your securities when desired or at an acceptable price unless an active trading market can be sustained.

If we do not meet the expectations of investors, stockholders or financial analysts, the market price of our securities may decline.

If we do not meet the expectations of investors or securities analysts, the market price of our securities may decline. In addition, fluctuations in the price of our securities could contribute to the loss of all or part of your investment. If an active market for our securities does not continue, the trading price of our securities could be volatile and subject to wide fluctuations in response to various factors, some of which are beyond our control. Any of the risk factors noted in this Annual Report could have a material adverse effect on your investment in our securities and our securities may trade at prices significantly below the price you paid for them. In such circumstances, the trading price of our securities may not recover and may experience a further decline.

Factors affecting the trading price of our securities may include:

- actual or anticipated fluctuations in our quarterly financial results or the quarterly financial results of companies perceived to be similar to us;
- changes in the market's expectations about our operating results;
- the public's reaction to our press releases, our other public announcements and our filings with the SEC;
- speculation in the press or investment community;
- announcements of technological innovation, new products, acquisitions, strategic alliances, significant agreements by us or competitors;
- success of competitors;
- our operating results falling below our financial guidance or other projections or failing to meet the expectation of securities analysts or investors in a particular period;
- changes in financial estimates and recommendations by securities analysts concerning us or the market in general;
- operating and stock price performance of other companies that investors deem comparable to us;
- our ability to market new and enhanced products on a timely basis;
- changes in laws and regulations affecting our business;
- commencement of, or involvement in, litigation involving us;
- changes in our capital structure, such as future issuances of securities or the incurrence of additional debt;
- the volume of shares of our Class A common stock available for public sale;
- any major change in our Board or management;
- sales of substantial amounts of Class A common stock by our directors, officers or significant stockholders or the perception that such sales could occur;
- the expiration of any market stand-off or contractual lock-up agreements;
- the realization of any of the risk factors described herein;
- additions or departures of key personnel;
- failure to comply with the requirements of the Nasdaq;
- failure to comply with the Sarbanes-Oxley Act or other laws or regulations;
- actual, potential or perceived control, accounting or reporting problems;
- changes in accounting principles, policies and guidelines; and
- general economic and political conditions such as recessions, fluctuating inflation, interest and tariff rates, uncertainty with respect to the U.S. federal budget, rising global tensions, global conflicts such as the war in Ukraine, fuel prices, international currency fluctuations and acts of war or terrorism.

Broad market and industry factors may materially harm the market price of our securities irrespective of our operating performance. The stock market in general and Nasdaq have experienced price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of the particular companies affected. The trading prices and valuations of these stocks, and of our securities, may not be predictable. A loss of investor confidence in the market for the stocks of other

companies which investors perceive to be similar to us could depress our stock price regardless of our business, prospects, financial conditions or results of operations. A decline in the market price of our securities also could adversely affect our ability to issue additional securities and our ability to obtain additional financing in the future.

In the past, securities class action litigation has often been initiated against companies following periods of volatility in their stock price. In particular, on September 7, 2022, a shareholder class action lawsuit was filed in the U.S. District Court for the District of Connecticut against the Company and certain of the Company's current and former officers. In addition, on November 28, 2023, a stockholder filed a lawsuit in the U.S. District Court for the District of Delaware against, among other parties, certain of the Company's current and former officers and directors and on June 25, 2024, a substantially similar stockholder derivative suit was filed in federal court in the District of Connecticut. For more information, see Note 10, "*Purchase Commitments and Contingencies*" in the consolidated financial statements included in this Annual Report. This type of litigation could result in substantial costs and divert our management's attention and resources, and could also require us to make substantial payments to satisfy judgments or to settle litigation. For example, on December 2, 2024, we settled a lawsuit that a stockholder commenced in the Delaware Court of Chancery on February 7, 2023 against, among other parties, certain of the Company's current and former directors, for approximately $21 million. See also Note 10, "*Purchase Commitments and Contingencies*" in the consolidated financial statements included in this Annual Report.

If securities or industry analysts cease publishing research or reports about us, our business, or our market, or if they change their recommendations regarding our Class A common stock adversely, then the price and trading volume of our Class A common stock could decline.

The trading market for our Class A common stock is influenced by the research and reports that industry or securities analysts publish about us, our business, our market, or our competitors. If any of the analysts who cover us change their recommendation regarding our stock adversely, or provide more favorable relative recommendations about our competitors, the price of our Class A common stock would likely decline. If any analyst who covers us were to cease coverage of us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our stock price or trading volume to decline.

Changes in laws, regulations or rules, or a failure to comply with any laws, regulations or rules, may adversely affect our business, investments and results of operations.

We are subject to laws, regulations and rules enacted by national, regional and local governments and Nasdaq. In particular, we are required to comply with certain SEC, Nasdaq and other legal or regulatory requirements. Compliance with, and monitoring of, applicable laws, regulations and rules may be difficult, time consuming and costly. Those laws, regulations or rules and their interpretation and application may also change from time to time and those changes could have a material adverse effect on our business, investments and results of operations. In addition, a failure to comply with applicable laws, regulations or rules, as interpreted and applied, could have a material adverse effect on our business and results of operations.

Anti-takeover provisions contained in our Charter and Bylaws, as well as provisions of Delaware law, could impair a takeover attempt.

Our Third Amended and Restated Certificate of Incorporation, as amended (our "Charter"), contains provisions that may discourage unsolicited takeover proposals that stockholders may consider to be in their best interests. We are also subject to anti-takeover provisions under Delaware law, which could delay or prevent a change of control. Together, these provisions may make more difficult the removal of management and may discourage transactions that otherwise could involve payment of a premium over prevailing market prices for our securities. These provisions will include:

- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- a classified board of directors with three-year staggered terms, which could delay the ability of stockholders to change the membership of a majority of the Board;
- the requirement that directors may only be removed from the Board for cause;
- the right of our Board to elect a director to fill a vacancy created by the expansion of our Board or the resignation, death or removal of a director in certain circumstances, which prevents stockholders from being able to fill vacancies on our Board;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- a prohibition on stockholders calling a special meeting and the requirement that a meeting of stockholders may only be called by a majority of the board, our chairman of the board or our chief executive officer and may not be called by any other person, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors;

- the requirement that changes or amendments to certain provisions of our Charter must be approved by holders of at least two-thirds of our Class A common stock; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our Board or to propose matters to be acted upon at a 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 us.

The JOBS Act permits "emerging growth companies" like us to take advantage of certain exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies.

We currently qualify as an "emerging growth company" as defined in Section 2(a)(19) of the Securities Act, as modified by the Jumpstart Our Business Startups Act (the "JOBS Act"). As such, we take advantage of certain exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies for as long as we continue to be an emerging growth company, including: (i) the exemption from the auditor attestation requirements with respect to internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act; (ii) the exemptions from say-on-pay, say-on-frequency and say-on-golden parachute voting requirements; and (iii) reduced disclosure obligations regarding executive compensation in our periodic reports. As a result, our stockholders may not have access to certain information they deem important. We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year: (a) following September 1, 2025, the fifth anniversary of the initial public offering of CMLS; (b) in which we have total annual gross revenue of at least $1.235 billion; or (c) in which we are deemed to be a large accelerated filer, which means the market value of our Class A common stock that is held by non-affiliates exceeds $700.0 million as of the prior June 30th, and (ii) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

In addition, Section 107 of the JOBS Act also provides that an emerging growth company can take advantage of the exemption from complying with new or revised accounting standards provided in Section 7(a)(2)(B) of the Securities Act as long as we are an emerging growth company. An emerging growth company can therefore delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. The JOBS Act provides that a company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies, but any such election to opt out is irrevocable. We have elected to avail ourselves of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we, as an emerging growth company, can adopt the new or revised standard at the time private companies adopt the new or revised standard. This may make comparison of our financial statements with another public company that is neither an emerging growth company nor an emerging growth company that has opted out of using the extended transition period difficult or impossible because of the potential differences in accounting standards used.

We cannot predict if investors will find our Class A common stock less attractive because we rely on these exemptions. If some investors find our Class A common stock less attractive as a result, there may be a less active trading market for our Class A common stock and our stock price may be more volatile.

We no longer qualify as a "smaller reporting company" and as a result, we will no longer be able to avail ourselves of certain reduced reporting requirements applicable to smaller reporting companies starting with our first quarterly report in 2025.

We currently take advantage of certain of the scaled disclosures available to "smaller reporting companies," as defined in Item 10(f)(1) of Regulation S-K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of consolidated financial statements. However, based on the market value of our Class A common stock held by non-affiliates as of June 28, 2024 (the last business day of our most recently completed second fiscal quarter), we will no longer be eligible to rely on the scaled disclosure exemptions available to smaller reporting companies starting with our Quarterly Report on Form 10-Q for the quarter ending March 31, 2025.

We expect that the loss of our "smaller reporting company" status and compliance with additional requirements will increase our legal and financial compliance costs. Any failure to comply with additional requirements in a timely manner, or at all, could have an adverse effect on our business and results of operations and could cause a decline in the price of our Class A common stock.

Our internal controls over financial reporting may not be effective which could have a significant and adverse effect on our business and reputation.

As a public company, we are required to comply with the SEC's rules implementing Sections 302 and 404 of Sarbanes-Oxley Act, which require management to certify financial and other information in our quarterly and annual reports and provide an annual management report on the effectiveness of internal control over financial reporting. To comply with the requirements of being a public company, we are required to provide management's assessment on internal controls, and we may need to undertake

various actions, such as implementing additional internal controls and procedures and hiring additional accounting or internal audit staff. Further, as an emerging growth company, our independent registered public accounting firm is not required to formally attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404 until the date we are no longer an emerging growth company. At such time, our independent registered public accounting firm may issue a report that is adverse in the event that it is not satisfied with the level at which the controls of the company are documented, designed or operating.

Testing and maintaining these controls can divert our management's attention from other matters that are important to the operation of our business. If we identify material weaknesses in the internal control over financial reporting of the company or are unable to comply with the requirements of Section 404 or assert that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal controls over financial reporting when we no longer qualify as an emerging growth company, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our Class A common stock could be negatively affected, and we could become subject to investigations by the SEC or other regulatory authorities, which could require additional financial and management resources.

Our Charter and our Bylaws designate the Court of Chancery of the State of Delaware and federal court within the State of Delaware as the exclusive forum for certain types of actions and proceedings that our stockholders may initiate, which could limit a stockholder's ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our Charter and our Amended and Restated Bylaws (as amended, our "Bylaws") designate the Court of Chancery of the State of Delaware and federal court within the State of Delaware as the exclusive forum for certain types of actions and proceedings that our stockholders may initiate, which could limit a stockholder's ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our Charter and our Bylaws provide that, subject to limited exceptions, the Court of Chancery of the State of Delaware and federal court within the State of Delaware will be exclusive forums for any:

- derivative action or proceeding brought on our behalf;
- action asserting a claim of breach of a fiduciary duty owed by, or other wrongdoing by, any of our directors, officers, stockholders, employees or agents to us or our stockholders;
- action asserting a claim against the us or any of our directors, officers, stockholders, employees or agents arising pursuant to any provision of the General Corporation Law, our Charter or our Bylaws or as to which the General Corporation Law confers jurisdiction on the Court of Chancery of the State of Delaware:
- action to interpret, apply, enforce or determine the validity of our Charter or our Bylaws; or
- other action asserting a claim against us or any of our directors, officers, stockholders, employees or agents that is governed by the internal affairs doctrine.

These provisions do not apply to actions brought to enforce a duty or liability created under the Exchange Act or any other claim for which federal courts have jurisdiction. Furthermore, in accordance with our Bylaws, unless we consent in writing to the selection of an alternative forum, the federal district courts of the U.S. will be, to the fullest extent permitted by law, the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Any person or entity purchasing or otherwise acquiring or holding any interest in any of our securities shall be deemed to have notice of and consented these provisions in our Charter and our Bylaws.

These provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, or other employees, which may discourage lawsuits with respect to such claims. Alternatively, if a court were to find the provisions contained in our Charter and our Bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations and financial condition.

The stockholders will not be deemed to have waived our compliance with the federal securities laws and the regulations promulgated thereunder.

Any person or entity purchasing or otherwise acquiring or holding any interest in any of our securities shall be deemed to have notice of and consented to our exclusive forum provisions. These provisions may limit a stockholders' ability to bring a claim, and may result in increased costs for a stockholder to bring a claim in a judicial forum of their choosing for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers, and other employees.

Risks Related to Our Common Stock and Warrants

The ownership of our outstanding Class A common stock is concentrated, with certain of our stockholders owning significant percentages of our outstanding shares.

Icahn School of Medicine at Mount Sinai ("ISMMS"), entities affiliated with Casdin Partners Master Fund, L.P. ("Casdin Partners"), and Corvex Management, L.P. ("Corvex Management") are some of our significant stockholders, which owned approximately 10%, 12%, and 9%, respectively, of our outstanding shares of our Class A common stock as of December 31, 2024. In addition, Mr. Eli D. Casdin, one of our directors, is affiliated with Casdin Partners and CMLS Holdings, LLC ("CMLS Holdings"), which owned approximately 1% of our outstanding shares of our Class A common stock as of December 31, 2024, and Mr. Keith Meister, one of our directors, is affiliated with Corvex Management and CMLS Holdings.

These stockholders may choose to dispose of some or all of the shares of our Class A common stock held by them. Any disposal of shares of Class A common stock by any of these stockholders, or the perception that these sales could occur, could cause the market price of our stock or warrants to decline.

We may amend the terms of the public warrants in a manner that may be adverse to holders with the approval by the holders of at least 50% of the then-outstanding public warrants. As a result, the exercise price of a holder's public warrants could be increased, the exercise period could be shortened and the number of shares of our Class A common stock purchasable upon exercise of a public warrant could be decreased, all without the approval of that warrant holder.

Our public warrants were issued in registered form under a warrant agreement between Continental Stock Transfer & Trust Company, as warrant agent, and us. The warrant agreement provides that the terms of the public warrants may be amended without the consent of any holder to cure any ambiguity or correct any defective provision, but requires the approval by the holders of at least 50% of the then-outstanding public warrants to make any change that adversely affects the interests of the registered holders. Accordingly, we may amend the terms of the public warrants in a manner adverse to a holder if holders of at least 50% of the then-outstanding public warrants approve of such amendment. Although our ability to amend the terms of the public warrants with the consent of at least 50% of the then-outstanding public warrants is unlimited, examples of such amendments could be amendments to, among other things, increase the exercise price of the public warrants, convert the warrants into cash or stock, shorten the exercise period or decrease the number of shares of common stock purchasable upon exercise of a public warrant.

We may redeem unexpired public warrants prior to their exercise at a time that is disadvantageous to warrant holders, thereby making their public warrants worthless.

We have the ability to redeem outstanding public warrants at any time after they become exercisable and prior to their expiration, at a price of $0.33 per public warrant; provided that the last reported sales price of our Class A common stock equals or exceeds $594.00 per share (as adjusted for stock splits, stock dividends, reorganizations, recapitalizations and the like) for any 20 trading days within a 30 trading-day period ending on the third trading day prior to the date on which we give notice of such redemption to the warrant holders. If and when the public warrants become redeemable by us, we may exercise our redemption right even if we are unable to register or qualify the underlying securities for sale under all applicable state securities laws. We will use our best efforts to register or qualify such shares of common stock under the blue-sky laws of the state of residence in those states in which the warrants were offered by us. Redemption of the outstanding public warrants could force the warrant holders: (i) to exercise their public warrants and pay the exercise price therefor at a time when it may be disadvantageous for them to do so; (ii) to sell their public warrants at the then-current market price when they might otherwise wish to hold their public warrants; or (iii) to accept the nominal redemption price which, at the time the outstanding public warrants are called for redemption, is likely to be substantially less than the market value of their public warrants. None of the private placement warrants will be redeemable by us so long as they are held by CMLS Holdings LLC, or its permitted transferees. Additionally, none of the private warrants issued to Perceptive are redeemable by us so long as the warrants are held by Perceptive, or its permitted transferees.

Our warrants are exercisable for our Class A common stock, which will increase the number of shares eligible for future resale in the public market and result in dilution to our stockholders.

As of December 31, 2024, our public warrants were exercisable for 457,323 shares of Class A common stock at $379.50 per share, and our private warrants were exercisable for 209,192 shares of Class A common stock at $379.50 per share. The additional shares of our Class A common stock issuable upon exercise of our warrants will result in dilution to the then existing holders of our Class A common stock and increase the number of shares eligible for resale in the public market. Sales of substantial numbers of such shares in the public market could adversely affect the market price of our Class A common stock.

Our warrants are accounted for as liabilities and the changes in value of our warrants could have a material effect on our financial results.

Included on our consolidated balance sheet as of December 31, 2024, are liabilities related to our public and private warrants which are each remeasured at fair value at each balance sheet date, with a resulting non-cash gain or loss related to the change in the fair value being recognized in earnings in the statement of operations. As a result of the recurring fair value measurement, our financial statements and results of operations may fluctuate quarterly, based on factors, which are outside of our control. Due to the recurring fair value measurement, we expect that we will recognize non-cash gains or losses on our warrants each reporting period in our results of operations and that the amount of such gains or losses could be material. If the price of our Class A common stock decreases, we expect we would recognize non-cash gains on our warrants in future reporting periods.

Future resales of our Class A common stock could cause the market price of our Class A common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our Class A common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our Class A common stock.

We had 28,016,545 shares of Class A common stock outstanding as of December 31, 2024. We have filed a registration statement which registers the offer and sale from time to time by certain selling stockholders of up to 10,803,779 shares of our Class A common stock. To the extent shares of our Class A common stock are sold into the market pursuant to an effective registration statement, under Rule 144 under the Securities Act or otherwise, particularly in substantial quantities the market price of our Class A common stock could decline.

There is no guarantee that the public warrants will ever be in the money, and they may expire worthless and the terms of our public warrants may be amended.

The exercise price for the public warrants is $379.50 per share of Class A common stock. There is no guarantee that the public warrants will ever be in the money prior to their expiration, and as such, the public warrants may expire worthless.

We cannot guarantee that we will be able to satisfy the continued listing standards of Nasdaq going forward and if we fail to satisfy the continued listing requirements of Nasdaq, including the minimum closing bid price requirement, Nasdaq may take steps to delist our Class A common stock.

Our Class A common stock and public warrants are listed on the Nasdaq Global Select Market under the symbols “WGS” and “WGSWW,” respectively. However, we cannot ensure that we will be able to satisfy the continued listing standards of Nasdaq, including the minimum closing bid price requirement, going forward. If we cannot satisfy the continued listing standards going forward, The Nasdaq Stock Market may commence delisting procedures against us, which could result in our Class A common stock or public warrants being removed from listing on Nasdaq. If either of our Class A common stock or public warrants were to be delisted, the liquidity of our Class A common stock or warrants could be adversely affected and the market price of our Class A common stock or warrants could decrease. Delisting could also adversely affect our securityholders’ ability to trade or obtain quotations on our securities because of lower trading volumes and transaction delays. These factors could contribute to lower prices and larger spreads in the bid and ask price for our securities. Investors may also not be able to resell their Class A common stock or warrants at or above the price they paid for such securities or at all.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

The Company is committed to maintaining the trust and confidence of our customers, healthcare providers, clients, business partners and employees through a cybersecurity program focused on protecting the confidentiality, security and availability of the information that we collect and store. We actively identify prevent, detect and mitigate cybersecurity threats and are positioned to effectively respond to cybersecurity incidents. Key components of our cybersecurity program include:

Governance: Our board of directors, in coordination with its audit committee, oversees the risks arising from cybersecurity threats, which are embedded in our enterprise risk management (“ERM”) approach. The Board’s audit committee receives regular reports on cybersecurity risks from our Head of Information Security, with prompt escalation of any incident that could materially affect core company operations to the Board. Further, our Head of Information Security works collaboratively across the company to implement and enhance our cybersecurity program. Through ongoing interactions with these teams, our Head of Information

Security monitors the prevention, detection, mitigation and remediation of cybersecurity threats and incidents in real time. Our Head of Information Security has served in various roles in information technology and information security for over 15 years and holds an undergraduate degree in Management Information System and a graduate degree in Human Resource Management and has attained multiple professional information security certification.

Incident Response Planning: We have established protocols to detect, respond to and recover from cybersecurity incidents promptly.

Technical Safeguards: We deploy commercially reasonable technical safeguards that are designed to protect our information systems from cybersecurity threats, including firewalls, intrusion prevention and detection systems, anti-malware functionality and access controls, which are evaluated and improved through vulnerability assessments and cybersecurity threat intelligence. In addition, we maintain a risk-based approach to identifying and overseeing cybersecurity risks presented by third parties, including vendors, service providers and other external users of our systems, as well as the systems of third parties that could adversely impact our business in the event of a cybersecurity incident affecting those third-party systems.

Employee Education and Awareness: We provide regular mandatory training for employees regarding cybersecurity threats to equip them with effective tools to address cybersecurity threats and to communicate our evolving information security policies, standards, processes and practices.

Continuous Monitoring: We engage in the routine, periodic assessment and testing of our standards, policies, processes and practices that are designed to address cybersecurity threats and incidents. These efforts include a wide range of activities, including audits, assessments and other exercises focused on evaluating the effectiveness of our cybersecurity measures and planning. We regularly engage third parties to perform assessments on our cybersecurity measures, including assessments, audits and independent reviews of our information security control environment and operating effectiveness. The results of such exercises are reported to our audit committee, and we adjust our cybersecurity policies, standards, processes and practices as necessary.

Artificial Intelligence

Artificial intelligence ("AI") has the potential to transform various work sectors significantly. We continue to enhance and broaden our offerings with AI technologies, and we are exploring potential third-party partnerships to help us offer more robust solutions for providers and patients. For example, we currently deploy a phenotype-driven algorithm that uses machine learning and is used to help identify genes to that may cause disease. While we are dedicated to actualizing AI's potential in our offerings, we are equally committed to ensuring the security of patient data in line with data privacy laws through the Company's AI Guidelines.

Cybersecurity Threats

Risks from cybersecurity threats, including as a result of any previous cybersecurity incidents, have not materially affected, and we believe that such risks are not reasonably likely to materially affect the Company, including its business strategy, results of operations or financial condition.

For more information on our cybersecurity risks, see "Risk Factors—*Risks Related to Cybersecurity, Privacy and Information Technology*".

Item 2. Properties

Properties for our core operations include our corporate office and headquarters located in Stamford, Connecticut, our primary operating laboratory located in Gaithersburg, Maryland, and a satellite meeting space located in New York City; each are leased spaces with an aggregate of approximately 115,000 square feet. The lease agreements for these properties expire in 2034, 2031, and 2026, respectively.

As previously disclosed, we exited our reproductive health and somatic tumor testing business in 2022. We are actively marketing for sublet our two laboratories in Connecticut as well as a portion of our headquarters in Stamford, Connecticut. The lease agreements for these properties expire in 2030 and 2036, respectively.

We believe that our current facilities are suitable and adequate to meet our current needs. See Note 9, "*Leases*" to our consolidated financial statements for more information on our future lease obligations.

Item 3. Legal Proceedings

Information regarding legal proceedings can be found in the consolidated financial statements in Note 10, "*Purchase Commitments and Contingencies*" included in this Annual Report.

Item 4. Mine Safety Disclosures

None.

Part II

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

Market Information

Our Class A common stock and public warrants are listed on the Nasdaq Global Select Market under the symbols "WGS" and "WGSWW," respectively.

Holders

As of February 14, 2025, there were 37 record holders of our Class A common stock and 5 record holders of our public warrants, based upon information received from our transfer agent. However, these numbers do not reflect beneficial owners whose shares were held of record by nominees or broker dealers. We believe a substantially greater number of beneficial owners hold shares of our Class A common stock or public warrants through brokers, banks, or other nominees.

Dividend Policy

We have never paid any cash dividends on our capital stock. We anticipate that we will retain earnings, if any, to support operations and to finance the growth and development of our business. In addition, the terms of our credit agreement with Perceptive restrict us from paying cash dividends. Therefore, we do not expect to pay cash dividends for the foreseeable future.

Sale of Unregistered Securities

None.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 6. Reserved

Not applicable.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. This discussion contains forward-looking statements and involves numerous risks and uncertainties. Actual results may differ materially from the results described in or implied by the forward-looking statements. You should carefully read the section entitled "Risk Factors" to gain an understanding of the important factors that could cause actual results to differ materially from these forward-looking statements.

Overview

See Note 1, "*Organization and Description of Business*" included within this Annual Report for further information.

Factors Affecting Our Operating Performance

We believe several important factors have impacted, and will continue to impact, our performance and results of operations. While each of these areas presents significant opportunities for us, they also pose significant risks and challenges that we must address. See the section titled "*Item 1A. Risk Factors*" for more information.

Test Volume

The principal focus of our commercial operations is to offer our diagnostic tests through both our direct sales force and laboratory distribution partners. Test volume correlates with genomic database size and long-term patient relationships. Thus, test volume drives database diversity and enables potential identification of variants of unknown significance and population-specific insights. The number of exome and genome tests resulted and the mix of test results are key indicators that we use to assess the operational efficiency of our business. Once the appropriate workflow is completed, the test is resulted and details are provided to ordered patients or healthcare professionals for reviews, which corresponds to the timing of our revenue recognition.

We believe the number of resulted exome and genome tests in any period is important and useful to our investors because it directly correlates with long-term patient relationships and the size of our genomic database. During the year ended December 31, 2024, we resulted 74,547 exome and genome tests, which represented 33% of all test results, compared to the year ended December 31, 2023, in which we resulted 49,439 exome and genome tests, which represented 22% of all test results.

Success Obtaining and Maintaining Reimbursement

Our ability to increase the number of billable tests and our revenue therefrom will depend on our success in achieving reimbursement for our tests from third-party payors. Reimbursement by a payor may depend on several factors, including a payor's determination that a test is appropriate, medically necessary, cost-effective, and has received prior authorization. The commercial success of our current and future products, if approved, will depend on the extent to which our customers receive coverage and adequate reimbursement from third-party payors including commercial and Medicaid. Since each payor makes its own decision as to whether to establish a policy or enter into a contract to provide coverage for our tests, as well as the amount it will reimburse us for a test, seeking these approvals is a time-consuming and costly process.

In cases where we or our partners have established reimbursement rates with third-party payors, we face additional challenges in complying with their procedural requirements for reimbursement. These requirements often vary from payor to payor and are reassessed by third-party payors regularly. As a result, in the past we have needed additional time and resources to comply with the requirements.

Third-party payors may decide to deny payment or seek to recoup payments for tests performed by us that they contend were improperly billed, not medically necessary or against their coverage determinations, or for which they believe they have otherwise overpaid. As a result, we may be required to refund payments already received, and our revenues may be subject to retroactive adjustment as a result of these factors among others.

We expect to continue to focus our resources on increasing the adoption of, and expanding coverage and reimbursement for exome and genome, and any future tests we may develop or acquire. If we fail to expand and maintain broad adoption of, and coverage and reimbursement for, our tests, our ability to generate revenue and our future business prospects may be adversely affected.

Ability to Lower the Costs Associated with Performing our Tests

Reducing the costs associated with performing our diagnostic tests is both our focus and a strategic objective. We source, and will continue to source, components of our diagnostic testing workflows from third parties. We also rely upon third-party service providers for data storage and workflow management.

Increasing Adoption of our Services by Existing and New Customers

Our performance depends on our ability to retain and broaden the adoption of our services with existing customers as well as our ability to attract new customers. Our success in retaining and gaining new customers is dependent on the market's confidence in our services and the willingness of customers to continue to seek more comprehensive and integrated genomic and clinical data insights.

Investment in Platform Innovation to Support Commercial Growth

We operate in a rapidly evolving and highly competitive industry. Our business faces changing technologies, shifting provider and patient needs, and frequent introductions of rival products and services. To compete successfully, we must accurately anticipate technology developments and deliver innovative, relevant, and useful products, services, and technologies on time. As our business evolves, the competitive pressure to innovate will encompass a wider range of products and services. We must continue to invest significant resources in research and development, including investments through acquisitions and partnerships. These investments are critical to the enhancement of our current diagnostics and health information and data science technologies from which existing and new service offerings are derived.

We expect to incur significant expenses to advance these development efforts, but they may not be successful. New potential services may fail at any stage of development and, if we determine that any of our current or future services are unlikely to succeed, we may abandon them without any return on our investment. If we are unsuccessful in developing additional services, our growth potential may be impaired.

Key Components of Results of Operations

Revenue

Diagnostic Test Revenue

The majority of our revenue is derived from genetic and genomic diagnostic testing services for three groups of customers: healthcare professionals working with patients with third-party insurance coverage or without third-party insurance coverage, institutional clients such as hospitals, clinics, state governments and reference laboratories, and self-pay patients. The amount of revenue recognized for diagnostic testing services depends on a number of factors, such as resulted test volumes, contracted rates with our customers and third-party insurance providers, insurance reimbursement policies, payor mix, historical collection experience, price concessions and other business and economic conditions and trends. To date, the majority of our diagnostic test revenue has been earned from orders received for patients with third-party insurance coverage. Our ability to increase our diagnostic test revenue will depend on our ability to increase our market penetration, obtain contracted reimbursement coverage from third-party payors, enter into contracts with institutions, and increase our reimbursement rate for tests performed.

Other Revenue

We also generate revenue from collaboration service agreements with biopharma companies and other third parties, pursuant to which we provide health information and patient identification support services. Certain of these contracts provide non-refundable payments, which we record as contract liabilities, and variable payments based upon the achievement of certain milestones during the contract term.

With respect to existing collaboration and service agreements, our revenue may fluctuate period to period due to the pattern in which we may deliver our services, our ability to achieve milestones, the timing of costs incurred, changes in estimates of total anticipated costs that we expect to incur during the contract period, and other events that may not be within our control. Our ability to increase our revenue will depend on our ability to enter into contracts with third-party partners.

Cost of Services

The cost of services reflect the aggregate costs incurred in performing services, which include expenses for reagents and laboratory supplies, compensation expenses for employees directly involved in revenue generating activities, shipping and handling fees, costs of third-party reference lab testing and phlebotomy services, if any, and allocated genetic counseling, facility

and information technology costs associated with delivery services. Allocated costs include depreciation of laboratory equipment, facility occupancy, and information technology costs. The cost of services are recorded as the services are performed.

We expect the cost of services to generally increase in absolute dollars with the anticipated growth in diagnostic testing volume and services we provide under our collaboration service agreements. However, we expect the cost per test to decrease over the long term due to the efficiencies we may gain from improved utilization of our laboratory capacity, automation, and other value engineering initiatives. These expected reductions may be offset by new tests which often have a higher cost per test during the introductory phases before we can gain efficiencies. The cost per test may fluctuate from period to period.

Research and Development Expenses

Research and development expenses represent costs incurred to develop our technology and future test offerings. These costs are principally associated with our efforts to develop the software we use to analyze data and process customer orders. These costs primarily consist of compensation expenses for employees performing research and development, innovation and product development activities, costs of reagents and laboratory supplies, costs of consultants and third-party services, equipment and related depreciation expenses, non-capitalizable software development costs, research funding to our research partners as part of research and development agreements and allocated facility and information technology costs associated with genomics medical research. Research and development costs are generally expensed as incurred and certain non-refundable advanced payments provided to our research partners are expensed as the related activities are performed.

We generally expect our research and development expenses to continue to increase in absolute dollars as we innovate and expand the application of our platforms. However, we expect research and development expenses to decrease as a percentage of revenue in the long term, although the percentage may fluctuate from period to period due to the timing and extent of our development and commercialization efforts and fluctuations in our compensation-related charges.

Selling and Marketing Expenses

Selling and marketing expenses primarily consist of compensation expenses for employees performing commercial sales, account management, marketing, and certain genetic counseling services. Selling and marketing costs are expensed as incurred.

We generally expect our selling and marketing expenses will continue to increase in absolute dollars as we expand our commercial sales and marketing and counseling teams and increase marketing activities. However, we expect selling and marketing expenses to decrease as a percentage of revenue in the long term, subject to fluctuations from period to period due to the timing and magnitude of these expenses.

General and Administrative Expenses

General and administrative expenses primarily consist of compensation expenses for employees in executive leadership, legal, finance and accounting, human resources, information technology, and other administrative functions. In addition, these expenses include office occupancy and information technology costs. General and administrative costs are expensed as incurred.

We generally expect our general and administrative expenses to continue to increase in absolute dollars as we increase headcount and incur costs associated with operating as a public company, including expenses related to legal, accounting, and regulatory matters, and maintaining compliance with requirements of Nasdaq and of the SEC. We expect these expenses to decrease as a percentage of revenue in the long term as revenue increases, although the percentage may fluctuate from period to period due to fluctuations in our compensation-related charges.

Results of Operations

Comparison of the Years Ended December 31, 2024 and 2023

The following table sets forth our results of operations for the periods presented (in thousands):

	Year Ended December 31,			
	2024	2023	$ Change	% Change
Revenue				
Diagnostic test revenue	$ 302,157	$ 195,654	$ 106,503	54 %
Other revenue	3,293	6,912	(3,619)	(52)%
Total revenue	305,450	202,566	102,884	51 %
Cost of services	111,053	112,560	(1,507)	(1)%
Gross profit	194,397	90,006	104,391	116 %
Research and development	45,722	58,266	(12,544)	(22)%
Selling and marketing	67,371	60,956	6,415	11 %
General and administrative	101,110	133,755	(32,645)	(24)%
Impairment loss	—	10,402	(10,402)	(100)%
Other operating expenses, net	3,407	7,223	(3,816)	(53)%
Loss from operations	(23,213)	(180,596)	157,383	(87)%
Non-operating (expenses) income, net				
Change in fair value of warrants and contingent liabilities	(13,370)	1,170	(14,540)	NM
Interest (expense) income, net	(3,032)	1,114	(4,146)	NM
Other (expense) income, net	(13,014)	1,619	(14,633)	NM
Total non-operating (expense) income, net	(29,416)	3,903	(33,319)	NM
Loss before income taxes	(52,629)	(176,693)	124,064	(70)%
Income tax benefit	343	926	(583)	(63)%
Net loss	$ (52,286)	$ (175,767)	$ 123,481	(70)%

NM – Not Meaningful

Revenue

Total revenue increased by $102.9 million, or 51%, to $305.5 million for the year ended December 31, 2024, from $202.6 million for the year ended December 31, 2023.

Diagnostic test revenue increased by $106.5 million, or 54%, to $302.2 million for the year ended December 31, 2024, from $195.7 million for the year ended December 31, 2023. The increase was attributable to a $109.2 million increase in exome and genome test revenue and an increase in other panel revenue of $5.0 million, which was partially offset by a $2.7 million decrease in hereditary cancer test revenue and a $5.0 million decrease in legacy Sema4 revenues. The increase in exome and genome revenue was driven by a 51% increase in test volume coupled with higher reimbursement rates resulting from lower denial rates and improved collections. Full year and fourth quarter 2024 revenues includes $6.8 million of discrete benefit in connection with a multi-year appeal recovery from a single third-party payor. The fourth quarter benefit is composed of $5.8 million to exome genome revenues and $1.0 million to other test lines.

Other revenue, representing revenue from biopharma and/or data partnership, decreased by $3.6 million, or 52%, to $3.3 million for the year ended December 31, 2024, from $6.9 million for the year ended December 31, 2023. The decrease reflected lower revenue from a partnership program which ended in 2024.

Gross Profit

Gross profit increased by $104.4 million for the year ended December 31, 2024, driven by a combination of a favorable shift in volume mix to higher margin whole exome and genome tests, an improvement in exome average reimbursement rates and continued cost per test leverage.

Research and Development

Research and development expenses decreased by $12.5 million, or 22%, to $45.7 million for the year ended December 31, 2024, from $58.3 million for the year ended December 31, 2023. The decrease was primarily attributable to costs incurred in the prior year from the now discontinued Legacy Sema4 business, which included restructuring costs associated with headcount reduction actions and accelerated amortization for capitalized software no longer in use.

Selling and Marketing

Selling and marketing expenses increased by $6.4 million, or 11%, to $67.4 million for the year ended December 31, 2024, from $61.0 million for the year ended December 31, 2023. The increase reflects our investment to support growth in our commercial team as well as incremental variable billing and selling cost

General and Administrative

General and administrative expenses decreased by $32.6 million, or 24%, to $101.1 million for the year ended December 31, 2024, from $133.8 million for the year ended December 31, 2023. The decrease was attributable to lower current period expenses related to professional services, software and information technology related costs, insurance costs, fixed asset depreciation and personnel-related costs from the now discontinued Legacy Sema4 business.

Impairment Loss

The non-cash charge of $10.4 million for the year ended December 31, 2023 reflected the impairment of certain capital and right-of-use asset leases. See Note 5, "*Property and Equipment, net*" to our consolidated financial statements for further information.

Other Operating Expenses, Net

Other operating expenses, net were $3.4 million for the year ended December 31, 2024, reflecting related party expenses.

Other operating expenses, net were $7.2 million for the year ended December 31, 2023 and included related party expenses of $5.3 million and a non-cash charge of $3.6 million to reserve for obsolete Legacy Sema4 inventory, partially offset by a gain of $1.7 million to recognize the sale of certain assets of Legacy Sema4.

Non-Operating (Expense) Income, Net

Non-operating expense, net of $29.4 million for the year ended December 31, 2024 primarily reflected a legal settlement, net of insurance, of $12.8 million, a non-cash charge of $10.1 million associated with the exercise of the Perceptive warrant and a non-cash charge of $3.3 million to account for the increase in fair value of our warrant liabilities. Net interest expense for the year ended December 31, 2024 was $3.0 million.

Non-operating income, net of $3.9 million for the year ended December 31, 2023, primarily reflected non-cash benefits of $1.2 million to account for the decrease in fair value of our warrants and contingent liabilities and $2.8 million for a principal loan forgiveness under the amendment to the Connecticut Department of Economic and Community Development ("DECD") loan, partially offset by $1.0 million in contract termination costs associated with the now discontinued Legacy Sema4 business. Net interest income for the year ended December 31, 2023 was $1.1 million.

See Note 4, "*Fair Value Measurement*", Note 8, "*Long-Term Debt*" and Note 10, "*Purchase Commitments and Contingencies*" to our consolidated financial statements for further information.

Reconciliation of Non-GAAP Financial Measures

In addition to our results determined in accordance with accounting principles generally accepted in the United States ("U.S. GAAP" or "GAAP"), we believe the following non-GAAP measures are useful in evaluating our operating performance. We use the following non-GAAP financial information to evaluate our ongoing operations and for internal planning and forecasting purposes. We believe that non-GAAP financial information, when taken collectively, may be helpful to investors because it provides consistency and comparability with past financial performance. However, non-GAAP financial information is presented for supplemental informational purposes only and should not be considered in isolation or as a substitute for financial information presented in accordance with GAAP. In addition, other companies, including companies in our industry, may calculate similarly-titled non-GAAP measures differently or may use other measures to evaluate their performance, all of which could reduce the usefulness of our non-GAAP financial measures as tools for comparison. A reconciliation is provided below for each non-GAAP financial measure to the most directly comparable financial measure stated in accordance with GAAP. Investors are encouraged to

review the related GAAP financial measures and the reconciliation of these non-GAAP financial measures to their most directly comparable GAAP financial measures, and not to rely on any single financial measure to evaluate our business.

Non-GAAP financial measures have limitations as analytical tools and you should not consider them in isolation, or as substitutes for analysis of our results as reported under GAAP. We may in the future incur expenses similar to the adjustments in the presentation of non-GAAP financial measures. Other limitations include that non-GAAP financial measures do not reflect:

- all expenditures or future requirements for capital expenditures or contractual commitments;
- changes in our working capital needs;
- the costs of replacing the assets being depreciated, which will often have to be replaced in the future;
- the non-cash component of employee compensation expense; and
- the impact of earnings or charges resulting from matters we consider not to be reflective, on a recurring basis, of our ongoing operations.

Adjusted Gross Profit and Adjusted Gross Margin

Adjusted gross profit is a non-GAAP financial measure that we define as revenue less cost of services, excluding depreciation and amortization expense, stock-based compensation expense and restructuring costs. We define adjusted gross margin as our adjusted gross profit divided by our revenue. We believe these non-GAAP financial measures are useful in evaluating our operating performance compared to that of other companies in our industry, as these metrics generally eliminate the effects of certain items that may vary from company to company for reasons unrelated to overall operating performance.

The following is a reconciliation of revenue to our adjusted gross profit and adjusted gross margin for the years ended December 31, 2024 and 2023 (in thousands):

	Year Ended December 31,	
	2024	**2023**
Revenue	$ 305,450	$ 202,566
Cost of services	111,053	112,560
Gross profit	**194,397**	**90,006**
Gross margin	*64 %*	*44 %*
Add:		
Depreciation and amortization expense	$ 4,047	$ 4,350
Stock-based compensation expense	431	(1,217)
Restructuring expense	54	139
Adjusted gross profit	**$ 198,929**	**$ 93,278**
Adjusted gross margin	*65 %*	*46 %*

Adjusted Net Income (Loss)

Adjusted net income (loss) is a non-GAAP financial measure that we define as net income (loss) adjusted for depreciation and amortization, stock-based compensation expenses, impairment loss, restructuring and business exit related charges, change in fair market value of financial liabilities, transaction costs and other (income) expense, net. We believe adjusted net income (loss) is useful in evaluating our operating performance compared to that of other companies in our industry, as this metric generally eliminates the effects of certain factors that may vary from company to company for reasons unrelated to overall operating performance.

The following is a reconciliation of our net loss to adjusted net income (loss) for the years ended December 31, 2024 and 2023 (in thousands):

	Year Ended December 31,	
	2024	2023
Net loss	$ (52,286)	$ (175,767)
Depreciation and amortization	21,953	33,734
Stock-based compensation expense	9,138	(326)
Impairment loss [1]	—	10,402
Restructuring costs [2]	1,752	6,532
Change in fair value of warrants and contingent liabilities [3]	13,370	(1,170)
Gain on sale of assets [4]	—	(1,677)
Provision for excess and obsolete inventory associated with Legacy Sema4	—	3,634
Gain on debt forgiveness [5]	—	(2,750)
Other [6]	12,789	1,131
Adjusted net income (loss)	$ 6,716	$ (126,257)

(1) Represents the impairment of certain capital and right-of-use asset leases.
(2) Represents costs incurred for restructuring activities, which include severance, and in the prior period, third-party consulting costs.
(3) Represents the change in fair market value of the liabilities associated with our public warrants, private placement warrants, Perceptive warrants and the earn-out shares.
(4) Represents a prior year gain recognized on the sale of certain assets sold as a result of an auction.
(5) Represents principal loan forgiveness under the amendment to the DECD loan.
(6) For the year ended December 31, 2024, represents a legal settlement for a certain litigation matter. See Note 10, "*Purchase Commitments and Contingencies*" to our consolidated financial statements for further information. For the year ended December 31, 2023, represents contract termination costs associated with the now discontinued Legacy Sema4 business.

Liquidity and Capital Resources

As of December 31, 2024, our existing cash and cash equivalents and available-for-sale marketable securities were $141.2 million.

We believe that our cash and cash equivalents and available-for-sale marketable securities provide us with sufficient liquidity for at least twelve months from the filing date of this Annual Report. Accordingly, our consolidated financial statements included in this Annual Report have been prepared on a basis that assumes we will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the ordinary course of business. Nevertheless, we may also seek additional funding in the future through the sale of common or preferred equity or convertible debt securities, by entering into other credit facilities or other forms of third-party funding, or other debt financing or by disposing of assets or businesses.

We have an effective shelf registration statement that we filed with the SEC in August of 2022, registering $300 million of shares of our Class A common stock and other securities. As of December 31, 2024, approximately $102 million of securities remained available under this registration statement. Further, we have entered into a sales agreement (the "Sales Agreement") with TD Securities (USA) LLC ("TD Cowen") pursuant to which we may, but are not obligated to, offer and sell, from time to time, shares of our Class A common stock with an aggregate offering price up to $75.0 million through TD Cowen, as sales agent, subject to the terms and conditions described in the Sales Agreement and SEC rules and regulations (our "ATM offering"). As of December 31, 2024, approximately $26.8 million of capacity remained available under this ATM offering.

Material Cash Requirements for Known Contractual Obligations and Commitments

The following is a description of commitments for known and reasonably likely cash requirements as of December 31, 2024 and December 31, 2023. We anticipate fulfilling such commitments with our existing cash and cash equivalents and available-for-sale marketable securities or through additional capital raised to finance our operations.

Our future minimum payments under non-cancellable operating lease and finance lease agreements were $62.3 million and $31.9 million, respectively as of December 31, 2024. The timing of these future payments, by year, can be found in our consolidated financial statements in Note 9, "*Leases*", included within this Annual Report.

As discussed in the notes to our consolidated financial statements, in 2022, we entered into an agreement with one of our third-party payors to settle for $42.0 million claims related to coverage and billing matters allegedly resulting in overpayments by the

payor to Legacy Sema4. As of December 31, 2024, remaining payments due to the payor were $12.0 million. For more information regarding this matter, see Note 3, "*Revenue Recognition*" included within this Annual Report.

Our future contractual purchase commitments were $37.6 million as of December 31, 2024. The timing of these future payments, by year, can be found in our consolidated financial statements in Note 10, "*Purchase Commitments and Contingencies*", included within this Annual Report.

Cash Flows

	Year Ended December 31,	
(in thousands)	**2024**	**2023**
Net cash used in operating activities	$ (28,496)	$ (180,147)
Net cash used in investing activities	(30,132)	(43,726)
Net cash provided by financing activities	44,162	186,238

Operating Activities

Net cash used in operating activities during the year ended December 31, 2024 was $28.5 million, driven by lower cash expenditures in the current year as compared with the prior year, which reflected improved gross margin profitability, as well as the realization of cost savings from the exited Legacy Sema4 business and previously executed cost reduction initiatives.

Net cash used in operating activities during the year ended December 31, 2023 was $180.1 million, which was primarily attributable to a net loss of $175.8 million and unfavorable working capital associated with the wind down of the Legacy Sema4 accounts payable, primarily during the second half of 2023, which was partially offset by the release of a third-party payor reserve.

Investing Activities

Net cash used in investing activities during the year ended December 31, 2024 was $30.1 million which included purchases of marketable securities of $66.3 million and $5.5 million in purchases of property and equipment, partially offset by $41.7 million in proceeds from the sales and maturities of marketable securities.

Net cash used in investing activities during the year ended December 31, 2023 was $43.7 million, which included purchases of marketable securities of $47.7 million, $12.1 million in consideration held in escrow paid for the Acquisition and $5.3 million in purchases of property and equipment, which was offset partially by $17.8 million in proceeds from maturities of marketable securities and $4.0 million in proceeds from the sale of assets.

Financing Activities

Net cash provided by financing activities during the year ended December 31, 2024 was $44.2 million, which included $46.5 million in proceeds from our ATM offering, net of issuance costs, partially offset by $2.7 million of finance lease payments and $0.5 million of principal payments on the DECD loan.

Net cash provided by financing activities during the year ended December 31, 2023 was $186.2 million, which was primarily driven by the $143.0 million net proceeds from the underwritten public offering and concurrent registered direct offering, net of issuance costs, and $48.5 million from the term loan facility with Perceptive (the "Perceptive Term Loan Facility"), which was offset partially by the DECD loan payment of $2.0 million and $3.6 million of finance lease payments.

Recent Accounting Pronouncements

Information on recent accounting pronouncements can be found in Note 2, "*Summary of Significant Accounting Policies*".

Filer Status

Loss of Smaller Reporting Company Status

As the market value of our shares of Class A common stock held by non-affiliates was between $250.0 million and $700.0 million as of June 28, 2024 (the last business day of our most recently completed second fiscal quarter) and our revenue for the year ended December 31, 2023 was more than $100.0 million, we continue to be deemed an accelerated filer under the Securities Exchange Act of 1934, as amended (the "Exchange Act") as of December 31, 2024. However, we are no longer a "smaller

reporting company" and will no longer be eligible to rely on the scaled disclosure exemptions available to smaller reporting companies starting with our first Quarterly Report on Form 10-Q in 2025.

JOBS Act Accounting Election

We are an "emerging growth company" within the meaning of the Jumpstart Our Business Startups Act (the "JOBS Act"). The JOBS Act allows an emerging growth company to delay the adoption of new or revised accounting standards that have different effective dates for public and private companies until those standards apply to private companies. We have elected to use this extended transition period and, as a result, our financial statements may not be comparable to companies that comply with public company effective dates. We also intend to rely on other exemptions provided by the JOBS Act, including not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act.

We will remain an emerging growth company until the earliest of (1) September 1, 2025, (2) the last day of the fiscal year in which we have total annual gross revenue of at least $1.235 billion, (3) the last day of the fiscal year in which we are deemed to be a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our Class A common stock held by non-affiliates exceeded $700.0 million as of the last business day of the second fiscal quarter of such year or (4) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these consolidated financial statements requires us to make judgments, estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. Our estimates are based on our historical experience and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about items that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

See Note 2, "*Summary of Significant Accounting Policies*" to our consolidated financial statements for a complete description of each of these critical accounting policies and estimates. Each of these critical accounting policies could potentially generate materially different results if we were to change underlying assumptions, estimates and/or judgments. Although actual results may differ from those estimates, we believe the estimates are reasonable and appropriate.

Revenue Recognition

We recognize revenue when, or as, performance obligations under the terms of a contract are satisfied, which occurs when control of the promised products or services are transferred to a customer. Revenue is measured as the amount of consideration we expect to receive in exchange for transferring products or services to a customer. Our contracts require significant judgments in determining the transaction price and satisfying performance obligations.

Diagnostic Test Revenue

We estimate a transaction price in arrangements with third-party insurance payors based on historical collection experience, contractual provisions and insurance reimbursement policies, payor mix, and other relevant information for applicable payor portfolios. The portfolio approach is used as a practical expedient to account for categories of diagnostic test contracts as collective groups rather than on an individual contract basis. Management believes that revenue recognized by utilizing the portfolio approach approximates the revenue that would have been recognized if an individual contract approach was used. For orders received for self-pay patients, we determine a transaction price associated with services rendered in consideration of implicit price concessions that are granted to such orders. The estimates for implicit price concessions require significant judgment and are based upon management's assessment of expected net collections, business and economic conditions, historical trends, trends in federal, state and private employer health care coverage and other collection indicators. For institutional clients, the customer is the institution. We determine a transaction price associated with services rendered in accordance with the contractual rates established with each customer.

We monitor these estimates at each reporting period based on actual cash collections in order to assess whether a revision to the estimate is required. Both the initial estimate and any subsequent revision to the estimate contain uncertainty and require the use of judgment in the estimation of the transaction price and application of the constraint for variable consideration. If actual results in the future vary from our estimates, we will adjust these estimates, which could affect revenue and earnings in the period such variances become known.

Other Revenue

We also recognize revenue from collaboration service agreements with biopharma companies and other third parties pursuant to which we health information and patient identification support services. Certain of these contracts provide non-refundable upfront payments, which we record as contract liabilities, and variable payments based upon the achievement of certain milestones during the contract term. Milestone payments are a form of variable consideration that are included in the transaction price only when it is probable that doing so will not result in a significant reversal of cumulative revenue recognized when the uncertainty associated with the milestone is subsequently resolved.

For certain service or collaboration contracts that require us to transfer control of the service over time, we recognize revenue over time using an input measure based on costs incurred on the basis that this measure best reflects the pattern of transfer of control of the services to the customer. The measure of progress is developed using our best estimate of the performance period and the anticipated costs to be incurred to perform such services, including any subcontracted service costs.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to market risks in the ordinary course of our business. These risks primarily relate to interest rates. Our cash, cash equivalents, available-for-sale marketable securities and restricted cash consists of bank deposits and money market funds, which totaled $142.2 million and $131.1 million at December 31, 2024 and 2023, respectively. Such interest-bearing instruments carry a degree of risk. However, because our investments are primarily high-quality credit instruments with short-term durations with high-quality institutions, we have not been exposed to, nor do we anticipate being exposed to, material risks due to changes in interest rates. A 100-basis-point change in interest rates would not have a material effect on the fair market value of our cash, cash equivalents and restricted cash.

We are also exposed to interest rate risk on our variable rate debt associated with the Perceptive Term Loan Facility. Changes in interest rates can impact future interest payments we are obligated to pay.

See Note 8, "*Long-Term Debt*" to our consolidated financial statements for further information.

Item 8. Financial Statements and Supplementary Data

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of GeneDx Holdings Corp.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of GeneDx Holdings Corp. (the Company) as of December 31, 2024 and 2023, the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows for each of the two years in the period ended December 31, 2024, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2024 and 2023, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2024, in conformity with U.S. generally accepted accounting principles.

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 in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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/ ERNST & YOUNG LLP

We have served as the Company's auditor since 2018.

New York, New York
February 20, 2025

GeneDx Holdings Corp.
Consolidated Balance Sheets
(in thousands, except share and per share amounts)

	December 31,	
	2024	2023
Assets		
Current assets:		
Cash and cash equivalents	$ 85,212	$ 99,681
Marketable securities	55,973	30,467
Accounts receivable	37,426	32,371
Due from related parties	203	445
Inventory, net	10,650	8,777
Prepaid expenses and other current assets	8,504	10,598
Total current assets	197,968	182,339
Operating lease right-of-use assets	25,613	26,900
Property and equipment, net	32,893	32,479
Intangible assets, net	158,600	172,625
Other assets	4,306	4,413
Total assets	$ 419,380	$ 418,756
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 30,044	$ 37,456
Due to related parties	1,607	1,379
Short-term lease liabilities	3,336	3,647
Other current liabilities	19,830	16,336
Total current liabilities	54,817	58,818
Long-term debt, net of current portion	51,913	52,688
Long-term lease liabilities	60,919	62,938
Other liabilities	5,519	14,735
Deferred taxes	965	1,560
Total liabilities	174,133	190,739
Purchase commitments and contingencies (Note 10)		
Stockholders' Equity:		
Preferred Stock, $0.0001 par value: 1,000,000 shares authorized, 0 shares issued and outstanding at December 31, 2024 and December 31, 2023, respectively	—	—
Class A common stock, $0.0001 par value: 1,000,000,000 shares authorized, 28,016,545 and 25,978,863 shares issued and outstanding at December 31, 2024 and December 31, 2023, respectively	2	2
Additional paid-in capital	1,596,889	1,527,778
Accumulated deficit	(1,352,474)	(1,300,188)
Accumulated other comprehensive income	830	425
Total stockholders' equity	245,247	228,017
Total liabilities and stockholders' equity	$ 419,380	$ 418,756

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

GeneDx Holdings Corp.
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except per share and share amounts)

	Year Ended December 31,	
	2024	**2023**
Revenue		
Diagnostic test revenue	$ 302,157	$ 195,654
Other revenue	3,293	6,912
Total revenue	305,450	202,566
Cost of services	111,053	112,560
Gross profit	194,397	90,006
Research and development	45,722	58,266
Selling and marketing	67,371	60,956
General and administrative	101,110	133,755
Impairment loss	—	10,402
Other operating expenses, net	3,407	7,223
Loss from operations	(23,213)	(180,596)
Non-operating (expenses) income, net		
Change in fair value of warrants and contingent liabilities	(13,370)	1,170
Interest (expense) income, net	(3,032)	1,114
Other (expense) income, net	(13,014)	1,619
Total non-operating (expense) income, net	(29,416)	3,903
Loss before income taxes	(52,629)	(176,693)
Income tax benefit	343	926
Net loss	$ (52,286)	$ (175,767)
Other comprehensive income, net of tax		
Unrealized gain related to available for sale securities, net	405	425
Comprehensive loss	$ (51,881)	$ (175,342)
Weighted average shares outstanding of Class A common stock	26,891,213	24,311,989
Basic and diluted net loss per share, Class A common stock	$ (1.94)	$ (7.23)

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

GeneDx Holdings Corp.
Consolidated Statements of Stockholders' Equity
(in thousands, except share amounts)

	Class A Common Stock		Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive income	Total stockholders' equity
	Shares	Par Value				
Balance at December 31, 2022	**11,773,065**	**$ 1**	**$ 1,378,125**	**$ (1,124,421)**	**—**	**$ 253,705**
Net loss	—	—	—	(175,767)	—	(175,767)
Common stock issued pursuant to stock option exercises	50,444	—	285	—	—	285
Stock-based compensation expense	—	—	(326)	—	—	(326)
Vested restricted stock units converted to common stock	431,671	—	—	—	—	—
Other comprehensive income, net of tax	—	—	—	—	425	425
Issuance of common stock in registered direct offering, net of issuance costs	676,868	—	7,564	—	—	7,564
Issuance of common stock for first Milestone Payment	701,460	—	6,692	—	—	6,692
Fractional shares issued upon reverse stock split	29,603	—	—	—	—	—
Issuance of common stock in underwritten public offering, net of issuance costs	12,315,752	1	135,438	—	—	135,439
Balance at December 31, 2023	**25,978,863**	**$ 2**	**$ 1,527,778**	**$ (1,300,188)**	**$ 425**	**$ 228,017**
Net loss	—	—	—	(52,286)	—	(52,286)
Common stock issued pursuant to stock option exercises	68,453	—	394	—	—	394
Common stock issued pursuant to Perceptive warrant exercise	645,414	—	12,586	—	—	12,586
Stock-based compensation expense	—	—	9,138	—	—	9,138
Other comprehensive income, net of tax	—	—	—	—	405	405
Vested restricted stock units converted to common stock	471,663	—	—	—	—	—
Issuance of common stock in ATM offering, net of issuance costs	825,379	—	46,496	—	—	46,496
Common stock issued pursuant to employee stock purchase plan	26,773	—	497	—	—	497
Balance at December 31, 2024	**28,016,545**	**$ 2**	**$ 1,596,889**	**$ (1,352,474)**	**$ 830**	**$ 245,247**

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

GeneDx Holdings Corp.
Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,	
	2024	2023
Operating activities		
Net loss	$ (52,286)	$ (175,767)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	21,953	33,734
Stock-based compensation expense	9,138	(326)
Change in fair value of warrants and contingent liabilities	13,370	(1,170)
Deferred tax benefit	(343)	(926)
Provision for excess and obsolete inventory	180	3,913
Change in third party payor reserves	607	(9,745)
Gain on sale of assets	—	(1,677)
Gain on debt forgiveness	—	(2,750)
Impairment loss	—	10,402
Other	3,630	2,406
Change in operating assets and liabilities:		
Accounts receivable	(5,421)	10,263
Inventory	(2,585)	975
Accounts payable and accrued expenses	(20,461)	(46,953)
Other assets and liabilities	3,722	(2,526)
Net cash used in operating activities	(28,496)	(180,147)
Investing activities		
Proceeds from maturities of marketable securities	41,060	17,765
Purchases of marketable securities	(66,302)	(47,670)
Purchases of property and equipment	(5,491)	(5,250)
Proceeds from sales of marketable securities	601	—
Consideration on escrow paid for Legacy GeneDx acquisition	—	(12,144)
Proceeds from sales of assets	—	4,034
Development of internal-use software assets	—	(461)
Net cash used in investing activities	(30,132)	(43,726)
Financing activities		
Proceeds from offerings, net of issuance costs	46,496	143,002
Exercise of stock options	394	285
Issuance of stock pursuant to employee stock purchase plan	497	—
Long-term debt principal payments	(497)	(2,000)
Finance lease payoff and principal payments	(2,728)	(3,598)
Proceeds from long-term debt	—	48,549
Net cash provided by financing activities	44,162	186,238
Net decrease in cash, cash equivalents and restricted cash	(14,466)	(37,635)
Cash, cash equivalents and restricted cash, at beginning of year	100,668	138,303
Cash, cash equivalents and restricted cash, at end of year	$ 86,202	$ 100,668
Supplemental disclosures of cash flow information		
Stock consideration paid pursuant to exercise of Perceptive warrant	$ 12,586	$ —
Cash paid for interest	$ 6,677	$ 3,041
Purchases of property and equipment in accounts payable and accrued expenses	$ 2,597	$ 134
Cash paid for taxes	$ 1,167	$ 1,465
Assets acquired under capital leases obligations	$ 689	$ —
Issuance of common stock for first Milestone Payment	$ —	$ 6,692
Lease liability from obtaining right-of-use asset	$ —	$ 637

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

GeneDx Holdings Corp.

Notes to Consolidated Financial Statements

1. Organization and Description of Business

GeneDx Holdings Corp., through its subsidiary GeneDx, LLC, is a leading genomics company—one that sits at the intersection of diagnostics and data science, pairing decades of genomic expertise with an ability to interpret clinical data at scale. The Company believes that everyone deserves personalized, targeted medical care—and that it all begins with a genetic diagnosis. Fueled by one of the world's largest rare disease data sets, the Company's industry-leading exome and genome tests translate complex genomic data into clinical answers that unlock personalized health plans, accelerate drug discovery, and improve health system efficiencies. The Company operates with conviction that what is best for patients must be embedded in every aspect of our work. In support of these beliefs, we value equitability, simplicity and transparency.

Unless otherwise stated herein or unless the context otherwise requires, references in these notes to:

- "GeneDx Holdings" refer to GeneDx Holdings Corp., a Delaware corporation;
- "Legacy GeneDx" refer to GeneDx, LLC, a Delaware limited liability company, which we acquired on April 29, 2022 (the "Acquisition");
- "Legacy Sema4" refer to Sema4 OpCo Inc., a Delaware corporation, which consummated the business combination with CM Life Sciences, Inc. ("CMLS") on July 22, 2021 (the "Business Combination"); and
- "we," "us" and "our," the "Company" and "GeneDx" refer, as the context requires, to GeneDx Holdings and its consolidated subsidiaries.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States ("U.S. GAAP"). These financial statements consolidate the operations and accounts of the Company and its wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated. Unless otherwise noted, all tabular dollars are in thousands, except per share amounts.

Emerging Growth Company

The Company is an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012. In addition, the Company was previously a "smaller reporting company", as defined in Item 10(f)(1) of the SEC's Regulation S-K and currently takes advantage of certain of the scaled disclosures available to smaller reporting companies. As such, the Company is eligible for exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies, including reduced reporting, including the reporting of two fiscal years of financial statements, not being required to provide an auditor attestation of internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act, and extended transition periods to comply with new or revised accounting standards for public business entities. The Company has elected to avail itself of this exemption and, therefore, will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Use of Estimates

The preparation of the Company's consolidated financial statements in conformity with U.S. GAAP requires management to make certain estimates, judgments and assumptions that affect the reported amounts of assets and liabilities and the related disclosures at the date of the consolidated financial statements as well as the reported amounts of revenues and expenses during the periods presented. The Company bases these estimates on current facts, historical and anticipated results, trends and various other assumptions that it believes are reasonable in the circumstances, including assumptions as to future events. These estimates include, but are not limited to, the transaction price for certain contracts with customers, potential or actual claims for recoupment from third-party payors, the valuation of stock-based awards, the valuation of warrant liabilities and income taxes. Actual results could differ materially from those estimates, judgments and assumptions.

Concentration of Credit Risk and Other Risks and Uncertainties

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents, marketable securities and accounts receivable. The majority of the Company's cash, cash equivalents and restricted cash are uninsured with account balances in excess of the Federal Deposit Insurance Company limits.

The Company's cash, cash equivalents and marketable securities are deposited with high-quality financial institutions. Management believes these financial institutions are financially sound and, accordingly, that minimal credit risk exists. The Company is exposed to credit risk in the event of a default by the financial institutions holding its cash in excess of government insured limits and in the event of default by corporations and governments in which it holds investments in cash equivalents and short-term debt securities, to the extent recorded on the consolidated balance sheet. The Company has not experienced any losses on its deposits of cash and cash equivalents.

The Company assesses both the self-pay patient and the third-party payor that reimburses the Company on the patient's behalf and, institutional billed clients when evaluating concentration of credit risk from customers. Significant patients and payors are those that represent more than 10% of the Company's total annual revenues or accounts receivable balance at each respective balance sheet date. The significant concentrations of accounts receivable as of December 31, 2024 and 2023 were primarily from large managed care insurance companies, institutional billed accounts, and data arrangements. There was no individual patient or client that accounted for 10% or more of revenue or accounts receivable for any of the years presented. The Company does not require collateral as a means to mitigate customer credit risk.

For each significant payor, revenue as a percentage of total revenues and accounts receivable as a percentage of total accounts receivable are as follows:

	Revenue		Accounts Receivable	
	Year Ended December 31,		As of December 31,	
	2024	2023	2024	2023
Payor A [(1)]	22%	18%	13%	*
Payor B	32%	28%	11%	10%

* less than 10%

(1) This payor group includes multiple individual plans and the Company calculates and presents the aggregated value from all plans, which is consistent with the Company's portfolio approach used in accounting for diagnostic test revenue.

The Company is subject to a concentration of risk from a limited number of suppliers for certain reagents and laboratory supplies. One supplier accounted for approximately 13% and 11% of purchases for the years ended December 31, 2024 and 2023, respectively. Another supplier accounted for approximately 10% and 11% of purchases for the years ended December 31, 2024 and 2023, respectively. This risk is managed by maintaining a target quantity of surplus stock. Alternative suppliers are available for some or all of these reagents and supplies.

Revenue Recognition

The Company recognizes revenue when control of the promised goods or services is transferred to the customer in an amount that reflects the consideration which the Company expects to be entitled to in exchange for those goods or services. If any changes in customer credit issues are identified which were not assessed at the date of service, provisions for credit losses are recognized and recorded.

Diagnostic test revenue

The Company's diagnostic test revenue contracts typically consist of a single performance obligation to deliver diagnostic testing services to the ordering facility or patient and therefore allocation of the contract transaction price is not applicable. Control over diagnostic testing services is generally transferred at a point in time when the customer obtains control of the promised service which is upon delivery of the test.

Diagnostic test revenues consist primarily of services reimbursed by third-party insurance payors. Third-party insurance payors include managed care health plans and commercial insurance companies, including plans offered through the health insurance exchanges, and employers. In arrangements with third-party insurance payors, the transaction price is stated within the contract, however, the Company accepts payments from third-party payors that are less than the contractually stated price and is therefore variable consideration and the transaction price is estimated.

When determining the transaction price, the Company uses a portfolio approach as a practical expedient to account for categories of diagnostic test contracts as collective groups rather than on an individual contract basis. The portfolio consists of major payor classes based on third-party payors. Based on historical collection trends and other analyses, the Company believes that revenue recognized by utilizing the portfolio approach approximates the revenue that would have been recognized if an individual contract approach was used.

Estimates of allowances for third-party insurance payors that impact the estimated transaction price are based upon the pricing and payment terms specified in the related contractual agreements. Contractual pricing and payment terms in third-party insurance agreements are generally based upon predetermined rates per diagnosis, per diem rates or discounted fee-for-service rates. In addition, for third-party payors in general, the estimated transaction price is impacted by factors such as historical collection experience, contractual provisions and insurance reimbursement policies, payor mix, and other relevant information for applicable payor portfolios.

For institutional clients, the customer is the institution. The Company determines the transaction price associated with services rendered in accordance with the contractual rates established with each customer.

Payment terms and conditions vary by contract and customer, however standard payment terms are generally less than 60 days from the invoice date. In instances where the timing of the Company's revenue recognition differs from the timing of its invoicing, the Company does not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the customer and the transfer of the promised services to the customer will be one year or less.

Other revenue

The Company enters into both short-term and long-term project-based collaboration and service agreements with customers. Certain of these contracts include a license to directly access the Company's intellectual property or participation by the Company on joint steering committees with the customer, which was considered to be immaterial in the context of the contract. The Company concludes that the goods and services transferred to our customers pursuant to these agreements generally comprise a single performance obligation on the basis that such goods and services are not distinct within the context of the contract. This is because the goods and services are highly interdependent and interrelated such that the Company would not be able to fulfill its underlying promise to our customers by transferring each good or service independently.

Certain of these contracts include non-refundable upfront payments and variable payments based upon the achievement of certain milestones or fixed monthly payments during the contract term. Non-refundable upfront payments received prior to the Company performing performance obligation are recorded as a contract liability upon receipt. Milestone payments are included in the transaction price only when it is probable that doing so will not result in a significant reversal of cumulative revenue recognized when the uncertainty associated with the milestone is subsequently resolved. For longer-term contracts, the Company does not account for a significant financing component since a substantial amount of the consideration promised by the customer is variable and the amount or timing of that consideration varies on the basis of a future event that is not substantially within the control of either party.

The Company satisfies its performance obligation generally over time if the customer simultaneously receives and consumes the benefits provided by the Company's services as the Company performs those services. The Company recognizes revenue over time using an input measure based on costs incurred on the basis that this measure best reflects the pattern of transfer of control of the services to the customer. In some contracts, the Company subcontracts certain services to other parties for which the Company is ultimately responsible. Costs incurred for such subcontracted services are included in the Company's measure of progress for satisfying its performance obligation and are recorded in cost of services in the consolidated statements of operations and comprehensive loss. Changes in the total estimated costs to be incurred in measuring the Company's progress toward satisfying its performance obligation may result in adjustments to cumulative revenue recognized at the time the change in estimate occurs.

See Note 3, "*Revenue Recognition*" for more information.

Cash, Cash Equivalents and Restricted Cash

The Company considers all highly liquid investments with original maturities of three months or less from the date of purchase to be cash equivalents. Cash equivalents consist of amounts invested in money market funds and debt securities. Carrying values of cash equivalents approximate fair value due to the short-term nature of these instruments. The current and long-term portions of restricted cash are included within prepaid expenses and other current assets and other assets.

Marketable Securities

Marketable securities are classified as current assets as these investments are intended to be available to the Company for use in funding current operations. Unrealized gains and losses on available for sale securities are deemed temporary and are classified in accumulated other comprehensive income within stockholders' equity. Changes in the fair value of available for sale securities impact earnings only when such securities are sold, or an allowance for expected credit losses or impairment is recognized. The cost of marketable securities sold is based on the specific identification method. We regularly evaluate our portfolio of marketable securities for expected credit losses and impairment for any decline in fair value determined to be other-than-temporary. In

making this judgement, we evaluate, among other things, the extent to which the fair value of a security is less than its amortized cost; the financial condition of the issuer, including the credit quality, and any changes thereto; and our intent to sell, or whether we will more likely than not be required to sell, the security before recovery of its amortized cost basis. Our assessment of whether a marketable security has a credit loss or is impaired could change in the future due to new developments or changes in assumptions related to any particular security.

See Note 4, "*Fair Value Measurements*" for more information.

Accounts Receivable

Accounts receivable consists of amounts due from customers and third-party payors for services performed and reflect the consideration to which the Company expects to be entitled in exchange for providing those services. Accounts receivable is estimated and recorded in the period the related revenue is recorded. During the years ended December 31, 2024 and 2023, the Company did not record provisions for credit losses. The Company wrote off $0.4 million of accounts receivable balances for the year ended December 31, 2024 and none for the year ended December 31, 2023.

Inventory, net

Inventory, net, which primarily consists of finished goods such as testing supplies and reagents, is capitalized when purchased and expensed when used in performing services. Inventory is stated at the lower of cost or net realizable value. Cost is determined using actual costs on a first-in, first-out basis. The Company periodically performs obsolescence assessments and writes off any inventory that is no longer usable. Any write-down of inventory to net realizable value creates a new cost basis.

Property and Equipment, net

Property and equipment, net are stated at cost less accumulated depreciation and amortization. Equipment includes assets under finance lease. Improvements are capitalized, while maintenance and repairs are expensed as incurred. When assets are retired or otherwise disposed of, the cost and accumulated depreciation and amortization are removed from the consolidated balance sheets and any resulting gain or loss is reflected in the consolidated statements of operations and comprehensive loss in the period realized.

Finance leases and leasehold improvements are amortized straight-line over the shorter of the term of the lease or the estimated useful life. All other property and equipment assets are depreciated using the straight-line method over the estimated useful life of the asset, which ranges from three to five years.

The Company reviews the recoverability of its long-lived assets when events or changes in circumstances occur that indicate that the carrying value of the asset or asset group may not be recoverable. An impairment loss is recognized when the total estimated future undiscounted cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount. Impairment, if any, is assessed using discounted cash flows or other appropriate measures of fair value.

See Note 5, "*Property and Equipment*".

Intangible Assets, Net

Amortizable intangible assets include trade names and trademarks, developed technology and customer relationships acquired as part of business combinations. Intangible assets are amortized on a straight-line basis. All intangible assets subject to amortization are reviewed for impairment in accordance with ASC Topic 360, *Property, Plant and Equipment*. There were no impairment losses recorded on intangible assets for any periods presented.

See Note 6, "*Intangible Assets*" for more information.

Fair Value Measurements

Financial assets and liabilities are recorded at fair value. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The Company determines the fair value of its financial instruments based on assumptions that market participants would use in pricing an asset or liability in the principal or most advantageous market. The following hierarchy lists three levels of fair value based on the extent to which inputs used in measuring fair value are observable in the market:

Level 1: Observable inputs such as quoted prices (unadjusted) in active markets that are accessible at the measurement date for identical assets or liabilities.

Level 2: Observable inputs such as quoted prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active or model-derived valuations whose significant inputs are observable.

Level 3: Unobservable inputs that are significant to the measurement of fair value but are supported by little to no market data.

The Company's financial assets and liabilities consist of cash and cash equivalents, marketable securities, accounts receivable, other current assets, accounts payable and accrued expenses, other current liabilities, and long-term debt. The Company's carrying value of cash and cash equivalents, accounts receivable, other current assets, accounts payable, accrued expenses and other current liabilities approximate their fair value due to the relatively short-term nature of these accounts.

See Note 4, "*Fair Value Measurements*" for more information.

Warrant Liability

The Company accounts for warrants as liability-classified instruments based on an assessment of the warrant terms and applicable authoritative guidance in accordance with ASC Topic 480, *Distinguishing Liabilities from Equity* ("ASC 480") and ASC Topic 815, *Derivatives and Hedging* ("ASC 815"). The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, whether the warrants meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815. This assessment is conducted at the time of warrant issuance. The warrant liabilities are recorded on the consolidated balance sheets at fair value on their respective issuance dates, with subsequent changes in respective fair values recognized on the consolidated statements of operations and comprehensive loss at each reporting date.

See Note 4, "*Fair Value Measurements*" for more information.

Stock-Based Compensation

The Company measures stock-based compensation at the grant date based on the fair value of the award and recognizes stock-based compensation expense over the requisite service period for each separate vesting portion of the award on a straight-line basis.

The Company uses the Black-Scholes option-pricing model to estimate the fair value of its stock option awards. Determining the fair value of stock option awards requires judgment, including estimating expected stock price volatility and expected option term. The Company estimates a volatility factor for the Company's options based on analysis of historical share prices of a peer group of public companies, the historical share prices of the Company, and the implied volatility of the Company's call options. The Company estimates the expected term of options granted using the "simplified method," which is the mid-point between the vesting date and the ending date of the contractual term. The Company does not rely on the historical holding periods of the Company's options due to the limited availability of exercise data. The Company uses a risk-free interest rate based on the U.S. Treasury yield curve in effect for bonds with maturities consistent with the expected term of the option. Expected dividend yield is based on the fact that the Company has never paid dividends.

Restricted stock awards are valued based on the fair value of the stock on the grant date. The Company issues new shares upon share option exercise and vesting of a restricted share unit. Forfeitures of stock-based compensation are recognized as they occur.

See Note 11, "*Stock-Based Compensation*" for more information.

Income Taxes

The Company accounts for income taxes using the asset and liability method and deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying values of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates in effect for the year in which those temporary differences are expected to be recovered or settled. A valuation allowance is established when it is more likely than not that some or all of the deferred tax assets will not be realized. Based on the Company's historical operating losses, the Company has recorded a valuation allowance to reduce deferred tax assets to the amount that is more likely than not to be realized.

The Company recognizes tax benefits from uncertain tax positions only if it is more likely than not, based on technical merits, that the position will be sustained upon examination by the appropriate taxing authorities. The amount of tax benefit recognized for an uncertain tax position is the largest that is more than 50 percent likelihood to be realized upon ultimate settlement. The Company records interest and penalties related to tax uncertainties, where appropriate, in income tax expense.

See Note 12, "*Income Taxes*" for more information.

Leases

Under the accounting standards update ("ASU") 2016-02, *Leases* to ASC Topic 842, the Company determines if an arrangement is or contains a lease at inception. A lease qualifies as a finance lease if any of the following criteria are met at the inception of the lease: (i) there is a transfer of ownership of the leased asset to the Company by the end of the lease term, (ii) the Company holds an option to purchase the leased asset that the Company is reasonably certain to exercise, (iii) the lease term is for a major part of the remaining economic life of the leased asset, (iv) the present value of the sum of lease payments equals or exceeds substantially all of the fair value of the leased asset, or (v) the nature of the leased asset is specialized to the point that it is expected to provide the lessor no alternative use at the end of the lease term. All other leases are classified as operating leases.

Right-of-use assets ("ROU assets") represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating and finance lease ROU assets and liabilities are recognized at the lease commencement date based on the present value of remaining future minimum lease payments over the lease term. The Company does not recognize a ROU asset or lease liability for leases with a term of 12 months or less and does not include variable costs, which are based on actual usage, in the measurement of ROU assets and lease liabilities. The ROU assets include any lease payments made prior to the commencement date and initial direct costs incurred and excludes lease incentives received. ROU assets are subsequently assessed for impairment in accordance with the Company's accounting policy for long-lived assets.

All lease liabilities are measured at the present value of the associated payments, discounted using the Company's incremental borrowing rate determined based on the rate of interest that the Company would pay to borrow on a collateralized basis an amount equal to the lease payments for similar term and in a similar economic environment on a collateralized basis, unless there is a rate implicit in the lease that is readily determinable. The lease liabilities are classified as current or non-current based on the expected timing of payments.

The Company recognizes lease expense for operating leases on a straight-line basis over the lease term, which may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise such options. Variable costs are expensed when the event determining the amount of variable consideration to be paid occurs. Interest expense for finance leases is recognized based on the accretion of the lease liability. The Company has operating and finance lease arrangements with lease and non-lease components. The Company accounts for lease and non-lease components as a single lease component for all leases.

See Note 9, "*Leases*" for more information.

Recently Issued Accounting Pronouncements Not Yet Adopted

Changes to U.S. GAAP are established by the Financial Accounting Standards Board (the "FASB") in the form of ASUs to the FASB's ASC. The Company considers the applicability and impact of all ASUs. ASUs not included in the disclosures in this report were assessed and determined to be either not applicable or are not expected to have a material impact on the consolidated financial statements.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes – Improvements to Income Tax Disclosures* ("ASU 2023-09"). The standard requires additional disclosures around disaggregated information about a reporting entity's effective tax rate reconciliation as well as information on income taxes paid. ASU 2023-09 will be effective for annual periods beginning after December 15, 2024, with early adoption permitted. The guidance will be applied on a prospective basis with the option to apply the standard retrospectively. The Company does not expect the adoption of ASU 2023-09 to have a material impact on its consolidated financial statements and related disclosures.

In November 2024, the FASB issued ASU 2024-03, *Disaggregation of Income Statement Expenses* ("ASU 2024-03"). The standard requires public business entities to disclose additional information about specific expense categories in the notes to financial statements at interim and annual reporting periods. ASU 2024-03 will be effective for annual periods beginning after December 15, 2026, and interim periods beginning after December 15, 2027, with early adoption permitted. The guidance will be applied on a prospective basis with the option to apply the standard retrospectively. The Company is currently evaluating the impact of the new guidance on its consolidated financial statements and related disclosures.

Recently Adopted Accounting Pronouncements

In November 2023, the FASB issued ASU 2023-07, *Improvements to Reportable Segment Disclosures* ("ASU 2023-07"). The standard requires enhanced segment reporting disclosures, including significant segment expenses and other segment items.

Additionally, the standard requires public entities to provide in interim periods all disclosures about a reportable segment's profit or loss and assets that are currently required annually. The guidance will be applied retrospectively to all periods presented in financial statements unless it is impractical to do so. The Company adopted ASU 2023-07 effective December 31, 2024 and it did not have a material impact on its consolidated financial statements and related disclosures.

3. Revenue Recognition

Disaggregated Revenue

The following table summarizes the Company's disaggregated revenue by payor category:

	Year ended December 31,					
	2024			2023		
	GeneDx	Other[1]	Total	GeneDx	Other[1]	Total
Diagnostic test revenue:						
Patients with third-party insurance	$ 231,542	$ 3,157	$ 234,699	$ 126,265	$ 8,226	$ 134,491
Institutional customers	65,115	—	65,115	59,497	—	59,497
Self-pay patients	2,343	—	2,343	1,702	(36)	1,666
Total diagnostic test revenue	299,000	3,157	302,157	187,464	8,190	195,654
Other revenue	3,293	—	3,293	6,912	—	6,912
Total	$ 302,293	$ 3,157	$ 305,450	$ 194,376	$ 8,190	$ 202,566

(1) Other represents revenues associated with the Legacy Sema4 diagnostic testing business.

Reassessment of Variable Consideration

Subsequent changes to the estimate of the transaction price, determined on a portfolio basis when applicable, are generally recorded as adjustments to revenue in the period of the change. The Company updates estimated variable consideration quarterly.

For the years ended December 31, 2024 and December 31, 2023, the total change in estimate resulted in a net increase to revenue of $15.1 million and $8.8 million respectively, resulting 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 potential and actual settlements with third party payors. The change in estimate also included an increase in revenue related to the release of a previously established payor reserve, as further disclosed in the "Certain Payor Matters" section below. During the year ended December 31, 2024, the Company recorded a discrete benefit of $6.8 million in connection with a multi-year appeal recovery from a single third-party payor.

Certain Payor Matters

As noted above, third-party payors, including government programs, may decide to deny payment or seek to recoup payments for tests performed by the Company that they contend were improperly billed, not medically necessary or against their coverage determinations, or for which they believe they have otherwise overpaid, including as a result of their own error. As a result, the Company may be required to refund payments already received, and the Company's revenues may be subject to retroactive adjustment as a result of these factors among others, including without limitation, differing interpretations of billing and coding guidance, and changes by government agencies and payors in interpretations, requirements, policies and/or "conditions of participation" in various programs. The Company processes requests for recoupment from third-party payors in the ordinary course of its business, and it is likely that the Company will continue to do so in the future. If a third-party payor denies payment for testing or recoups money from the Company in a later period, reimbursement and the associated recognition of revenue for the Company's testing services could decline.

From time to time, the Company may have an obligation to reimburse Medicare, Medicaid, and third-party payors for overpayments regardless of fault. Settlements with third-party payors for retroactive adjustments due to audits, reviews, or investigations are considered variable consideration and are included in the determination of the estimated transaction price for providing services. These settlements are estimated based on the terms of the payment agreement with the payor, correspondence from the payor, the Company's historical settlement activity (if any), and the Company's assessment of the probability a significant reversal of cumulative revenue recognized will occur when the uncertainty is subsequently resolved. Estimated settlements are adjusted in future periods as such adjustments become known (that is, if new information becomes available), or as years are settled or are no longer subject to such audits, reviews, and investigations.

On December 30, 2022, the Company entered into a settlement agreement with one of its third-party payors (the "Payor") in order to settle the claims related to coverage and billing matters allegedly resulting in the overpayments by the Payor to Legacy Sema4 (the "Disputed Claims"). Under the settlement agreement, $42.0 million is to be paid by the Company to the Payor in a series of payments each year through June 30, 2026. The first installment payment of $15.0 million was made on December 31, 2022, the second installment of $5.0 million was made on December 27, 2023, and the third installment of $10.0 million was made on December 31, 2024. As of December 31, 2024, $12.0 million in scheduled payments under the agreement remain, with $10.0 million due in December 2025 and $2.0 million in 2026. In consideration for these payments, the Payor provided releases of the Disputed Claims, effective March 31, 2023.

As a result of this matter, and in connection with a review of certain billing policies and procedures undertaken by management, the Company considered the need to establish reserves for potential recoupments of payments previously made by third-party payors. As of December 31, 2024 and December 31, 2023, $12.6 million and $27.0 million of liabilities were recorded in accounts payable and accrued expenses and other liabilities, respectively. The Company uses estimates, judgments, and assumptions to assess whether it is probable that a significant reversal in the amount of cumulative revenue may occur in future periods, based upon information presently available. These estimates are subject to change. In addition, as discussed above, the Company has made certain adjustments to its estimated variable consideration as result of this matter and other potential settlements with payors.

4. Fair Value Measurements

Financial assets and liabilities are recorded at fair value on the consolidated balance sheets on a recurring basis. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. For further information regarding the Company's fair value measurements, see Note 2, "*Summary of Significant Accounting Policies*" included within this Annual Report.

The following tables set forth the fair value of financial instruments that were measured at fair value on a recurring basis:

	December 31, 2024			
	Total	Level 1	Level 2	Level 3
Financial Assets:				
Money market funds	$ 57,907	$ 57,907	$ —	$ —
U.S. treasury bonds	30,990	—	30,990	—
Corporate and municipal bonds	25,679	—	25,679	—
Total financial assets	$ 114,576	$ 57,907	$ 56,669	$ —
Financial Liabilities:				
Public warrant liability	$ 2,415	$ 2,415	$ —	$ —
Private warrant liability	1,104	—	1,104	—
Total financial liabilities	$ 3,519	$ 2,415	$ 1,104	$ —

	December 31, 2023			
	Total	Level 1	Level 2	Level 3
Financial Assets:				
Money market funds	$ 92,702	$ 92,702	$ —	$ —
U.S. treasury bonds	6,128	—	6,128	—
Corporate and municipal bonds	24,098	—	24,098	—
Total financial assets	$ 122,928	$ 92,702	$ 30,226	$ —
Financial Liabilities:				
Public warrant liability	$ 149	$ 149	$ —	$ —
Private warrant liability	71	—	71	—
Perceptive warrant liability	2,515	—	—	2,515
Total financial liabilities	$ 2,735	$ 149	$ 71	$ 2,515

There were no transfers between Level 1, Level 2 and Level 3 during the years ended December 31, 2024 or December 31, 2023.

The Company's financial assets include investments in money market funds, U.S. treasury bonds, and corporate and municipal bonds. Investments in money market funds are classified within Level 1 of the fair value hierarchy as they are based on quoted prices in active markets. Investments in U.S. treasury bonds and corporate and municipal bonds are classified within Level 2 of the fair value hierarchy as they are based on quoted bid prices for comparable securities in the marketplace and broker/dealer quotes in active markets.

The Company's marketable securities presented in the consolidated balance sheet at December 31, 2024 have maturity dates ranging from 2025 through 2027 and are classified as current assets as these investments are intended to be readily available to fund current operations. The differences between the fair value and amortized cost basis of each security are the unrealized gains or losses recorded in accumulated other comprehensive income. As of December 31, 2024, the amortized cost for maturities less than one year and greater than one year were $36.6 million and $18.3 million, respectively.

Public and Private Warrants

As of the consummation of the CMLS and Legacy Sema4 Business Combination in July 2021, there were 666,516 warrants to purchase shares of Class A common stock outstanding, including 447,223 public warrants and 219,293 private placement warrants. As of December 31, 2024, there were 666,515 warrants to purchase shares of Class A common stock outstanding, including 457,323 public warrants and 209,192 private placement warrants outstanding. Each warrant expires five years after the Business Combination or earlier upon redemption or liquidation, and entitles the holder to purchase one share of Class A common stock at an exercise price of $379.50 per share, subject to adjustment, at any time commencing on September 4, 2021.

The Company may redeem the outstanding public warrants if the price per share of the Class A common stock equals or exceeds $594.00 as described below:

- in whole and not in part;
- at a price of $0.33 per public warrant;
- upon not less than 30 days' prior written notice of redemption to each warrant holder; and
- if, and only if, the closing price of the Class A common stock equals or exceeds $594.00 per share (as adjusted) for any 20 trading days within a 30-trading day period ending three trading days before sending the notice of redemption to warrant holders.

The Company may redeem the outstanding public warrants if the price per share of the Class A common stock equals or exceeds $330.00 as described below:

- in whole and not in part;
- at $3.30 per warrant upon a minimum of 30 days' prior written notice of redemption provided that holders will be able to exercise their warrants on a cashless basis prior to redemption and receive that number of shares based on the redemption date and the fair market value of the common stock;
- if, and only if, the closing price of the Class A common stock equals or exceeds $330.00 per share (as adjusted) for any 20 trading days within the 30-trading day period ending three trading days before the Company sends the notice of redemption to the warrant holders; and
- if the closing price of the common stock for any 20 trading days within a 30-trading day period ending three trading days before the Company sends notice of redemption to the warrant holders is less than $594.00 per share (as adjusted), the private placement warrants must also be concurrently called for redemption on the same terms as the outstanding public warrants, as described above.

The private placement warrants were issued to CMLS Holdings, LLC, Mr. Munib Islam, Dr. Emily Leproust and Mr. Nat Turner, and are identical to the public warrants underlying the units sold in the initial public offering, except that (1) the private placement warrants and the common stock issuable upon the exercise of the private placement warrants would not be transferable, assignable or salable until 30 days after the completion of a Business Combination, subject to certain limited exceptions, (2) the private placement warrants are exercisable on a cashless basis, (3) the private placement warrants are non-redeemable (except as described above, upon a redemption of warrants when the price per share of Class A common stock equals or exceeds $330.00) so long as they are held by the initial purchasers or their permitted transferees, and (4) the holders of the private placement warrants and the common stock issuable upon the exercise of the private placement warrants have certain registration rights. If the private placement warrants are held by someone other than the initial purchasers or their permitted transferees, the private placement warrants will be redeemable by the Company and exercisable by such holders on the same basis as the public warrants.

The public warrants are classified within Level 1 of the fair value hierarchy as they are traded in active markets and the fair value is determined on the basis of quoted market prices. The private placement warrants are classified within Level 2 of the fair value

hierarchy as management determined the fair value of each private placement warrant is the same as that of a public warrant because the terms are substantially the same.

For the years ended December 31, 2024 and 2023, a loss of $3.3 million and gain of $0.2 million was recorded within the change in the change in fair market value of warrants and contingent liabilities in the consolidated statements of operations and comprehensive loss, respectively.

Perceptive Warrant

On October 27, 2023 (the "Closing Date"), the Company entered into a Credit Agreement and Guaranty (the "Credit Agreement") with Perceptive Credit Holdings IV, LP, as lender and administrative agent ("Perceptive"), which provides for a senior secured delayed draw term loan facility in an aggregate principal amount of up to $75.0 million (the "Perceptive Term Loan Facility"). As consideration for the Credit Agreement, the Company issued to Perceptive a warrant to purchase up to 1,200,000 shares (the "Perceptive Warrants") of its Class A common stock. 800,000 warrant shares (the "Initial Warrant Shares") vested and became exercisable on the Closing Date and 400,000 warrant shares (the "Additional Warrant Shares" and, together with the Initial Warrant Shares, the "Warrant Shares") would have potentially vested and become exercisable on the Tranche B Borrowing Date, as defined in Note 8, "*Long-Term Debt*" included within this Annual Report. As the Company did not seek the additional funding from the Tranche B Loan, the Additional Warrant Shares did not vest and are not exercisable.

On April 30, 2024 (the "Exercise Date") Perceptive provided the Company with a notice to exercise the Initial Warrant Shares at an aggregate exercise price of $2.5 million and, as payment of the aggregate exercise price, instructed the Company to withhold a number of Initial Warrant Shares based on their aggregate fair market value as of the Exercise Date. The fair market value price of each Initial Warrant Share was equal to the 1-day volume weighted average price (the "1-day VWAP") of the Company's Class A common stock on the Exercise Date, or $16.4321. As a result, the Company issued 645,414 shares of its Class A common stock to Perceptive in satisfaction of the cashless exercise in respect of the Initial Warrant Shares. See Note 8, "*Long-Term Debt*" included within this Annual Report for further information.

For the year ended December 31, 2024, a loss of $10.1 million was recorded within the change in fair market value of warrants and contingent liabilities in the consolidated statements of operations and comprehensive loss based on re-measurement performed as of the Exercise Date.

Contingent Consideration

In connection with the Acquisition, up to $150.0 million of contingent payments was to be payable to OPKO Health, Inc. ("OPKO"), based upon achievement of 2022 and 2023 revenue milestones (the "Milestone Payments") pursuant to the merger agreement (the "Acquisition Merger Agreement"). The first Milestone Payment was paid out in full in April 2023 and the second Milestone Payment was valued at zero as the milestone was not met during fiscal year 2023.

During the year ended December 31, 2023, a gain of $0.9 million was recorded in the change in fair market value of warrants and contingent liabilities in the consolidated statements of operations and comprehensive loss.

Connecticut Department of Economic and Community Development Funding Commitment

The Company's loan from the Connecticut Department of Economic and Community Development ("DECD") is classified within Level 2 of the fair value hierarchy. The loan was recorded at its carrying value of $5.8 million and $6.3 million, respectively, at December 31, 2024 and December 31, 2023, with $1.2 million of recorded in other current liabilities on the consolidated balance sheets at December 31, 2024. The fair value was $4.9 million, which is estimated based on discounted cash flows using the yields of similar debt instruments of other companies with similar credit profiles.

5. Property and Equipment

Property and equipment consisted of the following:

	As of December 31,	
	2024	2023
Capitalized software	$ 32,171	$ 32,171
Laboratory equipment	18,267	15,538
Leasehold improvements	14,655	14,614
Computer equipment	6,912	5,819
Building under finance lease	4,529	4,529
Equipment under finance leases	3,293	2,604
Furniture, fixtures and other equipment	584	550
Construction in-progress	4,960	3,106
Total property and equipment	85,371	78,931
Less: accumulated depreciation and amortization	(52,478)	(46,452)
Property and equipment, net	$ 32,893	$ 32,479

For the years ended December 31, 2024 and 2023, depreciation and amortization expense was $7.9 million and $19.7 million, respectively, which included software amortization expense of zero and $6.6 million for the years ended December 31, 2024 and 2023. For intangible amortization, see Note 6, "*Intangible Assets*".

For the year ended December 31, 2024, the Company recorded the following:

- $0.6 million charge to accelerate the depreciation, net of trade-in credits, for certain lab equipment that was sold during the period as a trade-in associated with the purchase of new lab equipment; and
- $0.3 million charge to accelerate the depreciation for certain lab equipment that was retired during the period.

For the year ended December 31, 2023, the Company recorded the following:

- $4.0 million charge to accelerate the amortization for certain capitalized software projects associated with Legacy Sema4 that were not expected to be utilized;
- $9.9 million non-cash impairment charges (of which $5.6 million was allocated to the right-of-use asset associated with the sublease), driven by indicators of impairment related to the Icahn School of Medicine at Mount Sinai ("ISMMS") sublease agreements during the first and third quarters of 2023; and
- $1.7 million net gain on sale of assets primarily associated with the closure of Legacy Sema4 facilities.

Depreciation and amortization expense is included within the statements of operations and comprehensive loss as follows:

	Year Ended December 31,	
	2024	2023
Cost of services	$ 4,047	$ 4,350
Research and development	923	6,710
Selling and marketing	—	2
General and administrative	2,958	8,647
Total depreciation and amortization expense	$ 7,928	$ 19,709

6. Intangible Assets

The following table reflects, as of December 31, 2024 and December 31, 2023, the carrying values and remaining useful lives of acquired intangible assets:

	December 31, 2024			December 31, 2023			Weighted-Average Amortization Period (in years)
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Value	Gross Carrying Amount	Accumulated Amortization	Net Carrying Value	
Tradenames and trademarks	$ 50,000	$ (8,333)	$ 41,667	$ 50,000	$ (5,208)	$ 44,792	13.3
Developed Technology	48,000	(16,000)	32,000	48,000	(10,000)	38,000	5.3
Customer Relationships	98,000	(13,067)	84,933	98,000	(8,167)	89,833	17.3
	$ 196,000	$ (37,400)	$ 158,600	$ 196,000	$ (23,375)	$ 172,625	

The following table summarizes the Company's estimated future amortization expense of intangible assets with finite lives as of December 31, 2024:

2025	$ 14,025
2026	14,025
2027	14,025
2028	14,025
2029	14,025
Thereafter	88,475
Total estimated future amortization expense	$ 158,600

Amortization expense for tradenames and trademarks and developed technology of $9.1 million was recorded in general and administrative expenses for each of the years ended December 31, 2024 and 2023, within the consolidated statements of operations and comprehensive loss. Amortization expense for customer relationships of $4.9 million was recorded in selling and marketing expenses for each of the years ended December 31, 2024 and 2023, within the consolidated statements of operations and comprehensive loss.

7. Related Party Transactions

Related Party Revenues

Total related party diagnostic testing revenues were $1.7 million and $3.2 million for the years ended December 31, 2024 and 2023, respectively. Related party revenues primarily include diagnostic testing revenues from a subsidiary of OPKO and the prices charged represent market rates.

Related Party Expenses

Total related party costs are included within cost of services and related party expenses in the consolidated statements of operations and comprehensive loss as follows:

	Year Ended December 31,	
	2024	2023
Costs of services	$ 9,228	$ 4,338
General and administrative	—	435
Other operating expenses, net	3,407	5,266
Total related party costs	$ 12,635	$ 10,039

Expenses recognized pursuant to other service arrangements with ISMMS totaled $4.6 million and $6.8 million for the years ended December 31, 2024 and 2023, respectively. These amounts are included in either cost of services or other operating expenses, net on the consolidated statements of operations and comprehensive loss depending on the particular activity to which the costs relate. Payables due to ISMMS for the other service arrangements were $0.9 million and $1.0 million as of

December 31, 2024 and December 31, 2023, respectively. These amounts are included within due to related parties on the Company's consolidated balance sheets.

Additionally, the Company incurred $10.5 million and $3.4 million in purchases of diagnostic testing kits and materials and $8.1 million and $1.8 million was recorded in cost of services for the year ended December 31, 2024 and 2023, respectively, from an affiliate of a member of the Board of Directors who has served in the role since July 2021. The prices paid represent market rates. Payables due were $0.7 million and $0.4 million as of December 31, 2024 and 2023.

Legacy GeneDx and OPKO entered into a Transition Services Agreement dated as of April 29, 2022 (the "OPKO TSA") pursuant to which OPKO had agreed to provide services, at cost, subject to certain limited exceptions, in order to facilitate the transactions contemplated by the Acquisition Merger Agreement, including human resources, information technology support, and finance and accounting. Services in connection with the OPKO TSA were fully completed in October 2023. The Company recognized $1.6 million in costs for the year ended December 31, 2023 related to the agreement.

8. Long-Term Debt

As of December 31, 2024, long-term debt matures as follows:

2025	$	1,211
2026		1,235
2027		1,260
2028		51,285
2029		762
Total debt		55,753
Less: current portion of long-term debt		(1,211)
Less: long-term debt issuance costs		(2,629)
Total long-term debt, net of current portion and debt issuance costs	$	51,913

Perceptive Term Loan Facility

On October 27, 2023 (the "Closing Date"), the Company entered into the Perceptive Term Loan Facility. An initial tranche of $50.0 million (the "Tranche A Loan") was funded under the Perceptive Term Loan Facility on the Closing Date. In addition to the Tranche A Loan, the Perceptive Term Loan Facility included an additional tranche of $25.0 million (the "Tranche B Loan," and together with the Tranche A Loan, the "Term Loans"), which was accessible by the Company through December 31, 2024 so long as the Company satisfied certain customary conditions precedent, including a specified revenue milestone (the funding date of the Tranche B Loan, the "Tranche B Borrowing Date"). Although the requirements for the Tranche B funding were met, the Company did not seek the additional funding.

The Perceptive Term Loan Facility has a maturity date of October 27, 2028 (the "Maturity Date") and provides for an interest-only period during the term of the loan with principal due at the maturity date. The Company's net proceeds from the Tranche A Loan were approximately $48.8 million, after deducting debt issuance costs and expenses.

Interest Rate

The Perceptive Term Loan Facility will accrue interest at an annual rate equal to the sum of (a) Term SOFR (as defined in the Credit Agreement) and (b) an applicable margin of 7.5% (the "Applicable Margin"). Accrued interest on the Term Loans is payable monthly in arrears. Upon an Event of Default (as defined in the Credit Agreement), the Applicable Margin will automatically increase by an additional 4% per annum.

Amortization and Prepayment

Prior to the Maturity Date, there will be no scheduled principal payments under the Perceptive Term Loan Facility. On the Maturity Date, the Company is required to pay Perceptive the aggregate outstanding principal amount of the Term Loans and all accrued and unpaid interest thereon. The Term Loans may be prepaid at any time, subject to a prepayment premium equal to 0% to 10% of the aggregate outstanding principal amount being prepaid, depending on the date of prepayment.

Security Instruments and Warrant

In connection with the Credit Agreement, the Company also entered into a Security Agreement, dated as of the Closing Date, with Perceptive, pursuant to which all of its obligations under the Credit Agreement are secured by a first lien perfected security interest on substantially all of its existing and after-acquired assets, subject to customary exceptions.

On the Closing Date, as consideration for the Credit Agreement, the Company issued the Perceptive Warrant to Perceptive, which allowed them to purchase up to 1,200,000 Warrant Shares. The 800,000 Initial Warrant Shares vested and became exercisable on the Closing Date and 400,000 Additional Warrant Shares would have potentially vested and become exercisable on the Tranche B Borrowing Date. As the Company did not seek the additional funding from the Tranche B Loan, the Additional Warrant Shares did not vest and are not exercisable. The per share exercise price for the Initial Warrant Shares is $3.1752 (the "Initial Warrant Exercise Price"), which is equal to the10-day volume weighted average price (the "10-day VWAP") of the Company's Class A common stock at the end of the business day immediately prior to the Closing Date, and the per share exercise price for the Additional Warrant Shares would have been equal to the lower of (a) the Initial Warrant Exercise Price or (b) the 10-day VWAP ending on the end of the business day immediately preceding the Tranche B Borrowing Date. The Perceptive Warrant will be exercisable, in whole or in part, until the 10th anniversary of the applicable vesting date.

On April 30, 2024, Perceptive provided the Company with a notice to exercise the Initial Warrant Shares at an aggregate exercise price of $2.5 million and instructed the Company to withhold a number of Initial Warrant Shares as payment for the aggregate exercise price. As a result, the Company issued 645,414 shares of its Class A common stock in satisfaction of the cashless exercise in respect of the Initial Warrant Shares. See Note 4, "*Fair Value Measurement*" for further information.

Connecticut Department of Economic and Community Development Funding Commitment

In June 2017, ISMMS assigned a loan funding commitment from the DECD to the Company (the "DECD Loan Agreement") to support the Genetic Sequencing Laboratory Project in Branford, Connecticut, with funding based on the achievement of certain project development phases. The DECD Loan Agreement provided for a total loan commitment of $15.5 million at a fixed annual interest rate of 2.0% for a term of 10 years. The Company was required to make interest-only payments through July 2023 and principal and interest payments commencing in August 2023. The final payment of principal and interest was due in July 2028. However, under the terms of the DECD Loan Agreement, the DECD granted a partial principal loan forgiveness of up to $12.3 million in the aggregate. Such forgiveness was contingent upon the Company achieving certain job creation and retention milestones and $4.5 million had been forgiven at December 31, 2022. This commitment was collateralized by a security interest in certain machinery and equipment the Company acquired from ISMMS, as defined in a separate security agreement.

In January 2023, the Company amended the DECD Loan Agreement, which resulted in the Company agreeing to pay $2.0 million in principal, obtaining $2.8 million in debt forgiveness for achieving its Phase 2 job milestone, and agreeing to two new forgiveness milestone targets for its Phase 3 job milestone (eligible for $2.0 million in forgiveness) and a final phase job milestone (eligible for $1.0 million in forgiveness) (the "2022 Amended DECD Loan Agreement"). Upon execution of this amendment, the Company paid the $2.0 million in principal and received $2.8 million in debt forgiveness, and the Company recognized the debt forgiveness as other (expense) income, net in the consolidated statements of operations and comprehensive loss for the year ended December 31, 2023. The terms of the 2022 Amended DECD Loan Agreement require the Company to make interest-only payments through July 2024 and requires the Company to make principal and interest payments commencing in August 2024 through July 2029 at the same fixed annual interest rate of 2.0%. The other terms of the 2022 Amended DECD Loan Agreement remained the same.

During the year ended December 31, 2024, the Company made principal payments totaling $0.5 million. The outstanding loan balance of the DECD loan was $5.8 million at December 31, 2024.

9. Leases

The Company's leases primarily consist of office and lab space, and equipment for use in its operations. Its leases generally have lease agreements which expire in 2026 to 2036, some with the option to extend. The Company includes extension options that are reasonably certain to be exercised as part of the lease terms. As of December 31, 2024, none of the Company's lease terms included the extension option as the Company has determined that it is unlikely to exercise the extension option.

Operating Leases

The Company's primary operating lease arrangements include leased properties for its corporate office and headquarters located in Stamford, Connecticut, its primary operating laboratory located in Gaithersburg, Maryland, and a satellite meeting space located in New York City. The lease agreements for these properties expire in 2034, 2031, and 2026, respectively.

The Company's operating leases also include laboratories in Branford, Connecticut and Stamford, Connecticut, which as previously disclosed, have ceased operations as part of the Company's announced exits in 2022 from reproductive health and somatic tumor testing. The lease agreements for these properties expire in 2030 and 2036, respectively. These facilities as well as a portion of its headquarters located in Stamford, Connecticut are actively being marketed for sublet; however, the outstanding lease obligations remain obligations. At inception of the lease for the laboratory in Stamford, Connecticut, the value of the land was determined to be more than 25% of the total value and therefore the building is accounted for as a finance lease and the land as an operating lease.

Finance Leases

In addition to its leased laboratory building in Stamford, Connecticut noted above, the Company routinely enters into various finance lease agreements to obtain laboratory equipment that contain bargain purchase commitments at the end of the lease term. The leases are secured by the underlying equipment.

The tables below present financial information associated with the Company's operating and finance leases as of, and for the year ended, December 31, 2024 and 2023:

		December 31,	
	Classification	**2024**	**2023**
Assets			
Operating lease assets	Operating lease right-of-use assets	$ 25,613	$ 26,900
Finance lease assets	Property and Equipment, net	3,173	3,440
Total lease assets		$ 28,786	$ 30,340
Liabilities			
Current			
Operating	Short-term lease liabilities	$ 2,608	$ 2,331
Finance	Short-term lease liabilities	728	1,316
Non-current			
Operating	Long-term lease liabilities	$ 42,698	$ 44,428
Finance	Long-term lease liabilities	18,221	18,510
Total lease liabilities		$ 64,255	$ 66,585

	Year ended December 31,	
Lease cost	**2024**	**2023**
Operating lease cost		
Operating lease cost	$ 5,637	$ 5,806
Short-term lease cost	314	745
Variable lease cost	1,140	659
Total operating lease cost	$ 7,091	$ 7,210
Finance lease cost		
Depreciation and amortization of leased assets	$ 647	$ 1,970
Interest on lease liabilities	1,460	1,041
Total finance lease cost	$ 2,107	$ 3,011
Total lease cost	$ 9,198	$ 10,221

Future minimum lease payments under non-cancellable leases as of December 31, 2024 are as follows:

Maturity of lease liabilities	Operating lease	Finance lease	Total
2025	$ 6,201	$ 2,670	$ 8,871
2026	6,292	2,003	8,295
2027	6,263	2,045	8,308
2028	6,447	2,107	8,554
2029	6,601	2,170	8,771
Thereafter	30,539	20,877	51,416
Total	62,343	31,872	$ 94,215
Less: imputed interest	(17,037)	(12,923)	(29,960)
Present value of lease liabilities	$ 45,306	$ 18,949	$ 64,255

Other information related to leases as of and for the year ended December 31, 2024 and 2023 and are as follows:

	December 31,	
	2024	2023
Weighted-average remaining lease term (years)		
Operating leases	9.0	10.0
Finance leases	11.4	11.8
Weighted-average discount rate		
Operating leases	6.4%	6.4%
Finance leases	8.4%	8.1%
Cash paid for amounts included in the measurement of lease liabilities		
Operating cash flows from operating leases	$ 5,231	$ 5,482
Operating cash flows from finance leases	3,029	1,874
Financing cash flows from finance lease	2,728	3,598

10. Purchase Commitments and Contingencies

Purchase Commitments

The following sets forth purchase commitments with software and equipment providers as of December 31, 2024 with a remaining term of at least one year:

2025	$ 15,699
2026	8,394
2027	4,592
2028	4,021
2029	3,914
Thereafter	978
Total purchase commitments	$ 37,598

The Company enters into contracts with suppliers to purchase materials needed for diagnostic testing. These contracts generally do not require multi-year purchase commitments.

For further information regarding the Company's lease obligations, see Note 9, "*Leases*" included within this Annual Report.

Contingencies

The Company is or may become subject to various claims and legal actions arising in the ordinary course of business. The Company does not believe that the outcome of any existing matters will have a material effect on the Company's consolidated

financial statements. However, no assurance can be given that the ultimate resolution of such proceedings will not materially impact the Company's consolidated financial statements.

Except as described below, the Company was not a party to any material legal proceedings as of December 31, 2024, nor is it a party to any material legal proceedings as of the date of issuance of these consolidated financial statements.

On September 7, 2022, a shareholder class action lawsuit was filed in the United States District Court for the District of Connecticut, styled Helo v. Sema4 Holdings Corp., et al, 22-cv-1131 (D. Conn.) against the Company and certain of the Company's current and former officers. Following the appointment of a lead plaintiff, an amended complaint was filed on January 30, 2023. The defendants moved to dismiss the amended complaint on August 21, 2023, and that motion was granted on July 31, 2024. A second amended complaint was filed on September 13, 2024. As amended, the complaint purports to bring suit on behalf of the stockholders who purchased the Company's publicly traded securities between January 18, 2022 and August 15, 2022. The second amended complaint purports to allege that the defendants made false and misleading statements about the Company's business, operations, and prospects in violation of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and seeks unspecified compensatory damages, fees, and costs. The Company believes the allegations and claims are without merit.

On November 28, 2023, a stockholder filed a derivative suit, allegedly on behalf of the Company, based largely on the same allegations in the securities class action referenced above. The suit was filed in federal court in the District of Delaware, styled Ghazaleh v. Schadt, et al, 23-cv-01357 (D. Del.), and purports to assert claims against certain of the Company's former and current officers and directors under Section 10(b) of the Exchange Act, and for breach of fiduciary duty, aiding and abetting breach of fiduciary duty, unjust enrichment and corporate waste. The Company is named only as a nominal defendant. The complaint seeks damages on the Company's behalf, and seeks corporate governance and other relief. On March 11, 2024, the Court issued an order staying this suit pending resolution of the Helo class action referenced above.

On June 25, 2024, a substantially similar stockholder derivative suit was filed in federal court in the District of Connecticut, styled Scinto v. Schadt, et al, 2:24-cv-01100 (D. Conn.). The suit, also purportedly brought on the Company's behalf against certain of its former or current officers and directors, asserts claims for breach of fiduciary duty, unjust enrichment, corporate waste, and violations of Sections 10(b) and 14(a) of the Exchange Act. The Company is named only as a nominal defendant. The complaint seeks damages on the Company's behalf, as well as corporate governance reforms and other relief. On August 8, 2024, the Court issued an order staying this suit until the earlier of a commencement of discovery, announcement of settlement, or dismissal with prejudice in the Helo class action referenced above.

On February 7, 2023, a stockholder commenced a lawsuit in the Delaware Court of Chancery. The suit is brought as a class action on behalf of stockholders of CMLS who did not redeem their shares in connection with the Business Combination between CMLS and Legacy Sema4. The defendants named in the amended complaint include and directors of CMLS at the time of the transaction, including certain directors who continue to serve on the Company's Board of Directors, as well as CMLS Holdings LLC, Corvex Management LP, and Casdin Capital, LLC. The Company is not named as a defendant. The complaint alleges that the July 2, 2021 proxy statement mailed to CMLS stockholders in connection with the transaction contained false and misleading statements, and purports to assert a claim of breach of fiduciary duty against all individual defendants, and a similar claim against CMLS Holdings LLC and certain individuals for breach of fiduciary duty as control persons. The suit seeks to recover unspecified damages on behalf of the alleged class, among other relief. After defendants moved to dismiss the case, the plaintiff filed an amended complaint on July 6, 2023, revising certain allegations and adding third parties as defendants. The defendants answered the amended complaint on September 15, 2023. The Company is subject to certain claims for advancement and indemnification by the individual defendants in this proceeding.

During the second quarter of 2024, the parties reached an agreement in principle through mediation to resolve all claims for approximately $21 million, and during the third quarter of 2024, the parties executed a formal stipulation of settlement reflecting such agreement in principle. The settlement was paid into escrow on November 12, 2024 and was funded by the Company (based on its indemnification obligations), available insurance of approximately $10 million and proceeds of approximately $1.4 million from the insurance of a third-party defendant. The Delaware Court of Chancery approved the settlement on December 2, 2024. As of December 31, 2024, remaining unpaid litigation and indemnification costs were nominal.

Defined Contribution Plan

Substantially all of the Company's employees in the U.S. are eligible to participate in the defined contribution plan the Company sponsors. The defined contribution plan allows employees to contribute a portion of their compensation in accordance with specified guidelines. The Company, at its discretion, makes matching contributions. The Company contributed $5.9 million and $6.5 million for the years ended December 31, 2024 and 2023, respectively.

11. Stock-Based Compensation

Stock-Based Compensation Expense

Stock-based compensation expense is included within the consolidated statements of operations and comprehensive loss as follows:

	Year Ended December 31,	
	2024	2023
Cost of services	$ 431	$ (1,217)
Research and development	1,192	(2,585)
Selling and marketing	1,089	(1,266)
General and administrative	6,426	4,742
Total stock-based compensation expense[1,2]	$ 9,138	$ (326)

[1] *The Company recorded an aggregate reversal of stock-based compensation of $3.9 million and $24.7 million during the years ended December 31, 2024 and 2023, respectively, due to forfeiture activities upon employee terminations.*
[2] *Includes $0.6 million of expense related to the 2021 Employee Stock Purchase Plan during year ended December 31, 2024.*

Stock Incentive Plans

The Company maintains the Amended and Restated 2021 Equity Incentive Plan (as amended and restated, the "2021 Plan"), which allows for grants of stock-based awards. No awards granted under the 2021 Plan are exercisable after 10 years from the date of grant, and the awards granted under the 2021 Plan generally vest over a four-year period on a graded vesting basis; however, the Company has also granted certain restricted stock units ("RSUs") with vesting terms beginning 12 months from the grant date and vesting immediately on the grant date. On January 1 of each year through 2031, the aggregate number of shares of Class A common stock reserved for issuance under the 2021 Plan may be increased automatically by the number of shares equal to 5% of the total number of shares of all classes of common stock issued and outstanding immediately preceding December 31. In January 2024, the number of Class A common stock reserved for future issuance under the 2021 Plan automatically increased by 1,298,943 shares.

The Company also maintains the 2023 Equity Inducement Plan (the "Equity Inducement Plan"), which allows for grants of equity awards of the Company's Class A common stock to individuals who were not previously an employee or director of the Company, or following a bona fide period of non-employment, as an inducement material to such persons entering into employment with the Company.

As of December 31, 2024, there was an aggregate of 1,857,260 shares available for grants of stock options or other awards under the 2021 Plan and Equity Inducement Plan. In January 2025, the number of Class A common stock reserved for future issuance under the 2021 Plan automatically increased by 1,400,827 shares.

Stock Option Activity

All stock options granted under the 2021 Plan are accounted for as time-based equity awards. The following summarizes the stock option activity during the year ended December 31, 2024:

	Stock Options Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (years)	Aggregate Intrinsic Value
Balance at December 31, 2023	497,976	$ 42.80	5.55	$ —
Options granted	—	$ —		
Options exercised	(68,453)	$ 5.77		
Options forfeited and canceled	(88,243)	$ 63.45		
Balance at December 31, 2024	341,280	$ 44.83	5.99	$ 12,429
Options exercisable at December 31, 2024	290,963	$ 40.47	5.74	$ 11,799

Non-vested options outstanding at the end of the year were 50,317 with weighted average grant-date fair value of $14.52. As of December 31, 2024, unrecognized stock-based compensation cost related to the unvested portion of the Company's stock options was $0.5 million, which is expected to be recognized on a graded-vesting basis over a weighted-average period of 1.0 years.

The weighted-average grant-date fair value and total fair value of options with tranches vested was $34.42 and $0.7 million for the year ended December 31, 2024, respectively, and $25.07 and $1.5 million for the year ended December 31, 2023, respectively.

The aggregate intrinsic value of exercised options was $2.3 million and $0.3 million in the years ended December 31, 2024 and 2023, respectively, and is calculated based on the difference between the exercise price and the fair value of the Company's common stock as of the exercise date. The weighted-average grant-date fair value of options forfeited and canceled was $7.46 for the year ended December 31, 2024.

There were no options granted during the year ended December 31, 2024. The fair value of the stock option awards granted during the year ended December 31, 2023 were estimated using the Black-Scholes option pricing model with the following assumptions:

	2023
Expected volatility	105.0%
Weighted-average expected volatility	105.0%
Expected term (in years)	5.5
Risk-free interest rate	4.03%
Dividend yield	—
Fair value of Class A common stock	$6.35

Restricted Stock Units (RSU)

The Company issued time-based RSUs to employees under the 2021 Plan. The RSUs automatically convert to common stock on a one-for-one basis as the awards vest. The Company measures the value of RSUs at fair value based on the closing price of the underlying common stock on the grant date. The RSUs granted generally vest over a four-year vesting period from the grant date, however, the Company also granted certain RSUs with vesting term beginning 12 months from the grant date and vesting immediately on the grant date. The following table summarizes the activity related to the Company's time-based RSUs:

	Restricted Stock Units Outstanding	Weighted Average Grant Date Fair Value Per Unit
Balance at December 31, 2023	1,507,877	$ 15.48
Restricted Stock Units granted	1,187,165	$ 11.37
Restricted Stock Units vested	(471,663)	$ 17.72
Restricted Stock Units forfeited	(353,818)	$ 15.63
Balance at December 31, 2024	1,869,561	$ 12.03

The total fair value of RSUs vested for the years ended December 31, 2024 and 2023 was $2.1 million and $6.6 million, respectively. As of December 31, 2024, unrecognized stock-based compensation cost related to the Company's RSUs was $10.7 million, which is expected to be recognized on a graded-vesting basis over a weighted-average period of 1.8 years.

Employee Stock Purchase Plan

The 2021 Employee Stock Purchase Plan (the "2021 ESPP") authorizes the issuance of shares of Class A common stock pursuant to purchase rights granted to employees. On January 1 of each year through 2031, the aggregate number of shares of Class A common stock reserved for issuance under the 2021 ESPP may be increased automatically by the number of shares equal to 1% of the total number of shares of all classes of common stock issued and outstanding immediately preceding December 31.

The 2021 ESPP became open for enrollment in April 2024. Under the 2021 ESPP, eligible employees may purchase shares of the Company's Class A common stock at a discount through payroll deductions during each discrete six-month offering period. The purchase price under each discrete offering period is equal to 85% of the lesser of the fair market value of the Class A common stock on the first and last day of the offering period.

The first offering period was completed on October 31, 2024 and the Company issued 26,773 shares under the 2021 ESPP during the year ended December 31, 2024. A total of 569,831 shares of Class A common stock were reserved for future issuance under the 2021 ESPP as of December 31, 2024. In January 2025, the number of Class A common stock reserved for future issuance under the 2021 ESPP automatically increased by 280,165 shares.

12. Income Taxes

The components of income before incomes taxes consisted of the following:

	Year Ended December 31,	
	2024	2023
Foreign	$ 929	$ 623
Domestic	(53,558)	(177,316)
Loss before income tax provision (benefit)	(52,629)	(176,693)

	Year Ended December 31,	
	2024	2023
Current		
Federal	$ —	$ —
State and Local	—	—
Foreign	241	164
Total Current	$ 241	$ 164
Deferred		
Federal	$ (229)	$ 942
State and Local	(355)	(2,032)
Foreign	—	—
Total Deferred	(584)	(1,090)
Total income tax provision (benefit)	$ (343)	$ (926)

For the years ended December 31, 2024 and 2023, the Company recorded a total income tax benefit of $0.3 million and $0.9 million, respectively. Accordingly, the effective tax rate for the Company for the years ended December 31, 2024 and 2023 was 0.6% and 0.5%, respectively. A reconciliation of the anticipated income tax expense/(benefit) computed by applying the statutory federal income tax rate of 21% to loss before income taxes to the amount reported in the statement of operations and comprehensive loss is as follows:

	Year Ended December 31,	
	2024	2023
U.S. federal taxes at statutory rate	21.0%	21.0%
State taxes (net of federal benefit)	0.6	1.1
Research and development tax credits	—	(0.8)
Non-deductible stock-based compensation	(3.8)	(2.4)
162(m) limitation	(2.7)	(0.1)
Permanent items	(0.5)	(0.1)
Unrealized fair market value gain on warrants	(5.4)	0.1
Goodwill impairment	—	(0.1)
Change in valuation allowance	(10.7)	(18.4)
Other	2.1	0.2
Effective tax rate	0.6%	0.5%

The tax effects of temporary differences and carryforwards that give rise to significant portions of the net deferred tax assets and liabilities were as follows:

	As of December 31,	
	2024	2023
Deferred tax assets:		
Net operating loss carryforwards	$ 257,047	$ 257,960
Stock-based compensation	2,599	7,690
Accrued compensation	2,001	1,269
Accrued expenses	247	3,470
Research and development credits	6,477	6,374
Leases	14,801	14,054
Obsolete inventory reserve	12	136
Third party liability	2,971	7,514
Section 174 amortization	29,484	25,993
Capitalized software	766	1,211
Other	1,194	814
Total deferred tax assets	317,599	326,485
Valuation allowance	(272,275)	(271,567)
Deferred tax assets, net of valuation allowance	45,324	54,918
Deferred tax liabilities:		
Property and equipment	(1,013)	(1,279)
ROU asset	(6,252)	(7,353)
Intangible amortization	(39,024)	(47,846)
Total deferred tax liabilities	(46,289)	(56,478)
Net deferred tax liability after valuation allowance	$ (965)	$ (1,560)

As of December 31, 2024, the Company had the following tax net operating loss carryforwards available to reduce future federal and state taxable income, and tax credit carryforwards available to offset future federal and Connecticut income taxes:

	Amount	Expiration period
Tax net operating loss carryforwards:		
Federal (pre-2018 net operating losses)	$ 33,056	2036-2037
Federal (post-2017 net operating losses)	$ 871,367	No expiration
State and Local	$ 1,179,626	2027-2044
State and Local	$ 100,363	No expiration
Tax credit carryforwards:		
Federal research and development	$ 5,460	2038-2041
Connecticut research and development	$ 777	2036
Connecticut research and development	$ 511	No expiration

The Company had the following deferred tax valuation allowance balances:

Year	Balance at the Beginning of Period	Additions	Balance at the End of Period
2024	$ 271,567	708	$ 272,275
2023	$ 226,644	44,923	$ 271,567

Future realization of the tax benefits of existing temporary differences and carryforwards ultimately depends on the existence of sufficient taxable income within the carryforward period. As of December 31, 2024 and 2023 the Company performed an

evaluation to determine whether a valuation allowance was needed. Based on the Company's analysis, which considered all available evidence, both positive and negative, the Company determined that it is more likely than not that a significant portion of its deferred tax assets will not be realized. Accordingly, the Company maintained a full valuation allowance as of December 31, 2024 and 2023. The valuation allowance increased by $0.7 million in 2024 and $44.9 million in 2023, primarily due to the increase in net operating loss carryforwards.

Under Internal Revenue Code Section 382, if a corporation undergoes an "ownership change," the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income may be limited. Generally, an ownership change occurs when certain shareholders increase their aggregated ownership by more than 50 percentage points over their lowest ownership percentage in a testing period (typically three years). Future changes in stock ownership, which may be outside of the Company's control, may trigger an ownership change. In addition, future equity offerings or acquisitions that have an equity component of the purchase price could result in an ownership change. If an ownership change has occurred or does occur in the future, utilization of the NOL carryforwards or other tax attributes may be limited.

A reconciliation of the beginning and ending amounts of unrecognized tax benefits for the years ended December 31, 2024 and 2023 is as follows:

	As of December 31,	
	2024	2023
Unrecognized tax benefits – January 1	$ 718	$ 718
Gross increases – tax positions in current period	—	—
Unrecognized tax benefits – December 31	$ 718	$ 718

To the extent penalties and interest would be assessed on any underpayment of income tax, the Company's policy is that such amounts would be accrued and classified as a component of income tax expense in the financial statements. The Company had a nominal amount of accrued interest or penalties related to uncertain tax positions as of December 31, 2024 and 2023.

The Company files income tax returns for U.S federal jurisdiction, various state jurisdictions, and various foreign countries. In the normal course of business, the Company is subject to examination by federal, state and foreign jurisdictions, where applicable. There are currently no pending federal, state or foreign income tax examinations. As a result of the Company's net operating loss carryforwards, the Company's federal and state statutes of limitations remain open from 2016 and forward until the net operating loss carryforwards are utilized or expire prior to utilization.

13. Net Loss per Share

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 for the period. The following table sets forth the computation of basic and diluted net loss per share attributable to common stockholders:

	Year Ended December 31,	
	2024	2023
Numerator:		
Net loss attributable to common stockholders	$ (52,286)	$ (175,767)
Denominator:		
Basic and diluted weighted-average common shares outstanding	26,891,213	24,311,989
Basic and diluted loss per share	$ (1.94)	$ (7.23)

The following tables summarize the outstanding shares of potentially dilutive securities that were excluded from the computation of diluted net loss per share attributable to common stockholders for the period presented because including them would have been anti-dilutive:

	Year Ended December 31,	
	2024	2023
Outstanding options and RSUs to purchase Class A common stock	2,210,841	2,005,853
Outstanding warrants	666,515	1,466,515
Outstanding 2021 ESPP shares	20,566	—
Total	2,897,922	3,472,368

14. Restructuring Costs

The table below provides certain information concerning restructuring activity during the year ended December 31, 2024 and December 31, 2023:

	Reserve Balance at December 31, 2023	Charged to Costs and Expenses	Payments and Other	Reserve Balance at December 31, 2024
Severance	$ 1,853	$ 1,752	$ (2,859)	$ 746

	Reserve Balance at December 31, 2022	Charged to Costs and Expenses	Payments and Other	Reserve Balance at December 31, 2023
Severance	$ 4,770	$ 6,514	$ (9,431)	$ 1,853
Other	253	18	(271)	—
Total	$ 5,023	$ 6,532	$ (9,702)	$ 1,853

Expenses related to restructuring activities are included within the consolidated statements of operations and comprehensive loss as follows:

	Year Ended December 31,	
	2024	2023
Cost of services	$ 54	$ 139
Research and development	151	3,176
Selling and marketing	548	1,371
General and administrative	999	1,846
Total restructuring expense	$ 1,752	$ 6,532

On October 30, 2023, the Company announced a continued strategic realignment of its organization to key priorities which includes the elimination of approximately 50 positions impacted on August 23, 2023, and approximately 35 positions impacted on October 30, 2023. Together these actions reduced the size of the Company's workforce by 10% from the total number that existed at the time of the August reduction in force.

15. Supplemental Financial Information

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported on the consolidated balance sheets to the total of the same amounts shown on the consolidated statements of cash flows:

	As of December 31,	
	2024	2023
Cash and cash equivalents	$ 85,212	$ 99,681
Restricted cash (included in other assets)	990	987
Total	$ 86,202	$ 100,668

Restricted cash included in other assets as of December 31, 2024 and 2023 primarily consists of money market deposit accounts that secure an irrevocable standby letter of credit that serves as collateral for security deposit operating leases.

Prepaid expenses and other current assets consisted of the following:

	As of December 31,	
	2024	2023
Prepaid expenses	$ 7,425	$ 8,640
Other current assets	1,079	1,958
Total	$ 8,504	$ 10,598

Accounts payable and accrued expenses consisted of the following:

	As of December 31,	
	2024	2023
Accounts payable	$ 7,954	$ 10,238
Accrued expenses	11,504	12,179
Reserves for refunds to insurance carriers	10,586	15,039
Total	$ 30,044	$ 37,456

Other current liabilities consisted of the following:

	As of December 31,	
	2024	2023
Accrued compensation	$ 16,241	$ 12,465
Accrued severance	746	1,853
Other	2,843	2,018
Total	$ 19,830	$ 16,336

Other liabilities consisted of the following:

	As of December 31,	
	2024	2023
Warrant liability	$ 3,519	$ 2,735
Third party payor reserve	2,000	12,000
Total	$ 5,519	$ 14,735

2023 Capital Raise

On January 31, 2023, the Company raised approximately $150.0 million in gross proceeds and announced the closing of an underwritten public offering of 9,962,316 shares of its Class A common stock and a concurrent registered direct offering of 2,353,436 shares of its Class A common stock. The net offering proceeds received after deducting underwriters' discounts and commissions payable by the Company were approximately $135.4 million. On April 17, 2023, following the Company's receipt of stockholder approval for the issuance, the Company issued the remaining 676,868 shares of its Class A common stock to Corvex Select Equity Master Fund LP, Corvex Master Fund LP and Corvex Dynamic Equity Select Master Fund LP in its previously announced registered direct offering for gross proceeds of approximately $7.6 million.

2024 Sales Agreement

The Company entered into a sales agreement (the "Sales Agreement") with TD Securities (USA) LLC ("TD Cowen") in April 2024, pursuant to which the Company may, but is not obligated to, offer and sell, from time to time, shares of its Class A common stock with an aggregate offering price up to $75.0 million through TD Cowen, as sales agent, subject to the terms and conditions described in the Sales Agreement and SEC rules and regulations (the "ATM offering"). During the year ended December 31, 2024, the Company issued 825,379 shares of its Class A common stock in connection with the ATM offering at an average price

of $58.41 per share. Proceeds received, net of agent fees and other offering expenses, were $46.5 million. As of December 31, 2024, approximately $26.8 million of capacity remained available under this ATM offering.

16. Segment Reporting

The Company's structure is aligned with how the chief operating decision maker ("CODM") reviews the business, makes investing and resource allocation decisions and assesses operating performance. The Company's CODM is its Chief Executive Officer. At December 31, 2024, the Company has identified one reportable segment: GeneDx inclusive of Legacy GeneDx and Legacy Sema4 data revenues and associated costs. The GeneDx segment primarily provides pediatric and rare disease diagnostics with a focus on whole exome and genome sequencing and, to a lesser extent, data and information services. Other represents the revenues and costs associated with the Legacy Sema4 diagnostics business which was completely shut down in 2023.

The CODM evaluates segment performance based on revenue and adjusted gross profit.

	Year ended December 31,					
	2024			2023		
	GeneDx	Other	Total	GeneDx	Other	Total
Revenue	$ 302,293	$ 3,157	$ 305,450	$ 194,376	$ 8,190	$ 202,566
Adjusted cost of services	106,376	145	106,521	106,983	2,305	109,288
Adjusted gross profit [1]	195,917	3,012	198,929	87,393	5,885	93,278
Reconciliations:						
Depreciation and amortization			4,047			4,350
Stock-based compensation			431			(1,217)
Restructuring charges			54			139
Gross profit			$ 194,397			$ 90,006

(1) Adjusted cost of services and adjusted gross profit exclude depreciation and amortization expense, stock-based compensation expense and restructuring costs.

Management manages assets on a total company basis, not by reporting segment. The CODM does not regularly review any asset information by reporting segment and, accordingly, the Company does not report asset information by reporting segment.

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

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Disclosure controls and procedures are designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

As required by Rules 13a-15 and 15d-15 under the Exchange Act, our Chief Executive Officer and Chief Financial Officer carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as of December 31, 2024. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2024, the end of the period covered by this Annual Report on Form 10-K.

Management's Annual Report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting and for the assessment of the effectiveness of internal control over financial reporting as defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act. Internal control over financial reporting is a process designed under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States.

We do not expect that our disclosure controls and procedures, or our internal controls, will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within our Company have been detected.

Under the supervision and with the participation of our Chief Executive Officer and our Chief Financial Officer and oversight of the Board of Directors, our management conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2024, based on the criteria set forth in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 COSO framework). Based on this evaluation, management concluded that the Company's internal control over financial reporting was effective as of December 31, 2024.

Previously Reported Material Weakness

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 a company's annual or interim financial statements will not be prevented or detected on a timely basis. In connection with the preparation of the Annual Report on Form 10-K as of December 31, 2023, we previously reported the following material weakness in our internal control over financial reporting:

- Our accounting and operating systems lacked controls over access, and program change management that are needed to ensure access to financial data is adequately restricted to appropriate personnel, including consideration of the appropriate segregation of duties. As a result, it is possible that our business process controls that depend on the accuracy and completeness of data or financial reports generated by our information technology system could be adversely affected due to the lack of operating effectiveness of the information technology general controls ("ITGCs").

Remediation of Previously-Reported Material Weakness

To remediate this material weakness, we completed the following actions:

- We hired key personnel and expanded available resources with experience designing and implementing ITGCs, and through the use of outside consultants.
- We performed a risk assessment over the IT systems used as part of financial reporting.
- We rationalized user roles and permissions and established appropriate segregation of duties, where applicable.
- We implemented process improvements and standardized certain practices across relevant systems, including access provisioning, deprovisioning and user access review processes.

- We conducted training for personnel responsible for internal control performers to deepen their comprehension of risk assessment concepts and to refine their execution of controls pertaining to financial reporting.
- We strengthened and documented our procedures around ITGCs and communicated them to relevant personnel.

Management believes it has effectively designed and tested the operating effectiveness related to the previously-reported material weakness noted above. Accordingly, management has concluded that the material weaknesses has been remediated because each component of the material weakness has been operating effectively for a sufficient period of time.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

Other Information

None.

Rule 10b5-1 Plan Adoptions and Modifications

On November 7, 2024, a grantor annuity trust (the "GRAT") of which Jason Ryan, our chairman and a director, is the trustee, entered into a written plan for the potential transfer of up to an aggregate of 141,356 shares of our Class A common stock (the "Ryan GRAT 10b5-1 Plan"). The Ryan GRAT 10b5-1 Plan is intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act and will be effective from November 19, 2025 to March 5, 2027.

The Ryan GRAT 10b5-1 plan included a representation from the GRAT to the broker administering the plan that the GRAT was not in possession of any material nonpublic information regarding the Company or the securities subject to the plan. A similar representation was made to us in a certification from Mr. Ryan provided to us in connection with the adoption of the applicable plan under our insider trading policy. Those representations were made as of the date of adoption of the Ryan GRAT 10b5-1 Plan or the certification, as applicable, and speak only as of those dates. In making those representations, there is no assurance with respect to any material non-public information of which the GRAT or Mr. Ryan was unaware, or with respect to any material non-public information acquired by the GRAT, Mr. Ryan or us after the applicable date of the representation.

Other than as disclosed above, during the quarter ended December 31, 2024, none of our directors or officers adopted or terminated any "Rule 10b5-1 trading arrangements" or any "non-Rule 10b5-1 trading arrangements," as each term is defined in Item 408 of Regulation S-K.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

None.

Part III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Except as set forth below, the information required by this Item is incorporated by reference from our definitive proxy statement for our 2025 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2024.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item is incorporated by reference from our definitive proxy statement for our 2025 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2024.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this Item is incorporated by reference from our definitive proxy statement for our 2025 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2024.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this Item is incorporated by reference from our definitive proxy statement for our 2025 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2024.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this Item is incorporated by reference from our definitive proxy statement for our 2025 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2024.

Part IV

Item 15. Exhibits, Financial Statement Schedules

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

1. Consolidated financial statements: The consolidated financial statements are set forth under "Item 8. Financial Statements and Supplementary Data" of this Annual Report on Form 10-K.
2. Financial statement schedules: All schedules have been omitted because they are not required, not applicable, or the required information is included in the consolidated financial statements or notes thereto.
3. Exhibits: The exhibits listed in the accompanying Exhibit Index are filed or incorporated by reference as part of this Annual Report on Form 10-K.

		Incorporated by Reference			
No.	**Description of Exhibit**	**Form**	**Exhibit**	**Filing Date**	**Filed Herewith**
1.1	Underwriting Agreement by and between GeneDx Holdings Corp. and Jefferies LLC, dated January 26, 2023.	8-K	1.1	01/30/2023	
1.2	Sales Agreement, dated April 29, 2024, by and between GeneDx Holdings Corp. and TD Securities (USA) LLC.	8-K	1.1	04/29/2024	
2.1+	Agreement and Plan of Merger, dated February 9, 2021, by and among CMLS, Merger Sub and Legacy Sema4, as amended by Amendment to Agreement and Plan of Merger dated May 3, 2021.	DEF14M	Annex A	07/02/2021	
2.2	Agreement and Plan of Merger and Reorganization, dated as of January 14, 2022, by and among, Orion Merger Sub I, Inc., Orion Merger Sub II, LLC, GeneDx, Inc., GeneDx Holding 2, Inc. and OPKO Health, Inc.	8-K	2.1	01/18/2022	
2.3+	Amendment to Agreement and Plan of Merger and Reorganization, dated as of April 29, 2022, by and among, Sema4 Holdings Corp., Orion Merger Sub I, Inc., Orion Merger Sub II, LLC, GeneDx, Inc., GeneDx Holding 2, Inc. and OPKO Health, Inc.	8-K	99.2	05/02/2022	
3.1	Third Amended and Restated Certificate of Incorporation of Sema4 Holdings Corp.	8-K	3.1	07/28/2021	
3.2	First Certificate of Amendment of Restated Certificate of Incorporation of Sema4 Holdings Corp.	8-K	3.1	01/09/2023	
3.3	Second Certificate of Amendment to the Third Amended and Restated Certificate of Incorporation of GeneDx Holdings Corp.	8-K	3.1	04/17/2023	
3.4	Third Certificate of Amendment to the Third Amended and Restated Certificate of Incorporation of GeneDx Holdings Corp.	8-K	3.1	04/28/2023	
3.5	Amended and Restated Bylaws of GeneDx Holdings Corp.	8-K	3.2	01/09/2023	
4.1	Specimen Class A Common Stock Certificate.	S-1/A	4.2	08/24/2020	
4.2	Specimen Warrant Certificate.	S-1/A	4.3	08/24/2020	
4.3	Warrant Agreement, dated as of September 1, 2020, by and between CM Life Sciences, Inc. and Continental Stock Transfer & Trust Company, as warrant agent.	8-K	10.1	09/04/2020	
4.4	Warrant to Purchase Stock, dated October 27, 2023, by and among the Company and Perceptive Credit Holdings IV, LP.	8-K	4.1	10/30/2023	
4.5	Description of Securities.				X
10.1	Amended and Restated Registration Rights Agreement, dated as of July 22, 2021, by and among the Company, certain equity holders of the Company named therein and certain equity holders of Sema4 named therein.	8-K	10.2	07/28/2021	
10.2	Form Director of and Officer Indemnification Agreement.	8-K	10.4	07/28/2021	
10.3*	GeneDx Holdings Corp. Amended and Restated 2021 Equity Incentive Plan.	8-K	10.1	04/17/2023	
10.4*	Form of Stock Option Agreement under the 2021 Equity Incentive Plan.	8-K	10.6	07/28/2021	
10.5*	Form of RSU Agreement under the 2021 Equity Incentive Plan.	8-K	10.7	07/28/2021	
10.6*	Form of Earn-Out RSU Agreement.	8-K	10.8	07/28/2021	

10.7*	2021 Employee Stock Purchase Plan.	8-K	10.9	07/28/2021
10.8*	GeneDx Holdings Corp. 2023 Equity Inducement Plan.	8-K	10.1	07/24/2023
10.9*	Form of Option Award Agreement under the 2023 Equity Inducement Plan.	8-K	10.2	07/24/2023
10.10*	Form of Restricted Stock Unit Award Agreement under the 2023 Equity Inducement Plan.	8-K	10.3	07/24/2023
10.11	Sub-Sublease, dated as of June 6, 2017, by and between Icahn School of Medicine at Mount Sinai and the Company, as amended July 31, 2019.	8-K	10.17	07/28/2021
10.12	Sublease Agreement, dated as of November 8, 2019, by and between Marriott International, Inc. and the Company.	8-K	10.18	07/28/2021
10.13	Sublease, dated as of June 1, 2017, by and between Icahn School of Medicine at Mount Sinai and the Company, as amended December 22, 2017.	8-K	10.19	07/28/2021
10.14	Sublease, dated as of April 23, 2019, by and between Icahn School of Medicine at Mount Sinai and the Company.	8-K	10.20	07/28/2021
10.15	Lease Agreement, dated as of January 31, 2020, by and between 1 Commercial Street Associates, LLC and the Company.	8-K	10.21	07/28/2021
10.16#	Master Services Agreement, dated as of April 2, 2018, by and among the Company, Icahn School of Medicine at Mount Sinai, The Mount Sinai Hospital, and the parties thereto, as amended July 31, 2019.	8-K	10.22	07/28/2021
10.17#	Master Services Agreement, dated as of May 10, 2018, by and between the Company and Icahn School of Medicine at Mount Sinai, as amended July 31, 2019.	8-K	10.23	07/28/2021
10.18#	Data Structuring and Curation Agreement, dated as of August 1, 2019, by and between Icahn School of Medicine at Mount Sinai and the Company, as amended March 11, 2020.	8-K	10.24	07/28/2021
10.19#	BioMe Biospecimen and Data Access Agreement, dated as of July 19, 2019, by and between Icahn School of Medicine at Mount Sinai and the Company.	8-K	10.25	07/28/2021
10.20#	Non-Exclusive Patent License Agreement, dated as of June 1, 2017, by and between the Company and Icahn School of Medicine at Mount Sinai.	8-K	10.26	07/28/2021
10.21#	Supply Agreement, dated as of June 20, 2014, by and between the Company and Illumina, Inc., and amendments thereto.	8-K	10.27	07/28/2021
10.22*	Mount Sinai Genomics, Inc. 2017 Equity Incentive Plan, as amended, and forms of equity agreements thereunder.	S-8	99.6	09/27/2021
10.23	Loan and Security Agreement, dated as of November 15, 2021, between Silicon Valley Bank, the Company and Sema4 OpCo, Inc.	10-Q	10.26	11/15/2021
10.24	Subscription Agreement, dated as of February 9, 2021, by and among the Company and the subscriber parties thereto.	8-K	10.1	02/11/2021
10.25	Form of Subscription Agreement, dated as of January 14, 2022 by and among the Company and the subscriber parties thereto.	8-K	10.1	01/18/2022
10.26	Form of Shareholder Agreement, dated as of January 14, 2022 by and among the Company and the stockholder parties identified therein.	8-K	10.2	01/18/2022
10.27	Form of Support Agreement dated as of January 14, 2022 by and among the Company and the stockholder parties identified therein.	8-K	10.3	01/18/2022
10.28	Form of Lock-Up Agreement, by and among the Company and the stockholder parties identified therein.	8-K	10.4	01/18/2022
10.29*	Executive Chairman Agreement, dated as of January 17, 2022, by and between the Company and Jason Ryan.	10-K	10.31	03/14/2022
10.30*	Amendment No. 1 to Executive Chairman Agreement.	8-K	10.1	04/14/2023
10.31+	Transition Services Agreement, dated as of April 29, 2022, by and between GeneDx, Inc. and OPKO Health, Inc.	8-K	10.1	05/02/2022
10.32*	Employment Agreement, dated as of January 14, 2022, as amended April 29, 2022, by and between Sema4 Holdings Corp. and Katherine Stueland.	8-K	10.2	05/02/2022
10.33*	Employment Agreement of Kevin Feeley, dated January 14, 2022.	10-K	10.32	03/16/2023

10.34*	Amendment No. 1 to the Employment Agreement of Kevin Feeley, dated August 25, 2022.	8-K	10.1	08/26/2022	
10.35#	Amendment No. 1 to BioMe Biospecimen and Data Access Agreement, dated as of January 19, 2023, by and between Icahn School of Medicine at Mount Sinai and Sema4 OpCo, Inc.	10-K	10.34	03/16/2023	
10.36	2022 Replacement Promissory Note.	10-K	10.35	03/16/2023	
10.37	Credit Agreement and Guaranty, dated October 27, 2023, by and among the Company and Perceptive Credit Holdings IV, LP.	8-K	10.1	10/30/2023	
10.38	Security Agreement, dated October 27, 2023, by and among the Company and Perceptive Credit Holdings IV, LP.	8-K	10.2	10/30/2023	
10.39	Form of Subscription Agreement.	8-K	10.1	01/30/2023	
10.40+	Letter Agreement, Amendment No. 2 to Sub-Sublease, dated as of March 20, 2023, by and between Icahn School of Medicine at Mount Sinai and the Company.	10-Q	10.3	05/09/2023	
10.41*	Employment Agreement by and between Dr. Bryan Dechairo and GeneDx, LLC, dated as of October 10, 2024.	8-K	10.1	01/02/2025	
10.42*	Amendment to Form of Restricted Stock Unit Award Agreement under the 2023 Equity Inducement Plan.				X
19.1	Insider Trading Policy.				X
21.1	Subsidiaries of the Company.				X
23.1	Consent of Ernst & Young LLP, independent registered accounting firm for GeneDx Holdings Corp.				X
24.1	Power of Attorney (included on signature page to this Annual Report on Form 10-K).				X
31.1	Certification of Principal Executive Officer Pursuant to Securities Exchange Act Rules 13a-14(a) and 15(d)-14(a), as adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
31.2	Certification of Principal Financial Officer Pursuant to Securities Exchange Act Rules 13a-14(a) and 15(d)-14(a), as adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
32.1**	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
32.2**	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
97.1	Policy Relating to Recovery of Erroneously Awarded Compensation.				X
101.INS	Inline XBRL Instance Document				X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document				X
101.SCH	Inline XBRL Taxonomy Extension Schema Document				X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document				X
101.LAB	Inline XBRL Taxonomy Extension Labels Linkbase Document				X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document				X
104	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101.)				X

* Management Contract or Compensatory Plan

** Furnished.

\+ Certain of the exhibits and schedules to this Exhibit have been omitted in accordance with Regulation S-K Item 601(a)(5). The Company agrees to furnish a copy of all omitted exhibits and schedules to the SEC upon its request.

\# The Company has omitted portions of the exhibit as permitted under Regulation S-K Item 601(b)(10).

Item 16. Form 10-K Summary

We may voluntarily include a summary of information required by Form 10-K under this Item 16. We have elected not to include such summary information.

SIGNATURES

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

GENEDX HOLDINGS CORP.

Date: February 20, 2025

By: /s/ Katherine Stueland
Name: Katherine Stueland
Title: Chief Executive Officer and Director (Principal Executive Officer)

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

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Katherine Stueland Katherine Stueland	Chief Executive Officer and Director (Principal Executive Officer)	February 20, 2025
/s/ Kevin Feeley Kevin Feeley	Chief Financial Officer (Principal Financial Officer)	February 20, 2025
/s/ Jason Ryan Jason Ryan	Chairman of the Board	February 20, 2025
/s/ Eli D. Casdin Eli D. Casdin	Director	February 20, 2025
/s/ Emily Leproust Emily Leproust	Director	February 20, 2025
/s/ Keith Meister Keith Meister	Director	February 20, 2025
/s/ Joshua Ruch Joshua Ruch	Director	February 20, 2025
/s/ Richard Pfenninger, Jr. Richard Pfenninger, Jr.	Director	February 20, 2025