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, 2022

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)

(800) 298-6470
Registrant's telephone number, including area code

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Class A common stock, par value $0.0001 per share	**WGS**	**The Nasdaq Global Select Market**
Warrants to purchase one share of Class A common stock, each at an exercise price of $11.50 per share	**WGSWW**	**The Nasdaq Global Select Market**

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 $218 million as of June 30, 2022, based on the closing sale price of such stock as reported on the Nasdaq Global Select Market.

The registrant had outstanding 798,247,286 shares of Class A common stock as of March 14, 2023.

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 2023 Annual Meeting of Stockholders (the "2023 Proxy Statement").

TABLE OF CONTENTS

EXPLANATORY NOTE

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

- "GeneDx Holdings" refer to GeneDx Holdings Corp., a Delaware corporation (f/k/a Sema4 Holdings Corp. ("Sema4 Holdings"));
- "Legacy GeneDx" refer to GeneDx, LLC, a Delaware limited liability company (formerly, GeneDx, Inc., a New Jersey corporation), which we acquired on April 29, 2022 (the "Acquisition");
- "Legacy Sema4" refer to Mount Sinai Genomics, Inc. d/b/a as Sema4, 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:
    - Legacy Sema4 prior to the Business Combination, and GeneDx Holdings and its consolidated subsidiaries following the consummation of the Business Combination; and
    - Legacy GeneDx prior to the Acquisition, and GeneDx Holdings and its consolidated subsidiaries following the consummation of the Acquisition.

In addition, as described in more detail herein, we are pursuing a new strategic direction focused on our whole exome and genome sequencing business coupled with our Centrellis® data platform. We completed the exit of our reproductive and women's health testing business, during the first quarter of 2023, and we also completed the exit of our somatic tumor testing services during the fourth quarter of 2022. For more information, see Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations. Unless the context otherwise requires, the description of our business and operations in this Annual Report assumes the completion of the exits from somatic tumor testing services and the reproductive and women's health testing business.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Certain matters discussed in this Annual 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 Annual 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, including supply chain interruptions and manufacturing constraints, arising from or related to public health

emergencies such as but not limited to the COVID-19 pandemic, 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, (the "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 estimates of the fair value of the milestone payments related to the Acquisition and our conclusions regarding the appropriateness of the carrying value of intangible assets and goodwill;
- our ability to satisfy Nasdaq listing rules;
- our stock price and its volatility; and
- our ability to attract and retain key personnel.

The forward-looking statements contained in this Annual 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

We are pursuing a new strategic direction focused on our exome and genome sequencing business coupled with our Centrellis® data platform. We completed the exit of our reproductive and women's health testing business, during the first quarter of 2023, and we also completed the exit of the somatic tumor testing business during the fourth quarter of 2022. For more information, see "Management's Discussion and Analysis of Financial Condition and Results of Operations." Unless the context otherwise requires, the description of our business and operations below assumes the completion of the exits from the somatic tumor testing and the reproductive and women's health testing businesses.

Purpose

We operate with conviction that what is best for patients must be embedded in every aspect of our work. At GeneDx, we believe:

- genomic information has broad utility, and every person should have access to their genome—delivered expertly, ethically and responsibly—to guide health decisions throughout life;
- exome and Whole Genome Sequencing ("WGS") will facilitate a transition from hypothesis-based to genome-guided healthcare which will improve outcomes for patients and healthcare systems that benefit society as a whole;
- the ability to curate and combine genomic information with clinical and electronic medical record ("EMR") data will transform therapeutic development, bringing better therapies to patients, faster; and
- patients should control and have the ability to direct the use of their genomic information to both benefit themselves and advance scientific understanding that helps others.

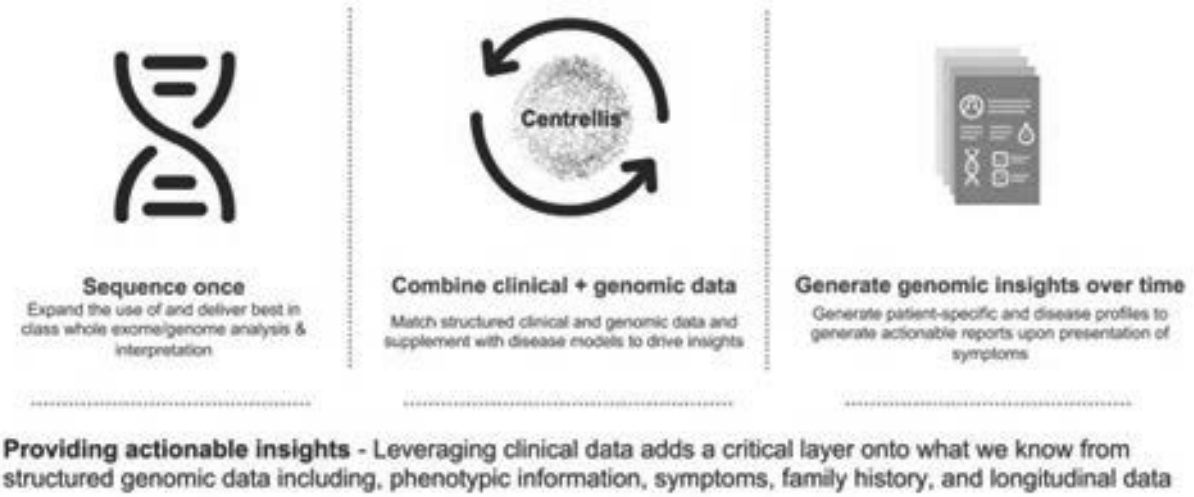
In support of these beliefs, we value equitability, simplicity and transparency. Through this value system, we aim to deliver personalized and actionable health insights to inform diagnosis, direct treatment and improve drug discovery, bringing better health from genomics to patients around the world.

Overview

GeneDx is focused on delivering personalized and actionable health insights to inform diagnosis, direct treatment and improve drug discovery. We sit at the intersection of diagnostics and data science, pairing decades of genomic expertise with an ability to interpret clinical data at scale. We believe we are well-positioned to accelerate the use of genomics and leverage large-scale clinical data to enable precision medicine as the standard of care. Our initial focus is in pediatric and rare diseases, two areas in which we believe we have competitive advantage and can deliver on our vision today.

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. More than 20 years later, we have amassed one of the world's largest rare disease data sets and remain a leader in genomics. In May 2022, GeneDx was acquired by and integrated with Sema4 Holdings, adding Legacy Sema4's Centrellis®, a highly innovative health information platform to our portfolio of solutions. Centrellis® integrates digital tools and artificial intelligence, allowing our scientists to ingest and synthesize clinical and genomic data to deliver better, more comprehensive health insights.

Today, we are powered by our industry-leading genomic interpretation platform and Centrellis®. 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 for generations by sequencing once and analyzing for a lifetime.



Industry Background

Targeted genetic tests and panel testing make up the vast majority of diagnostics tests ordered today. While panel testing can be immensely valuable, 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 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 will require having a robust, well-characterized dataset that can maximize answers and minimize unknowns and that can 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 companies in the industry have grown through a focus 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 the genome and exome can change the way proteins are formed or are 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 over 20 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 400,000 exomes to date. We have performed over a million genetic tests and worked tirelessly to develop the following:

- A curated database of disease-associated genomic variants.
- Proprietary bioinformatics and variant interpretation pipelines.
- 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 approximately 250 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 2.7 million structured phenotypes with nearly 60% of all exomes 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. 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, as new data increases the potential for greater insights. Comparing new cases against the data from previous cases helps to confirm whether a genetic variant is significant. Once new findings are identified, we aim to proactively reach out to healthcare providers and offer to reanalyze their patients' previous results. Over time, our objective is to fully automate this reanalysis process in a convenient, easy to understand, efficient method.

In this new world of "one test," people may be able to carry their genomic data—their DNA blueprints—with them throughout their life. GeneDx intends to assist in providing new answers from within, decoding more insights over time. 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.

Delivering Health Insights

Centrellis®, our health information platform, is supported and fueled by genomic information from our diagnostic business and combined with an ever growing population of clinical health records and data. We engage with patients, physicians, health systems, and other partners based on principles of transparency, choice, and consent. Driven by our direct engagement with patients and strategic relationships with multiple health systems, the database we have built contains extensive Electronic Medical Record (EMR) data, totaling approximately 3.1 million patient health records, and has been designed to enable Centrellis® to draw from its extensive data assets in a way that enables physicians to proactively diagnose and manage disease. Our datasets include over 20 years of records abstracted from approximately 56 million clinical documents, 47 million phenotypes and 8 million disease diagnoses. We expect our current and targeted strategic relationships will provide us with access to additional active patient cohorts and datasets to continue to build our information base and enable our iterative, data-driven business model, including our genomic test solutions franchise.

Market Opportunity

Our primary growth engine in the short term will be expanding our current market-leading exome sequencing capabilities in the Neonatal Intensive Care Units ("NICU") and Pediatric Developmental Disorder setting, as well as providing interpretation and information services for customers that sequence locally but look to GeneDx for analysis and interpretation, and providing our Centrellis® platform services to biopharmaceutical ("biopharma") partners.

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 nearly 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.

Our longer-term growth strategy is the expansion into whole genome testing for Adult Disorders and Newborn Screening, 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.

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 $30 billion global market opportunity.

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. Importantly, we believe that we return fewer uncertain findings compared to public data sets, 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 exome sequencing costs since 2013. Much of this decline was driven by reduced sequencing costs shared across the industry; however, we have reduced costs 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.

To achieve these objectives, we plan to:

- Complete the build out of our commercial footprint to nearly 60 field-based sales representatives in 2023, and 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 payers 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.
- 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;
- 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.
- Optimize Centrellis® to become a solutions provider of choice for biopharma. Such solutions will focus on three value-added services:

- FIND: Finding rare disease patients for clinical trial recruitment and/or delivery of targeted therapeutics, eventually moving into other disease areas such as cardiology and oncology.
- UNDERSTAND: Supporting research and development for targeted therapies with analytic reports leveraging clinicogenomics data across multiple therapeutic areas with an initial emphasis in rare disease and oncology.
- PLATFORM: In the long term, 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. 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 several 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—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 biopharmaceutical 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 Baylor, Centogene, Exact Sciences, Invitae as well as other commercial and academic labs.

Customers and Seasonality

We receive payment for our products and services from third-party payers, patients, business-to-business clients, and from other healthcare partners. Substantially all of our revenue for the year ended December 31, 2022 has been primarily derived from diagnostic test reports and we expect this trend to continue in the near-term. During the year ended December 31, 2022, 94% of pediatric specialists in the United States who order exome testing have ordered from GeneDx. 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.

Less than 5% 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 have historically experienced higher revenue in our fourth quarter compared to other quarters in our fiscal year due in part to seasonal demand of our tests from patients who have met their annual insurance deductible. However, changes in our product and payer mix might cause these historical seasonal patterns to be different than future patterns of 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 audited consolidated financial statements. We expect incrementally less concentration among third-party payors following the exits from reproductive health and somatic tumor testing.

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 on-line 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, as of January 23, 2023, we have six pending non-provisional utility patent applications and one provisional patent application. The utility patent applications include a U.S. patent application related to a genome annotation software platform for annotating genomic intervals that are clinically relevant for analysis, a U.S. patent application related to a genetic carrier screening process, and U.S. and European patent applications 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 2040, 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 narrowed from initial filings due to any amendments that may arise throughout their prosecution.

We do not presently have any patents or patent applications 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. We had 1,100 team members as of January 20, 2023 who are champions of not only our organization, but our patients, providers and partners.

Our values

Our values guide our interactions. Our model represents the interconnectedness of sometimes opposing values, where both are required to accomplish our mission. These values are:

- Bravery & Humility
- Openness & Accountability
- Equitability & Integrity
- Rigorous & Efficient Development
- Simplicity & Curiosity

Diversity and Inclusion

We believe that a diverse and inclusive workforce is important. Our JEDI (Justice, Equity, Diversity and Inclusion) initiatives enable us to build a diverse and inclusive workplace that help make progress in our belief of equitability. Every team has a JEDI goal to ensure we are accountable to one another and this commitment.

Talent Development

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 and a 401(K) plan with matching opportunities. 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 payers, 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 and Stamford laboratories have been accredited by the College of American Pathologists ("CAP"), which means that our laboratories have been certified as following CAP guidelines in operating the laboratory and in performing tests that ensure the quality of our results. Because our laboratories are 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 that are not inconsistent 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 and Stamford facilities in Maryland, New York,

California, Pennsylvania and Rhode Island; our Stamford laboratory also maintains a Connecticut clinical laboratory permit. In addition to having laboratory licenses in New York, our laboratories are also required to obtain approval on a test-specific basis for the tests they run 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 payers. 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 provide our tests as LDTs. Under the FDA's regulatory framework, in vitro diagnostic devices (IVDs) are a type of medical device, including tests that can be used in the diagnosis or detection of diseases, such as cancer, or other conditions. The FDA considers LDTs to be a subset of IVDs that are intended for clinical use and are designed, manufactured, and used within a single laboratory that is certified under CLIA. Such LDT testing is primarily under the purview of CMS and state agencies that provide oversight over clinical laboratory operations. Although the FDA has taken the position that it has statutory authority to assure that medical devices, including certain LDTs, are safe and effective for their intended use, the FDA has historically exercised enforcement discretion with respect to most LDTs and has not required laboratories that furnish LDTs to comply with the agency's requirements for medical devices (e.g., establishment registration, device listing, premarket clearance or approval, quality systems regulations, and post-market controls). In recent years, the FDA has stated it intends to end its policy of general enforcement discretion and regulate certain LDTs as medical devices. For example, in 2014 the FDA issued two draft guidance documents that set forth a proposed risk-based regulatory framework that would apply varying levels of FDA oversight to LDTs. These documents have not been finalized to date. Subsequently, in August 2020, the U.S. Department of Health and Human Services – the parent agency of the FDA – announced that the FDA will not require premarket review of LDTs absent notice-and-comment rulemaking, as opposed to through guidance documents and other informal issuances. In November 2021, the Biden Administration rescinded this policy. At this time, it is unclear when, or if, the FDA will finalize its plans to end enforcement discretion, and even then, the new regulatory requirements are expected to be phased-in over time. Nevertheless, the FDA may decide to regulate certain LDTs on a case-by-case basis at any time.

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 ("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 offered for clinical use within 45 days of enactment of the bill. 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 ("cGMP") 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 U.S. 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 ("OSHA") has established extensive requirements relating specifically to workplace safety for healthcare employers in the U.S. 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 United States 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 payer.

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 payers or to state program payers. 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 (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 payers including commercial payers and government payers, 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 payer.

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 payer. 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.

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 Consumer Privacy Act

The California Consumer Privacy Act, as amended by the California Privacy Rights Act ("CPRA," and 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 data set, 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 also 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 we have actual knowledge that the personal information relates to an individual under 16 years of age.

In addition to the CCPA, four new state privacy laws have gone or will go into effect in 2023, including the Virginia Consumer Data Protection Act, the Utah Consumer Privacy Act, the Colorado Privacy Act, and the Connecticut Data Privacy Act. In 2023, a number of other states are considering 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, 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 U.S. 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 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 became effective on April 5, 2021. Under the 21st Century Cures Act, health care providers that violate the information blocking prohibition will be subject to appropriate

disincentives, which the HHS has yet to establish through required rulemaking. Developers of certified information technology and health information networks/health information exchanges, however, may be subject to civil monetary penalties of up to $1 million per violation. The HHS Office of Inspector General has the authority to impose such penalties and on April 24, 2020, published a proposed rule to codify new authority in regulation, which the agency proposed would be effective 60 days after it issues a final rule but in no event before November 2, 2020. The HHS Office of Inspector General has not yet issued a final rule.

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 of 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 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 2024 and every three years thereafter (or annually for "advanced diagnostic laboratory tests"), private payer 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 payer rates for our tests on an every-three-years basis, starting next in 2024. CMS uses the rates and volumes reported by laboratories to develop Medicare payment rates for the tests equal to the volume-weighted median of the private payer 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 payer 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 cross-walk 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 and 2022 and will continue to be held at such levels in 2023. Then, where applicable based upon median private payer rates reported in 2017 or 2024, reduced by up to 15% per test per year in each of 2024 through 2026 (with a second round of private payer rate reporting in 2024 to establish rates for 2025 through 2027).

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 ("MACs"). 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 denied claims and/or in substantial obligations to repay overpayments to payors. Laboratories must bill various payers, such as private third-party payers, 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 payers;
- patient financial assistance programs;
- missing, incomplete or inaccurate billing information provided by ordering physicians;
- billings to payers with whom we do not have contracts;
- disputes with payers as to which party is responsible for payment; and
- disputes with payers 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.

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 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 have limited experience with the development and commercialization of our databases and our health information and genomic platforms.
- 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 have identified material weaknesses, some of which have a pervasive effect across the organization, and may identify additional material weaknesses or significant deficiencies, in our internal controls over financial reporting. Our failure to remedy these matters could result in a material misstatement of our financial statements.
- 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.
- Future 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.
- If we fail to comply with the continued listing requirements of the Nasdaq, our Class A common stock may be delisted and the price of our Class A common stock and our ability to access the capital markets could be negatively impacted.

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 payer'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 payers (e.g., Medicare and Medicaid).

Since each payer 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 payer 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 United States, 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 payer to payer 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. We have been required to repay certain amounts to payers as a result of such audits, including but not limited to the $42 million settlement

regarding certain overpayments to Legacy Sema4 allegedly received from a payor, and may be required to repay other payers for alleged overpayments due to lack of compliance with their reimbursement policies. For more information regarding this matter, see Note 4, "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 have limited experience with the development and commercialization of our databases and our health information and genomic platforms.

We have limited experience with the development or commercialization of clinical or research products in connection with the databases we manage and to which we have access, including our Centrellis® platform. Our partners' usage of an advanced machine learning engine for therapeutic decision-making are at an early stage of development and usage under current and proposed collaborations, and we are continuing to develop new processes that may support the development of new therapeutics applications such as the delivery of personalized clinically actionable insights into clinical reports, clinical trial matching, real-world evidence trials, and clinical decision support, via an advanced programmable interface layer. Although our partners have invested significant financial resources to develop and utilize new technologies to support preclinical studies and other early research and development activities, and provide general and administrative support for these operations, our future success is dependent on our current and future partners' ability to successfully derive actionable insights from the database and our platform, and our partners' ability, where applicable, to obtain regulatory approval for new therapeutic solutions based off existing models or to obtain regulatory approval and marketing for, and to successfully commercialize, new therapeutics. The use of our platform and the databases it manages and to which it has access for these purposes will require additional regulatory investments for Centrellis®, such as "good practice" quality guidelines and regulations ("GxP") and data quality and integrity controls.

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 its inception, including net losses of $549.0 million, $245.4 million and $241.3 million for the years ended December 31, 2022, 2021 and 2020, respectively. As of December 31, 2022, we had an accumulated deficit of $1.1 billion. We expect to continue to generate significant operating losses for the foreseeable future.

We may seek to sell common or preferred equity or convertible debt securities, enter into a credit facility or another form of third-party funding or seek other debt financing. For example, we have an effective shelf registration statement that we filed with the SEC in August of 2022, registering $300 million shares of our Class A common stock and other securities. Following our recent public offerings of Class A common stock in January 2023, approximately $150 million of securities remained available under this registration statement.

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 Centrellis® solution;
- 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.

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, CAP, and other certifications to conduct our tests at our laboratories 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 laboratories.

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 laboratory licenses in New York, our clinical reference laboratories are approved on test-specific bases for the tests they run 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 United States. 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 College of American Pathologists ("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 United States require CAP accreditation as a condition to permitting clinical laboratories to test samples taken from their citizens. We have CAP accreditations for our laboratories. Failure to maintain CAP accreditation could have a material adverse effect on the sales of our tests and the results of our operations.

Due to the high degree of uncertainty regarding the implementation and impact of the CARES Act and other legislation related to COVID-19, there can be no assurance that we will be able to comply with the applicable terms and conditions of the CARES Act and retain such assistance.

On March 27, 2020, the CARES Act was signed into law, aimed at providing emergency assistance and health care for individuals, families, and businesses affected by the COVID-19 pandemic and generally supporting the U.S. economy. The CARES Act, among other things, includes provisions relating to refundable payroll tax credits, deferment of employer social security payments, net operating loss carryback periods, alternative minimum tax credit refunds, and modifications to the net interest deduction limitations. The CARES Act and similar legislation intended to provide assistance related to the COVID-19 pandemic also authorized $175.0 billion in funding to be distributed by the U.S. Department of Health and Human Services (the "HHS") to eligible health care providers. This funding, known as the Provider Relief Fund, is designated to fund eligible healthcare providers' healthcare-related expenses or lost revenues attributable to COVID-19. On December 27, 2020, the Consolidated Appropriations Act, 2021 was signed into law, which adds $3.0 billion to the Provider Relief Fund. Payments from the Provider Relief Fund are subject to certain eligibility criteria, as well as reporting and auditing requirements, but do not need to be repaid to the U.S. government if recipients comply with the applicable terms and conditions.

In 2020, we received $5.4 million as part of the stimulus, comprised of $2.6 million received under the PRF and $2.8 million received under the ERC. In 2021, we received an additional $5.6 million under the PRF distribution. Funds provided under the PRF distributions to healthcare providers are not loans and will not be required to be repaid; however, as a condition to receiving these payments, providers must agree to certain terms and conditions and submit sufficient documentation demonstrating that the funds are being used for healthcare-related expenses or lost revenue attributable to the COVID-19 pandemic. Funds provided under the ERC distributions are refundable tax credits for 50% of qualified wages paid to employees during the pandemic. A company is eligible for the ERC (1) its operations have been fully or partially suspended because of COVID-19, or (2) its gross receipts in a calendar quarter in 2020 declined by more than 50% from the same period in 2019. At the time of applying for the ERC, we concluded that the eligibility requirements were met. However, subsequent to the filing of the application, our revenue was revised due to a change in estimate as a result of finalizing our accounting records, which impacted the applicable periods and calculations for determining eligibility and may no longer meet the eligibility requirements. As such, we have deferred the recognition of the funds received under the ERC distribution and recorded the proceeds in other liabilities on the balance sheets as of December 31, 2022, and December 31, 2021.

Due to the high degree of uncertainty regarding the implementation of the CARES Act, the Consolidated Appropriations Act, 2021, other stimulus legislation and our revenue revisions, there can be no assurance that the terms and conditions of the PRF, ERC or other relief programs will not change or be interpreted in ways that affect our ability to comply with such terms and conditions in the future, which could affect our ability to retain such assistance. We will continue to monitor our compliance with the terms and conditions of the PRF, including demonstrating that the distributions received have been used for healthcare-related expenses or lost revenue attributable to COVID-19, and the terms and conditions of the ERC. If we are unable to comply with current or future terms and conditions, our ability to retain some or all of the distributions received may be impacted, and we may be subject to actions including payment recoupment, audits and inquiries by governmental authorities, and criminal, civil or administrative penalties.

The COVID-19 pandemic affected and any similar public health emergency in the future may materially and adversely affect our business and financial results.

The COVID-19 pandemic, together with related precautionary measures in response to the pandemic, materially disrupted our business during certain periods in 2021. Although our test volumes improved to what would be considered normalized market conditions during 2022, the COVID-19 pandemic, or other similar public health emergencies in the future, may disrupt our business in the future and materially and adversely affect our business and financial results.

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 United States. 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 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, including our Chief Executive Officer, Katherine Stueland, 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. We plan to develop and launch new versions of our Centrellis® platform and our core diagnostic products, which will affect a broad range of business processes and functional areas. The time and resources required to implement these new systems is uncertain, and failure to complete these activities in a timely and efficient manner could adversely affect our operations. Future growth in our business could also make it difficult for it to maintain our corporate culture. If we are unable to manage our growth effectively, it may be difficult for us to execute our business strategy and our business could be harmed.

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

When cleared, authorized or approved, we and our collaborators may market, sell, and distribute our products and services outside of the United States, and our business would be subject to risks associated with doing business outside of the United States, including an increase in our expenses and diversion of our management's attention from the development of future products and services. Accordingly, our business and financial results in the future could be adversely affected due to a variety of factors, including:

- multiple, conflicting and changing laws and regulations such as 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 Google Cloud Platform ("GCP"). 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 GCP. 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 GCP, 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 Centrellis® platform 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 including Centrellis®, and related products and services and their potential advantages over existing clinical artificial intelligence 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 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.

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 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 the Centrellis® platform and key elements of our long-term business model. 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. Accordingly, we have entered into service and collaboration agreements under which our partners, including health systems, have provided, and may in the future provide, funding, data access, and other resources for developing and potentially commercializing our products and services. These collaborations may result in us incurring significant expenses in pursuit of potential products and services, and we may not be successful in identifying, developing or commercializing any potential products or 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, EMR, 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. As is typical for companies in our industry, it is continually evaluating and pursuing various strategic or commercial relationships, some of which may involve the sale and issuance of our Class A common stock, which could result in additional dilution of the percentage ownership of our stockholders and could cause the price of our Class A common stock and warrants to decline.

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.

If we are unable to deploy and maintain effective sales, marketing and medical affairs capabilities, we will have difficulty achieving market awareness and selling our products and services.

To achieve commercial success for our tests and our future products and services, we must continue to develop and grow our sales, marketing and medical affairs organizations to effectively explain to healthcare providers the reliability, effectiveness and benefits of our current and future products and services as compared to alternatives. We may not be able to successfully manage our dispersed or inside sales forces or our sales force may not be effective. Because of the competition for their services, we may be unable to hire, partner with or retain additional qualified sales representatives or marketing or medical affairs personnel, either as our employees or independent contractors or through independent sales or other third-party organizations. Market competition for commercial, marketing and medical affairs talent is significant, and we may not be able to hire or retain such talent on commercially reasonable terms, if at all.

We may never become profitable.

We have incurred losses since our formation and we expect to continue to generate significant operating losses for the foreseeable future. As of December 31, 2022, and December 31, 2021, we have an accumulated deficit of approximately $1.1 billion and $575.4 million, respectively. We expect to continue investing significantly toward development and commercialization of our products and services and expect to continue efforts to reduce operating costs. If our revenue does not grow significantly, or if we are unable to achieve planned cost reductions, we will not be profitable. We cannot be certain that the revenue from the sale of any products or services based on our technologies will be sufficient to make us profitable.

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 revenues and results of operations 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 across our Centrellis platform may affect our operating margins.

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

We have identified material weaknesses, some of which have a pervasive effect across the organization, and may identify additional material weaknesses or significant deficiencies, in our internal controls over financial reporting. Our failure to remedy these matters could result in a material misstatement of our financial statements.

In the course of preparing Legacy Sema4's financial statements as of December 31, 2020, we previously identified material weaknesses in our internal control over financial reporting. Certain of these material weaknesses remain unremediated as of December 31, 2022. For a discussion of these material weaknesses, see "Item 9A. Controls and Procedures",

Our management is actively engaged and committed to taking the steps necessary to remediate the control deficiencies that constituted the material weaknesses. However, we cannot guarantee that the steps we have taken or may subsequently take have been or will be sufficient to remediate the material weaknesses or ensure that our internal controls are effective. For a discussion of our remediation plan and actions, see "Item 9A. Controls and Procedures."

Furthermore, as a public company, we are required to comply with certain rules and requirements related to our disclosure controls and procedures and our internal control over financial reporting. Any failure to develop or maintain effective controls as a public company, any deficiencies found in the technology system we use to support our controls, or any difficulties encountered in their implementation or improvement, could harm our operating results or cause us to fail to meet our reporting obligations and may result in a restatement of our financial statements for prior periods. For more information, see "*Risks Related to Being a Public Company—Our internal controls over financial reporting may not be effective and our independent registered public accounting firm may not be able to certify as to their effectiveness, which could have a significant and adverse effect on our business and reputation.*"

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

As of December 31, 2022, our total gross deferred tax assets were $281.0 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, 2022, 2021, and 2020, 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 partial valuation allowance as of December 31, 2022 and a full valuation allowance as of December 31, 2021 and 2020.

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 Mount Sinai, a related party, for a portion of our data programs, and we have entered into certain other arrangements with Mount Sinai.

We rely on the Mount Sinai Health System (together with its related entities, ("Mount Sinai"), which is a related party, for substantially all of the de-identified clinical records in our databases. In addition, we sublease certain facilities from Mount Sinai, we provide certain research and data services to Mount Sinai, and we and Mount Sinai have entered into certain collaborative and commercial arrangements. Certain of our employees perform duties for or on behalf of Mount Sinai. Furthermore, we may in the future enter into other contracts for services or other engagements with Mount Sinai.

Mount Sinai is primarily made up of not-for-profit hospitals, a medical and graduate school and employed clinicians. The charitable missions of the Mount Sinai entities include patient care, teaching and research. As such, the Mount Sinai entities are required to deal with us strictly on an arms-length, fair market value basis, and the interests of Mount Sinai may not necessarily be aligned with our interests or those of our other stockholders.

We are subject to risks as a result of our reliance on Mount Sinai, and if our transactions and relationship with Mount Sinai were to cease, our business could be disrupted and it could have a material adverse effect on our business, research, financial condition and results of operations.

In addition, Icahn School of Medicine at Mount Sinai ("ISMMS") is one of our significant stockholders. ISMMS may choose to dispose of some or all of the shares of our Class A common stock held by it. Any disposal of shares of Class A common stock by ISMMS, or the perception that these sales could occur, could cause the market price of our stock or warrants to decline.

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 have incurred and will continue to incur significant transaction and transition costs in connection with the Acquisition.

We have incurred significant, non-recurring costs in connection with consummating the Acquisition and with the integration of the businesses, which may adversely affect our results of operations.

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.

From time to time, we may decide to exit certain businesses or otherwise undertake restructuring, reorganization, or other strategic initiatives and business transformation plans to realign our resources with our growth strategies, operate more efficiently and control costs. The successful implementation of our restructuring activities may from time to time require us to effect business and asset dispositions, workforce reductions, management restructurings, decisions to limit investments in or otherwise exit businesses, facility consolidations and closures, and other actions, each of which may depend on a number of factors that may not be within our control. For example, as described in more detail elsewhere in this Annual Report, we exited our reproductive and women's health testing business, during the first quarter of 2023 and we exited our somatic tumor testing business during the fourth quarter of 2022.

Any such effort to realign or streamline our organization may result in the recording of restructuring or other charges, such as asset impairment charges, contract and lease termination costs, exit costs, termination benefits and

other restructuring costs. In particular, we expect that material cash and non-cash charges will be incurred and recorded in our future reporting periods as a result of the exit of the reproductive and women's health testing and somatic tumor testing businesses. Further, as a result of restructuring initiatives, we may experience a loss of continuity, loss of accumulated knowledge and proficiency, adverse effects on employee morale, loss of key employees and/or other retention issues during transitional periods. Reorganization and restructuring can impact a significant amount of management and other employees' time and focus, which may divert attention from operating and growing our business. Further, upon completion of any restructuring initiatives, our business may not be more efficient or effective than prior to the implementation of the plan and we may be unable to achieve anticipated operating enhancements or cost reductions, which would adversely affect our business, competitive position, operating results and financial condition.

We have assumed Legacy GeneDx's risks arising from various legal proceedings.

In connection with the Acquisition, as of the closing, we assumed Legacy GeneDx's risks arising from legal proceedings. In particular, Legacy GeneDx has received from the Medicaid offices of certain states requests for refunds of up to approximately $1.8 million of previously issued reimbursements for certain services and testing provided by Legacy GeneDx both prior to and following the Acquisition. This amount represents the initial amounts expressed in writing by the Medicaid offices as well as our estimate based on our participation in discussions with OPKO and the Medicaid offices. We are working with OPKO to investigate these issues and in discussions with these payors regarding their requests and, at this time, we can express no opinion as to the likelihood of an unfavorable outcome or the range of potential loss in this matter. Although we expect OPKO's indemnification obligations under the merger agreement related to the Acquisition (the "Acquisition Merger Agreement") would apply to certain of the requested refunds related to the services and testing provided prior to the closing of the Acquisition, we would be responsible for any refunds related to services and testing provided after the closing of the Acquisition. Furthermore, following the closing of the Acquisition, the strategies or motivations of a party or parties with respect to actual or potential litigation against us may change. We cannot predict with certainty the eventual outcome of Legacy GeneDx's pending or future legal proceedings and the ultimate outcome of such matters could be material to our results of operations, cash flows and financial condition.

Finally, the Acquisition may result in post-transaction disputes with OPKO or the other counterparties to the Acquisition Merger Agreement and the related agreements regarding a number of matters, including any post-closing adjustments to the Cash Consideration, the occurrence or non-occurrence of any Milestone Event (as defined in the Acquisition Merger Agreement for the Acquisition) or payment of any Milestone Payment (as defined in the Acquisition Merger Agreement) or any liabilities for which we or OPKO believes it was indemnified under the Acquisition Merger Agreement.

We may seek to grow our business through additional acquisitions of complementary products or technologies and we may from time to time dispose of 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.

Future changes in FDA enforcement discretion for LDTs could subject our operations to much more significant regulatory requirements.

We currently offer a laboratory-developed test ("LDT") version of certain tests. The FDA has a policy of enforcement discretion with respect to LDTs, whereby the FDA does not actively enforce its medical device regulatory requirements for such tests. However, in October 2014, the FDA issued two draft guidance documents stating that the FDA intended to modify its policy of enforcement discretion with respect to LDTs in a risk-based manner consistent with the existing classification of medical devices. Although the FDA halted finalization of the guidance in November 2016 to allow for further public discussion on an appropriate oversight approach to LDTs and to give Congressional authorizing committees the opportunity to develop a legislative solution, it is unclear if Congress or the FDA will modify the current approach to the regulation of LDTs in a way that would subject our current or future services marketed as LDTs to the enforcement of FDA regulatory requirements. The FDA Commissioner and the Director of the Center for Devices and Radiological Health ("CDRH") have expressed significant concerns regarding disparities between some LDTs and *in vitro* diagnostics that have been reviewed, cleared, authorized or approved by the FDA. If the FDA were to determine that certain tests offered by us as LDTs are not within the policy for LDTs 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 disagree with our LDT status or modify its approach to regulating 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* or approval of a PMA. Furthermore, pending legislative proposals, if passed, 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, or 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.

Recently, the FDA has also taken a more active role in certain diagnostic areas, including the oversight of pharmacogenetic ("PGx") tests. In 2019, the FDA contacted several laboratories to demand changes to PGx test reports and marketing materials. In February 2020, the FDA issued a statement indicating that it continues to have concerns about the claims that certain clinical laboratories make with respect to their PGx tests, and published tables that list PGx associations for which the FDA has determined that the data support therapeutic management recommendations, a potential impact on safety or response, or a potential impact on pharmacokinetic properties only, respectively. To date, however, the FDA has not provided any general guidance on the types of claims or other characteristics that will cause a PGx test to fall outside FDA's enforcement discretion. As such, the extent to which the FDA will allow any laboratory to offer PGx tests in their current form without meeting FDA regulatory requirements for medical devices is unclear at this time.

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 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. 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 payer 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 knowingly presenting (or causing the presentation of) a false claim for reimbursement by a federal health care program. 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 payer, 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 payers;

- 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..

In addition, the growth of our business and our expansion outside of the United States 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 payer 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 payers 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 United States 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 United States. The laws of some foreign countries do not protect proprietary rights to the same extent as the laws of the United States, and we may encounter difficulties in establishing and enforcing 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 while 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 United States 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 United States 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, payers 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 payers 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 Unfair and Deceptive Acts and Practices ("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 United States, Europe and elsewhere are often uncertain, contradictory and in flux. The GDPR took effect on May 25, 2018. The GDPR took effect on May 25, 2018. 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.
Further, the United Kingdom's decision to leave the EU, often referred to as Brexit, has created uncertainty with regard to data protection regulation in the United Kingdom. In particular, it is still unclear whether the transfer of personal information from the EU to the United Kingdom will in the future remain lawful under the GDPR. The United Kingdom-EU post-Brexit trade deal provides that transfers of personal information to the United Kingdom will not be treated as restricted transfers to a non-EU country for a period of up to six months from January 1, 2021. However, unless the EU Commission makes an "adequacy finding" with respect to the United Kingdom before the end of that transition period, from that date the United Kingdom will be a "third country" under the GDPR and transfers of personal information from the EU to the United Kingdom will require an "adequacy mechanism," such as the SCCs.

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 United States are beginning to propose laws similar to 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 United States 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. 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. 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 artificial intelligence 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 United States 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 United States. 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 will incur increased 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, including if we fail to comply with the continued listing requirements of Nasdaq and our securities are delisted from the Nasdaq. See "--Risks Related to Our Common Stock and Warrants--If we fail to comply with the continued listing requirements of the Nasdaq, our Class A common stock and our public warrants may be delisted and the price of our Class A common stock and our warrants and our ability to access the capital markets could be negatively impacted.". 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 factors listed below 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 the 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, rising inflation and interest rates, 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 United States District Court for the District of Connecticut against the Company and certain of the Company's current and former officers. For more information, see "Item 3. Legal Proceedings." 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.

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 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 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.

Additionally, we are a "smaller reporting company" 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 audited consolidated financial statements. We will remain a smaller reporting company until the last day of the fiscal year in which (i) the market value of our Class A common stock held by non-affiliates exceeds $250 million as of the prior June 30, or (ii) our annual revenues exceeded $100 million during such completed fiscal year and the market value of our Class A common stock held by non-affiliates exceeds $700 million as of the prior June 30.

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.

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 (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 United States 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

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 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 $0.01 per public warrant; provided that the last reported sales price of our common stock equals or exceeds $18.00 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, (the "Former Sponsor") 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, 2022, our public warrants are exercisable for 14,758,305 shares of Class A common stock at $11.50 per share. Our private warrants are exercisable for 7,236,667 shares of Class A common stock at $11.50 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, 2022 are derivative liabilities related to our warrants. Accounting Standards Codification 815, Derivatives and Hedging ("ASC 815"), provides for the remeasurement of the fair value of such derivatives 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 and that the amount of such gains or losses could be material. For example, during 2022, we recognized $21.1 million in non-cash gains on our warrants due to the change in fair market value. If the price of our Class A common stock increases, we expect we would incur non-cash losses 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 outstanding 388,511,138 shares of Class A common stock as of December 31, 2022. We have filed a registration statement which registers the offer and sale from time to time by certain selling stockholders of up to 356,524,688 shares of our Class A common stock, although the 110,864,198 shares of our Class A common stock registered on behalf of OPKO pursuant to this registration statement will be subject to certain transfer restrictions pursuant to the shareholder agreements that were entered into in connection with the Acquisition. 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 and following the end of the transfer restrictions provided for in the shareholder agreements in the case of OPKO and the other stockholders party to such shareholder agreements, 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 $11.50 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.

If we fail to comply with the continued listing requirements of the Nasdaq, our Class A common stock and our public warrants may be delisted and the price of our Class A common stock and our public warrants and our ability to access the capital markets could be negatively impacted.

Our Class A common stock and public warrants are listed on the Nasdaq under the symbols "WGS" and "WGSWW," respectively. On December 28, 2022, we received a written notice from the Listing Qualifications Department of The Nasdaq Stock Market LLC that we were not in compliance with the Minimum Bid Price Requirement set forth in Nasdaq Listing Rule 5450(a)(1) for the last 30 consecutive trading days for continued listing on the Nasdaq. The Minimum Bid Price Requirement requires listed securities to maintain a minimum bid price of $1.00 per share, and Nasdaq Listing Rule 5810(c)(3)(A) provides that a failure to meet the Minimum Bid Price Requirement exists if the deficiency continues for a period of 30 consecutive trading days. The notification provided that we had 180 calendar days, or until June 26, 2023, to regain compliance with the Minimum Bid Price Requirement. To regain compliance, the closing bid price of our Class A common stock must be at least $1.00 per share for a minimum of 10 consecutive trading days prior to June 26, 2023, and we must otherwise satisfy The Nasdaq's requirements for listing.

No assurance can be given that we will meet applicable Nasdaq continued listing standards or that future noncompliance will not occur. Failure to meet applicable Nasdaq continued listing standards could result in a delisting of our Class A common stock or our public warrants from the Nasdaq, which could materially reduce the liquidity of our Class A common stock or public warrants and result in a corresponding material reduction in the price of our Class A common stock or public warrants. Investors' ability to sell or purchase our securities when they wish to do so would also be impaired. In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the inability to expand our business, potential

loss of confidence by investors and employees, and fewer business development and strategic investment opportunities.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Properties for our core operations include our corporate office and headquarters located at 333 Ludlow Street, Stamford, Connecticut 06902, our primary operating laboratory located at 207 Perry Parkway, Gaithersburg, Maryland 20877, and a satellite meeting space located at 200 Park Avenue South, New York, NY 10002; each are leased spaces. As of the date of this Annual Report, our laboratory in Stamford, CT will fully cease operations by the end of March 2023 and, as of the date of this Annual Report, our laboratory in Branford, CT has fully ceased operations as part of the Company's announced exits in 2022 from reproductive health and somatic tumor testing. These facilities are actively being marketed for sublet; however, the outstanding lease obligations remain obligations of the Company.

Our material lease agreements for our offices and laboratory facilities as shown in the table below. We believe that our current facilities are suitable and adequate to meet our current needs.

Properties	Term	Space
Stamford, CT Corporate Headquarter	Through 2033	30,000 sq.ft.
Stamford, CT Office	Through 2033	60,000 sq.ft.
Branford, CT Laboratory (1)	Through 2030	40,000 sq ft.
Stamford, CT Laboratory (1)	Through 2046	67,000 sq.ft.
New York, NY Office	Through 2023	10,000 sq.ft.
Gaithersburg, MD Laboratory	Through 2031	84,000 sq.ft.

(1) Laboratory has ceased operations and is actively being marketed for sublet. In an effort to downsize our corporate headquarter space, we are also actively marketing certain floors of the headquarter building for sublet.

Item 3. Legal Proceedings

Except as described below, we, and our subsidiaries, are currently not a party to, and our property is not currently the subject of, any material pending legal proceedings; however, we may become involved in various claims and legal actions arising in the ordinary course of business.

On September 7, 2022, a shareholder class action lawsuit was filed in the United States District Court for the District of Connecticut 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. As amended, the complaint purports to bring suit on behalf of stockholders who purchased the Company's publicly traded securities between March 14, 2022 and August 15, 2022. The complaint purports to allege that 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, and seeks unspecified compensatory damages, fees and costs. The Company believes the allegations and claims made in the complaint are without merit.

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. The suit names as defendants all directors of CMLS at the time of the transaction, including directors who continue to serve on the Company's board of directors, as well as CMLS Holdings LLC, the Former Sponsor. 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 the Former Sponsor 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. The Company believes the allegations and claims made in the complaint are without merit. The Company is subject to certain claims for advancement and indemnification by the individual defendants in this proceeding.

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

Since January 10, 2023, our Class A common stock and public warrants have been trading on the Nasdaq Global Select Market under the symbols "WGS" and "WGSWW," respectively. From July 23, 2021 to January 9, 2023, our Class A common stock and public warrants traded on the Nasdaq Global Select Market under the symbols "SMFR" and "SMFRW", respectively. Prior to the Business Combination, CMLS's Class A common stock, CMLS's public warrants, and CMLS's public units were listed on the Nasdaq Capital Market under the symbols "CMLF", "CMFLW", and "CMLFU" respectively.

Holders

As of March 6, 2023, there were 44 record holders of our Class A common stock and 4 record holders of our public warrants, based upon information received from our transfer agent. However, this number does 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 the revolving credit facility with Silicon Valley Bank ("SVB,") preclude us from paying cash dividends without the prior written consent of SVB, which credit facility was recently assumed by Silicon Valley Bridge Bank, N.A. following the closure of SVB by banking regulators. 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

We are 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. We are focused on delivering personalized and actionable health insights to inform diagnosis, direct treatment and improve drug discovery. We believe we are well-positioned to accelerate the use of genomics and leverage large-scale clinical data to enable

precision medicine as the standard of care. Our initial focus is in pediatric and rare diseases, two areas in which we believe we have competitive advantage and can deliver on our vision today.

Corporate History Overview

Legacy Sema4 was established out of the Mount Sinai Health System and commenced operations as a commercial entity on June 1, 2017. Legacy Sema4 derived the majority of its revenue from diagnostic testing services, which primarily related to reproductive and women's health and somatic tumor testing. In addition, between May 2020 through March 31, 2022, Legacy Sema4 provided COVID-19 diagnostic testing services.

Business Combination

On July 22, 2021, Legacy Sema4 completed the Business Combination with CMLS, received net cash proceeds of $510 million, and CMLS changed its name to Sema4 Holdings. The Business Combination was accounted for as a reverse recapitalization with Legacy Sema4 as the accounting acquirer and CMLS as the acquired company for accounting purposes.

Legacy GeneDx

Legacy GeneDx was founded in 2000 by scientists from the National Institutes of Health and, prior to the Acquisition by the Company, was a wholly-owned subsidiary of OPKO Health, Inc. ("OPKO"). Legacy GeneDx derived its revenue primarily from diagnostic testing services, including revenue related to exome sequencing and whole genome sequencing.

Acquisition

On April 29, 2022, Sema4 Holdings acquired Legacy GeneDx from OPKO for an upfront payment of $150 million in cash, and 80 million shares of Class A common stock, subject to adjustment, with up to an additional $150 million revenue-based milestones (payable in cash or up to 30.9 million shares of Class A common stock at our discretion). Our results of operations include the results of operations of Legacy GeneDx from the date of acquisition. For more information, see "—Acquisition of Legacy GeneDx" below.

New Strategic Direction for GeneDx and Legacy Sema4 Business Exits

On August 11, 2022, our board of directors approved a restructuring plan that contemplated exiting Legacy Sema4's somatic tumor testing services and the closing of the laboratory in Branford, CT, which we completed as of December 31, 2022. In connection with the plan, we also eliminated approximately 250 positions.

On November 14, 2022, we announced our plan to pursue a new strategic direction focused on our exome and whole genome sequencing business coupled with our Centrellis data platform. As part of our strategic realignment, on November 11, 2022, our board of directors approved our exit from Legacy Sema4's reproductive and women's health testing business, which includes carrier screening, noninvasive prenatal, and other ancillary reproductive testing offerings. We exited the operations of the reproductive and women's health testing services during the first quarter of 2023. As a result of this business exit, we eliminated approximately 500 positions, and ceased operations at the Stamford, CT laboratory. The combined reductions in workforce eliminated approximately 32.5% of our workforce in 2022. Our go-forward testing services will be consolidated and performed out of our Gaithersburg, MD laboratory which was primarily used for our pediatric and rare disease testing services.

Effective January 9, 2023, Sema4 Holdings Corp. changed its name to GeneDx Holdings Corp.

Factors Affecting Our 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.

Number of resulted tests

A test is resulted once the appropriate workflow is completed and details are provided to the ordered patients or healthcare professional for reviews, which corresponds to the timing of our revenue recognition. We believe the number of resulted 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.

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. 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. In particular, the Legacy Sema4 business recently entered into a settlement agreement with one of its third-party payors in order to settle the claims related to coverage and billing matters allegedly resulting in the overpayments by the payor to the Legacy Sema4 business including those related to multi-gene tests, such as carrier screening services the "Disputed Claims"). Under the settlement agreement, the total settlement amount is $42 million, to be paid by us to the payor in a series of installments over the next four years with the final installment payment scheduled to be on or before June 30, 2026. The first payment of $15 million was made on December 30, 2022. In consideration for the payments, the payor has agreed to provide releases of the Disputed Claims, which releases will become effective on or about April 1, 2023. For more information regarding this matter, see Note 4, "Revenue Recognition" to our audited consolidated financial statements included within this Annual Report.

We expect to continue to focus our resources on increasing the adoption of, and expanding coverage and reimbursement for, our current 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 are seeking to leverage and deploy our platforms to develop a pipeline of future disease-specific research and diagnostic and therapeutic products and services. We have limited experience in the development or commercialization of clinical or research products in connection with our database and platform.

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 Performance Indicators

We use the following key financial and operating metrics to evaluate our business and operations, measure our performance, identify trends affecting our business, project our future performance, and make strategic decisions. These key financial and operating metrics should be read in conjunction with the following discussion of our results of operations and financial condition together with our consolidated financial statements and the related notes and other financial information included elsewhere in this report.

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 volumes drive database diversity and enable potential identification of variants of unknown significance and population-specific insights. The number of tests resulted and the mix of test results, with a focus on driving whole exome and whole genome sequencing, 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.

During the year ended December 31, 2022, we resulted 528,876 tests in our laboratories, 121,214 of which were processed by Legacy GeneDx compared to the period ended December 31, 2021, in which we resulted approximately 709,942 tests in Legacy Sema4 laboratories. This decrease in resulted volume from 2021 to 2022 largely resulted from the Company's decision to discontinue COVID-19, somatic oncology and reproductive health testing in 2022, which was partially offset by inclusion of volumes from GeneDx's laboratory following the closing of the Acquisition of GeneDx as further discussed below.

Acquisition of Legacy GeneDx

In January 2022, we and our wholly-owned subsidiaries, Orion Merger Sub I, Inc. ("Merger Sub I") and Orion Merger Sub II, LLC ("Merger Sub II") entered into an Agreement and Plan of Merger and Reorganization (as amended, the "Acquisition Merger Agreement"), with GeneDx, Inc., a New Jersey corporation ("Legacy GeneDx")

and a wholly-owned subsidiary of OPKO, GeneDx Holding 2, Inc. ("Holdco"), and OPKO to acquire 100% of Legacy GeneDx (the "Acquisition"). Subject to the terms and conditions of the Acquisition Merger Agreement, we agreed to pay consideration to OPKO for the Acquisition of (i) $150 million in cash at the closing of the Acquisition, subject to certain adjustments as provided in the Acquisition Merger Agreement, (ii) 80 million shares of our Class A common stock to be issued at the closing of the Acquisition and (iii) up to $150 million payable following the closing of the Acquisition, if certain revenue-based milestones were achieved for each of the fiscal years ending December 31, 2022 and December 31, 2023. These milestone payments, if and to the extent earned under the terms of the Acquisition Merger Agreement, will be satisfied through the payment and/or issuance of a combination of cash and/or shares of our Class A common stock (valued at a fixed $4.86 per share, subject to adjustment for stock splits and similar changes), with such mix to be determined in our sole discretion.

The Acquisition closed on April 29, 2022. Our net loss for the year ended December 31, 2022 includes the results of operations of Legacy GeneDx from the date of acquisition.

Concurrently with the execution of the Acquisition Merger Agreement, we entered into subscription agreements with certain institutional investors, pursuant to, and on the terms and subject to the conditions of which, these investors collectively subscribed for 50 million shares of our Class A common stock for an aggregate purchase price equal to $200 million (the "Acquisition PIPE Investment"). The Acquisition PIPE Investment was consummated substantially concurrently with the closing of the Acquisition.

Russia and Ukraine Conflict

During the first quarter of 2022, Russia commenced a military invasion of Ukraine, and the ensuing conflict has created disruption in the region and around the world. We continue to utilize Ukraine-based contractors as of December 31, 2022. To date, this has not had a material effect on our operations, and we have taken additional measures in securing and monitoring data and remote access.

We continue to closely monitor the ongoing conflict and related sanctions, which could impact our business, financial results and results of operations in the future.

COVID-19 Impact

During the year ended December 31, 2022, we resulted 73,408 COVID-19 tests, compared to the year ended December 31, 2021, in which we resulted 418,053 COVID-19 tests.

In March 2020, the Coronavirus Aid, Relief and Economic Security Act ("CARES Act"), was signed into law. The CARES Act was a stimulus bill that, among other things, provided assistance to qualifying businesses and individuals and included funding for the healthcare system. We received $5.4 million in 2020 as part of the stimulus, comprised of $2.6 million received under the Provider Relief Fund (the "PRF"), and $2.8 million received under the Employee Retention Credit (the "ERC"). In 2021, we received an additional $5.6 million under the PRF.

Funds provided under the PRF to healthcare providers are not loans and will not be required to be repaid; however, as a condition to receiving these payments, providers must agree to certain terms and conditions and submit sufficient documentation demonstrating that the funds are being used for healthcare-related expenses or lost revenue attributable to the COVID-19 pandemic. We have concluded it is probable that all terms and conditions associated with the funds received under the PRF distribution have been met. As a result, we recorded the funds received under the PRF in other income in the statements of operations and comprehensive loss during the periods in which we received the funds.

Funds provided under the ERC are refundable tax credits for 50% of qualified wages paid to employees during the pandemic. A company is eligible for the ERC (1) its operations have been fully or partially suspended because of COVID-19 or (2) its gross receipts in a calendar quarter in 2020 declined by more than 50% from the same period in 2019. At the time of applying for the ERC, we concluded that it was reasonably possible the eligibility requirements would be met; however, due to a change in circumstances, we are re-evaluating our position. As such, we deferred

the recognition of the funds received under the ERC and recorded the proceeds in other current liabilities on the audited consolidated balance sheets.

Recent Developments

Effective January 9, 2023 Sema4 Holdings Corp. changed its name to GeneDx Holdings Corp.

In January 2023, the Company raised approximately $150.0 million in gross proceeds from the sale of an aggregate 328,571,429 shares of its Class A common stock in an underwritten public offering and the sale of 100,000,000 shares of its Class A common stock shares directly to institutional investors affiliated with a member of our board of directors, in a concurrent registered direct offering. Both transactions were executed at $0.35 per share. 77,663,376 shares in the direct offering were issued and the remaining 22,336,624 shares are subject to stockholder approval to satisfy Nasdaq requirements with respect to the issuance of such shares of Class A common stock. The net offering proceeds received after deducting underwriters' discounts and commissions payable by the Company were approximately $137.6 million. As part of the underwritten offering, the Company granted the underwriter a 30-day option to purchase up to an additional 49,285,714 shares of Class A common stock at the same price. On January 27, 2023, the underwriter partially exercised the option to purchase an additional 185,000 shares of Class A common stock.

Additional net proceeds of $7.6 million are expected to be received during the second quarter of 2023 once the issuance of the remaining 22,336,624 shares receives stockholder approval and the Company issues such shares. .

On March 14, 2023, we announced that 100% of our cash, cash equivalents, and restricted cash now resides at a designated systematically important financial institution.

Components of Results of Operations

Revenue

During the periods discussed below, we derived the majority of our revenue from genetic and genomic diagnostic testing services. We recognized revenue from collaboration service agreements with biopharma companies and other third parties pursuant to which we provide health information and patient identification support services. The Legacy GeneDx business provided genetic and genomic diagnostic testing related to pediatrics, rare disease and hereditary cancer screening. The Legacy Sema4 diagnostics business provided reproductive and women’s health testing and screening, as well as somatic tumor testing. As discussed above, we discontinued Legacy Sema4’s COVID-19 testing services as of March 31, 2022 and no longer provide such testing services. We also discontinued Legacy Sema4’s somatic tumor profiling business as of December 31, 2022 and we ceased the operations of Legacy Sema4’s reproductive and women’s health testing services during the first quarter of 2023.

We recognize revenue when control of the promised goods or services is transferred to the customer in an amount that reflects the consideration which we expect to be entitled to in exchange for those goods or services.

Diagnostic Test Revenue

We primarily generate revenue from performing 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, or self-pay patients. Customers are billed upon delivery of test results. The amount of revenue recognized for diagnostic testing services depends on a number of factors, such as 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 generate revenue from health information and patient identification support services under both short-term and long-term project-based collaboration and service agreements with third parties. 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. These costs include expenses for reagents and laboratory supplies, personnel-related expenses (comprising salaries and benefits) and stock-based compensation 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 IT 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 line 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 personnel-related expenses (comprising salaries and benefits), stock-based compensation 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 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 personnel-related expenses (comprising salaries and benefits) and stock-based compensation for employees performing commercial sales, account management, marketing, and allocation of 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 personnel-related expenses (comprising salaries and benefits) and stock-based compensation 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, maintaining compliance with requirements of Nasdaq and of the SEC, director and officer insurance premiums. 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.

Related Party Expenses

Related party expenses consist of amounts due to ISMMS for expenses under our Transition Services Agreement with ISMMS (the "ISMMS TSA") which expired at the end of the first quarter of 2021, and other service agreements. In addition, Legacy GeneDx and OPKO entered into a Transition Services Agreement dated as of April 29, 2022 (the "OPKO TSA"), pursuant to which OPKO agreed to provide, at cost, certain services in support of the Acquisition of the Legacy GeneDx business through December 31, 2022, subject to certain limited exceptions, in order to facilitate the transactions contemplated by the Acquisition Merger Agreement. Additional information can be found in the audited financial statements in Note 7, *"Related Party Transactions"* included within this Annual Report.

We generally expect related party expenses to decrease as we establish our own internal and external resources to fulfill the administrative and other services we have historically procured from ISMMS and following the expiration of the OPKO TSA.

Interest Income

Interest income consists of interest earned on money market funds.

Interest Expense

Interest expense consists of interest costs incurred related to our finance leases and our long-term debt arrangements, including unused line fee and the amortization of deferred transaction costs related to the loan and security agreement originally entered into with Silicon Valley Bank that provides a $125 million revolving credit facility described elsewhere in this report. No amounts have been drawn under the revolving credit facility as of December 31, 2022.

Other Income, Net

Other income, net primarily consists of funding received under the CARES Act. We recognized $5.6 million of additional funding received under the CARES Act during the year ended December 31, 2021 and the amount is included in other income, net for the year ended December 31, 2021.

Results of Operations

A discussion regarding our financial condition and results of consolidated operations for the year ended December 31, 2022 compared to the year ended December 31, 2021 and for the year ended December 31, 2021 compared to the year ended December 31, 2020 is presented below.

Comparison of the Years Ended December 31, 2022 and 2021

The following table sets forth our results of operations for the periods presented:

	Year Ended December 31,	
	2022	2021
	(in thousands)	
Revenue		
Diagnostic test revenue	$ 227,334	$ 205,100
Other revenue	7,360	7,095
Total revenue	234,694	212,195
Cost of services	261,444	228,797
Gross loss	(26,750)	(16,602)
Research and development	86,203	105,162
Selling and marketing	134,913	112,738
General and administrative	203,329	205,988
Related party expenses	6,312	5,659
Impairment Loss	210,145	—
Loss from operations	(667,652)	(446,149)
Other income (expense):		
Change in fair market value of warrant and earn-out contingent liabilities	70,229	198,401
Interest income	2,541	79
Interest expense	(3,207)	(2,835)
Other income, net	57	5,114
Total other income (expense), net	69,620	200,759
Loss before income taxes	(598,032)	(245,390)
Income tax provision	49,052	—
Net loss and comprehensive loss	$ (548,980)	$ (245,390)

Revenue

	Year Ended December 31,		Change 2021 to 2022	
	2022	2021	$	%
	(dollars in thousands)			
Diagnostic test revenue	$227,334	$205,100	$ 22,234	11 %
Other revenue	7,360	7,095	265	4 %
Total revenue	$234,694	$212,195	$ 22,499	11 %

Total revenue increased by $22.5 million, or 11%, to $234.7 million for the year ended December 31, 2022, from $212.2 million for the year ended December 31, 2021.

Diagnostic test revenue increased by $22.2 million, or 11%, to $227.3 million for the year ended December 31, 2022, from $205.1 million for the year ended December 31, 2021. The increase was primarily attributable to the inclusion of $114.9 million of Legacy GeneDx diagnostics revenue from the date of Acquisition, partially offset by a decrease of $92.6 million from Legacy Sema4's diagnostics business.

For the year ended December 31, 2022, Legacy Sema4 diagnostic testing revenue decreased by $92.6 million to $112.5 million compared to $205.1 million for the year ended December 31, 2021. This decrease in diagnostic testing revenue was primarily due to a combination of the cessation of COVID-19 operations in the first quarter of 2022 resulting in a year over year decline in revenue recognized of $18.9 million, increases in third-party payor denials on both somatic oncology and women's health testing resulting in $44.1 million of lower reimbursement, and significant reversals in the amount of cumulative revenue recognized of $54.0 million in connection with establishment of liabilities and reserves for actual and potential recoupment of payments previously made by third-party payors. These decreases in revenue recognized were partially offset by increased volume of 13.4 % within the Legacy Sema4 women's health and oncology testing lines that resulted in increased revenue of $24.4 million compared to the year ended December 31, 2021.

Other revenue increased by $0.3 million, or 4%, to $7.4 million for the year ended December 31, 2022, from $7.1 million for the year ended December 31, 2021. The increase was primarily attributable to the inclusion of $1.5 million of Legacy GeneDx collaboration services activities from the date of the Acquisition, partially offset by a decrease of $1.2 million from Legacy Sema4's biopharma business.

Cost of Services

	Year Ended December 31,		Change 2021 to 2022	
	2022	2021	$	%
	(dollars in thousands)			
Cost of services	$261,444	$228,797	$ 32,647	14 %

Cost of services increased by $32.6 million, or 14%, to $261.4 million for the year ended December 31, 2022, from $228.8 million for the year ended December 31, 2021. The increase was primarily driven by the inclusion of $67.5 million of Legacy GeneDx cost of services from the time of the Acquisition, partially offset by a $34.4 million decrease in Legacy Sema4 cost of services, primarily driven by a decrease in stock-based compensation along with lower activity due to the exit of the Company's somatic tumor and COVID-19 testing businesses.

Research and Development

	Year Ended December 31,		Change 2021 to 2022	
	2022	2021	$	%
	(dollars in thousands)			
Research and development	$ 86,203	$105,162	$ (18,959)	(18)%

Research and development expenses decreased by $19.0 million, or 18%, to $86.2 million for the year ended December 31, 2022, from $105.2 million for the year ended December 31, 2021. The decrease was primarily driven by a decrease of $45.4 million in stock-based compensation expense year-over-year which was primarily due to the reversal of stock-based compensation expense by $11.3 million based on forfeiture of unvested equity awards upon termination of our executives. This decrease was offset by the inclusion of $13.1 million of Legacy GeneDx's research and development costs from the time of the Acquisition.

Selling and Marketing

	Year Ended December 31,		Change 2021 to 2022	
	2022	2021	$	%
	(dollars in thousands)			
Selling and marketing	$134,913	$112,738	$ 22,175	20 %

Selling and marketing expenses increased by $22.2 million, or 20%, to $134.9 million for the year ended December 31, 2022, from $112.7 million for the year ended December 31, 2021. The increase was primarily attributable to the inclusion of Legacy GeneDx's selling and marketing expenses of $34.2 million from the time of the Acquisition and intangible asset amortization of $3.3 million, partially offset by a $15.3 million decrease in Legacy Sema4 selling and marketing expenses. The decrease in Legacy Sema4 selling and marketing expenses was primarily driven by a decrease in stock based compensation of $22.3 million, which was offset by an increase in restructuring expenses of $7.9 million due to restructuring activities in 2022.

General and Administrative

	Year Ended December 31,		Change 2021 to 2022	
	2022	2021	$	%
	(dollars in thousands)			
General and administrative	$203,329	$205,988	$ (2,659)	(1)%

General and administrative expenses decreased by $2.7 million, or 1%, to $203.3 million for the year ended December 31, 2022, from $206.0 million for the year ended December 31, 2021. The decrease was primarily attributable to a $34.7 million decrease in Legacy Sema4 general and administrative expenses, which was partially offset by the inclusion of GeneDx general and administrative expenses of $25.9 million from the time at Acquisition and $6.1 million in intangible asset amortization. The decrease in Legacy Sema4 expenses was primarily driven by a decrease in stock-based compensation of $90.1 million which is primarily due to forfeiture of unvested equity awards upon termination of our executives. The decrease was partially offset by restructuring expenses of $7.3 million due to restructuring activities in 2022 associated to the Legacy Sema4. There was also an increase of $25.2 million in outside consulting expenses, $3.9 million increase in insurance expenses, and an $10.0 million increase in software related expenses.

Related Party Expenses

	Year Ended December 31,		Change 2021 to 2022	
	2022	2021	$	%
	(dollars in thousands)			
Related party expenses	$ 6,312	$ 5,659	$ 653	12 %

Related party expenses increased by $0.7 million, or 12%, to $6.3 million for the year ended December 31, 2022, from $5.7 million for the year ended December 31, 2021. The increase was primarily attributable to fees related to supporting certain services pursuant to the TSA with OPKO as a result of the Acquisition of Legacy GeneDx and an increase in information technology related services provided by ISMMS.

Interest Income

	Year Ended December 31,		Change 2021 to 2022	
	2022	2021	$	%
	(dollars in thousands)			
Interest income	$ 2,541	$ 79	$ 2,462	3116 %

Interest income for the year ended December 31, 2022 was due to increases in the average cash balances held in our interest-bearing and money market deposit accounts and increases in interest rates.

Interest Expense

	Year Ended December 31,		Change 2021 to 2022	
	2022	2021	$	%
	(dollars in thousands)			
Interest expense	$ 3,207	$ 2,835	$ 372	13 %

Interest expense increased by $0.4 million, or 13%, to $3.2 million for the year ended December 31, 2022, from $2.8 million for the year ended December 31, 2021. The increase was driven by the unused line fee and amortization of deferred transaction costs related to the loan and security agreement originally entered into with Silicon Valley Bank at the end of 2021.

Other Income, Net

	Year Ended December 31,		Change 2021 to 2022	
	2022	2021	$	%
	(dollars in thousands)			
Other income, net	$ 57	$ 5,114	$ (5,057)	(99)%

Other income, net increased by $5.1 million or 99% to less than $0.1 million for the year ended December 31, 2022, from $5.1 million for the year ended December 31, 2021. The decrease in other income, net was primarily attributable to the $5.6 million in funding that we received and recognized as other income under the CARES Act in the first quarter of 2021, partially offset by $0.3 million in penalties related to an early repayment of debt.

Comparison of the Years Ended December 31, 2021 and 2020

The following table sets forth our results of operations for the periods presented:

	Year Ended December 31,	
	2021	2020
	(in thousands)	
Revenue		
Diagnostic test revenue	$ 205,100	$ 175,351
Other revenue	7,095	3,971
Total revenue	212,195	179,322
Cost of services	228,797	175,296
Gross (loss) profit	(16,602)	4,026
Research and development	105,162	72,700
Selling and marketing	112,738	63,183
General and administrative	205,988	100,742
Related party expenses	5,659	9,395
Loss from operations	(446,149)	(241,994)
Other income (expense):		
Change in fair market value of warrant and earn-out contingent liabilities	198,401	—
Interest income	79	506
Interest expense	(2,835)	(2,474)
Other income, net	5,114	2,622
Total other income (expense), net	200,759	654
Loss before income taxes	(245,390)	(241,340)
Net loss and comprehensive loss	(245,390)	(241,340)

Revenue

	Year Ended December 31,		Change 2020 to 2021	
	2021	2020	$	%
	(dollars in thousands)			
Diagnostic test revenue	$205,100	$175,351	$ 29,749	17 %
Other revenue	7,095	3,971	3,124	79 %
Total revenue	$212,195	$179,322	$ 32,873	18 %

Total revenue increased by $32.9 million, or 18%, to $212.2 million for the year ended December 31, 2021, from $179.3 million for the year ended December 31, 2020.

Diagnostic test revenue increased by $29.7 million, or 17%, to $205.1 million for the year ended December 31, 2021, from $175.4 million for the year ended December 31, 2020. The increase was primarily attributable to a 135% increase in oncology test volumes, a 38% increase in women's health test volumes and an overall increase in volumes of 31%, partially offset by the change in the mix of tests performed and reduced reimbursement rates. COVID-19 testing was introduced in May of 2020, which had a lower impact on total test volume during the year ended December 31, 2020, compared to the year ended December 31, 2021 (with COVID-19 test volumes growing 26% year over year) .

Other revenue increased by $3.1 million, or 79%, to $7.1 million for the year ended December 31, 2021, from $4.0 million for the year ended December 31, 2020. The increase was primarily attributable to growth in

collaboration service activities due to the execution of third-party contracts which generated $3.7 million more in revenues in 2021 compared to 2020. This was partially offset by reduced revenues recognized related to an existing third-party contract by $0.8 million.

Cost of Services

	Year Ended December 31,		Change 2020 to 2021	
	2021	2020	$	%
	(dollars in thousands)			
Cost of services	$228,797	$175,296	$ 53,501	31 %

Cost of services increased by $53.5 million, or 31%, to $228.8 million for the year ended December 31, 2021, from $175.3 million for the year ended December 31, 2020. The increase was primarily driven by the following cost components: a $9.7 million increase in stock-based compensation expense primarily driven by the increase in fair value of the liability-classified awards until the Closing Date and an increase in the number of stock-based compensation awards granted; a $7.9 million increase in personnel-related expenses driven by an increase in average headcount; a $8.2 million increase in consulting and outside service costs driven by temporary hires contracted to perform COVID-19 testing activities; a $5.0 million increase in logistical expenses and other lab services as a result of an increase in operations; a $9.6 million increase in reagents and laboratory supplies expense due primarily to the 32% increase in volumes; a $2.4 million increase in software expenses due to increased cloud storage and expanded computing capacity requirements from New York City to Stamford, Connecticut for testing data; a $2.1 million increase in the inventory obsolescence reserve for expiring COVID-19 and certain carrier screening testing kits; a $2.2 million increase in occupancy expenses; a $5.1 million increase in depreciation expenses in connection with our laboratory move at the end of 2020, with production activities commencing at the Stamford facility in the first quarter of 2021 and a $1.3 million increase in equipment maintenance and general office expenses.

Research and Development

	Year Ended December 31,		Change 2020 to 2021	
	2021	2020	$	%
	(dollars in thousands)			
Research and development	$105,162	$ 72,700	$ 32,462	45 %

Research and development expenses increased by $32.5 million, or 45%, to $105.2 million for the year ended December 31, 2021, from $72.7 million for the year ended December 31, 2020. The increase was primarily attributable to the following cost components: a $20.5 million increase in stock-based compensation expense driven by the increase in fair value of the liability-classified awards until the Closing Date and an increase in the number of stock-based compensation awards granted; a $0.9 million increase in software expenses due to increased cloud storage; a $0.3 million increase in personnel-related expenses driven by an increase in average headcount a $4.8 million increase in depreciation expenses; a $3.6 million increase in expenses for reagents, laboratory supplies and laboratory software for research and development; and a $2.2 million increase in consulting fees.

Selling and Marketing

	Year Ended December 31,		Change 2020 to 2021	
	2021	2020	$	%
	(dollars in thousands)			
Selling and marketing	$112,738	$ 63,183	$ 49,555	78 %

Selling and marketing expenses increased by $49.6 million, or 78%, to $112.7 million for the year ended December 31, 2021, from $63.2 million for the year ended December 31, 2020. The increase was primarily attributable to the following cost components: an $17.3 million increase in stock-based compensation expense driven by the increase in fair value of the liability-classified awards until the Closing Date and an increase in the number of stock-based compensation awards granted; a $19.6 million increase in personnel-related expenses driven by increased headcount; a $4.1 million increase in consulting service expenses mainly to support revenue cycle transformation initiatives; a $3.2 million increase in information technology-related expenses; a $1.8 million increase in other administrative and office expenses; a $2.0 million increase in travel and business expenses due to the lifting of COVID-19 travel restrictions and a $1.5 million increase in counseling services.

General and Administrative

	Year Ended December 31,		Change 2020 to 2021	
	2021	2020	$	%
	(dollars in thousands)			
General and administrative	$205,988	$100,742	$105,246	104 %

General and administrative expenses increased by $105.3 million, or 104%, to $206.0 million for the year ended December 31, 2021, from $100.7 million for the year ended December 31, 2020. The increase was primarily attributable to the following cost components: a $51.7 million increase in stock-based compensation expense driven by the increase in fair value of the liability-classified awards until the Closing Date and an increase in the number of stock-based compensation awards granted; a $21.1 million increase in professional services incurred mainly in connection with the Business Combination; a $20.0 million increase in personnel-related expenses driven by an increase in average headcount including executive headcount; a $5.0 million increase in software expenses due to increased cloud storage requirements; a $7.0 million increase in insurance expenses driven by the commencement of director's insurance policy; and a $0.8 million increase in capital taxes as a result of the Business Combination. These increases were partially offset by a $0.4 million decrease in occupancy and depreciation expenses in connection with our laboratory move from New York City to Stamford, Connecticut.

Related Party Expenses

	Year Ended December 31,		Change 2020 to 2021	
	2021	2020	$	%
	(dollars in thousands)			
Related party expenses	$ 5,659	$ 9,395	$ (3,736)	(40)%

Related party expenses decreased by $3.7 million, or 40%, to $5.7 million for the year ended December 31, 2021, from $9.4 million for the year ended December 31, 2020. The decrease was primarily attributable to the following cost components: a $3.2 million decrease in rent and facility expenses driven by a reduction of office and lab space leased from ISMMS pursuant to the TSA which ended in the first quarter of 2021; and a $0.5 million decrease in fees associated with information technology support pursuant to the TSA with ISMMS.

Interest Income

	Year Ended December 31,		Change 2020 to 2021	
	2021	2020	$	%
	(dollars in thousands)			
Interest income	$ 79	$ 506	$ (427)	(84)%

Interest income decreased by $0.4 million, or 84%, to $0.1 million for the year ended December 31, 2021, from $0.5 million for the year ended December 31, 2020. The decrease was due to declines in interest rates on money market fund accounts.

Interest Expense

	Year Ended December 31,		Change 2020 to 2021	
	2021	2020	$	%
	(dollars in thousands)			
Interest expense	$ 2,835	$ 2,474	$ 361	15 %

Interest expense increased by $0.4 million, or 15%, to $2.8 million for the year ended December 31, 2021, from $2.5 million for the year ended December 31, 2020. The increase was driven by new capital lease obligations for our Stamford laboratory facility which commenced operations in 2021 as well as the unused line fee and the amortization of deferred transaction costs related to the loan and security agreement originally entered into with Silicon Valley Bank at the end of 2021.

Other Income, Net

	Year Ended December 31,		Change 2020 to 2021	
	2021	2020	$	%
	(dollars in thousands)			
Other income, net	$ 5,114	$ 2,622	$ 2,492	95 %

Other income, net increased by $2.5 million or 95% to $5.1 million for the year ended December 31, 2021, from $2.6 million for the year ended December 31, 2020. The increase in other income, net was primarily attributable to the $5.6 million in funding that we received and recognized as other income under the CARES Act in the first quarter of 2021, partially offset by $0.3 million in penalties related to an early repayment of debt. This is compared to $2.6 million in funding received in 2020.

Reconciliation of Non-GAAP Financial Measures

In addition to our results determined in accordance with 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, 2022, 2021 and 2020 (in thousands):

	Year Ended December 31,		
	2022	**2021**	**2020**
Revenue	$ 234,694	$ 212,195	$ 179,322
Cost of services	261,444	228,797	175,296
Gross (Loss) Profit	**(26,750)**	**(16,602)**	**4,026**
	(11)%	(8)%	2 %
Add:			
Depreciation and amortization expense	$ 31,328	$ 14,094	$ 9,055
Stock-based compensation expense	5,080	22,567	12,942
Restructuring expense (1)	1,926	—	—
Labor costs due to laboratory move [(2)]	—	—	16,391
COVID-19 costs [(3)]	—	—	3,179
Adjusted Gross Profit	**$ 11,584**	**$ 20,059**	**$ 45,593**
Adjusted Gross Margin	5 %	9 %	25 %

(1) Represents costs incurred for restructuring activities, which include severance packages offered to impacted employees and third party consulting costs incurred during 2022.

(2) Represents labor costs in respect of laboratory employees' time spent to support our laboratory move from New York City to Stamford, Connecticut in 2020. During the move, our laboratory employees dedicated their time to re-validating and re-establishing instruments and equipment, rebuilding interface, obtaining a CLIA license, and other tasks to make sure the move was done correctly. For GAAP purposes we included these activities in Cost of Services. However, as the laboratory move and effort spent by our employees are one-time activities, we adjusted our Gross Profit to reflect management's view of our normal operations.

(3) Represents labor costs in respect laboratory employees' downtime. During the second quarter of 2020, we did not reduce the workforce in our laboratory due to the COVID-19 pandemic. However, we suffered significantly due to the decrease in volume in Women's Health and other products. Accordingly, we have adjusted our Gross Profit to reflect the management-assessed impact from the decrease in productivity of existing laboratory employees due to the COVID-19 pandemic in the second quarter of 2020.

Adjusted EBITDA

Adjusted EBITDA is a non-GAAP financial measure that we define as net loss adjusted for interest expense (income), net, depreciation and amortization, stock-based compensation expenses, transaction costs, other (income) expense, net, COVID-19 costs, impairment loss, restructuring and business exit related charges, acquisition costs and change in fair market value of warrant and earn-out contingent liabilities. We believe Adjusted EBITDA 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 EBITDA for the years ended December 31, 2022, 2021, and 2020 (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Net loss	$ (548,980)	$ (245,390)	$ (241,340)
Interest expense (income), net [1]	666	2,756	1,968
Income tax benefit	(49,052)	—	—
Depreciation and amortization	59,309	21,807	11,734
Stock-based compensation expense	41,975	219,421	120,231
Impairment loss [2]	210,145	—	—
Restructuring and other business exit transaction costs [3]	25,810	—	—
Transaction, acquisition and business acquisition costs [4]	13,436	5,496	—
Other (income) expense, net [5]	(57)	(5,291)	(2,622)
COVID-19 costs [6]	—	—	3,179
Change in fair market value of warrant and earn-out contingent liabilities [7]	(70,229)	(198,401)	—
Adjusted EBITDA	$ (316,977)	$ (199,602)	$ (106,850)

(1) Represents the total of interest expense related to our finance leases and interest-bearing loans and interest income on money market funds.
(2) Represents impairment charge incurred in connection with the business exit activities and discontinuance of testing for Legacy Sema4.
(3) Represents costs incurred for restructuring and business exit activities, which include severance packages offered to impacted employees and third party consulting costs incurred during 2022. Certain professional service costs incurred in connection with the business exit are also included..
(4) For fiscal year 2021, represents professional service costs incurred in connection with pursuing the business combination transaction that did not meet the requirement for capitalization. For fiscal year 2022, this represents professional service costs incurred in connection with the Legacy GeneDx Acquisition transaction, which include due diligence, legal and business integration costs.
(5) For the fiscal years ended December 31, 2020 and 2021, primarily consists of funding received under the CARES Act Provider Relief Fund.
(6) Represents labor costs in respect laboratory employees' downtime. During the second quarter of 2020, we did not reduce the workforce in our laboratory due to the COVID-19 pandemic. However, we suffered significantly due to the decrease in volume in Women's Health and other products. Accordingly, we have adjusted our Gross Profit to reflect the management-assessed impact from the decrease in productivity of existing laboratory employees due to the COVID-19 pandemic in the second quarter of 2020.
(7) For the years ended December 31, 2022 and 2021, represents the change in fair market value of the liabilities associated with our public warrants, private placement warrants and the earn-out shares issuable under the terms of the merger agreement for our business combination.

Liquidity and Capital Resources

On July 22, 2021, we completed the Business Combination with CMLS, consummated the related private placement financing the "Business Combination PIPE Investment"), and received net cash proceeds of $510 million.

On November 15, 2021, we entered into a loan and security agreement (the "SVB Agreement",) with Silicon Valley Bank ("SVB",) whereby SVB agreed to provide a $125 million revolving credit facility with a maturity date of November 15, 2024. No amounts were drawn as of December 31, 2022. Advances under the SVB Agreement will bear interest at a floating rate per annum equal to the greater of (1) 4.00% and (2) the prime rate plus an applicable margin. On March 10, 2023, SVB was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation ("FDIC") as receiver. On March 14, 2023, Silicon Valley Bridge Bank, N.A., a new bank that is regulated by the Office of the Comptroller of the Currency, announced that it had assumed all loan positions, including as lender, issuing bank, administrative agent and any other function that was formerly performed by SVB, and that all commitments to advance under existing credit agreements would be honored in accordance with and pursuant to the terms thereof.

On April 29, 2022, upon the closing of the Acquisition, we received gross proceeds of $200 million from the issuance of 50 million shares of our Class A common stock pursuant to the Acquisition PIPE Investment. The gross proceeds were partially used to pay for the cash consideration of the Acquisition and transaction costs incurred in connection with the Acquisition.

On January 31, 2023, we announced the closing of an underwritten public offering and a concurrent registered direct offering of shares of our Class A common stock. The total gross proceeds are expected to be approximately $150 million, including proceeds from the issuance of the additional shares in the direct offering. See "-Recent Developments' above.

Management believes that our cash and cash equivalents provide us with sufficient liquidity for at least twelve months from the filing date of this Annual Report.

Accordingly, the 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, the entry into other credit facilities or another form of third-party funding or by seeking other debt financing. For example, we have an effective shelf registration statement that we filed with the SEC in August of 2022, registering $300 million shares of our Class A common stock and other securities. Following the Offerings in January 2023, approximately $150 million of securities remained available under this registration statement. The Company does not know what impact the ongoing situation at SVB will ultimately have on the SVB Agreement.

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, 2022 and December 31, 2021. We anticipate fulfilling such commitments with our existing cash and cash equivalents, which amounted to $123.9 million and $400.6 million as of December 31, 2022 and December 31, 2021, respectively, or through additional capital raised to finance our operations.

Our future minimum payments under non-cancellable operating lease and finance lease agreements were $80.1 million and $60.8 million, respectively as of December 31, 2022. 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 above, the Legacy Sema4 business recently entered into a settlement agreement with one of its third-party payors in order to settle the claims related to coverage and billing matters allegedly resulting in the overpayments by the payor to the Legacy Sema4 business including those related to multi-gene tests, such as carrier screening services. Under the settlement agreement, the total settlement amount is $42 million, to be paid by us to the payor in a series of installments over the next four years with the final installment payment scheduled to be on or before June 30, 2026. The first installment payment of $15 million was made on December 30, 2022. In consideration for the payments, the payor has agreed to provide releases of the Disputed Claims, which releases will become effective 91 days after the first installment payment was received by the payor. For more information regarding this matter, see Note 4, "Revenue Recognition" to our audited consolidated financial statements included within this Annual Report.

Our future contractual purchase commitments were $8.8 million as of December 31, 2022. The timing of these future payments, by year, can be found in our consolidated financial statements in Note 10, *"Commitments and Contingencies,"* included within this Annual Report.

Cash Flows

	Year Ended December 31,		
	2022	2021	2020
		(in thousands)	
Net cash used in operating activities	$ (319,155)	$ (190,434)	$ (93,128)
Net cash used in investing activities	(141,326)	(20,786)	(31,974)
Net cash provided by financing activities	197,315	493,729	129,056

Operating Activities

Net cash used in operating activities during the year ended December 31, 2022 was $319.2 million, which was primarily attributable to a net loss of $549.0 million, a change in fair value of the warrant and earn-out liabilities of $70.2 million and an income tax benefit of $49.1 million. This was partially offset by non-cash depreciation and amortization of $59.3 million, non-cash stock-based compensation expense of $42.0 million, impairment loss of $210.1 million, a provision for excess and obsolete inventory of $1.1 million and non-cash lease expense of $2.2 million. The net change in our operating assets and liabilities primarily reflected a $2.4 million decrease in inventories, a $34.5 million increase in accounts payable and accrued expenses driven by the payor settlement accrual which was partially offset by timing of vendor payments, a $19.5 million decrease in other current liabilities mainly driven by the payment of 2021 bonuses, offset by the accrual of the 2022 expected payment, a $5.5 million decrease in accounts receivable primarily from self-pay payors and a $11.1 million increase in prepaid expenses and other current assets mainly driven by the amortization of insurance policy premiums.

Net cash used in operating activities during the year ended December 31, 2021 was $190.4 million, which was primarily attributable to a net loss of $245.4 million and a change in fair value of the warrant and earn-out contingent liabilities of $198.4 million, partially offset by non-cash depreciation and amortization of $21.8 million, non-cash stock-based compensation expense of $219.4 million, and a reserve against obsolete inventory of $2.1 million. The net change in our operating assets and liabilities primarily reflected a $5.5 million decrease in accounts receivable due to a decrease in institutional customer receivables which is in line with the respective revenue stream, a $10.6 million increase in inventories driven by a higher volume of purchases to support increasing testing volumes, a $14.3 million increase in prepaid expenses and other current assets mainly driven by new insurance policy premiums paid during the year, a $25.9 million increase in accounts payable and accrued expenses due to additional volume in the fourth quarter related to COVID-19 testing, resulting in increased related accruals and extended payment terms for large vendors, and a $3.2 million increase in other current liabilities mainly driven increased bonus accruals.

Net cash used in operating activities during the year ended December 31, 2020 was $93.1 million, which was primarily attributable to a net loss of $241.3 million, partially offset by non-cash depreciation and amortization of $11.7 million, non-cash stock-based compensation expense of $120.2 million and a net change in our operating assets and liabilities of $13.8 million. The net change in our operating assets and liabilities primarily reflected an increase in accounts receivable of $10.6 million driven by a slowdown in collections due to the COVID-19 pandemic, a $9.0 million increase in inventories in preparation for the move of certain laboratory operations to a new location in December 2020, an increase in accounts payable and accrued expenses of $14.8 million due to timing of vendor payments and increased spending during the year related to COVID-19 diagnostic testing and a $16.0 million increase in other current liabilities driven by higher personnel-related accruals due to increased headcount at 2020 year-end as compared to 2019 year-end, as well as an increase in accrued payroll taxes due to the deferral of U.S. payroll taxes as part of the CARES Act.

Investing Activities

Net cash used in investing activities during the year ended December 31, 2022 was $141.3 million, which was primarily attributable to the $127 million net of cash spent for the Acquisition of Legacy GeneDx, $7.2 million in

purchases of property and equipment and $7.2 million related to spend on development of internal-use software assets.

Net cash used in investing activities during the year ended December 31, 2021 was $20.8 million, which was attributable to $9.4 million in purchases of property and equipment and $11.4 million of costs related to development of internal-use software assets.

Net cash used in investing activities during the year ended December 31, 2020 was $32.0 million, which was attributable to $24.1 million in purchases of property and equipment and $7.9 million of costs related to development of internal-use software assets.

Financing Activities

Net cash provided by financing activities during the year ended December 31, 2022 was $197.3 million, which was primarily driven by the $197.7 million proceeds from the Acquisition PIPE Investment, net of issuance costs of $2.3 million. Additionally, $2.9 million relates to cash received from exercise of employee stock options, which was offset by $3.3 million of finance lease principal payments.

Net cash provided by financing activities during the year ended December 31, 2021 was $493.7 million, which was attributable to the consummation of our Business Combination including: $350.0 million from the Business Combination PIPE Investment proceeds; $442.7 million from an equity infusion from the Business Combination, net of redemptions; offset by $230.7 million in the cash payments to certain Legacy Sema4 stockholders; payment of transaction costs of $51.8 million; and $3.8 million of stock appreciate rights pay-outs. These amounts were further offset by an $8.7 million repayment of long-term debt and $3.7 million of capital lease principal payments.

Net cash provided by financing activities during the year ended December 31, 2020 was $129.0 million, which was primarily attributable to $117.3 million in net cash proceeds from the issuance of our Series C redeemable convertible preferred stock and $15.9 million in net cash proceeds from the issuance of long-term debt. These increases were partially offset by $4.0 million in principal payments on our capital lease obligations and $0.2 million in principal payments on our long-term debt obligations.

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 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 further discussion on our accounting policies. We have identified below our accounting policies that we believe 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. A 1% decrease or increase in our collection rate from third-party insurance payers within GeneDx, which we believe could be a reasonably likely change, would result in an unfavorable or favorable adjustment to diagnostic test revenue of approximately $9.9 million.

Other revenue

We also recognize revenue from service agreements and collaboration agreements with biopharma companies and other third parties pursuant to which we provide diagnostic testing and related data aggregation reporting 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.

Capitalized Internal-Use Software Costs

We capitalize certain costs related to the development of our software applications for internal use. Capitalization begins during the application development stage, once the preliminary project stage has been completed. If a project constitutes an enhancement to existing software, we assess whether the enhancement creates additional functionality to the software, thus qualifying the work incurred for capitalization. Costs incurred prior to meeting these criteria together with costs incurred for training and maintenance are expensed as incurred. Once the project is available for general release, capitalization ceases and we estimate the useful life of the asset and begin amortization. We exercise judgment in determining the point at which various projects may be capitalized, in assessing the ongoing value of the capitalized costs and in determining the estimated useful lives over which the costs are amortized. We periodically assess whether triggering events are present which would indicate that the internal-use software is impaired. To the extent that we change our estimates related to internal-use software, the amount of internal-use software development costs we capitalize and amortize could change in future periods.

Goodwill

In accordance with ASC 350, *Intangibles - Goodwill and Other* we do not amortize goodwill but rather test them for impairment. ASC 350 requires us to perform an impairment review of our goodwill balance at least annually, which we do in the fourth quarter of each year for our single consolidated reporting unit, and whenever events or changes in circumstances indicate that the carrying amount of these assets may not be recoverable.

Intangible assets

Amortizable intangible assets include trade names and trademarks, developed technology and customer relationships acquired as part of business combinations. All intangible assets subject to amortization are reviewed for impairment in accordance with ASC 360, Property, Plant and Equipment. The recoverability test was performed on a company-wide single asset group level.

Contingent consideration based on milestone achievement

We estimate the fair value of the total earn-out shares based on a Monte Carlo simulation valuation model and assuming the Company will pay the earn-out in shares. Key assumptions include revenue projections, revenue volatility, the Company's expectation to settle the liability in shares and the share price per share.

Earn-out Contingent Liability

We estimate the fair value of the total earn-out shares based on a Monte Carlo simulation valuation model. The fair value of the earn-out contingent liability is sensitive to expected volatility estimated based on selected guideline public companies and the Company's common stock price which is sensitive to changes in the forecasts of earnings and/or the relevant operating metrics. The model used requires the use of assumptions regarding variables that are complex, subjective and generally require judgment to determine.

Stock-Based Compensation

Stock-based compensation for all employee and non-employee stock-based awards, including restricted stock units, is measured at fair value on the date of grant and recognized over the service period. The fair value of restricted stock units are calculated based on the fair value of our common stock on the date of grant, while the fair value of stock options are calculated using a Black-Scholes option-pricing model. The Black-Scholes option-pricing model requires the use of assumptions regarding a number of variables that are complex, subjective and generally require significant judgment to determine. Changes in the assumptions can materially affect the fair value and ultimately how much stock-based compensation expense is recognized. Key assumptions include expected volatility, expected term, risk-free interest rate and dividend yield. The volatility is estimated 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. When selecting these comparable companies, we considered the enterprise value, risk profiles, position within the industry, and whether there was sufficient historical share price information to meet the expected life of the stock-based awards. The expected term of the Company's options has been determined utilizing the "simplified" method as the awards granted are qualified as "plain-vanilla" options. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant for bonds with maturities consistent with the expected holding periods corresponding with the expected term of the option. We estimate zero dividend yield as we have not historically paid dividends on common stock and do not anticipate paying dividends in the foreseeable future.

Income Taxes

We account for income taxes in accordance with ASC Topic 740, "Income Taxes," under which deferred income taxes are provided for temporary differences between the financial reporting and tax basis of our assets and liabilities. We reduce deferred tax assets, if necessary, by a valuation allowance if it is more likely than not that we will not realize some or all of our deferred tax assets. In making such a determination, we consider all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations.

We recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by taxing authorities, based on the technical merits of the position.

JOBS Act Accounting Election

We are an "emerging growth company" within the meaning of 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 $1.07 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.

Recent Accounting Pronouncements

Information on recent accounting pronouncements can be found in GeneDx's audited consolidated financial statements in Note 2, "Summary of Significant Accounting Policies".

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, and restricted cash consists of bank deposits and money market funds, which totaled $138.3 million and $401.5 million at December 31, 2022 and 2021, 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. The majority of our cash, cash equivalents and restricted cash are uninsured with account balances in excess of the Federal Deposit Insurance Company limits. On March 14, 2023, we announced full access to our capital with nearly 100% of the Company's cash and cash equivalents held in an institution designated as systematically important financial institutions.

The revolving credit facility under the SVB Agreement includes variable interest rate terms for the outstanding principal amount of any advance. Therefore, changes change in interest rates can impact our interest payments we are obligated to pay. As of December 31, 2022, no amounts have been drawn under the SVB Agreement. Additional information on our long-term debt can be found in out audited financial statements in Note 8, *"Long-Term Debt."*

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, 2022 and 2021, the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2022, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022, in conformity with U.S. generally accepted accounting principles.

Adoption of ASU 2016-02

As discussed in Note 2 to the consolidated financial statements, effective January 1, 2022, the Company changed its method of accounting for leases due to the adoption of ASU 2016-02, Leases.

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
March 16, 2023

Auditor Firm Id: No. 42 Auditor Name: Ernst & Young LLP Auditor Location: New York, New York, United States

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

	December 31,	
	2022	2021
Assets		
Current assets:		
Cash and cash equivalents	$ 123,933	$ 400,569
Restricted cash	13,470	—
Accounts receivable, net	42,634	26,509
Due from related parties	708	54
Inventory, net	13,665	33,456
Prepaid expenses	11,822	19,154
Other current assets	6,390	3,802
Total current assets	212,622	483,544
Property and equipment, net	51,527	62,719
Intangible assets, net	186,650	—
Operating lease right-of-use assets	32,758	—
Long-term restricted cash	900	900
Other assets	6,485	6,930
Total assets	$ 490,942	$ 554,093
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 46,017	$ 44,693
Accrued expenses	38,861	20,108
Due to related parties	3,593	2,623
Contract liabilities	40	473
Current portion of lease liabilities	6,121	—
Other current liabilities	49,665	33,387
Total current liabilities	144,297	101,284
Long-term debt, net of current portion	6,250	11,000
Long-term lease liabilities	60,013	—
Other liabilities	22,000	21,907
Deferred taxes	2,659	—
Warrant liability	418	21,555
Earn-out contingent liability	1,600	10,244
Total liabilities	237,237	165,990
Commitments and contingencies (Note 10)		
Stockholders' Equity:		
Preferred Stock, $0.0001 par value: 1,000,000 shares authorized at December 31, 2022 and December 31, 2021; 0 shares issued and outstanding at December 31, 2022 and December 31, 2021, respectively	—	—
Class A common stock, $0.0001 par value: 1,000,000,000 shares authorized, 388,511,138 shares issued and outstanding at December 31, 2022 and $0.0001 par value: 380,000,000 shares authorized, 242,647,604 shares issued and outstanding at December 31, 2021	38	24
Additional paid-in capital	1,378,088	963,520
Accumulated deficit	(1,124,421)	(575,441)
Total stockholders' equity	253,705	388,103
Total liabilities and stockholders' equity	$ 490,942	$ 554,093

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,		
	2022	2021	2020
Revenue			
Diagnostic test revenue (including related party revenue of $2,209, $90 and $285 for the years ended December 31, 2022, 2021, and 2020, respectively)	$ 227,334	$ 205,100	$ 175,351
Other revenue (including related party revenue of $353, $232 and $3 for the years ended December 31, 2022, 2021, and 2020, respectively)	7,360	7,095	3,971
Total revenue	234,694	212,195	179,322
Cost of services (including related party expenses of $4,169, $3,975 and $2,189 for the years ended December 31, 2022, 2021, and 2020, respectively)	261,444	228,797	175,296
Gross (loss) profit	(26,750)	(16,602)	4,026
Research and development	86,203	105,162	72,700
Selling and marketing	134,913	112,738	63,183
General and administrative	203,329	205,988	100,742
Related party expenses	6,312	5,659	9,395
Impairment loss	210,145	—	—
Loss from operations	(667,652)	(446,149)	(241,994)
Other income (expense):			
Change in fair market value of warrant and earn-out contingent liabilities	70,229	198,401	—
Interest income	2,541	79	506
Interest expense	(3,207)	(2,835)	(2,474)
Other income, net	57	5,114	2,622
Total other income, net	69,620	200,759	654
Loss before income taxes	(598,032)	(245,390)	(241,340)
Income tax benefit	49,052	—	—
Net loss and comprehensive loss	$ (548,980)	$ (245,390)	$ (241,340)
Weighted average shares outstanding, Class A common stock	337,819,680	108,077,439	5,131
Basic and diluted net loss per share, Class A common stock	$ (1.63)	$ (2.27)	$ (47,036)

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

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

	Redeemable Convertible Preferred Stock		Class A Common Stock		Class B Common Stock				
	Shares	Amount	Shares	Par Value	Shares	Par Value	Additional paid-in capital	Accumulated deficit	Total stockholders' equity (deficit)
Balance at December 31, 2019	147,038,267	$ 217,115	124	$ —	—	$ —	$ —	$ (88,711)	$ (88,711)
Net loss	—	—	—	—	—	—	—	(241,340)	(241,340)
Common stock issued pursuant to stock option exercises	—	—	—	—	130,557	—	—	—	—
Issuance of Preferred Series C, net of issuance costs	24,496,946	117,324	—	—	—	—	—	—	—
Balance at December 31, 2020	171,535,213	$ 334,439	124	$ —	130,557	$ —	$ —	$ (330,051)	$ (330,051)
Net loss	—	—	—	—	—	—	—	(245,390)	(245,390)
Common stock issued pursuant to stock option exercises	—	—	995,526	—	1,253,179	—	1,783	—	1,783
Conversion of Preferred into Common Stock	(171,535,213)	(334,439)	148,543,062	15	—	—	104,517	—	104,532
Common Stock into Class A Common Stock	—	—	1,309,320	—	(1,383,736)	—	(744)	—	(744)
Net equity infusion from the Business Combination	—	—	90,333,562	9	—	—	510,742	—	510,751
Stock based compensation modification reclassification	—	—	—	—	—	—	304,837	—	304,837
Stock-based compensation expense	—	—	—	—	—	—	42,385	—	42,385
Vested restricted stock units converted to common stock	—	—	1,466,010	—	—	—	—	—	—
Balance at December 31, 2021	—	$ —	242,647,604	$ 24	—	$ —	$ 963,520	$ (575,441)	$ 388,103

Net loss	—	—	—	—	—	—	—	(548,980)	$ (548,980)
Common stock issued pursuant to stock option exercises	—	—	11,021,636	1	—	—	2,947	—	2,948
Stock based compensation expense	—	—	—	—	—	—	41,975	—	41,975
Shares issued for PIPE, net of issuance costs	—	—	50,000,000	5	—	—	197,654	—	197,659
Shares issued for acquisition (1)	—	—	80,000,000	8	—	—	171,992	—	172,000
Vested restricted stock units converted to common stock	—	—	4,841,898	—	—	—	—	—	—
Balance at December 31, 2022	—	$ —	**388,511,138**	**$ 38**	—	$ —	**$ 1,378,088**	**$ (1,124,421)**	**$ 253,705**

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,		
	2022	2021	2020
Operating activities			
Net loss	$ (548,980)	$ (245,390)	$ (241,340)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization expense	59,309	21,807	11,734
Stock-based compensation expense	41,975	219,421	120,231
Change in fair value of warrant and contingent liabilities	(70,229)	(198,401)	—
Income tax benefit	(49,124)	—	—
Provision for excess and obsolete inventory	1,125	2,129	—
Non-cash lease expense	2,225	1,555	2,400
Loss on extinguishment of debt	—	301	—
Impairment loss	210,145	—	—
Amortization of debt issuance costs	518	66	—
Change in operating assets and liabilities, net of effects from purchase of business:			
Accounts receivable	5,527	5,535	(10,611)
Inventory	2,350	(10,624)	(8,979)
Prepaid expenses and other current assets	11,130	(14,250)	2,498
Due to/from related parties	317	1,433	(442)
Other assets	(2)	(1,861)	1,175
Accounts payable and accrued expenses	34,459	25,916	14,805
Contract liabilities	(433)	(1,310)	(559)
Other current liabilities	(19,467)	3,239	15,960
Net cash used in operating activities	$ (319,155)	$ (190,434)	$ (93,128)
Investing activities			
Purchase of business, net of cash acquired	$ (127,004)	$ —	$ —
Purchases of property and equipment	(7,156)	(9,400)	(24,094)
Development of internal-use software assets	(7,166)	(11,386)	(7,880)
Net cash used in investing activities	$ (141,326)	$ (20,786)	$ (31,974)
Financing activities			
Proceeds from issuance of Series C redeemable convertible preferred stock, net of issuance costs	$ —	$ —	$ 117,324
Proceeds from PIPE issuance	197,659	350,000	—
Proceeds from equity infusion from the merger, net of redemptions	—	442,684	—
Legacy Sema4 Shareholder payout	—	(230,665)	—
Payment of transaction costs	—	(51,760)	—
Stock Appreciation Rights payout	—	(3,795)	—
Repayment of long-term debt	—	(8,741)	—
Exercise of stock options	2,948	1,271	—
Proceeds from long-term debt	—	—	15,928
Long-term debt principal payments	—	(1,000)	(186)
Debt issuance costs	—	(537)	—
Finance lease principal payments	(3,292)	(3,728)	(4,010)
Net cash provided by financing activities	$ 197,315	$ 493,729	$ 129,056
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (263,166)	$ 282,509	$ 3,954
Cash, cash equivalents and restricted cash, at beginning of year	401,469	118,960	115,006

Cash, cash equivalents and restricted cash, at end of year	$ 138,303	$ 401,469	$ 118,960
Supplemental disclosures of cash flow information			
Cash paid for interest	$ 1,932	$ 2,751	$ 1,745
Cash paid for taxes	$ 1,241	$ 349	$ —
Stock consideration paid for purchase of business	$ 172,000	$ —	$ —
Purchases of property and equipment in accounts payable and accrued expenses	$ —	$ 761	$ 447
Software development costs in accounts payable and accrued expenses	$ 461	$ 1,149	$ 1,473
Debt issuance costs incurred but unpaid	$ —	$ 1,000	$ —

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. ("GeneDx Holdings") (formerly, Sema4 Holdings Corp. ("Sema4 Holdings")) through its subsidiaries Sema4 OpCo, Inc., formerly Mount Sinai Genomics Inc., a Delaware corporation ("Legacy Sema4") and GeneDx, LLC, provides genomics-related diagnostic and information services and pursues genomics medical research. GeneDx utilizes an integrated portfolio of laboratory processes, software tools and informatics capabilities to process DNA-containing samples, analyze information about patient-specific genetic variation and generate test reports for clinicians and their patients. GeneDx provides a variety of genetic diagnostic tests, and screening solutions, and information with a focus on pediatrics, rare diseases for children and adults, and hereditary cancer screening. GeneDx Holdings' operating subsidiaries primarily serve healthcare professionals who work with their patients and bills third-party payors across the United States.

On July 22, 2021 (the "Closing Date"), CM Life Sciences, Inc. ("CMLS") completed the acquisition of Legacy Sema4, pursuant to that certain Agreement and Plan of Merger (as amended, the "Business Combination Merger Agreement"), dated February 9, 2021. On the Closing Date, S-IV Sub, Inc. merged with and into the Legacy Sema4, with Legacy Sema4 surviving the merger as a wholly-owned subsidiary of CMLS (the "Business Combination Merger" and, together with the other transactions contemplated by the Business Combination Merger Agreement, the "Business Combination"). In connection with the consummation of the Business Combination, CMLS changed its name to "Sema4 Holdings Corp." and Legacy Sema4 changed its name to "Sema4 OpCo, Inc." All equity securities of Legacy Sema4 were converted into the right to receive the applicable portion of the merger consideration.

The Business Combination Merger was accounted for as a reverse recapitalization with Legacy Sema4 as the accounting acquirer and CMLS as the acquired company for accounting purposes. The shares and net loss per common share, prior to the Business Combination Merger, have been retroactively restated as shares reflecting the exchange ratio established in the Business Combination Merger (1 share of Legacy Sema4 Class A common stock for 123.8339 shares of Sema4 Holdings Class A common stock (the "Class A common stock") (the "Conversion Ratio").

Prior to the Business Combination Merger, shares of CMLS Class A common stock, CMLS's public warrants, and CMLS's public units were traded on the Nasdaq Capital Market under the ticker symbols "CMLF", "CMFLW", and "CMLFU" respectively. On July 23, 2021, shares of Sema4 Holdings Class A common stock and Sema4 Holdings' public warrants began trading on the Nasdaq Global Select Market (the "Nasdaq") under the ticker symbols "SMFR" and "SMFRW," respectively.

In addition, on April 29, 2022, the Company consummated the transactions contemplated by that certain Agreement and Plan of Merger, dated as of January 14, 2022 (as amended, the " Acquisition Merger Agreement"), by and among the Company and GeneDx, Inc. ("Legacy GeneDx"), a New Jersey corporation and wholly-owned subsidiary of OPKO Health, Inc. ("OPKO"), GeneDx Holding 2, Inc., which held 100% of Legacy GeneDx ("Holdco2"), at the Effective Time (as defined in the Acquisition Merger Agreement) and OPKO, which provided for, among other things, the acquisition of Legacy GeneDx from OPKO. After giving effect to the mergers and the other transactions contemplated by the Acquisition Merger Agreement (the "Acquisition"), Legacy GeneDx was converted into a Delaware limited liability company and became the Company's wholly-owned indirect subsidiary. See Note 3, "Business Combination," for additional details regarding the Business Combination and Acquisition.

On January 9, 2023, Sema4 Holdings Corp. changed its name to GeneDx Holdings Corp. Upon the name change, the Company's Class A common stock and public warrants are listed on the Nasdaq under the symbols "WGS" and "WGSWW," respectively.

Unless otherwise stated herein or unless the context otherwise requires, references in these notes to the "Company," or "GeneDx" refer to (i) Legacy Sema4 prior to the consummation of the Business Combination; and

(ii) GeneDx Holdings and its subsidiaries following the consummation of the Business Combination (including, following the consummation of the Acquisition, Legacy GeneDx).

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 of America ("U.S. GAAP"). The Company's historical financial information includes costs of certain services historically provided by Icahn School of Medicine at Mount Sinai ("ISMMS") pursuant to the Transition Services Agreement ("TSA"). These financial statements consolidate the operations and accounts of the Company and its wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated.

Use of Estimates

The preparation of audited 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 audited 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 capitalization of software costs, the valuation of stock-based awards, inventory, earn-out contingent liabilities and earn-out Restricted Stock Units ("RSUs"). 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 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. On March 14, 2023, we announced full access to our capital with now 100% of the Company's cash, cash equivalents and marketable securities held in institutions designated as systematically important financial institutions.

The Company's cash and cash equivalents are deposited with high-quality financial institutions. The Company has balances in financial institutions that exceed federal depository insurance limits. Management believes these financial institutions are financially sound and, accordingly, that minimal credit risk exists. The Company has not experienced any losses on its deposits of cash and cash equivalents.

The Company assesses both the customer and, if applicable, the third party payor that reimburses the Company on the customer's behalf when evaluating concentration of credit risk. Significant customers 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, 2022 and 2021 were primarily from large managed care insurance companies. There was no individual customer 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 group, 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,	
	2022	2021	2020	2022	2021
Payor group A (1)	*	22%	27%	*	15%
Payor group B (2)	30%	13%	14%	14%	*
Payor group D	*	*	*	*	15%
Payor group E	15%	*	*	14%	*

* less than 10%

(1) This payor group represented less than 10% of the Company's total revenues in 2022 due primarily to a reversal of revenue related to certain overpayments previously made by this payor. Refer to Note 4, "Revenue Recognition."

(2) 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 5%, 7% and 11% of purchases for the years ended December 31, 2022, 2021 and 2020, respectively. Another supplier accounted for approximately 12%, 11% and 10% of purchases for the years ended December 31, 2022, 2021 and 2020, 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.

Impact of COVID-19

Beginning in April 2020, the Company's diagnostic test volumes decreased significantly as compared to the prior year as a result of the initial outbreak of the COVID-19 pandemic and the related limitations and priorities across the healthcare system. In response, beginning in May 2020, the Company entered into several service agreements with state governments and healthcare institutions to provide testing for the presence of COVID-19 variants. Test volumes have since improved to what would, at this time, be considered normalized market conditions. A COVID-19 resurgence in the United States could however have a material impact on the Company's consolidated results of operations, cash flows and financial condition.

In March 2020, the Coronavirus Aid, Relief and Economic Security Act ("CARES Act") was signed into law which was a stimulus bill that, among other things, provided assistance to qualifying businesses and individuals and included funding for the healthcare system. During 2020, as part of the stimulus provided by the CARES Act, the Company received $5.4 million, comprised of $2.6 million received under the Provider Relief Fund ("PRF") distribution and $2.8 million received under the Employee Retention Credit ("ERC") distribution which was recorded in other current liabilities within the consolidated balance sheets as of December 31, 2022 and December 31, 2021.

During 2021, the Company received an additional $5.6 million under the PRF distribution, which was recognized in other income in the consolidated statements of operations and comprehensive loss.

Additionally, under the CARES Act, the Company deferred payment of U.S. social security taxes in 2020. As a result, $3.8 million of employer payroll tax payments were initially deferred as of December 31, 2020 with $1.9 million paid in both December 2021 and December 2022 with no remaining liability as of December 31, 2022.

Following the Company's announcement that it would discontinue COVID-19 testing services by March 31, 2022, the Company no longer provides COVID-19 testing services. During the year ended December 31, 2022, the Company wrote off an accounts receivable balance of $0.4 million related to COVID-19 testing services.

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. Carrying values of cash equivalents approximate fair value due to the short-term nature of these instruments.

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

	As of December 31,		
	2022	2021	2020
Cash and cash equivalents	$ 123,933	$ 400,569	$ 108,132
Restricted cash	14,370	900	10,828
Total	$ 138,303	$ 401,469	$ 118,960

Restricted cash as of December 31, 2022 includes $13.5 million held in escrow as restricted cash related to the closing of the Acquisition of Legacy GeneDx. The escrow amount is to be held for a period of 12 months following the closing date of the Acquisition as a fund for OPKO's indemnification obligations pursuant to the Acquisition Merger Agreement. In addition, restricted cash, non-current, as of December 31, 2022 consists of money market deposit accounts that secure an irrevocable standby letter of credit that serves as collateral for security deposit operating leases (see Note 9, *"Leases"*).

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, 2022 and 2021, the Company did not record provisions for doubtful accounts. The Company did not write off any accounts receivable balances for the years ended December 31, 2022 and 2021, and $0.2 million of accounts receivable was written off for the year ended December 31, 2020.

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. During the fourth quarter of 2022, the Company identified indicators of impairment specifically with the planned exit and discontinuance of testing for Legacy Sema4. Certain inventory testing supplies and reagents have been or are being liquidated or disposed of rather than used to produce revenue. As a result, the Company recorded a $22.5 million impairment charge within impairment loss in the Company's consolidated statements of operations and comprehensive loss for the year ended December 31, 2022. There was no impairment loss recorded for the years ended December 31, 2021 and December 31, 2020.

Additionally, in the normal course of business the Company recorded a reserve offsetting inventory in the consolidated balance sheets, for excess and obsolete inventory of $1.1 million and $2.1 million for the years ended December 31, 2022 and December 31, 2021, respectively.

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. During the fourth quarter of 2022, the Company identified indicators that it is more likely than not that the fair value of certain asset groups was less than their carrying value, see Note 6, *"Property and Equipment, net."*

Business Combinations

The Company accounts for acquisitions of entities that include inputs and processes and have the ability to create outputs as business combinations. The tangible and identifiable intangible assets acquired and liabilities assumed in a business combination are recorded based on their estimated fair values as of the business combination date, including identifiable intangible assets which either arise from a contractual or legal right or are separable from goodwill. The Company bases the estimated fair value of identifiable intangible assets acquired in a business combination on third-party valuations that use information and assumptions provided by the Company's management, which consider estimates of inputs and assumptions that a market participant would use. Any excess purchase price over the estimated fair value assigned to the net tangible and identifiable intangible assets acquired and liabilities assumed is recorded as goodwill. The use of alternative valuation assumptions, including estimated revenue projections, growth rates, estimated cost savings, cash flows, discount rates, estimated useful lives and probabilities surrounding the achievement of contingent milestones could result in different purchase price allocations and amortization expense in current and future periods.

Goodwill

In accordance with ASC 350, Intangibles-Goodwill and Other ("ASC 350"), the Company's goodwill is not amortized but is tested for impairment on an annual basis or whenever events or changes in circumstances indicate that the carrying amount of these assets may not be recoverable. Under ASC 350, the Company will perform annual impairment reviews of goodwill during the fourth fiscal quarter or more frequently if business factors indicate. In the fourth quarter of 2022, the Company identified indicators of impairment that indicate that it is more likely than not that the fair value of a reporting unit is less than its carrying value and as a result goodwill was fully written off with $174.5 million recorded within impairment loss in the Company's consolidated statements of operations and comprehensive loss for the year ended December 31, 2022, see Note 18, *"Goodwill and Intangible Assets."* There was no goodwill for the years ended December 31, 2021 and December 31, 2020.

Intangible Assets

Amortizable intangible assets include trade names and trademarks, developed technology and customer relationships acquired as part of business combinations. Intangible assets acquired through our business combinations in the second quarter of 2022 are amortized on a straight line basis. All intangible assets subject to amortization are reviewed for impairment in accordance with ASC 360, Property, Plant and Equipment. There were no impairment losses recorded on intangible assets for any periods presented.

Capitalized Software

The Company capitalizes certain costs incurred related to the development of our software applications for internal use during the application development state. If a project constitutes an enhancement to existing software, the Company assesses whether the enhancement creates additional functionality to the software, thus qualifying the work incurred for capitalization. Costs incurred prior to meeting these criteria together with costs incurred for training and maintenance are expensed as incurred. Once the project is available for general release, capitalization ceases and we estimate the useful life of the asset and begin amortization.

Capitalized software costs are amortized using the straight-line method over an estimated useful life of three years. Capitalized software is reviewed for impairment whenever events or changes in circumstances may indicate that the carrying amount of an asset may not be recoverable. In the fourth quarter of 2022, the Company identified indicators of impairment that the carrying value of the capitalized software may not be recoverable. As a result, certain costs previously capitalized were written down with $8.7 million recorded within cost of services, research and development and general and administrative expenses in the Company's consolidated statements of operations and comprehensive loss.

Cloud Computing

The Company capitalizes certain costs incurred during the application development stage and all costs incurred during the preliminary project and post-implementation stages are expensed as incurred. Amortization begins when the cloud computing arrangement is ready for its intended use and is calculated on a straight-line basis over the fixed noncancellable periods plus renewal periods the Company deems it reasonably certain to exercise. During the year ended December 31, 2022, $0.3 million of implementation costs are capitalized and recorded in other current and non-current assets for amortization.

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, restricted cash, accounts receivable, accounts payable, accrued liabilities, and long-term debt. The Company's cash and cash equivalents, restricted cash, accounts receivable, accounts payable and accrued liabilities approximate their fair value due to the relatively short-term nature of these accounts.

The Company's loan from the Connecticut Department of Economic and Community Development is classified within level 2 of the fair value hierarchy. As of December 31, 2022, this loan is recorded at its carrying value of $11.0 million in the consolidated balance sheet. The fair value is $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.

Warrant Liability

As of the consummation of the Merger in July 2021, there were 21,995,000 warrants to purchase shares of Class A common stock outstanding, including 14,758,333 public warrants and 7,236,667 private placement warrants. As of December 31, 2022 and 2021, there were 21,994,972 warrants to purchase shares of Class A common stock outstanding, including 14,758,305 public warrants and 7,236,667 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 $11.50 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 $18.00 as described below:

- in whole and not in part;
- at a price of $0.01 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 $18.00 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 common stock equals or exceeds $10.00 as described below:

- in whole and not in part;
- at $0.10 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 $10.00 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 $18.00 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 $10.00) 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 Company accounts for warrants as liability-classified instruments based on an assessment of the warrant terms and applicable authoritative guidance in accordance with ASC 480-Distinguishing Liabilities from Equity ("ASC 480") and ASC 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 and as of each subsequent quarterly period end date while the warrants are outstanding.

Contingent Consideration (Legacy GeneDx)

In connection with the Acquisition of Legacy GeneDx, up to $150 million of contingent payments will be payable to OPKO in cash and/or shares of Company's Class A common stock with such mix to be determined in the

Company's sole discretion, based upon achievement of 2022 and 2023 revenue milestones, pursuant to the Acquisition Merger Agreement (the "Milestone Payments"). If the Company elects to pay in shares of Class A common stock, the Acquisition Merger Agreement provides that the shares issues are to be valued at a fixed $4.86 per share for a maximum of 30.9 million shares.

Subject to the terms and conditions of the Acquisition Merger Agreement, (a) the first Milestone Payment of $112.5 million will become due and payable if the revenue of the Legacy GeneDx group for the fiscal year 2022 equals or exceeds $163 million and (b) the second Milestone Payment of $37.5 million will become due and payable if the revenue of the Legacy GeneDx group for the fiscal year 2023 equals or exceeds $219 million (each of clauses (a) and (b), a "Milestone Event"); provided that 80% of the Milestone Payment for the first milestone period or the second milestone period, as applicable, will become payable in respect of such period if the Legacy GeneDx group achieves 90% of the applicable Milestone Event revenue target for such period, which amount will scale on a linear basis up to 100% of the applicable Milestone Payment at 100% of the applicable revenue target. The milestone payments would require issuance of shares of Company's Class A common stock up to 23.2 million shares and 7.7 million shares for the first Milestone Payment and second Milestone Payment, respectively. The fair value of the Milestone Payment is classified within level 3 of the fair value hierarchy. As of December 31, 2022, the fair value of the second Milestone Payment was determined to be $1.6 million, which is estimated using a Monte Carlo simulation valuation model and assuming the Company will pay the earn-out in shares. The total liability as of December 31, 2022, is $7.6 million, $6.0 million of which represents the fair value of the first Milestone Payment which was already earned and is expected to be paid via issuance of shares of Company's Class A common stock based on the results of 2022.

Earn-out contingent liability

In connection with the Merger, all Legacy Sema4 stockholders and option holders at that time became entitled to a pro rata share of 19,021,576 earn-out shares and earn-out Restricted Stock Units ("RSUs"). Based on an assessment of the earn-out shares for the Legacy Sema4 stockholders, the Company considered ASC 480 and ASC 815 and accounted for the earn-out shares as a liability. The Company subsequently measures the fair value of the liability at each reporting period and reports the changes in fair value recorded as a component of other income (expense), net in the consolidated statements of operations and comprehensive loss.

As for the earn-out RSUs for the Legacy Sema4 option holders, a total of 2.7 million RSUs were granted on December 9, 2021. The vesting of such arrangement is conditioned on the satisfaction of both a service requirement and on the satisfaction of a market-based requirement. The market-based requirement would be achieved if the Company's stock price is greater than or equal to $13 (Triggering Event I), $15 (Triggering Event II) and $18 (Triggering Event III) during the applicable performance period, based on the volume-weighted average price for a period of at least 20 days out of 30 consecutive trading days. Therefore, the Company accounts for this arrangement in accordance with ASC 718- Compensation — Stock Compensation ("ASC 718") and stock-compensation expense is recognized over the longer of the expected achievement period for the market-based requirement and the service requirement. The Company recorded $0.9 million and $0.2 million in relation to the earn-out RSU for the years ended December 31, 2022 and 2021, respectively. In the event that any earn-out RSUs that are forfeited as a result of a failure to achieve the service requirement, the underlying shares will be reallocated on an annual basis to the Legacy Sema4 stockholders and to the Legacy Sema4 option holders who remain employed as of the date of such reallocation. The Company accounts for the re-allocations to Legacy Sema4 option holders as new grants.

The fair value of the earn-out RSUs are classified within level 3 of the fair value hierarchy and the estimated fair value is determined using a Monte Carlo valuation analysis.

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. Determining the fair value of stock option awards requires judgment, including estimating stock price volatility and expected option life. Restricted stock awards are valued based on the fair value

of the stock on the grant date. The Company uses the Black-Scholes option-pricing model to estimate the fair value of its stock option awards.

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.

Income Taxes

Income taxes are accounted for under 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.

Leases

Under ASU 2016-02, Leases (ASC 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 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 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. In the fourth quarter of 2022, the Company identified indicators of impairment that indicate that it is more likely than not that the fair value of a reporting unit is less than its carrying value, see Note 9, *"Leases"*.

Revenue Recognition

The Company adopted Accounting Standards Codification ("ASC") Topic 606 ("ASC 606"), *Revenue from Contracts with Customers*, on January 1, 2019 using the modified retrospective method applied to contracts which were not completed as of the adoption date. 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 doubtful accounts 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.

Segment Information

Historically, the Company operated in one segment. During 2022, with the Acquisition of Legacy GeneDx, the change in Chief Operating Decision Maker ("CODM") and the announced exit from the majority of the Legacy Sema4 diagnostics operations, the Company's CODM began to evaluate the Company's business separately for GeneDx, inclusive of Legacy GeneDx and Legacy Sema4 data revenues and associated costs and corporate support costs, and the existing Legacy Sema4 diagnostics business during the fourth quarter of 2022. As a result, the Company has concluded that two reportable segments exist and have been presented for 2022. The majority of the Company's operations for 2021 and 2022 are included in the Legacy Sema4 segment and the majority of the GeneDx segment for 2022 was resultant from the 2022 Acquisition, and thus did not exist within the Company's consolidated results for 2021 and 2020. As a result, the Company has not presented segments for 2021 and 2020. See Note 17, "*Segment Reporting*", for 2022 segment disclosures.

Emerging Growth Company

The Company is an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012. 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 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.

Recently Adopted Accounting Pronouncements

The Company adopted ASU No. 2016-02, Leases (ASC 842) on January 1, 2022 using the modified retrospective method. The Company also elected to use the package of practical expedients permitted under the transition guidance which allows for the carry forward of historical lease classification for existing leases on the adoption date and does not require the assessment of existing lease contracts to determine whether the contracts contain a lease or initial direct costs. Prior periods were not retrospectively adjusted.

The adoption of this standard as of January 1, 2022, resulted in the recognition of operating lease ROU assets in the amount of $39.2 million and operating lease liabilities in the amount of $42.2 million. The adoption did not have material impact on finance leases. The adoption did not have material impact on the consolidated statements of operations and comprehensive loss or cash flows.

In November 2021, the FASB issued ASU 2021-10, Government Assistance (Topic 832), Disclosures by Business Entities About Government Assistance, which requires entities to provide disclosures on material government assistance transactions for annual reporting periods. The disclosures include information around the nature of the assistance, the related accounting policies used to account for government assistance, the effect of government assistance on the entity's financial statements, and any significant terms and conditions of the agreements, including commitments and contingencies. The Company adopted ASU 2021-10 effective January 1, 2022. The Company did not receive any such grants during the year ended December 31, 2022.

Recently Issued Accounting Pronouncements Not Yet Adopted

In June 2016, the FASB issued ASU 2016-13, Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments ("ASU 2016-13"). The new credit losses standard changes the impairment model for most financial assets and certain other instruments. For trade and other receivables, contract assets recognized as a result of applying ASC 606, loans and certain other instruments, entities will be required to use a new forward looking "expected loss" model that generally will result in earlier recognition of credit losses than under today's incurred loss model. As an emerging growth company, ASU 2016-13 is effective for annual periods beginning after December 15, 2022, with early adoption permitted. Application of the amendments is through a cumulative-effect adjustment to the opening retained earnings as of the beginning of the first reporting period in which the guidance is effective. The guidance was adopted by the Company as of January 1, 2023. The Company is currently evaluating the impact of the new guidance on its consolidated financial statements and related disclosures.

3. Business Combination

As discussed in Note 1, on July 22, 2021, the Company consummated the Business Combination and received net cash proceeds of $510.0 million.

Pursuant to the Business Combination, the following occurred:

- Holders of 10,188 shares of CMLS's Class A common stock sold in its initial public offering (the "public shares") exercised their right to have such shares redeemed for a full pro rata portion of the trust account holding the proceeds from CMLS's initial public offering (the "IPO"), which was approximately $10.00 per share, or $101,880 in aggregate.

- Each share of CMLS's Class B common stock was automatically converted into common stock of the Company.

- Each share of the Legacy Sema4 Class B common stock was converted into 1/100th of a share of Legacy Sema4 Class A common stock and each share of Legacy Sema4 common stock and preferred stock was canceled and received a portion of the merger consideration, resulting in certain Legacy Sema4 stockholders receiving $230,665,220 of cash and the Legacy Sema4 stockholders receiving an aggregate of 178,336,298 shares of common stock of the Company.

- Pursuant to subscription agreements entered into on February 9, 2021, certain investors agreed to subscribe for an aggregate of 35,000,000 newly-issued shares of common stock at a purchase price of $10.00 per share for an aggregate purchase price of $350,000,000 (the "PIPE Investment"). Concurrently with the closing of the Business Combination, the Company consummated the PIPE Investment.

- After giving effect to the Merger, the redemption of public shares and the conversion of the CMLS Class B common stock as described above, and the consummation of the PIPE Investment, there were 240,190,402 shares of the Company's common stock issued and outstanding.

The Company recorded $51.8 million of transaction costs which consist of direct, incremental legal, professional, accounting, and other third-party fees that were directly related to the execution of the Merger in additional paid-in capital. Upon consummation of the Merger, $9.0 million of the transaction costs relates to costs incurred by Legacy Sema4 and reclassed to offset against equity from prepaid expense and other current assets.

Legacy GeneDx Acquisition

As discussed in Note 1, on April 29, 2022, the Company completed the Acquisition of Legacy GeneDx. At the closing of the Acquisition, the Company paid OPKO cash consideration of $140.5 million (net of transaction expenses and other customary purchase price adjustments) and issued to OPKO 80 million shares of the Company's Class A common stock ($172 million based on the closing date share price of $2.15 per share). A portion of this cash ($13.4 million) and share consideration (8.3 million shares) will be held in escrow for 12 months following the closing date of the Acquisition. In addition, up to $150 million is payable following the closing of the Acquisition, if certain revenue-based milestones are achieved for each of the fiscal years ending December 31, 2022 and December 31, 2023. These milestone payments, if and to the extent earned under the terms of the Acquisition Merger Agreement, will be satisfied through the payment and/or issuance of a combination of cash and shares of the Company's Class A common stock (valued at a fixed $4.86 per share, subject to adjustment for stock splits and similar changes), with such mix to be determined in the Company's sole discretion. As of the acquisition date, the fair value of the earn-out was determined to be $52.0 million and was included in the aggregate purchase price of $364.5 million. Concurrently with the closing of the Acquisition, the Company also issued and sold in private placement 50,000,000 shares of the Company's Class A common stock to certain institutional investors for aggregate gross proceeds of $200 million (the "Acquisition PIPE Investment").

The following table presents the net purchase price and the fair values of the assets and liabilities of GeneDx on a preliminary basis (in thousands):

Cash and cash equivalents	$	—
Accounts receivables		21,651
Inventory		6,210
Prepaid expenses		4,671
Other current assets		320
Property and equipment		29,509
Other non-current assets		6,464
Trade names and trademarks		50,000
Developed technology		48,000
Customer relationships		98,000
Accounts payable and accrued expenses		(12,862)
Other current liabilities		(15,781)
Deferred tax liabilities		(51,779)
Long-term lease liabilities		(5,798)
Fair value of net assets acquired		178,605
Goodwill (1)		185,871
Aggregate purchase price	$	364,476

(1) Goodwill represents the excess of the purchase price over the fair value of the net tangible and intangible assets acquired. see Note 18, *"Goodwill and Intangible Assets"* for more detail.

The amounts above represent the preliminary fair value estimates and the Company has identified certain adjustments during the measurement period that are primarily related to the Legacy GeneDx accrued expenses that do not represent GeneDx's assumed liabilities. These measurement period adjustments are reflected in the goodwill balance and shown in Note 18, *"Goodwill and Intangible Assets."* Further adjustments may be made as the Company obtains additional information during the remaining measurement period and finalizes its fair value

estimates. Specifically, the Company is still in the process of reviewing and finalizing the net working capital adjustment with OPKO. Upon final agreement, the Company may have further adjustments.

Increases or decreases in the estimated fair values of the net assets acquired may impact the Company's consolidated statements of operations and comprehensive loss in future periods. The Company expects that the values assigned to the assets acquired and liabilities assumed will be finalized during the one-year measurement period following the Acquisition closing date.

For the year ended December 31, 2022, $12.1 million of Legacy GeneDx Acquisition-related costs are reflected within general and administrative expenses in the Company's consolidated statements of operations and comprehensive loss. These costs include third-party professional firms' services related to due diligence, advisory and legal services. The Company's consolidated results include $116.4 million of revenue and $(25.9) million of pretax loss for the year ended December 31, 2022 from Legacy GeneDx.

Pro forma financial information

The pro forma information below gives effect to the Acquisition as if it had been completed on January 1, 2021 ("the pro forma acquisition date"). The pro forma information is not necessarily indicative of the Company's revenue results had the Acquisition been completed on the pro forma acquisition date, nor is it necessarily indicative of the Company's future results. The pro forma revenue information reflects Legacy GeneDx's historic revenue and does not include any additional revenue opportunities following the Acquisition. The purchase price allocations for the assets acquired and liabilities assumed are based on preliminary valuations and are subject to change as the Company obtains additional information during the acquisition measurement period. Increases or decreases in the estimated fair values of the net assets acquired may impact the Company's consolidated statements of operations and comprehensive loss in future periods. The Company expects that the values assigned to the assets acquired and liabilities assumed will be finalized during the one-year measurement period following the Acquisition closing date. The pro forma revenues and net loss include the following adjustments based on the Company's preliminary analysis and are subject to change as additional analysis is performed:

- revised amortization expense resulting from the acquired intangible assets,
- historical intercompany revenue recognized by Legacy GeneDx with OPKO or other related parties,
- income tax benefits resulting from the deferred tax liabilities acquired, and
- revised stock based compensation reflecting the inducement awards issued to the Legacy GeneDx employees.

	December 31,	
	2022 (in thousands)	2021 (in thousands)
Pro forma revenues	$ 282,959	$ 326,720
Pro forma net loss	$ (613,199)	$ (252,506)

For year ended December 31, 2022 and 2021 pro forma revenues combine the Company and Legacy GeneDx and included Legacy GeneDx revenue of $165.2 million and $118.3 million, respectively.

4. Revenue Recognition

Disaggregated revenue

The following table summarizes the Company's disaggregated revenue (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Diagnostic test revenue:			
Patients with third-party insurance	$ 173,624	$ 169,576	$ 138,153
Institutional customers	46,124	31,717	35,200
Self-pay patients	7,586	3,807	1,998
Total diagnostic test revenue	227,334	205,100	175,351
Other revenue	7,360	7,095	3,971
Total	$ 234,694	$ 212,195	$ 179,322

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 year ended December 31, 2022, a change in estimate included a decrease in revenue related to a payor, as further disclosed in the "—Certain payor matters" below, for tests in which the performance obligation of delivering the test results was met in prior periods. The decrease was further offset by other upward adjustments made for tests in which the performance obligation of delivering the test results was met in prior periods related to other payors.

During 2022, the Company recorded $54.0 million to decrease revenue 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. As described in more detail below, third-party payors may decide to deny payment or seek to recoup payments for tests performed by the Company for a number of reasons and, as a result, the Company may be required to refund payments previously received, and the Company's revenues may be subject to retroactive adjustment as a result. The Company processes requests for recoupment from third-party payors in the ordinary course of its business and reflects in the Company's transaction price estimations. See "—Certain payor matters" below for further details regarding an ongoing matter related to certain overpayments the Company allegedly received from a third-party payor; the Company has established certain liabilities and reversed certain of its previously recorded revenue as a result of this matter and other potential settlements with payors.

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.

As an integral part of the Company's billing compliance program the Company instituted a third-party review of billing claims and compliance practices, and initiated improvements including implementing a package of new billing compliance policies and procedures and strengthening the Company's billing compliance team. 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.

Throughout 2022, the Company was engaged in discussions with one of its third-party payors (the "Payor") regarding certain overpayments. On December 30, 2022, the Company entered into a settlement agreement with the Payor in order to settle the claims related to coverage and billing matters allegedly resulting in the overpayments by the Payor to the Company (the "Disputed Claims"). Under the settlement agreement, $42.0 million is to be paid by the Company to the Payor in a series of installments over the next four years with the final installment payment scheduled to be on or before June 30, 2026. The first installment payment of $15.0 million was made on December 31, 2022. In consideration for these payments, the Payor has agreed to provide releases of the Disputed Claims, which releases become effective on or about April 1, 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, 2022, $39.0 million has been accrued. See Note 16, "Supplemental Financial Information." 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.

Remaining performance obligations

Due to the long-term nature of collaboration service agreements, the Company's obligations pursuant to such agreements represent partially unsatisfied performance obligations as of December 31, 2022. The revenues under existing service agreements with original expected durations of more than one year are estimated to be approximately $6.8 million. The Company expects to recognize the majority of this revenue over the next 2.5 years.

Costs to fulfill contracts

Costs associated with fulfilling the Company's performance obligations pursuant to its collaboration service agreements include costs for services that are subcontracted to ISMMS. Amounts are generally prepaid and then expensed in line with the pattern of revenue recognition. Prepayment of amounts prior to the costs being incurred are recognized on the balance sheets as current or non-current asset based upon forecasted performance.

As of December 31, 2022 and 2021, the Company had outstanding deferred costs to fulfill contracts of $0.3 million and $1.8 million, respectively. At each period, all outstanding deferred costs were recorded as other current assets.

Amortization of deferred costs was $1.5 million, $1.4 million and $0.9 million for the years ended December 31, 2022, 2021 and 2020, respectively. The amortization of these costs is recorded in cost of services of the consolidated statements of operations and comprehensive loss.

5. Fair Value Measurements

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

	December 31, 2022			
	Total	Level 1	Level 2	Level 3
Financial Assets:				
Money market funds	$ 16,901	$ 16,901	$ —	$ —
Total financial assets	$ 16,901	$ 16,901	$ —	$ —
Financial Liabilities:				
Public warrant liability	$ 280	$ 280	$ —	$ —
Private warrant liability	138	—	138	—
Earn-out contingent liability	—	—	—	—
Contingent consideration based on milestone achievement	7,619	—	—	7,619
Total financial liabilities	$ 8,037	$ 280	$ 138	$ 7,619

	December 31, 2021			
	Total	Level 1	Level 2	Level 3
Financial Assets:				
Money market funds	$ 385,370	$ 385,370	$ —	$ —
Total financial assets	$ 385,370	$ 385,370	$ —	$ —
Financial Liabilities:				
Public warrant liability	$ 14,463	$ 14,463	$ —	$ —
Private warrant liability	7,092	—	7,092	—
Earn-out contingent liability	10,244	—	—	10,244
Total financial liabilities	$ 31,799	$ 14,463	$ 7,092	$ 10,244

Of the $123.9 million cash and cash equivalents presented on the consolidated balance sheets, $16.9 million is in money market funds and is classified within Level 1 of the fair value hierarchy as the fair value is based on quoted prices in active markets.

The Company's outstanding warrants include publicly-traded warrants (the "Public Warrants") which were originally issued in the IPO and warrants sold in a private placement to CMLS Holdings LLC (the "Private Warrants"). The Company evaluated its warrants under ASC 815-40, Derivatives and Hedging—Contracts in Entity's Own Equity, and concluded that they do not meet the criteria to be classified in stockholders' equity. Since the Public Warrants and Private Warrants meet the definition of a derivative under ASC 815, the Company recorded these warrants as non-current liabilities on the balance sheet at fair value upon the closing of the Business Combination, with subsequent changes in their respective fair values recognized in other income (expense), net on the consolidated statements of operations and comprehensive loss at each reporting date. The Public Warrants are classified within Level 1 of the fair value hierarchy as they are traded in active markets. The Private Warrants are classified within Level 2 of the fair value hierarchy as management determined the fair value of each Private Warrant is the same as that of a Public Warrant because the terms are substantially the same. For the year ended December 31, 2022, a gain of $21.1 million was recorded within the change in the change in fair market value of warrant and earn-out contingent liabilities in the consolidated statements of operations and comprehensive loss based on re-measurement performed as of the period end date.

The earn-out contingent liabilities include the Company's contingent obligation to issue earn-out shares for Legacy Sema4 stockholders ("Earn-out Shares") as well as the Company's contingent obligation to make an additional Milestone Payment of up to $150 million, up to 30.9 million shares of its Class A common stock, or a combination of cash and shares at our discretion, to OPKO if certain revenue-based milestones are achieved for each of the fiscal years ended December 31, 2022 and December 31, 2023. As of December 31, 2022, the first milestone was met and is anticipated to be paid by the Company issuing approximately 23.2 million shares of Class A common stock, which is determined to be approximately $6 million in fair value as of December 31, 2022.

The Earn-out Shares are accounted for as a liability and required remeasurement at each reporting date. The estimated fair value of the total Earn-out Shares as of December 31, 2022 is determined based on a Monte Carlo simulation valuation model. The fair value of the earn-out contingent liability is sensitive to the expected volatility for the Company and the Company's Class A common stock price which is sensitive to changes in the forecasts of earnings and/or the relevant operating metrics. The expected volatility for the Company is based on the historical volatility of selected guideline companies, the historical volatility of the Company, and the implied volatility of the Company's call options. The key assumptions utilized in determining the Earn-out Shares valuation as of December 31, 2022 and December 31, 2021 were as follows:

	December 31, 2022	December 31, 2021
Stock price	$0.26	$4.46
Expected volatility	107.5%	62.5%
Expected term (in years)	0.6	1.6
Risk-free interest rate	4.76%	0.58%

The fair value determined and recorded as of December 31, 2022 and December 31, 2021 was zero and $10.2 million, respectively. During the year ended December 31, 2022 a gain of $10.2 million was recorded within the change in fair market value of warrant and earn-out contingent liabilities in the consolidated statements of operations and comprehensive loss based on re-measurement performed as of the period end date.

The Milestone Payments contingent liability represents additional acquisition consideration to pay up to $150 million, up to 30.9 million shares of the Company's Class A common stock or a combination of cash and shares at the Company's discretion based on the achievement of Legacy GeneDx revenue-based milestones in fiscal years 2022 and 2023. Subject to the terms and conditions of the Acquisition Merger Agreement, (a) the first Milestone Payment representing 75% of the aggregate became due as the Legacy GeneDx group's revenue exceeded $163 million for the year ended December 31, 2022 and (b) the second Milestone Payment representing the final 25% will become due and payable if the revenue of the Legacy GeneDx group for the fiscal year 2023 equals or exceeds $219 million; provided that 80% of the Milestone Payment will become payable in respect of such period if the Legacy GeneDx group achieves 90% of the applicable Milestone Event revenue target, which amount will scale on a linear basis up to 100% of the applicable Milestone Payment at 100% of the applicable revenue target. Each Milestone Payment will be satisfied through the payment and/or issuance of a combination of cash and shares of the Company's Class A common stock (valued at a fixed $4.86 per share), with such mix to be determined at the Company's sole discretion. Settlement of the first Milestone Payment is expected to be paid via issuance of shares of Company's Class A common stock based on the results of 2022.

The Company recorded the fair value of the Milestone Payments for $7.6 million as of December 31, 2022, of which $6.0 million has been earned and is presented as current liabilities in the consolidated balance sheets. For the year ended December 31, 2022, a gain of $38.9 million was recorded in the change in fair market value of warrant and earn-out contingent liabilities in the consolidated statements of operations and comprehensive loss based on re-measurement performed as of the period end date. The fair value of the remaining earn-out was determined based on a Monte Carlo simulation valuation model and the key assumptions include revenue projections, revenue volatility of 25%, the Company's expectation to settle the liability in shares and share price of $0.26 per share.

The earn-out contingent liabilities are categorized as Level 3 of the fair value hierarchy as the Company utilizes unobservable inputs in estimating the fair value. There were no transfers between Level 1, Level 2 and Level 3 during the periods presented.

6. Property and Equipment

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

	As of December 31,	
	2022	2021
Laboratory equipment	$ 41,255	$ 28,552
Equipment under finance leases	21,384	21,384
Leasehold improvements	35,561	21,905
Capitalized software	32,171	25,693
Building under finance lease	6,276	6,276
Construction in-progress	3,386	940
Computer equipment	9,177	6,634
Furniture, fixtures and other equipment	3,777	3,241
Total property and equipment	152,987	114,625
Less: accumulated depreciation and amortization	(101,460)	(51,906)
Property and equipment, net	$ 51,527	$ 62,719

For the years ended December 31, 2022, 2021 and 2020, depreciation and amortization expense was $50.0 million, $21.8 million and $11.7 million, respectively, which included software amortization expense of $15.4 million, $5.6 million and $3.0 million for the years ended December 31, 2022, 2021 and 2020, respectively. For intangible amortization, see Note 18, *"Goodwill and Intangible Assets."*

For the year ended December 31, 2022, the Company accelerated depreciation and amortization charge of $24.0 million due to the change in the Company's useful lives on certain fixed assets that are related to the business exit activity.

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

	Year Ended December 31,		
	2022	2021	2020
Cost of services	$ 31,328	$ 14,094	$ 9,055
Research and development	14,960	5,819	1,040
Selling and marketing	4	3	—
General and administrative	3,667	1,891	1,639
Total depreciation and amortization expenses	$ 49,959	$ 21,807	$ 11,734

7. Related Party Transactions

Related party revenues

Related party revenues primarily include diagnostic testing revenues generated by GeneDx from BioReference Laboratories, Inc. ("BRLI"), which is a subsidiary of OPKO. The prices charged represent market rates. Revenue recorded from this contract was $1.7 million for the year ended December 31, 2022.

Related party expenses

On June 1, 2017, the Company signed a contribution and funding agreement and other agreements with ISMMS, whereby ISMMS contributed certain assets and liabilities related to the Company's operations, provided certain services to the Company, and also committed to funding the Company up to $55.0 million in future capital contributions in exchange for equity in the Company, of which $55.0 million was drawn as of December 31, 2019. Following the transaction, the Company commenced operations and began providing the services and performing research.

For years ended December 31, 2021 and 2020, the Company incurred certain costs with ISMMS. Expenses recognized under the TSA totaled $1.4 million and $7.2 million for the years ended December 31, 2021 and 2020, respectively, and are presented within related party expenses in the consolidated statements of operations and comprehensive loss. The Company did not incur any costs under the TSA in the year ended December 31, 2022. The Company did not have any TSA payables due to ISMMS of as of December 31, 2022 and 2021. The ISMMS TSA expired on March 28, 2021.

Expenses recognized pursuant to other service arrangements with ISMMS totaled $7.4 million, $7.0 million and $4.4 million for the years ended December 31, 2022, 2021 and 2020, respectively. These amounts are included in either cost of services or related party expenses 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 $2.4 million and $2.6 million as of December 30, 2022 and 2021, respectively. These amounts are included within due to related parties on the Company's consolidated balance sheets.

Additionally, the Company incurred $1.7 million in purchases of diagnostic testing kits and materials for the year ended December 31, 2022 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 $0.4 million as of December 31, 2022.

GeneDx and OPKO entered into a Transition Services Agreement dated as of April 29, 2022 (the "OPKO TSA") pursuant to which OPKO has agreed to provide, at cost, certain services in support of the Acquisition of the GeneDx business through December 31, 2022, 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. The Company recognized $1.3 million and in costs for the year ended December 31, 2022, respectively. As of December 31, 2022, $0.4 million was unpaid and included in due to related parties in consolidated balance sheets.

The Company also recorded $1.3 million of receivables from OPKO related to the Acquisition closing working capital adjustment. This amount is presented as other current assets in consolidated balance sheets as of December 31, 2022.

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 (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Costs of services	$ 4,169	$ 3,975	$ 2,189
Related party expenses	6,312	5,659	9,395
Total related party costs	$ 10,481	$ 9,634	$ 11,584

8. Long-Term Debt

Loan and Security Agreement (the "SVB Agreement")

On November 15, 2021, the Company and Sema4 OpCo (together, the "Borrower") entered into the SVB Agreement with Silicon Valley Bank ("SVB"). The SVB Agreement provides for a Revolver up to an aggregate principal amount of $125.0 million, including a sublimit of $20.0 million for Letters of Credit (as such terms are defined in the SVB Agreement). The outstanding principal amount of any Advance (as such term is defined in the

SVB Agreement) will bear interest at a floating rate per annum equal to the greater of (1) 4.00% and (2) the Prime Rate plus the Prime Rate Margin. The Revolver will mature on November 15, 2024.

The obligations under the SVB Agreement are secured by a first priority perfected security interest in substantially all of the Company's assets except for (i) Governmental Collection Accounts (as defined in the SVB Agreement), (ii) more than 65% of the presently existing and thereafter arising issued and outstanding shares of capital stock owned by Borrowers in a Foreign Subsidiary (as such term is defined in the SVB Agreement) and (iii) intellectual property pursuant to the terms of the SVB Agreement.

The SVB Agreement contains affirmative and negative covenants, including, among other things, restrictions on indebtedness, liens, investments, mergers, dispositions, and dividends and other distributions.

The SVB Agreement requires the Borrower to comply with certain financial covenants if Liquidity (as such term is defined in the SVB Agreement) falls below $135.0 million. These financial covenants include (i) a minimum Adjusted Quick Ratio (as such term is defined in the SVB Agreement) and (ii) the achievement of certain minimum revenue targets. On a monthly basis, the Borrowers would be required to maintain a minimum Adjusted Quick Ratio of greater than or equal to 1.25 to 1.0. The Borrower must also maintain certain trailing six-month minimum revenue targets through maturity if outstanding borrowings under the Revolver exceed $50.0 million.

The SVB Agreement also includes customary events of default, including failure to pay principal, interest or certain other amounts when due, material inaccuracy of representations and warranties, violation of covenants, certain bankruptcy and insolvency events, certain undischarged judgments, material invalidity of guarantees or grant of security interest, material adverse change, and involuntary delisting from the Nasdaq Stock Market, in certain cases subject to certain thresholds and grace periods. If one or more events of default occurs and continues beyond any applicable cure period, SVB may, without notice or demand to the Borrower, terminate its commitment to make further loans and declare all of the obligations of the Borrowers under the SVB Agreement to be immediately due and payable. The Company is in compliance with all covenants as of December 31, 2022.

No amounts have been drawn under the SVB Agreement as of December 31, 2022.

On March 10, 2023, SVB was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation ("FDIC") as receiver. On March 14, 2023, Silicon Valley Bridge Bank, N.A., a new bank that is regulated by the Office of the Comptroller of the Currency, announced that it had assumed all loan positions, including as lender, issuing bank, administrative and any other function that was formerly performed by SVB, and that all commitments to advance under existing credit agreements will be honored in accordance with and pursuant to the terms thereof.

2016 Funding Commitment

In April 2016, ISMMS received a $5.0 million loan funding commitment (the "DECD Loan Agreement") from the Connecticut Department of Economic and Community Development ("DECD") to support the Genetic Sequencing Laboratory Project in Branford, Connecticut (the "Project"). The DECD made a commitment to offer a total of $9.5 million in loan funding for leasehold improvements, construction, equipment, research and development, and administrative expenses over a period of ten years at an annual interest rate of 2.0% (collectively, "Phase 1" and "Phase 2" of funding for the Project). On June 1, 2017, as part of the Spin-out, ISMMS assigned both the agreement underlying the Project and the DECD Loan Agreement to Sema4 OpCo, Inc. ("OpCo"). ISMMS guaranteed the Company's obligation to repay the DECD.

In June 2018, the Company amended the existing $9.5 million DECD Loan Agreement (the "2018 Amended DECD Loan Agreement") with the DECD by increasing the total loan commitment to $15.5 million at the same fixed annual interest rate of 2.0% for a term of 10 years from the date the new funds are disbursed ("Phase 3" of funding for the Project). The terms of the Amended DECD Loan Agreement require the Company to make interest-only payments through July 2023 and principal and interest payments commencing in August 2023 through July 2028.

In addition, under the terms of the 2018 Amended DECD Loan Agreement, the DECD provided the Company with the ability to seek partial principal loan forgiveness of up to $12.3 million in the aggregate, contingent upon the Company achieving job creation and retention milestones.

The outstanding loan balance from the DECD was $11.0 million at December 31, 2021, following the achievement of the Phase 1 funding milestone. In January 2023, the Company amended the 2018 Amended DECD Loan Agreement, which resulted in agreeing to pay $2.0 million in principal, obtaining $2.75 million in debt forgiveness for achieving its Phase 2 job milestone, and agreeing to two new forgiveness milestone targets for Phase 3 (eligible for $2 million in forgiveness) and the Final Phase (eligible for $1 million in forgiveness) (the "2022 Amended DECD Loan Agreement"). Upon execution of this amendment in January 2023, we have paid the $2.0 million in principal and received $2.75 million in debt forgiveness, both of which were classified as current liabilities as of December. The terms of the 2022 Amended DECD Loan Agreement require the Company to make interest-only payments through July 2024 and principal and interest payments commencing in August 2024 through July 2029 at the same fixed annual interest rate of 2.0%.

As of December 31, 2022, the long-term debt matures as follows (in thousands):

2023	$ 4,750
2024	497
2025	1,211
2026	1,234
2027	1,260
Thereafter	2,048
Total maturities of long-term debt	11,000
Less: Current portion of long-term debt	(4,750)
Total long-term debt, net of current portion	$ 6,250

Debt due to the DECD is collateralized by providing a security interest in certain machinery and equipment the Company holds at its Stamford headquarters, as defined in a separate security agreement. The DECD Security Agreement provides a security for the payment and performance of meeting the Company's obligations to the DECD until the obligations have been fully satisfied.

9. Leases

Lease Accounting

The Company adopted ASC 842 on January 1, 2022 on a modified retrospective basis. As a result, the Company's lease disclosures as of and for the year ended December 31, 2022 are reported under ASC 842. Comparative financial information as of and for the years ended December 31, 2021 and 2022 have not been restated and continues to be reported under ASC 840, the lease accounting standard in effect for that period.

The Company enters into contracts in the normal course of business and assesses whether any such contracts contain a lease. The Company determines if an arrangement is a lease at inception if it conveys the right to control the identified asset for a period of time in exchange for consideration. The Company classifies leases as operating or financing in nature. 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.

Operating Leases

The Company's operating lease arrangements are principally for office space and laboratory facilities. The Company's headquarter lease was initially entered into via sub-lease agreements with ISMMS and a third party and they will expire in 2034. We also entered into a separate lease with a third party for space in the same building as our headquarters and that lease expires in 2029. The agreements include escalating rent and rent-free period provisions. Pursuant to the terms of the lease agreement, the Company was required to have issued an irrevocable standby letter of credit to the lessor for $0.9 million, which was included in restricted cash, non-current on the consolidated balance sheets as of December 31, 2021 and 2022. The Company identified impairment indicators with respect to certain office space which was determined to be excess. The Company performed quantitative analysis as of December 31, 2022. The fair value was determined primarily based on estimating sublease income for the lease and discount rate. The Company utilized third party information in the estimation process. Based on the analysis, the Company recorded an impairment charge of $10.0 million.

In April 2019, the Company entered into a sublease agreement to rent a building to be used for office and laboratory facility (the "Stamford Lease") for a base term of 325 months, expiring in October 2046. The Company has the option to renew the lease at the end of the initial base term for either one period of 10 years, or two periods of 5 years. There is also an early termination option in which the Company may cancel the lease after the 196th month with cancellation fees. At inception of the Stamford Lease, 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.

In January 2020, the Company entered into a lease agreement which expanded the Company's existing laboratory facility in Branford, Connecticut. The lease commenced in February 2020 with a 10 year term. The lease includes escalating rent fees over the lease term.

In April 2022, the Company acquired an operating lease for office space and laboratory operations in Gaithersburg, Maryland, in connection with the Acquisition. The lease includes a base term of 9 years remaining from the date of acquisition and an escalating rent provision.

In July 2022, the Company executed a lease agreement to extend the lease term of existing office spaces in New York, New York, commencing in September 2022 for a period of 13 months.

Finance Leases

The Company 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. As discussed above, the Company also leases a building used for office and laboratory space in which the building is accounted for as a finance lease and the land is as an operating lease. The interest rate used for the Stamford Lease is 13.1%, which is used to measure the operating and finance lease liability. During the prior year, the Company accounted for finance leases under ASC 840 as capital leases. As of December 31, 2021, the finance lease obligations of $3.4 million and $18.4 million were included in other current liabilities and other liabilities, respectively on the consolidated balance sheets.

The tables below present financial information associated with the Company's leases. This information is presented as of, and for the year ended, December 31, 2022 because, the Company adopted the ASC 842 using a transition method that does not require application to periods prior to adoption (in thousands).

	Classification	December 31, 2022
Assets		
Operating lease assets	Operating lease right-of-use assets	$ 32,758
Finance lease assets	Property and Equipment, net	8,604
Total lease assets		$ 41,362
Liabilities		
Current		
Operating	Short-term lease liabilities	$ 2,409
Finance	Short-term lease liabilities	3,712
Non-current		
Operating	Long-term lease liabilities	$ 44,468
Finance	Long-term lease liabilities	15,545
Total lease liabilities		$ 66,134

Lease cost	Year ended December 31, 2022
Operating lease cost	
Operating lease cost	$ 6,044
Short-term lease cost	1,131
Variable lease cost	1,111
Total operating lease cost	$ 8,286
Finance lease cost	
Depreciation and amortization of leased assets	$ 5,518
Interest on lease liabilities	$ 2,152
Total finance lease cost	$ 7,670
Total lease cost	$ 15,956

Future minimum lease payments under non-cancellable leases as of December 31, 2022 are as follows:

Maturity of lease liabilities	Operating leases	Finance leases	Total
2023	$ 4,597	$ 3,729	8,326
2024	5,521	2,763	8,284
2025	5,952	2,451	8,403
2026	6,103	2,003	8,106
2027	6,251	2,045	8,296
Thereafter	51,640	47,839	99,479
Total	80,064	60,830	$ 140,894
Less: imputed interest	(33,187)	(41,573)	$ (74,760)
Present value of lease liabilities	$ 46,877	$ 19,257	$ 66,134

Other information related to leases as of and for the year ended December 31, 2022 are as follows:

	December 31, 2022
Weighted-average remaining lease term (years)	
Operating leases	12.2
Finance leases	19.0
Weighted-average discount rate	
Operating leases	6.9%
Finance leases	11.2%
Cash paid for amounts included in the measurement of lease liabilities	
Operating cash flows from operating leases	$ 4,183
Operating cash flows from finance leases	2,225
Financing cash flows from finance lease	3,292

10. Commitments and Contingencies

Purchase Obligations

The following sets forth purchase obligations as of December 31, 2022 with a remaining term of at least one year (in thousands):

Contractual Obligations	2023	2024	2025	Total Commitments
Software provider	$ 5,561	$ 2,436	$ 257	$ 8,254
Equipment provider	179	182	139	$ 500
	$ 5,740	$ 2,618	$ 396	$ 8,754

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

Contingencies

The Company is a party to various actions and claims arising in the normal course of business. The Company does not believe that the outcome of these matters will have a material effect on the Company's consolidated financial position, results of operations or cash flows. However, no assurance can be given that the final outcome of such proceedings will not materially impact the Company's consolidated financial condition or results of operations.

Except as described below, the Company was not a party to any material legal proceedings as of December 31, 2022, nor is it a party to any material legal proceedings as of the date of issuance of these audited 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 against the Company and certain of the Company's current and former officers. The complaint purports to bring suit on behalf of stockholders who purchased the Company's publicly traded securities between March 14, 2022 and August 15, 2022. Following the appointment of a lead plaintiff, an amended complaint was filed on January 30, 2023. As amended, the complaint purports to allege that 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, and seeks unspecified compensatory damages, fees and costs. The Company believes the allegations and claims made in the complaint are without merit.

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. The suit names as defendants all directors of CMLS at the time of the transaction, including directors who continue to serve on the Company's Board of Directors, as well as CMLS Holdings 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. The Company believes the allegations and claims made in the complaint are without merit. The Company is subject to certain claims for advancement and indemnification by the individual defendants in this proceeding.

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 $9.8 million, $8.0 million and $5.5 million for the years ended December 31, 2022, 2021 and 2020, respectively.

11. Stock-Based Compensation

Stock Incentive Plans

The Company's 2017 Equity Incentive Plan (the "2017 Plan"), as amended in February 2018, allowed the grant of options, restricted stock awards, stock appreciation rights and restricted stock units. No options granted under the 2017 Plan are exercisable after 10 years from the date of grant, and option awards generally vest over a four-year period.

The 2017 Plan was terminated in connection with the adoption of the Company's 2021 Equity Incentive Plan (the "2021 Plan"). Any awards granted under the 2017 Plan that remained outstanding as of the Closing Date and were converted into awards with respect to the Company's Class A common stock in connection with the consummation of the Business Combination continue to be subject to the terms of the 2017 Plan and applicable award agreements, except for a modification of the repurchase provision, which is discussed further below.

On July 22, 2021, in connection with the Business Combination, the 2021 Plan became effective and 32,734,983 authorized shares of common stock were reserved for issuance thereunder. This Plan will be administered by the Compensation Committee of the Company's Board of Directors, including determination of the vesting, exercisability and payment of the awards to be granted under this Plan. 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.

As of December 31, 2022, there was an aggregate of 9,648,510 shares available for grants of stock options or other awards under the 2021 Plan.

Employee Stock Purchase Plan

The 2021 Employee Stock Purchase Plan (the "2021 ESPP") became effective in connection with the Business Combination. The 2021 ESPP authorizes the issuance of shares of common stock pursuant to purchase rights granted to employees. A total of 4,804,011 shares of common stock have been reserved for future issuance under the 2021 ESPP. On each January 1 of each of 2022 through 2031, the aggregate number of shares of common stock reserved for issuance under the 2021 Plan may be increased automatically by the number of shares equal to one percent (1%) of the total number of shares of all classes of common stock issued and outstanding on the immediately preceding December 31. The Company did not make any grants of purchase rights under the 2021 ESPP during the year ended December 31, 2022.

Stock Option Activity

Under the 2017 Plan, the Company had a call option to repurchase awards for cash from the plan participants upon termination of the participant's employment or consulting agreement (the "2017 Plan Call Option"). The options granted under the 2017 plan were accounted for as liability awards due to the 2017 Plan Call Option. The Company had a history of repurchase practice and the intention to repurchase the vested options. Therefore, the fair value of the liability awards was remeasured at each reporting period until the stockholder bears the risks and rewards of equity ownership for a reasonable period of time, which the Company concludes is at least six months.

Upon consummation of the Business Combination, the Company's Board of Directors waived the Company's right under the 2017 Plan Call Option to repurchase awards for cash from the plan participants upon termination of the participant's employment or consulting agreement. As such, the Company modified the liability awards to equity awards and reclassified the modification date fair value of the awards to stockholders' equity in the consolidated financial statements as of July 22, 2021.

All stock options granted under the 2021 Plan are accounted for as equity awards.

The following summarizes the stock option activity, which reflects the conversion of the options granted under the 2017 Plan into awards with respect to the Company Class A common stock in connection with the consummation of the Business Combination (in thousands, except share and per share amounts):

	Stock Options Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (years)	Aggregate Intrinsic Value
Balance at December 31, 2021	30,905,543	$ 1.24	6.80	$ 109,887
Options granted	13,347,197	$ 2.28		
Options exercised	(11,021,636)	$ 0.27		
Options forfeited and canceled	(6,868,297)	$ 3.80		
Balance at December 31, 2022	26,362,807	$ 1.51	6.08	$ 775,842
Options exercisable at December 31, 2022	15,157,018	$ 1.02	4.02	$ 803,370

Non-vested options outstanding at the end of the year was 11,205,789 with weighted average grant-date fair value of $2.17.

The weighted-average grant-date fair value of options granted and total fair value of the options with tranches vested was $1.55 and $24.5 million for the year ended December 31, 2022, respectively. The weighted-average grant-date fair value of options forfeited and canceled was $4.92 for the year ended December 31, 2022. The aggregate intrinsic value of exercised options was $18.1 million, $17.1 million and $0.6 million in the years ended December 31, 2022, 2021 and 2020, 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 total payments for share-based liabilities were $0.1 million and $0.3 million in the years ended December 31, 2021 and 2020, respectively, while no payments were made in the year ended December 31, 2022.

The fair value of the stock option awards for the period ended December 31, 2022, and as of December 31, 2021, and 2020 were estimated using the Black-Scholes option pricing model with the following assumptions:

	2022	2021	2020
Expected volatility	65.20%-90.00%	49.60%-67.70%	65.80%
Weighted-average expected volatility	75.00%	66.15%	65.80%
Expected term (in years)	5.48-6.18	5.00-6.06	0.50–1.49
Risk-free interest rate	1.65%-3.38%	0.71%-1.26%	0.10%
Dividend yield	—	—	—
Fair value of Class A common stock	$0.99-$3.45	$7.62-$11.60	$5.49

We estimated a volatility factor for the Company's options based on analysis of historical share prices of a peer group of public companies. We did not rely on the volatility of the Company's common stock because of its limited trading history. We estimated 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. We did not rely on the historical holding periods of the Company's options due to the limited availability of exercise data. We used 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.

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, 2021	12,589,558	7.64
Restricted Stock Units granted	29,004,515	$1.63
Restricted Stock Units vested	(4,841,898)	$6.46
Restricted Stock Units forfeited	(8,535,177)	$5.51
Balance at December 31, 2022	28,216,998	$2.36

The total fair value of RSUs vested for the year ended December 31, 2022 was $33.7 million.

Additionally, the Company issued 126,980 RSUs subject to both service and performance based vesting conditions to the Executive Chairman of the Company. The grant date was established during the second quarter period and vesting of the RSUs will be based on the achievement of performance goals established for calendar year 2022. As of December 31, 2022, these RSUs were all forfeited due to the established performance goals not being achieved.

Earn-out RSUs

The grant date fair value determined for Triggering Event I, II and III was $1.82, $1.39 and $0.94 per unit, respectively. At year-end, any re-allocated RSUs due to the Legacy Sema4 option holders' forfeiture activities were accounted for as new grants and the fair value determined for Triggering Event I, II and III was $0, $0 and $0 per unit, respectively. Based on the grant date fair value, the Company expects to record total expense related to the Earn-out RSU Awards of $3.5 million. The Company expects to recognize the stock-compensation cost over the longer of the derived service period or service period.

Stock Appreciation Rights (SAR) Activity

The Company historically granted SAR to one employee and one consultant with exercise condition of a liquidation event. As a result of the Business Combination, settlement of the outstanding vested SARs in exchange for a cash payment and to cancel the outstanding unvested SARs was agreed upon and an expense of $3.8 million related to the vested SAR was recognized by the Company. There were no outstanding SARs as of December 31, 2022.

Stock-Based Compensation Expense

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

	Year Ended December 31,		
	2022	2021	2020
Cost of services	$ 5,080	$ 22,567	$ 12,942
Research and development	1,755	47,183	26,650
Selling and marketing	6,498	29,110	11,755
General and administrative	28,642	120,561	68,884
Total stock-based compensation expense	$ 41,975	$ 219,421	$ 120,231

As of December 31, 2022, unrecognized stock-based compensation cost related to the unvested portion of the Company's stock options was $12.7 million, which is expected to be recognized on a graded-vesting basis over a weighted-average period of 1.7 years. As of December 31, 2022, unrecognized stock-based compensation cost

related to the Company's RSUs was $34.5 million, which is expected to be recognized on a graded-vesting basis over a weighted-average period of 1.7 years.

12. Common Stock

There were 388,511,138 shares and 242,647,604 shares of GeneDx Holdings Class A common stock issued and outstanding as of December 31, 2022 and 2021, respectively. Each share of common stock entitles the holder to one vote and to receive dividends when and if declared by the board of directors of the Company. No dividends have been declared through December 31, 2022.

13. Income Taxes

The components of income before incomes taxes consisted of the following (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Foreign	$ 104	$ —	$ —
Domestic	(598,136)	(245,390)	(241,340)
Total	(598,032)	(245,390)	(241,340)

	Year Ended December 31,		
	2022	2021	2020
Current			
Federal	$ —	$ —	$ —
State and Local	—	—	—
Foreign	72	—	—
Total Current	$ 72	$ —	$ —
Deferred			
Federal	$ (40,828)	$ —	$ —
State and Local	(8,296)	—	—
Foreign	—	—	—
Total Deferred	(49,124)	—	—
Total Tax Expense	$ (49,052)	$ —	$ —

For the years ended December 31, 2022, 2021 and 2020, the Company recorded a total income tax benefit of $49,052, $0, $0, respectively. Accordingly, the effective tax rate for the Company for the years ended December 31, 2022, 2021 and 2020 was 8.2%, 0%, 0%, 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 (in thousands):

	Year Ended December 31,		
	2022	2021	2020
U.S. federal taxes at statutory rate	21.0%	21.0%	21.0%
State taxes (net of federal benefit)	1.4	10.5	2.1
Research and development tax credits	0.3	0.7	0.6
Non-deductible stock-based compensation	(1.0)	(11.3)	(7.8)
162(m) Limitation	—	(5.7)	—
Permanent Items	0.5	(0.2)	—
Unrealized fair market value gain on warrants	1.7	17.0	—
Goodwill Impairment	(6.1)	—	—
Change in valuation allowance	(9.6)	(32.0)	(15.9)
Effective tax rate	8.2%	—%	—%

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

	As of December 31,	
	2022	2021
Deferred tax assets:		
Net operating loss carryforwards	$ 199,426	$ 132,075
Stock-based compensation	13,379	12,311
Accrued compensation	2,233	4,170
Transaction costs	—	416
Research and development credits	8,600	7,285
Leases	12,971	1,443
Unearned revenue	10	145
Deferred employer taxes	133	932
Interest expense	7	372
Property and equipment	4,039	608
Obsolete inventory reserve	5,889	655
Accrued expenses	10,142	—
Section 174 amortization	23,193	—
Other	941	51
Total deferred tax assets	280,963	160,463
Valuation allowance	(226,644)	(155,668)
Deferred tax assets, net of valuation allowance	54,319	4,795
Deferred tax liabilities:		
ROU asset	(8,589)	—
Capitalized software	(141)	(4,795)
Intangible amortization	(48,248)	—
Total deferred tax liabilities	(56,978)	(4,795)
Net deferred tax liability after valuation allowance	$ (2,659)	$ —

As of December 31, 2022, 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 (in thousands):

	Amount	Expiration period
Tax net operating loss carryforwards:		
Federal (pre-2018 net operating losses)	$ 33,056	2036-2037
Federal (post-2017 net operating losses)	$ 656,536	No expiration
State and Local	$ 974,006	2028-2042
State and Local	$ 42,314	No expiration
Tax credit carryforwards:		
Federal research and development	$ 6,943	2038-2040
Connecticut research and experimental	$ 1,542	2035-2036
Connecticut research and development	$ 555	No expiration

The Company had the following deferred tax valuation allowance balances (in thousands):

Year	Balance at the Beginning of Period	Additions	Write-Offs/Other	Balance at the End of Period
2022	$ 155,668	70,976	—	$ 226,644
2021	$ 58,264	97,404	—	$ 155,668
2020	$ 20,082	38,182	—	$ 58,264

The CARES Act, among other things, includes provisions relating to refundable payroll tax credits, net operating loss carryback periods, alternative minimum tax credit refunds, modifications to the net interest deduction limitations and technical corrections to tax depreciation methods for qualified improvement property.

The CARES Act also provides for the elective deferral of the deposit and payment of the employer share of Social Security taxes for the period beginning March 27, 2020 and ending December 31, 2020. Under the CARES Act, 50% percent of the employer portion of Social Security tax is to be remitted no later than December 31, 2021, with the remaining 50% to be remitted no later than December 31, 2022. The Company has evaluated the effect of the elective deferral on its income tax positions and determined that the corresponding deduction related to the employer portion of Social Security tax is not deductible in the year ended December 31, 2020, resulting in a nominal deferred tax asset. The Company continues to evaluate the potential effects the CARES Act may have on its operations and consolidated financial statements in future periods.

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, 2022, 2021, and 2020 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 partial valuation allowance as of December 31, 2022 and a full valuation allowance as of December 31, 2021 and 2020. The valuation allowance increased by $71.0 million in 2022, $97.4 million in 2021 and $38.1 million in 2020 primarily due to the increase in net operating loss carryforwards, research and development tax credits, accrued compensation expenses, stock-based compensation, lease liability, Section 174 amortization and accrued expenses.

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). The Company has not completed a study to assess whether an ownership change has occurred or whether there have been multiple ownership changes since becoming a "loss corporation" as defined in Section 382. 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.

ASC 740 addresses the determination of whether tax benefits claimed or expected to be claimed on a tax return should be recorded in the financial statements by prescribing a model for recognizing, measuring, and disclosing uncertain tax positions. Unrecognized income tax benefits represent income tax positions taken on income tax returns but not yet recognized in the financial statements.

As of December 31, 2022, 2021 and 2020, the Company had nominal gross unrecognized tax benefits which, if recognized, would not impact the effective tax rate due to the Company's valuation allowance position. Due to the uncertainties associated with any examinations that may arise with the relevant tax authorities, it is not possible to reasonably estimate the impact of any significant increase or decrease to the unrecognized tax benefits within the next twelve months.

A reconciliation of the beginning and ending amounts of unrecognized tax benefits for the years ended December 31, 2022, 2021 and 2020 is as follows (in thousands):

	As of December 31,		
	2022	2021	2020
Unrecognized tax benefits – January 1	$ 537	$ 537	$ 374
Gross increases – tax positions in current period	181	—	163
Unrecognized tax benefits – December 31	$ 718	$ 537	$ 537

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. As of December 31, 2022, 2021 and 2020, the Company has accrued interest or penalties related to uncertain tax positions of less than $0.1 million, $0, and $0 respectively.

The Company files U.S federal and multiple state income tax returns as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by federal and state jurisdictions, where applicable. There are currently no pending federal or state 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.

14. 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 (in thousands, except for share and per share amounts):

	Year Ended December 31,		
	2022	2021	2020
Numerator:			
Net loss attributable to common stockholders	$ (548,980)	$ (245,390)	$ (241,340)
Denominator:			
Denominator for basic and diluted earnings per share-weighted-average common shares	337,819,680	108,077,439	5,131
Basic and diluted loss per share	$ (1.63)	$ (2.27)	$ (47,036)

As a result of the Merger, the Company has retroactively adjusted the weighted-average number of shares of common stock outstanding prior to the Merger by multiplying them by the conversion ratio of 123.8339 used to determine the number of shares of common stock into which they converted. The common stock issued as a result of the redeemable convertible preferred stock conversion upon closing of the Merger was included in the basic and diluted loss per share calculation on a prospective basis.

Prior to the consummation of the Merger, the Company applied the two-class method to calculate its basic and diluted net loss per share of common stock, as there were outstanding Class B common stock and redeemable convertible preferred stock that were participating securities. The two-class method is an earnings allocation formula that treats a participating security as having rights to earnings that otherwise would have been available to common stockholders. As the securities were all converted into the Company's Class A common stock upon consummation of the Merger, all outstanding Legacy Sema4 Class B common stock has been retroactively converted to the Company's Class A common stock.

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,		
	2022	2021	2020
Outstanding options and RSUs	54,579,805	35,519,867	32,339,971
Outstanding warrants	21,994,972	21,994,972	—
Outstanding earn-out shares	18,228,934	16,351,897	—
Outstanding earn-out RSUs	792,642	2,669,679	—
Redeemable convertible preferred stock (on an if-converted basis)	—	—	157,618,388
Total	95,596,353	76,536,415	189,958,359

15. Restructuring Costs

During the year ended December 31, 2022, the Company's Compensation Committee of the Board of Directors approved by written consents, dated February 17, 2022, May 2, 2022 and August 11, 2022, a restructuring plan which was fully executed by management and restructuring charges were incurred and recorded in connection therewith, including an exit of the Company's somatic tumor testing business. These costs include severance packages offered to the employees impacted by the plan, third party consulting costs, and costs related to closing

the Company's laboratory in Branford, CT. The plan resulted in the Company eliminating approximately 250 positions.

Additionally, on November 14, 2022, the Company announced its plan to pursue a new strategic direction focused on the Company's pediatric and rare disease testing business coupled with the Company's Centrellis data platform. The Company's strategic realignment was unanimously approved by the board of directors on November 11, 2022 included exiting its reproductive and women's health testing business, which included carrier screening, noninvasive prenatal, and other ancillary reproductive testing offerings. The Company ceased accepting samples for these tests on December 14, 2022 and notified its customers impacted by the decision immediately. The Company expects to exit the operations of the reproductive and women's health testing services by the end of the first quarter of 2023. As a result of this announcement, the Company expects to eliminate approximately 500 positions, and to cease operations at its Stamford, CT laboratory. When combined with the Company's prior reductions in force during 2022, the exit will result in the elimination of approximately 32.5% of its workforce.

The table below provides certain information concerning restructuring activity during the year ended December 31, 2022 (in thousands):

	Reserve Balance at December 31, 2021	Charged to Costs and Expenses	Payments and Other	Reserve Balance at December 31, 2022
Severance	$ —	$ 19,239	$ (14,469)	$ 4,770
Others	—	4,922	(4,669)	253
Total	$ —	$ 24,161	$ (19,138)	$ 5,023

The Company may incur additional expenses not currently contemplated due to events associated with the reduction in force. The charges that the Company expects to incur in connection with the reduction in force are estimates and subject to a number of assumptions, and actual results may differ materially.

16. Supplemental Financial Information

Accrued expenses consisted of the following (in thousands):

	As of December 31,	
	2022	2021
Accrued purchases	$ 20,314	19,758
Reserves for refunds to insurance carriers	17,001	—
Other	1,546	350
Total	$ 38,861	$ 20,108

Other current liabilities consisted of the following (in thousands):

	As of December 31,	
	2022	2021
Accrued bonus	$ 8,429	$ 13,561
Accrued payroll	3,905	7,013
Accrued benefits	1,529	1,057
Accrued commissions	1,656	2,826
Accrued Severance	4,770	—
Current portion of long-term debt	4,750	—
Indemnification liabilities	13,470	—
Current portion of the contingent consideration liabilities	6,019	—
Other (1)	5,137	8,930
Total current other liabilities	$ 49,665	$ 33,387

(1) The 2021 amount includes $3.4 million that was separately disclosed under current portion of capital lease obligations on the consolidated balance sheets in the prior year.

17. Segment Reporting

The Company's business is aligned with how the chief operating decision maker ("CODM") reviews performance and makes decisions in managing the Company. As of December 31, 2022, the Company has identified two reportable segments: (i) GeneDx inclusive of Legacy GeneDx and Legacy Sema4 data revenues and associated costs and (ii) Legacy Sema4 diagnostics. 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. The Legacy Sema4 diagnostics segment provided reproductive and women's health and somatic oncology diagnostic testing and screening products. Segment information is consistent with how management reviews the business, makes investing and resource allocation decisions and assesses operating performance. The CODM evaluates segment performance based on revenue and adjusted gross margin. Prior to the acquisition of Legacy GeneDx in April 2022, the Company had one segment which is characterized as "Legacy Sema4" in the table below. Prior to the date of the acquisition, consolidated results were the same as the results of this segment and therefore 2021 and 2020 have not been presented below.

(in thousands)	**GeneDx**	**Legacy Sema4**	**Total**
Fiscal Year Ended December 31, 2022:			
Revenue	$ 122,234	$ 112,460	$ 234,694
Adjusted cost of services	74,213	148,897	223,110
Adjusted gross margin (loss)	48,021	(36,437)	11,584
Reconciliations:			
Depreciation and amortization	2,440	28,888	31,328
Stock-based compensation	680	4,400	5,080
Restructuring charges	129	1,797	1,926
Gross margin (loss)	$ 44,772	$ (71,522)	$ (26,750)

The following table summarizes the Company's disaggregated revenue (in thousands):

	Year Ended December 31, 2022		
	GeneDx	**Legacy Sema4**	**Consolidated**
Diagnostic test revenue:			
Patients with third-party insurance	$ 72,890	$ 100,734	$ 173,624
Institutional customers	40,754	5,370	$ 46,124
Self-pay patients	1,230	6,356	7,586
Total diagnostic test revenue	114,874	112,460	227,334
Other revenue	7,360	—	7,360
Total	$ 122,234	$ 112,460	$ 234,694

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.

18. Goodwill and Intangible Assets

As discussed in Note 3, Business Combinations, upon the acquisition of GeneDx in April 2022, the Company recorded initial goodwill of $181.5 million through its preliminary purchase allocation. The purchase price allocation for acquired businesses may be modified for up to one year from the date of acquisition if additional facts or circumstances lead to changes in our preliminary purchase accounting estimates. The measurement period is still open as of December 31, 2022.

The changes in the carrying amounts of goodwill were as follows (in thousands):

	December 31, 2022
Balance as of December 31, 2021	$ —
Additions	185,871
Measurement period adjustments	(11,412)
Impairment charges	(174,459)
Balance as of December 31, 2022	$ —

During the fourth quarter of 2022, the Company identified indicators that it was more likely than not that the fair value of the GeneDx reporting unit was less than its carrying value. The factors contributing to the indicators include, but are not limited to, significant decline in the Company's stock price coupled with lower than anticipated business financial performance of the Legacy Sema4 business.

The Company performed quantitative analysis as of December 31, 2022 to determine the fair value of the GeneDx reporting unit. The fair value was determined through estimating the Company's discounted future cash flows expected to be generated. Significant assumptions inherent in the valuation are employed and include, but are not limited to, prospective financial information, growth rates, terminal value, discount rates, and comparable multiples from publicly traded companies in our industry. Based on the analysis, the Company concluded that the reporting unit's carrying value was greater than the fair value. Accordingly, an impairment charge totaling $174.5 million was recognized.

The following table reflects the fair values and remaining useful lives of the acquired intangible assets identified based on the Company's preliminary purchase accounting assessments for the GeneDx acquisition (in thousands):

	Gross Carrying Amount	Accumulated Amortization	Net Carrying Value	Weighted-Average Amortization Period (in years)
Tradenames and trademarks	$ 50,000	$ (2,083)	$ 47,917	15.3
Developed Technology	48,000	(4,000)	44,000	7.3
Customer Relationships	98,000	(3,267)	94,733	19.3
	$ 196,000	$ (9,350)	$ 186,650	

Amortization expense for tradenames and trademarks and developed technology of $6.1 million was recorded in general and administrative for the year ended December 31, 2022 within the consolidated statements of operations and comprehensive loss. Amortization expense for customer relationships of $3.3 million was recorded in selling and marketing for the year ended December 31, 2022 within the consolidated statements of operations and comprehensive loss.

The following table summarizes the Company's estimated future amortization expense of intangible assets with finite lives as of December 31, 2022 (in thousands):

2023	$	14,025
2024		14,025
2025		14,025
2026		14,025
2027		14,025
Thereafter		116,525
Total estimated future amortization expense	$	186,650

19. Subsequent Events

Name Change

Effective January 2023, the Company changed its name from "Sema4 Holdings Corp." to "GeneDx Holdings Corp."

Offerings

In January 2023, the Company raised approximately $150.0 million in gross proceeds from the sale of an aggregate 328,571,429 shares of its Class A common stock in an underwritten public offering and the sale of 100,000,000 shares of its Class A common stock shares directly to institutional investors affiliated with a member of our board of directors, in a concurrent registered direct offering. Both transactions were executed at $0.35 per share. 77,663,376 shares in the direct offering were issued and the remaining 22,336,624 shares are subject to stockholder approval to satisfy Nasdaq requirements with respect to the issuance of such shares of Class A common stock. The net offering proceeds received after deducting underwriters' discounts and commissions payable by the Company were approximately $137.6 million. As part of the underwritten offering, the Company granted the underwriter a 30-day option to purchase up to an additional 49,285,714 shares of Class A common stock at the same price. On January 27, 2023, the underwriter partially exercised the option to purchase an additional 185,000 shares of Class A common stock.

Additional net proceeds of $7.6 million are expected to be received during the second quarter of 2023 once the issuance of the remaining 22,336,624 shares receives stockholder approval and the Company issues such shares.

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 controls and other procedures that 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, 2022. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were not effective as of December 31, 2022 because of the material weaknesses in internal control over financial reporting discussed below.

Notwithstanding the material weaknesses in internal control over financial reporting described below, our management has concluded that our consolidated financial statements included in this Annual Report on Form 10-K are fairly stated in all material respects in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP").

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 of America.

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, 2022, 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, due to the material weaknesses described below, management concluded that the Company's internal control over financial reporting were not effective.

As discussed elsewhere in this Annual Report on Form 10-K, we completed our acquisition of Legacy GeneDx on April 29, 2022. The SEC permits companies to exclude acquisitions from their assessment of internal control over financial reporting during the first year in which the acquisition was completed, and our management has elected to exclude Legacy GeneDx from our assessment as of December 31, 2022.

Material Weaknesses

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 Legacy Sema4's audited financial statements as of December 31, 2020, we previously identified material weaknesses in our internal controls over financial reporting. Certain of these material weaknesses remain unremediated as of December 31, 2022.

Specifically, as of December 31, 2022, the material weaknesses that remain unremediated include the following:

- We do not have sufficient, qualified finance and accounting staff with the appropriate U.S. GAAP technical accounting expertise to effectively maintain processes and controls that allow for the timely production of accurate financial information in accordance with internal financial reporting timelines, commensurate with our size and the nature and complexity of our operations.
- We did not maintain formal processes and controls to achieve complete, accurate and timely financial accounting, reporting and disclosures, including controls over the preparation and review of account reconciliations, journal entries, classification of certain costs, non-recurring complex transactions and the accounting in accordance with U.S. GAAP.
- 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 the Company's business process controls that depend on the accuracy and completeness of data or financial reports generated by the Company's information technology system could be adversely affected due to the lack of operating effectiveness of the information technology general controls ("ITGCs").

Remediation Plan

Our management is actively engaged and committed to taking the steps necessary to remediate the control deficiencies that constituted the material weaknesses. The Company has continued to improve its organizational capabilities and continues to implement processes and controls to remediate the material weaknesses.

During 2021 and 2022, we made the following enhancements to our control environment:

- We have hired key personnel, obtained qualified accountants through the acquisition of Legacy GeneDx, and supplemented interim staffing needs with third-party consultants that have the appropriate technical accounting skills to enable us to achieve complete, accurate, and timely financial accounting and reporting. In addition, we have reallocated responsibilities across the organization to ensure that the appropriate level of knowledge and experience is applied based on risk and complexity of transactions.

- We added information technology employees with appropriate experience, certification, education and training to the organization to strengthen our IT team, to enable us to improve the ITGCs over our accounting and operating systems.

- We engaged outside consultants to assist in the design, implementation, documentation, and remediation of internal controls that address the relevant risks, and to assist us in the evaluation of our relevant accounting and operating systems, to enable us to improve our processes and controls over financial reporting.

- We provided training to internal control performers in order to enhance their level of understanding over the appropriate design, implementation and effectiveness of controls.

- We have strengthened and documented our internal accounting policies and procedures and communicated the policies to relevant personnel.

- We have completed the design of our internal controls, and have completed detailed remediation plans at the risk and control level.

Management has been actively engaged in remediation efforts to address the material weaknesses throughout 2022 and these efforts will continue into fiscal year 2023.

While we believe significant progress was made in 2022 to enhance and strengthen our internal control over financial reporting, material control weaknesses are not considered remediated until new internal controls have been operational for a sufficient period of time, are tested, and management concludes that these controls are operating effectively. As of December 31, 2022, there was not a sufficient period of time available to sufficiently test nor conclude that these controls are operating effectively. We will continue to monitor the effectiveness of our

remediation measures in connection with our future assessments of the effectiveness of internal control over financial reporting and disclosure controls and procedures, and we will make any changes to the design of our plan and take such other actions that we deem appropriate given the circumstances.

Changes in Internal Control Over Financial Reporting

Our management has evaluated, with the participation of our Chief Executive Officer and Chief Financial Officer, changes in our internal controls over financial reporting (as defined in Rule 13a-15(f) and 15d-15(f) of the Exchange Act) during the fourth quarter of 2022. Except as described above, there were no changes in the Company's internal control over financial reporting that occurred during the quarter ended December 31, 2022 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting, other than as described herein. We are continuing to take steps to remediate the material weakness in our internal control over financial reporting, as discussed above.

Inherent Limitation on the Effectiveness of Internal Control

Our management, including our Chief Executive Officer and Chief Financial Officer, does 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.

Item 9B. Other Information

Other Events

As previously disclosed, we expect to call a special meeting of stockholders for the approval of the issuance of the additional 22,336,624 shares of Class A common stock in our registered direct offering for purposes of complying with Nasdaq listing rules. At the special meeting, we also intend to seek stockholder approval of a reverse stock split of our outstanding shares of Class A common stock at a ratio to be set by our board of directors within a range approved by our stockholders, an amendment to our certificate of incorporation to limit the liability of certain of our officers as permitted pursuant to recent amendments to the Delaware corporate law, and an amendment to our 2021 Equity Incentive Plan to increase the aggregate number of shares of Class A common stock authorized for issuance under the plan by 26,000,000 shares.

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 2023 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2022.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item is incorporated by reference from our definitive proxy statement for our 2023 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2022.

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 2023 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2022.

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 2023 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2022.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this Item is incorporated by reference from our definitive proxy statement for our 2023 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2022.

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**
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	Certificate of Amendment of Restated Certificate of Incorporation of Sema4 Holdings Corp.	8-K	3.1	01/09/2023	
3.3	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	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*	2021 Equity Incentive Plan.	8-K	10.5	07/28/2021	

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*	Amended and Restated Employment Agreement of Eric Schadt.	8-K	10.10	07/28/2021
10.9	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
10.10	Sublease Agreement, dated as of November 8, 2019, by and between Marriott International, Inc. and the Company.	8-K	10.18	07/28/2021
10.11	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
10.12	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
10.13	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
10.14#	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
10.15#	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
10.16#	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
10.17#	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
10.18#	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
10.19#	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
10.20*	Mount Sinai Genomics, Inc. 2017 Equity Incentive Plan, as amended, and forms of equity agreements thereunder.	S-8	99.6	09/27/2021

10.21	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	
10.22	Lockup Agreement, dated as of February 9, 2021, by and among the Company and the stockholder parties identified therein.	8-K	10.2	02/11/2021	
10.23	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	
10.24	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	
10.25	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	
10.26	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	
10.27	Form of Lock-Up Agreement, by and among the Company and the stockholder parties identified therein.	8-K	10.4	01/18/2022	
10.28*	Executive Chairman Agreement, dated as of January 17, 2022, by and between the Company and Jason Ryan.	10-K	10.31	03/14/2022	
10.29+	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	
10.30*	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	
10.31*	Amendment No.1 to the Amended and Restated Employment Agreement of Eric Schadt, dated June 14, 2022	8-K	10.1	06/14/2022	
10.32*	Employment Agreement of Kevin Feeley, dated January 14, 2022				X
10.33*	Amendment No. 1 to the Employment Agreement of Kevin Feeley, dated August 25, 2022	8-K	10.1	08/26/2022	
10.34#	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.				X
10.35	2022 Replacement Promissory Note				X
10.36*	Separation Agreement, dated as of August 12, 2022, by and between Sema4 Holdings Corp. and Eric Schadt	10-Q	10.6	08/15/2022	
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
101.INS	XBRL Instance Document	
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document	X
101.SCH	XBRL Taxonomy Extension Schema Document	X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document	X
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document	X
101.PRE	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: March 16, 2023

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, Jason Ryan and Kevin Feeley 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)	March 16, 2023
/s/ Kevin Feeley Kevin Feeley	Chief Financial Officer (Principal Financial Officer)	March 16, 2023
/s/ Jason Ryan Jason Ryan	Executive Chairman and Director	March 16, 2023
/s/ Eli D. Casdin Eli D. Casdin	Director	March 16, 2023
/s/ Dennis Charney Dennis Charney	Director	March 16, 2023
/s/ Emily Leproust Emily Leproust	Director	March 16, 2023
/s/ Keith Meister Keith Meister	Director	March 16, 2023
/s/ Joshua Ruch Joshua Ruch	Director	March 16, 2023
/s/ Richard Pfenninger, Jr. Richard Pfenninger, Jr.	Director	March 16, 2023
/s/ Rachel Sherman Rachel Sherman	Director	March 16, 2023