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, 2023

☐ **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: 0-26642

MYRIAD GENETICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**87-0494517**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
322 North 2200 West, Salt Lake City, UT	**84116**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (801) 584-3600

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.01 par value	MYGN	Nasdaq Global Select Market

Securities registered pursuant to Section 12(g) of the Exchange 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 Exchange Act. Yes ☐ No ☒

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

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

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

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

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

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

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

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

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

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant (without admitting that any person whose shares are not included in such calculation is an affiliate), computed by reference to the price at which the common stock was last sold on June 30, 2023 was $1,897,979,976.

As of February 21, 2024 the registrant had 89,874,886 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

The following documents (or parts thereof) are incorporated by reference into the following parts of this Form 10-K: Certain information required in Part III of this Annual Report on Form 10-K is incorporated from the Registrant's Proxy Statement, to be filed no later than 120 days following December 31, 2023, for the Annual Meeting of Stockholders expected to be held on June 6, 2024.

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Cautionary Statement Regarding Forward-Looking Statements

The Securities and Exchange Commission encourages companies to disclose forward-looking information so that investors can better understand a company's future prospects and make informed investment decisions. This Annual Report on Form 10-K contains such "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995.

Words such as "may," "anticipate," "estimate," "expects," "projects," "intends," "plans," "believes," "seek," "could," "continue," "likely," "will," "strategy" and "goal" and words and terms of similar substance used in connection with any discussion of future operating or financial performance identify forward-looking statements. All forward-looking statements are management's present expectations of future events and are subject to a number of known and unknown risks and uncertainties that could cause actual results, conditions, and events to differ materially and adversely from those anticipated. These risks include, but are not limited to:

- the risk that sales and profit margins of our existing tests may decline;
- the risk that we may not be able to operate our business on a profitable basis;
- risks related to our ability to achieve certain revenue growth targets and generate sufficient revenue from our existing product portfolio or in launching and commercializing new tests to be profitable;
- risks related to changes in governmental or private insurers' coverage and reimbursement levels for our tests or our ability to obtain reimbursement for our new tests at comparable levels to our existing tests;
- risks related to increased competition and the development of new competing tests;
- the risk that we may be unable to develop or achieve commercial success for additional tests in a timely manner, or at all;
- the risk that we may not successfully develop new markets or channels for our tests;
- the risk that licenses to the technology underlying our tests and any future tests are terminated or cannot be maintained on satisfactory terms;
- risks related to delays or other problems with operating our laboratory testing facilities and the transition of such facilities to our new laboratory testing facilities;
- risks related to public concern over genetic testing in general or our tests in particular;
- risks related to regulatory requirements or enforcement in the United States and foreign countries and changes in the structure of the healthcare system or healthcare payment systems;
- risks related to our ability to obtain new corporate collaborations or licenses and acquire or develop new technologies or businesses on satisfactory terms, if at all;
- risks related to our ability to successfully integrate and derive benefits from any technologies or businesses that we license, acquire or develop;
- the risk that we are not able to secure additional financing to fund our business, if needed, in a timely manner or on favorable terms, if it all;
- risks related to our projections or estimates about the potential market opportunity for our current and future products;
- the risk that we or our licensors may be unable to protect or that third parties will infringe the proprietary technologies underlying our tests;
- the risk of patent-infringement claims or challenges to the validity of our patents;
- risks related to changes in intellectual property laws covering our tests, or patents or enforcement, in the United States and foreign countries;
- risks related to security breaches, loss of data and other disruptions, including from cyberattacks;
- risks of new, changing and competitive technologies in the United States and internationally and that we may not be able to keep pace with the rapid technology changes in our industry, or properly leverage new technologies to achieve or sustain competitive advantages in our products;
- the risk that we may be unable to comply with financial or operating covenants under our credit or lending agreements;
- the risk that we may not be able to maintain effective disclosure controls and procedures and internal control over financial reporting;
- risks related to current and future investigations, claims or lawsuits, including derivative claims, product or professional liability claims, and risks related to the amount of our insurance coverage limits and scope of insurance coverage with respect thereto; and
- other factors discussed under the heading "Risk Factors" contained in Item 1A of this Annual Report on Form 10-K.

In light of these assumptions, risks and uncertainties, the results and events discussed in the forward-looking statements contained in this Annual Report on Form 10-K or in any document incorporated by reference might not occur. Stockholders are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date of this Annual Report on Form 10-K. We are not under any obligation, and we expressly disclaim any obligation, to update or alter any forward-looking statements, whether as a result of new information, future events or otherwise except as required by law. All forward-looking statements in this Annual Report on Form 10-K attributable to us or to any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section.

"We," "us," "our," "Myriad" and the "Company" as used in this Annual Report on Form 10-K refer to Myriad Genetics, Inc., a Delaware corporation, and its subsidiaries.

Myriad, the Myriad logo, BRACAnalysis, BRACAnalysis CDx, Colaris, ColarisAP, MyRisk, Myriad myRisk, MyRisk Hereditary Cancer, myChoice, Tumor BRACAnalysis CDx, MyChoice CDx, Prequel, Prequel with Amplify, Amplify, Foresight, Foresight Universal Plus, Precise Tumor, Precise Oncology Solutions, Precise Liquid, Precise MRD, FirstGene, SneakPeek, SneakPeek Early Gender DNA Test, SneakPeek Snap, Urosuite, Mygenehistory, Health.Illuminated., RiskScore, Prolaris, GeneSight, and EndoPredict are registered trademarks or trademarks of Myriad. Solely for convenience, trademarks, trade names and service marks referred to in this Annual Report on Form 10-K may appear without the ®, ™ or SM symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the right of the applicable licensor to these trademarks, trade names and service marks.

Market, Industry and Other Data

This Annual Report on Form 10-K may contain estimates, forecasts, projections and other information concerning our industry, our business and relevant markets, including data regarding the estimated size of relevant markets, patient populations, and the perceptions and preferences of patients and physicians regarding certain therapies, as well as data regarding market research and estimates. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are assumed in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources that we believe to be reliable. In some cases, we may not expressly refer to the sources from which this data is derived. In that regard, when we refer to one or more sources of this type of data in any paragraph, you should assume that other data of this type appearing in the same paragraph is derived from the same sources, unless otherwise expressly stated or the context otherwise requires.

PART I

Item 1. BUSINESS

Overview and Mission

We are a leading genetic testing and precision medicine company dedicated to advancing health and well-being for all. We develop and offer tests that help assess the risk of developing disease or disease progression and guide treatment decisions across medical specialties where genetic insights can significantly improve patient care and lower health care costs. Our genetic tests provide insights that help people take control of their health and enable healthcare providers to better detect, treat, and prevent disease.

Our Business Strategy

Personalized genetic data, digital, and virtual consumer trends are converging to change traditional models of care. We believe significant growth opportunities exist to help patient populations with pressing health care needs through innovative genetic and precision medicine solutions and services. Our focus is on innovation and growth in three key areas where we have specialized products, capabilities, and expertise: Oncology, Women's Health, and Pharmacogenomics. The pillars of our long-term growth strategy are founded on investments in science and innovation, technology-enabled operations, an elevated customer experience, strong commercial execution, and scalable operations. We believe our path to continued growth is driven by articulating our clinical differentiation, raising awareness with patients who we believe would benefit from our testing products, and innovation that improves clinical outcomes, ease of use, and access. By investing in tech-enabled commercial tools, new laboratory facilities, advanced automation, and standardized processes and technology, we believe we will be able to reduce complexity and cost, while enhancing our ability to scale and grow. We plan to expand some of our current products, such as our Foresight Universal Plus Test, which is an expanded carrier screening test that we anticipate launching in the second half of 2024. We also plan to launch new products, such as FirstGene, Precise Liquid, and Precise minimal residual disease, which we expect will help accelerate our growth. We intend to develop and enhance our products to support growth, improve patient and provider experience, and reach more patients of all backgrounds. We are committed to disciplined management of a key set of initiatives to fulfill our mission and drive long-term growth and profitability.

Testing

Our tests are generally designed to analyze genes and their expression levels to assess an individual’s risk for developing disease, determine a patient’s likelihood of responding to a particular drug, assess a patient’s risk of disease progression, identify factors which could lead to serious conditions in pregnancy, or provide other prenatal insights. We focus our efforts in the following three key areas where we have specialized products, capabilities, and expertise:

Oncology: Clarifying cancer risk and cancer treatment with genetic and genomic insights and companion diagnostic tests that are designed to work with corresponding drugs and treatments.

Women's Health: Providing differentiated genetic insights for women of all ancestries, assessing cancer risk, and offering prenatal testing solutions.

Pharmacogenomics: Providing genetic insights to help physicians understand how genetic alterations impact patient response to anti-depressants and other drugs.

The following tests are included in the key areas outlined above:

Oncology	Women's Health	Pharmacogenomics
MyRisk	MyRisk	GeneSight
BRACAnalysis CDx	Prequel	
MyChoice CDx	Foresight	
Prolaris	SneakPeek	
EndoPredict		
Precise Tumor		

Descriptions of our tests are as follows:

MyRisk™ Hereditary Cancer Test: *DNA sequencing test for assessing the risks for hereditary cancers.* Our MyRisk test is designed to determine a patient's hereditary cancer risk for breast, ovarian, uterine, renal, colorectal, endometrial, melanoma, pancreatic, prostate, skin and gastric cancers. The test analyzes 48 separate genes to look for deleterious mutations that put a patient at a substantially higher risk than the general population for developing one or more of these cancers. All 48 genes in the panel are well documented in clinical literature for the role they play in hereditary cancer and have been shown to have actionable clinical interventions for the patient to facilitate earlier cancer detection, lower disease risk or reduce risk of cancer recurrence. The MyRisk Genetic Test Result and MyRisk Management Tool® summarize medical society guidelines for managing a patient with a genetic mutation in view of their personal and family history of cancer. MyRisk also includes RiskScore® for all ancestries. RiskScore incorporates the patient's own clinical risk factors, family history, and unique genetic, ancestry-informed breast cancer risk markers to provide a personalized five-year and lifetime assessment of the risk of developing breast cancer—regardless of ancestry.

BRACAnalysis CDx® Germline Companion Diagnostic Test: *DNA sequencing test to help determine beneficial therapy for patients with metastatic breast, ovarian, metastatic pancreatic, or metastatic prostate cancer with deleterious or suspected deleterious germline BRCA variants.* Results of our BRACAnalysis CDx test are used as an aid to identify patients who are eligible for treatment with U.S. Food and Drug Administration (FDA) approved poly-ADP ribose polymerase (PARP) inhibitors. Currently, we are the only laboratory with an FDA-approved test for this indication and have received approvals from the FDA in ovarian cancer, metastatic breast cancer, pancreatic cancer, and advanced prostate cancer. The test is an in vitro diagnostic device intended for the qualitative detection and classification of variants in the protein coding regions and intron/exon boundaries of the *BRCA1* and *BRCA2* genes using genomic DNA obtained from whole blood specimens collected in ethylenediaminetetraacetic acid (EDTA).

MyChoice® CDx Companion Diagnostic Test: *tumor test that determines homologous recombination deficiency (HRD) status in patients with ovarian cancer.* This FDA-approved test helps provide information on the magnitude of benefit for PARP inhibitor therapy. HRD status is determined using two independent methods: *BRCA1* and *BRCA2* status that encompasses sequence variants and large rearrangements, and Genomic Instability Status (GIS) encompassing loss of heterozygosity, telomeric allelic imbalance, and large-scale state transitions across the entire genome. We believe that the combination of these methods is a more comprehensive way to measure HRD status, versus either one alone.

Prolaris® Prostate Cancer Prognostic Test: *RNA expression tumor analysis for assessing the aggressiveness of prostate cancer.* Our Prolaris test is a gene expression assay that assesses whether a patient is likely to have a slow growing, indolent form of prostate cancer that can be safely monitored through active surveillance, or a more aggressive form of the disease that may warrant aggressive intervention such as a radical prostatectomy or radiation therapy. The Prolaris test was developed to improve physicians' ability to predict disease outcome and thereby to optimize patient treatment.

EndoPredict® Breast Cancer Prognostic Test: *RNA expression test for assessing the aggressiveness of breast cancer.* The EndoPredict test is a next-generation RNA expression test used to determine which women with breast cancer may benefit from chemotherapy. EndoPredict predicts the likelihood of metastases to help guide treatment decisions for chemotherapy and extended endocrine therapy. EndoPredict has been shown to accurately predict risk of distant recurrence in Her 2-, ER+, node negative, and node positive breast cancer patients with no confusing intermediate results in 13 published clinical studies with more than 2,200 patients and is Conformitè Europëenne (CE) marked, which signifies European certification for clinical use.

Precise™ Tumor Molecular Profile Test: *a tumor profile test offered as part of Precise™ Oncology Solutions, a comprehensive solution for advanced precision oncology.* Precise Oncology Solutions combines our leading germline hereditary cancer tests (MyRisk/BRACAnalysis CDx), our HRD companion diagnostic test (MyChoice CDx), and a comprehensive genetic tumor panel. We believe Precise Oncology Solutions will help providers determine a clear, integrated, and personalized treatment plan for patients with cancer.

Prequel® Prenatal Screen: *a non-invasive prenatal screening (NIPS) test conducted using maternal blood to screen for severe chromosomal disorders in a fetus.* The Prequel test uses whole genome sequencing to assess for trisomies and monosomies in all 23 chromosomal pairs including the sex chromosomes, along with microdeletions associated with common genetic diseases. Prequel has a low test failure rate at less than 1 in 1,000 patients and has been validated in multiple clinical studies to be highly accurate. Prequel uses AMPLIFY™ technology that raises NIPS test performance most significantly for the types of patients who have traditionally had test failures on standard NIPS tests due to certain clinical factors. AMPLIFY is a NIPS technology that substantially reduces low fetal fraction test failures in order to allow for equity in care across all patients, regardless of body mass index (BMI), race, or ethnicity.

Foresight® Carrier Screen: *a prenatal test for future parents to assess their risk of passing on a recessive genetic condition to their offspring.* The Foresight test screens for carrier status of up to 176 genes associated with serious and prevalent inherited conditions. The test has been shown to have a detection rate of 99% across all ethnicities. Research has also shown that with prior knowledge of recessive genetic conditions, 76% of patients took preventive actions such as in-vitro fertilization with pre-implantation genetic testing to reduce the risk of having an affected offspring.

SneakPeek® Early Gender DNA Test: *a non-invasive blood test that predicts the gender of a fetus as early as six weeks of gestation with 99% accuracy.* Innovative cell free DNA technology and precise algorithms in the SneakPeek test are used to screen for a single, Y chromosome marker in the maternal blood sample. If Y chromosome markers are found in the mother's blood, the baby is male. If no Y chromosome markers are detected, the baby is female.

GeneSight® Psychotropic Mental Health Medication Test: *DNA genotyping test to aid psychotropic drug selection for patients suffering from depression, anxiety, attention-deficit/hyperactivity disorder (ADHD) and other mental health conditions.* The GeneSight test provides healthcare professionals with information about which medications may require dose adjustments, may be less likely to work for a patient, or may have an increased risk of side effects based on a patient's genetic makeup. Genesight covers over 60 medications commonly prescribed for depression, anxiety, ADHD, and other psychiatric conditions. Because genes influence the way a person’s body responds to specific medications, the medications may work differently for each person. Using DNA gathered from a simple cheek swab, the GeneSight test analyzes a patient’s genes and provides individualized information to help healthcare providers select medications that better match the patient’s genetic variations. Multiple clinical studies have shown that when clinicians used the GeneSight test to help guide treatment decisions in major depressive disorders, patients were more likely to respond to treatment compared to the standard of care.

Sales and Marketing

We sell our tests primarily through our own sales force and marketing efforts in the United States, Japan, Germany, and France, and we service additional global accounts through indirect sales channels. Our U.S. sales force is comprised of approximately 500 individuals across our dedicated sales channels. We continue to optimize our sales and marketing channels through increased digital marketing, direct to patient marketing, enhanced virtual sales tools, and inside sales teams to drive efficiency in our sales model. For example, in 2023, we formalized a national account focus in our Oncology and Women's Health products to address the needs of our largest accounts who are dealing with population health and value-based care decisions, while our field sales teams remained focused on core customers across channels. We continue to expand and strengthen our inside sales team with improved segmentation and territory alignment and by expanding our inside sales team to cover additional products. Our inside sales team focuses on a broader base of qualified leads, freeing up the field sales team to target higher potential clinical leads. We believe inside sales can be more cost effective in terms of customer acquisition costs. We believe we will be better able to execute on our strategies and fulfill our mission by engaging with providers and patients by meeting them when they are in the consumer or patient journey.

Research and Development

Our products stem from expert and innovative investigation into the biological underpinnings of serious human disease. We plan to continue to use our proprietary DNA sequencing and RNA expression technologies, including our supporting bioinformatics and robotic technologies, in an effort to efficiently discover and validate important biomarkers. We embed these biomarkers along with relevant clinical information in complex, proprietary tests that we believe are highly accurate and informative, and intended to help physicians better manage their patients’ health care. We believe that our technologies provide us with a significant competitive advantage and the potential for the continued development of numerous product opportunities. For example, in 2023 we completed analytical validation of FirstGene, a new product that is designed to report maternal and fetal carrier status, fetal aneuploidy risk, and Rhesus D antigen (RhD) status using a single maternal blood draw during pregnancy. Also in 2023, we achieved enrollment targets for a FirstGene prospective clinical validation study. We completed the development of, and launched, a research-use only minimum residual disease (MRD) product, and initiated study partnerships with MD Anderson Cancer Center and Memorial Sloan Kettering Cancer Center. We also launched a prospective study, MONITOR-Breast, that we expect will generate evidence of the clinical validity of our MRD testing product. For the years ended December 31, 2023, 2022, and 2021, we incurred research and development expense of $88.7 million, $85.4 million, and $81.9 million, respectively.

Industry and Competition

Healthcare is evolving to be more patient-centered and value-based. Patients, healthcare providers, payors, and health systems are looking to apply the power of genetic insights, molecular diagnostics, and precision medicine to advance care, improve access, and lower cost. We believe key industry trends include:

- accelerating shifts in consumer engagement, early detection, home-based care models, the rise of low-cost sequencing, telemedicine, and virtual care;
- expanding access to genetic insights, particularly among underserved populations with increased focus on health equity, reducing disparities in health care outcomes, and ensuring increased access for challenged communities;
- broader, more innovative use of large data sets and analytics;
- increasing adoption of biomarker laws on a state-by-state basis, which we expect will result in more growth and adoption of genetic testing by clinicians and acceptance by local reimbursement agencies; and
- growth in personalized medicine and the interest in new partnership models to advance companion diagnostics and serve patients with specific treatments based on their own genetic makeup and biology.

We believe these market trends create new opportunities to position us for organic growth and commercial success through the launch of new products and the enhancement of our existing products. Our focus is on articulating the clinical differentiation of our products and our commitment to being a reliable testing partner to patients and providers and innovative science that improves health outcomes, access for all, and ease of experience in the testing process. We expect to use our ability to innovate not only in research, development, and technology, but also in go-to-market approaches, commercial capabilities, and tech-enabled applications to adapt quickly to customer preferences and market dynamics.

To measure our success in driving towards a strong and friction-less experience for our patients and clinicians, we periodically conduct an internal Net Promoter Score survey with current users of our products. We have maintained a very healthy score since the implementation of the program in 2022, which gives us a strong benchmark to continue to work against as we strive to improve and innovate.

Oncology

In oncology, we offer testing for patients who have cancer and companion diagnostic tests that work with corresponding drugs and treatments. Our competitors in the oncology market include Invitae Corporation, Ambry Genetics Corporation, Natera, Inc., Foundation Medicine, Inc, Caris Life Sciences, Tempus, Laboratory Corporation of America Holdings, Quest Diagnostics Incorporated, and other commercial and academic laboratories.

As a leader in genetic testing and precision medicine, we provide insights that help people take control of their health, and enable healthcare providers to better detect, treat, and prevent disease. We believe that the key opportunities to grow our Oncology business are our expansion of companion diagnostics, market expansion through new clinical guidelines, and providing new offerings. For example, in the second quarter of 2023, we added Folate Receptor Alpha (FRα) to our Precise Oncology Solutions offering to expand treatment options for women living with ovarian cancer. FRα establishes patient eligibility for ELAHERE® (“mirvetuximab soravtansine-gynx”), the only FDA-approved drug indicated for patients who are FRα-positive and resistant to platinum-based chemotherapy. FRα is a newly recommended biomarker test included in the National Comprehensive Cancer Network treatment guidelines for ovarian cancer. Additionally, in the fourth quarter of 2023, we launched the Myriad Collaborative Research Registry™ (MCRR). The MCRR includes new data across germline and tumor testing results from our cancer products on more than one million patients. The latest enhancements make the MCRR freely available for research use and supports transparent clinical data sharing to advance the field.

In late 2024, we also plan to add a new liquid biopsy therapy selection test called Precise Liquid to the comprehensive Precise Oncology Solutions offering. The test is a comprehensive genomic profiling test that may serve as a first-line offering or as a reflex test if the solid tumor is insufficient, and it will allow blood for therapy selection at diagnosis and in the metastatic setting. We are also developing Precise MRD, a monitoring test based on whole genome sequencing to deeply interrogate tumors, detect cancer recurrence earlier, and help guide treatment decisions.

Women's Health

In the women's health market, we serve women assessing their genetic predisposition to cancer, offer prenatal tests for the assessment of fetal chromosomal disorders, and screen prospective parents for recessive genetic conditions that can be passed on to their offspring. We also offer the SneakPeek Early Gender DNA Test which can reveal a baby's gender as early as six weeks into pregnancy. We compete with multiple companies, including large national reference laboratories, specialty laboratories, academic/university laboratories, and kit-based products with our MyRisk, Foresight, Prequel and SneakPeek tests. Our competitors include Natera, Inc., Ambry Genetics Corporation, Laboratory Corporation of America Holdings, a subsidiary of Konica Minolta Inc., Quest Diagnostics Incorporated, and Peekaboo Early Detection Gender DNA Test. We compete mainly based on our test breadth and accuracy, equity in care capability, and our commercial scale.

We see opportunities to improve both our economics and the customer experience on these products. We remain focused on reimbursement for prenatal and carrier screening and finding streamlined patient payment models. We have recently expanded our physical footprint by growing our SneakPeek product presence into the retail pharmacy setting, which we believe is a strong opportunity for us to target consumers with our prenatal portfolio of offerings beyond directly through physicians. We also plan to improve customer experience with our online unified ordering portal to engage with patients and physicians, our cost estimators across our product lines, our remote product-specific customer service teams, and artificial intelligence-based tools for interacting with patients.

We expect to further simplify and advance prenatal care with the launch of FirstGene™, a comprehensive prenatal screening test. FirstGene combines the power of our Prequel NIPS with AMPLIFY technology on a whole exome platform with our Foresight Carrier Screen into a new 4-in-1 prenatal offering for NIPS, carrier screen, fetal recessive status, and feto-maternal blood compatibility. This new test, which is expected to launch in the first half of 2025, is designed to streamline the testing process and simplify workflow with a single maternal blood draw while providing early insight on the fetus with improved sensitivity for all pregnancies, helping to reduce unnecessary amniocentesis. We have previously announced our support for the guideline update by the American College of Medical Genetics and Genomics (ACMG), which reaffirmed the clinical value of NIPS to screen for a range of chromosomal abnormalities. ACMG continues to recommend offering screening for common trisomies (on chromosomes 13, 18, and 21) in all pregnancies, and guidance that provides a strong recommendation for offering screening for sex-chromosome aneuploidies (SCAs) and conditional support for offering screening for 22q microdeletion syndrome. As part of the NIPS within FirstGene, both SCAs and 22q are expected to be available as additional opt-in screening.

Foresight Universal Plus is an expanded carrier screening test with the same technology that differentiates Foresight's clinical utility in carrier screening. We plan to launch this test in the second half of 2024 in anticipation of the expansion of American College of Obstetricians and Gynecologists (ACOG) guidelines, which we anticipate will be expanded to include 274 genes. This new test will also include merged couple reporting to fully realize the value of this test to those individuals who are thinking about family planning.

Pharmacogenomics

In Pharmacogenomics, we help physicians understand how genetic alterations may impact patient response to antidepressants and other drugs. We believe our GeneSight Psychotropic Mental Health Medication Test meets a significant unmet clinical need and is a leading product to help physicians anticipate patient response to psychotropic drugs, the selection of which has historically been done through trial and error based approaches. The test is clinically proven to improve response rates in patients compared to standard of care. Our competitors in this market include Genomind, Tempus, Quest Diagnostics Incorporated, and Laboratory Corporation of America Holdings.

Key opportunities to grow our business in this market include growing awareness of pharmacogenomic opportunities for mental health treatment and driving physician adoption and utilization of our product to help guide treatment options. We are broadening access to GeneSight among front-line providers of mental health treatment, including primary care physicians and nurse practitioners who treat the majority of patients suffering from depression and anxiety, and through the expansion of sales and digital marketing capabilities. Moving forward, we are exploring the extension of GeneSight in other indications as well as other areas such as postpartum depression through our Women's Health business.

Seasonality

We have historically experienced seasonality in our testing business. In the quarter ended March 31, we typically experience a decrease in volumes due to the annual reset of patient deductibles. Additionally, the volume of testing is typically negatively impacted by the summer season, which is generally reflected in the quarter ended September 30. Conversely, the quarter ended December 31 is generally strong as we typically experience an increase in volumes from patients who have met their annual insurance deductible. In the fiscal year ended December 31, 2023, we did not experience seasonality to the same extent we have in prior years. For example, in the quarter ended September 30, 2023, we did not see the customary impact from the summer season as volumes decreased less than one percent in comparison to the quarter ended June 30, 2023. Historical patterns of seasonality may not continue in future years.

Human Capital Management

As a leader in genetic testing and precision medicine, our mission is to advance health and well-being for all by helping people take control of their health and enabling healthcare providers to better detect, treat and prevent disease. We believe the success of our mission depends, in part, on our ability to attract and retain qualified personnel. Our key human capital management objectives are to recruit, retain, and motivate the exceptional people needed to carry out our mission. To support these objectives and help our employees balance their work and personal lives, we maintain a flexible work environment and competitive compensation and benefits programs.

As of December 31, 2023, we have approximately 2,700 full-time equivalent employees. Most of our employees are engaged directly in sales and marketing, production, customer experience, billing, administration, technology, development, and research. Our employees are not covered by a collective bargaining agreement, and we consider our relations with our employees to be good.

One of our key human capital metrics is employee turnover. For the year ended December 31, 2023, our global voluntary employee turnover rate was 9%.

Diversity, Equity and Inclusion (DE&I): Our DE&I objective is to make Myriad a place where all employees have a sense of belonging. Myriad supports a culture of diversity, equity, and inclusion aligned with our company mission, vision, and values to drive company performance by creating opportunities and experiences for learning, development, and a sense of belonging for all employees. Our DE&I plan is focused on our people, mission, and community. We have seven employee-led resource groups (ERGs) that represent and support diverse communities in our workforce. These ERGs mentor, foster, encourage, and inspire employees in all stages of their careers by providing access to senior leadership, peer groups, mentoring, and other valuable resources to help them pursue their career ambitions.

As of December 31, 2023, 63% of our employees were women, and women held 42% of Myriad leadership roles (vice president and above). One third of the members of our Board of Directors are women, including the chairperson, and 44% of our Board members come from diverse gender, ethnic, and cultural backgrounds.

Compensation, Health, Wellness, Family Resources, and Other Benefits: Our compensation program is designed to attract and reward talented individuals who possess the skills necessary to support our business objectives, assist in the achievement of our strategic goals and create long-term value for our stockholders. We provide competitive salaries, stock ownership opportunities, and incentive and bonus programs. We also provide an expansive benefit offering including medical, dental and vision health care coverage, insurance and disability coverage, 401(k) investment plans with Company matching, tax advantaged savings accounts, paid time off and leaves of absence, parental leave, family formation benefits, employee assistance programs, including free mental health resources for employees and their dependents, community outreach programs, training and development opportunities, and wellness programs.

Career Development and Training: We offer several career development and training opportunities to our employees, including a curriculum of Company-sponsored technical, business and leadership courses, on-the-job training and a support network to all new employees, and tuition reimbursement for approved external training and educational pursuits.

Oversight and Management: We regularly conduct surveys to obtain feedback from our employees on a variety of topics, including employee engagement, Company strengths and focus areas, and culture drivers. The results are reviewed by our Board of Directors, the Compensation and Human Capital Committee, and senior leadership, who analyze areas of progress or deterioration and prioritize actions and activities in response to this feedback to drive meaningful improvements in employee engagement. Our most recent survey shows how these intentional efforts are making a difference as 86% of our employees rated us as a Great Place to Work®.

Social Responsibility and Community: At Myriad, corporate responsibility plays an important role in our approach to developing valuable and transformative diagnostic tests across major diseases to improve patients' lives. We believe that our corporate social responsibility programs build greater value for our patients, healthcare professionals and stockholders, support and improve the communities where we live and work, and empower our employees to become more engaged in the well-being of their own communities.

The corporate social responsibility programs at Myriad align with a clearly defined set of strategic priorities including:

- *Patient Assistance*: We are working to improve overall health care quality and increase access to diagnostic testing for uninsured and underinsured populations by offering robust financial assistance and free testing to those in need.
- *Advocacy*: We collaborate with and support key patient advocacy and support organizations where we can make a positive difference in addressing complex health challenges, providing and improving the quality of life for patients.
- *Environmental*: As described further below, we have created a Green Team that helps foster environmental and sustainability stewardship.
- *Scholarship*: We provide financial support for academic scholarship and education at both the undergraduate and post-graduate levels and contribute to advancing education and training for women and minorities in medicine and science.
- *Philanthropy*: We provide financial support to nonprofit organizations and share the expertise of our employees in the communities where we operate.

Environmental and Sustainability

We strive to do business in ways that protect both the health and safety of our employees and the world in which we operate by establishing, promoting, maintaining, and improving a culture of sustainability and environmental responsibility. In order to achieve our objectives, we have increased our focus on environmental and sustainability efforts that we are working towards fully implementing. The Nominating, Environmental, Social and Governance Committee of our Board of Directors is responsible for reviewing and evaluating our environmental, climate, safety, social and other corporate responsibility strategies, practices, and initiatives. We have also formed an internal Environmental, Social, and Governance (ESG) Committee in an effort to develop and maintain sustainable business practices.

In connection with our 2022 Environmental, Social and Governance Report, we completed our first carbon inventory, measuring our Scope 1 and Scope 2 emissions from the use of our laboratories and office spaces during the year ended December 31, 2022. Energy and emissions data was captured for select buildings with the largest footprint and used to model emissions from our remaining operations where limited or no data was available.

For more information on our approach to sustainability, please refer to our 2022 Environmental, Social and Governance Report, which is available on our website.

Patents and Proprietary Rights

We own or have license rights to various issued patents and patent applications in the United States and foreign countries. These patents and patent applications relate to a variety of subject matter, including diagnostic biomarkers, gene expression signatures, assays, assay reagents, informatics and data analytics, methods for determining genetic predisposition, methods for disease diagnosis, methods for determining disease progression, methods for determining disease treatment, and general molecular diagnostic techniques. For some of the patent assets, we hold rights through exclusive or non-exclusive license agreements. Material issued patent assets relating to our tests that generate material revenue are described in the table below, along with any related pending applications. These issued patents are expected to begin expiring on the respective dates noted below and any related applications, if issued as patents and depending on term adjustments or terminal disclaimers, if applicable, are expected to have similar expiration timeframes. These patents and applications contain multiple claims including but not limited to those claims described below.

Test	Patent Assets	Expiration	Claims
Prolaris Prostate Cancer Prognostic Test	We own one or more issued patents and pending patent applications in the U.S. and other jurisdictions relating to Prolaris testing.	These pending and issued patents have terms expected to begin expiring in 2030.	Claims relating to biomarkers, kits, systems and methods for detecting, diagnosing, prognosing and selecting therapy for prostate cancer.
EndoPredict Breast Cancer Prognostic Test	We own one or more issued patents and pending patent applications in the U.S. and other jurisdictions relating to EndoPredict testing.	These pending and issued patents have terms expected to begin expiring in 2031.	Claims relating to biomarkers, kits, systems and methods for prognosing and selecting therapy for breast cancer.
MyChoice CDx Companion Diagnostic Test	We own or hold a license to one or more issued patents and pending patent applications in the U.S. and other jurisdictions relating to MyChoice CDx testing.	These pending and issued patents have terms expected to expire in 2031.	Claims relating to biomarkers, kits, systems and methods for detecting homologous recombination deficiency and selecting therapy based on such detection.
GeneSight Psychotropic Mental Health Medication Test	We hold a license to one or more issued patents and pending patent applications in the U.S. and other jurisdictions relating to GeneSight testing.	These pending and issued patents have terms expected to begin expiring in 2024.	Claims relating to biomarkers, systems and methods for detecting single nucleotide polymorphisms and selecting and/or optimizing therapy based on such detection.
Foresight Carrier Screen	We own one or more issued patents and pending patent applications in the U.S. and other jurisdictions that relate to laboratory and informatic methods used to enhance Foresight testing.	These pending and issued patents have terms expected to begin expiring in 2032.	Claims relating to systems and methods for detecting genetic sequences.
Prequel Prenatal Screen	We own or hold a license to one or more issued patents and pending patent applications in the U.S. and other jurisdictions that relate to laboratory and informatic methods used to enhance Prequel testing.	These pending and issued patents have terms expected to begin expiring in 2032.	Claims relating to systems and methods for detecting genetic sequences.
MRD	We own one or more issued patents and pending patent applications in the U.S. or other jurisdictions relating to MRD testing.	These pending and issued patents have terms expected to begin expiring in 2026.	Claims relating to systems and methods for preparing enriched DNA fractions, detecting circulating tumor DNA, and identifying tumor variants

We intend to seek patent protection in the United States and major foreign jurisdictions for these and other inventions which we believe are patentable and where we believe our interests would be best served by seeking patent protection. However, any patents issued to us or our licensors may not afford meaningful protection for our products or technology or may be subsequently circumvented, invalidated or narrowed or found unenforceable. Any patent applications which we have filed, or will file, or to which we have licensed or will license rights may not issue, and patents that do issue may not contain commercially valuable claims. In addition, others may obtain patents having claims which cover aspects of our tests or processes which are necessary for or useful to the development, use or performance of our products. Should any other group obtain patent protection with respect to our discoveries, our commercialization of our tests could be limited or prohibited.

Others may offer genomic laboratory testing services which may infringe patents we control. We may seek to negotiate a license to use our patent rights or decide to seek enforcement of our patent rights through litigation. Patent litigation is expensive, the outcome is often uncertain and we may not be able to enforce our patent rights against others.

Our tests and processes may also conflict with patents which have been or may be granted to competitors, academic institutions or others. In addition, third parties could bring legal actions against us seeking to invalidate our owned or licensed patents, claiming damages, or seeking to enjoin clinical testing, development and marketing of our tests or processes. If any of these actions are successful, in addition to any potential liability for damages, we could lose patent coverage for our tests, be required to cease the infringing activity or obtain a license in order to continue to develop or market the relevant test or process. We may not prevail in any such action, and any license required under any such patent may not be made available on acceptable terms, if at all. Our failure to maintain patent protection for our tests and processes or to obtain a license to any technology that we may require to commercialize our tests and technologies could have a material adverse effect on our business.

We also rely upon unpatented proprietary technology, and in the future may determine in some cases that our interests would be better served by protecting certain technologies as trade secrets or through confidentiality agreements rather than patents or licenses. These include some of our genomic, proteomic, RNA expression, mutation analysis, robotic and bioinformatic technologies which may be used in discovering and characterizing new biomarkers and ultimately used in the development or analysis of tests. We also maintain a database of gene mutations and their status as either harmful or benign for some of our tests. To further protect our trade secrets and other proprietary information, we require that our employees and consultants enter into confidentiality and invention assignment agreements. However, those confidentiality and invention assignment agreements may not provide us with adequate protection. We may not be able to protect our rights to such unpatented proprietary technology and others may independently develop substantially equivalent technologies. If we are unable to obtain strong proprietary rights to our processes or tests, competitors may be able to market competing processes and tests.

License Agreements

We are a party to license agreements which give us the rights to use certain technologies in the research, development, testing processes, and commercialization of our tests. These licenses generally end on the expiration of the last to expire patent rights covered by the applicable license agreement. We may not be able to continue to license these technologies on commercially reasonable terms, if at all. In addition, each license may be terminated by the licensor in the event of an uncured breach by us of any material term of the applicable license agreement. Patents underlying our license agreements may not afford meaningful protection for our technology or tests or may be subsequently circumvented, invalidated or narrowed, or found unenforceable. Our failure to maintain rights to this technology could have a material adverse effect on our business. The table below lists important licenses to technology that is incorporated into tests that generate material revenue:

Entity	Subject	Royalties	Expiration
University of Texas M.D. Anderson Cancer Center (UTMDACC)	Exclusive world-wide right to certain rights of UTMDACC in intellectual property relating to our MyChoice HRD testing.	We pay UTMDACC a royalty based on net sales of our MyChoice HRD test.	License runs for the term of the UTMDACC agreement and, in any event, expires or may be terminated upon expiration of the last to expire patent right covered by the UTMDACC agreement.
Mayo Foundation for Medical Education and Research (Mayo)	Exclusive world-wide license to certain rights of Mayo in intellectual property relating to our GeneSight testing.	We pay Mayo a royalty based on net sales of our GeneSight test.	License runs for the term of the Mayo agreement and, in any event, expires or may be terminated upon expiration of the last to expire patent right covered by the Mayo agreement.
Children's Medical Center in Boston (CMCC)	Exclusive world-wide right to certain rights of CMCC in intellectual property relating to our MyChoice HRD testing.	We pay CMCC a royalty based on net sales of our MyChoice HRD test.	License runs for the term of the CMCC agreement and, in any event, expires or may be terminated upon expiration of the last to expire patent right covered by the CMCC agreement.
Institut Curie and INSERM (INSERM)	Exclusive world-wide right to certain rights of INSERM in intellectual property relating to our MyChoice HRD testing.	We pay INSERM a royalty based on net sales of our MyChoice HRD test.	License runs for the term of the INSERM agreement and, in any event, expires or may be terminated upon expiration of the last to expire patent right covered by the INSERM agreement.
Illumina, Inc.	Non-exclusive license to certain rights held by or licensed to Illumina to intellectual property relating to non-invasive prenatal screening and the Prequel test.	We pay Illumina a royalty based on the volume of Prequel testing administered by us.	License runs for the term of the Illumina agreement and, in any event, expires or may be terminated upon expiration of the last to expire patent right covered by the Illumina agreement.

Governmental Regulation

Our operations are regulated by federal, state and foreign governmental authorities. 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

Each of 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 are subject to the Clinical Laboratory Improvement Amendments of 1988 (CLIA). CLIA requires such laboratories to be certified by the federal government and mandates compliance with various operational, personnel, facilities administration, quality and proficiency testing requirements intended to ensure that testing services are accurate, reliable and timely. CLIA certification also is a prerequisite to be eligible to bill state and federal health care programs, as well as many private third-party payors, for laboratory testing services. Our laboratories in Salt Lake City, Utah, Mason, Ohio, and South San Francisco, California are CLIA certified to perform high complexity tests.

CLIA requires each of our certified clinical laboratories to enroll in an approved proficiency testing program if performing testing in any category for which proficiency testing is required. Each of our clinical laboratories periodically tests specimens received from an outside proficiency testing organization and then submits the results back to that organization for evaluation. If one of our laboratories fails to achieve a passing score on a proficiency test, then it may lose its right to perform testing. Further, failure to comply with other proficiency testing regulations, such as the prohibition on referral of a proficiency testing specimen to another laboratory for analysis, can result in revocation of the laboratory's CLIA certification.

As a condition of CLIA certification, each of our clinical laboratories is subject to survey and inspection every other year, 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. Because our clinical laboratories are accredited by the College of American Pathologists (CAP), which is a CMS-approved accreditation organization, they are typically subject to CAP rather than CMS inspections.

Our laboratories are licensed by the appropriate state agencies in the states in which they operate, if such licensure is required. In addition, our laboratories hold state licenses or permits, as applicable, from various states, including, but not limited to, California, New York, Pennsylvania, Rhode Island and Maryland, to the extent that they accept specimens from one or more of these states, each of which requires out-of-state laboratories to obtain licensure.

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 financial penalties or fines, or imprisonment. Loss of a laboratory's CLIA certificate or state license may also result in the inability to receive payments from state and federal health care programs as well as private third-party payors. We believe that we are in material compliance with CLIA and all applicable licensing laws and regulations.

Food and Drug Administration

In the United States, in vitro diagnostic (IVD) products are subject to regulation by the FDA as medical devices to the extent that they are intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease. They are subject to premarket review and post-market controls that will differ depending on how the FDA classifies a specific IVD, which is further defined in the FDA's implementing regulations as a device intended for use in the collection, preparation, and examination of specimens taken from the human body. For certain types of tests known as laboratory developed tests (LDTs)—which are in vitro diagnostic tests that are designed, manufactured and used within a single laboratory—FDA regulation is less clear than for IVDs. Historically, the FDA has exercised enforcement discretion for LDTs, which means that the FDA generally has not enforced premarket review and other applicable FDA requirements. However, as LDTs have increased in complexity, the FDA has taken a risk-based approach to their regulation. Congress has also signaled interest in clarifying the regulatory landscape for LDTs. Following several years of inaction by Congress on this issue, the FDA issued a proposed rule in October 2023 to regulate LDTs under the current medical device framework and proposed to phase out the current enforcement discretion policy; the public comment period ended in early December 2023.

The FDA's proposal envisions that the LDT enforcement policy phase-out process would occur in gradual stages over a total period of four years, with premarket approval applications for high-risk tests to be submitted by the 3.5-year mark, although more details are expected to be provided with the upcoming final rule. The likelihood of the FDA finalizing the proposed rule in April 2024 (as is currently projected), as well as potential litigation challenging the agency's authority to take such action, is uncertain at this time. Affected stakeholders continue to press for a comprehensive legislative solution to create a harmonized paradigm for oversight of LDTs by both the FDA and CMS, instead of implementation of the proposed FDA administrative action, which may be disruptive to the industry and to patient access to certain diagnostic tests. In the absence of a comprehensive legislative solution, however, the FDA has indicated its intent to finalize this rulemaking. Ensuring compliance with the agency's future implementation plans for bringing LDTs under the medical device framework is expected to require significant time, financial resources, and other resources, including specialized personnel, on the part of clinical laboratories engaged in developing and offering such diagnostic tests.

Separately, members of Congress have been working with stakeholders for several years on a possible bill to reform the regulation of in vitro clinical tests including LDTs. For example, as drafted and re-introduced for consideration by the current Congress, the Verifying Accurate, Leading-edge IVCT Development (VALID) Act would codify into law the term as "in vitro clinical test" (IVCT) and establish a new regulatory framework for the review and oversight of IVCTs separate and apart from the medical device framework under the Food, Drug and Cosmetic Act (FDCA). The new IVCT product category would include products currently regulated as IVDs, in addition to LDTs. The proposed regulatory framework adopts various concepts from the FDCA, utilizing a risk-based approach that aims to ensure that all marketed IVCTs have a reasonable assurance of both analytical and clinical validity, and includes a proposed future user fee program for IVCTs. If enacted, the VALID Act would also create a new system for clinical laboratories and hospitals to submit their clinical tests electronically to the FDA for approval, among other potentially significant changes to current regulatory requirements applicable to the laboratory industry as a whole. This system is aimed at reducing the amount of time that it takes for the agency to approve such tests, and it would also establish a new program to expedite the development of diagnostic tests that can be used to address a current unmet need for patients.

It is unclear whether the VALID Act will be passed by Congress in its current form or signed into law by the President; if enacted, however, it is expected to require clinical laboratories to spend significant time, resources, and money towards ensuring compliance. Until the FDA finalizes LDT regulations through its recently initiated notice-and-comment rulemaking process, or the VALID Act or other legislation is passed reforming the federal government's current regulatory approach to LDTs, it is unknown how the FDA may regulate our LDT products in the future or what testing and data may be required to support clearance or approval for such products.

In Vitro Diagnostics as Medical Devices

The information that must be submitted to the FDA in order to obtain clearance or approval to market a new IVD varies depending on how the device is classified by the FDA. Medical devices are classified into one of three classes on the basis of the controls deemed by the FDA to be necessary to reasonably ensure their safety and effectiveness. Class I devices are subject to general controls, including labeling and adherence to the FDA's quality system regulations, which are device-specific good manufacturing practices. Class II devices are subject to premarket notification, general controls and sometimes special controls, such as performance standards and post-market surveillance. Class III devices are subject to most of the previously identified requirements as well as to premarket approval. All Class I devices are exempt from premarket review, most Class II devices require 510(k) clearance, and all Class III devices must receive premarket approval before they can be sold in the United States. If a previously unclassified new medical device does not qualify for the 510(k) pathway because no predicate device to which it is substantially equivalent can be identified, the device is automatically classified into Class III. However, if such a device would be considered low or moderate risk, it may be eligible for the De Novo classification process. The De Novo classification process allows a device developer to request that the novel medical device be reclassified as either a Class I or Class II device, rather than having it regulated as a high-risk Class III device subject to the premarket approval requirements. The payment of a fee, typically adjusted annually, to the FDA is usually required when a 510(k) notification, premarket approval application, or De Novo classification request is submitted.

510(k) Premarket Notification and De Novo Classification

A 510(k) notification requires the sponsor to demonstrate that an IVD is substantially equivalent to another marketed device, termed a "predicate device," that is legally marketed in the United States and for which a premarket approval (PMA) application was not required. A device is substantially equivalent to a predicate device if it has the same intended use and technological characteristics as the predicate; or has the same intended use but different technological characteristics, where the information submitted to the FDA does not raise new questions of safety and effectiveness and demonstrates that the device is at least as safe and effective as the legally marketed device. Clinical trials are almost always required to support a PMA application and are sometimes required for a De Novo classification request or a 510(k) premarket notification. Further, Congress recently amended the FDCA to require sponsors of most clinical studies of investigational medical devices intended to support marketing authorization to design and submit a diversity action plan for such clinical trial. The action plan must include the sponsor's diversity goals for enrollment, as well as a rationale for the goals and a description of how the sponsor will meet them. The FDA may grant a waiver for some or all of the requirements for a diversity action plan. It is unknown at this time how the diversity action plan may affect clinical trial planning or what specific information the FDA will expect in such plans, but if the FDA objects to a sponsor's diversity action plan or otherwise requires significant changes to be made, it could delay initiation of the relevant clinical trial.

If the FDA determines that the applicant's device is substantially equivalent to the identified predicate device(s), the agency will issue a 510(k) clearance letter that authorizes commercial marketing of the device for one or more specific indications for use. Requests for additional data, including clinical data, will increase the time necessary to review the notice. If the FDA believes that the IVD is not substantially equivalent to a predicate device, it will issue a "Not Substantially Equivalent" letter, stating that the new device may not be commercially distributed and designating the device as a Class III device, which will require the submission and approval of a PMA application before the new device may be marketed. Alternatively, the applicant may be able to submit a De Novo classification request to have it regulated as a Class I or Class II device. The FDA's De Novo regulations became effective on January 3, 2022. Among other things, if the manufacturer seeks reclassification into Class II, the classification request must include a draft proposal for special controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the device.

As an alternative to the De Novo classification process, the manufacturer could also file a reclassification petition seeking to change the automatic Class III designation of a novel post-amendment device under Section 513(f)(3) of the FDCA. The FDA can also initiate reclassification of an existing device type on its own initiative, and it recently issued a final rule to clarify the administrative process through which the agency reclassifies a medical device.

After a new medical device receives 510(k) clearance from the FDA, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance or could require the submission of a PMA application. The FDA continues to reevaluate the 510(k) pathway and other medical device programs and has taken what it describes as a risk-based approach to develop innovative regulatory policy to propose a more "contemporary" approach to the life cycle oversight of medical devices and IVDs. We cannot predict what if any additional regulatory changes will occur or how they will affect our current or future products.

Premarket Approval

The PMA process is more complex, costly and time consuming than the 510(k) process. As with a De Novo classification request, a PMA application must be supported by more detailed and comprehensive scientific evidence, including clinical data, to demonstrate the safety and efficacy of the IVD for its intended purpose. If the device is determined to present a "significant risk," the sponsor may not begin a clinical trial until it submits an investigational device exemption (IDE) to the FDA and obtains approval to begin the trial.

After the PMA application is submitted, the FDA has 45 days to make a threshold determination that the PMA application is sufficiently complete to permit a substantive review. If the PMA application is complete, the FDA will file the PMA. The FDA is subject to a performance goal review time for a PMA application that is 180 days from the date of filing, although in practice this review time is longer. Questions from the FDA, requests for additional data including additional clinical data and referrals to advisory committees may delay the process considerably. The total process may take several years and there is no guarantee that the PMA application will ever be approved. Even if approved, the FDA may limit the indications for which the device may be marketed. New PMA applications or PMA supplements may be required for modifications to the manufacturing process, labeling, device specifications, materials or design of a device that is approved through the PMA process.

Regulation of Companion Diagnostic Devices

If a sponsor or the FDA believes that a diagnostic test is essential for the safe and effective use of a corresponding therapeutic product, the sponsor of the therapeutic product will typically work with a collaborator to develop an IVD companion diagnostic device. The FDA has issued a final guidance document entitled "*In Vitro* Companion Diagnostic Devices" that is intended to assist companies developing in vitro companion diagnostic devices and companies developing therapeutic products that depend on the use of a specific in vitro companion diagnostic for the safe and effective use of the product. In the guidance, the FDA defined an IVD companion diagnostic device as a device that provides information that is essential for the safe and effective use of a corresponding therapeutic product. The FDA also noted that in some cases, if evidence is sufficient to conclude that the IVD companion diagnostic device is appropriate for use with a class of therapeutic products, the intended use/indications for use should name the therapeutic class, rather than each specific product within the class. In April 2020, FDA published another final guidance entitled "Developing and Labeling In Vitro Companion Diagnostic Devices for a Specific Group or Class of Oncology Therapeutic Products" that expands on the idea of a class of therapeutic products. The more recent guidance describes considerations for the development and labeling of *in vitro* companion diagnostic devices to support the indicated uses of multiple drug or biological oncology products, when appropriate. The FDA expects that the therapeutic sponsor will address the need for an approved or cleared IVD companion diagnostic device in its therapeutic product development plan and that, in most cases, the therapeutic product and its corresponding IVD companion diagnostic will be developed contemporaneously. To that end, the FDA has also issued draft guidance entitled "Principles for Codevelopment of an In Vitro Companion Diagnostic Device with a Therapeutic Product" to serve as a practical guide to assist therapeutic product sponsors and IVD sponsors in developing a therapeutic product and an accompanying IVD companion diagnostic, as well as final guidance entitled "Developing and Labeling In Vitro Companion Diagnostic Devices for a Specific Group or Class of Oncology Therapeutic Products" to facilitate class labeling on diagnostic tests for oncology therapeutic products.

The FDA has indicated that it will apply a risk-based approach to determine the regulatory pathway for IVD companion diagnostic devices, as it does with all medical devices. This means that the regulatory pathway will depend on the level of risk to patients, based on the intended use of the IVD companion diagnostic device and the controls necessary to provide a reasonable assurance of safety and effectiveness.

If the companion diagnostic test will be used to make critical treatment decisions such as patient selection, treatment assignment, or treatment arm, it will likely be considered a significant risk device for which a clinical trial will be required. The sponsor of the IVD companion diagnostic device will be required to comply with the FDA's IDE requirements that apply to clinical trials of significant risk devices. If the diagnostic test and the therapeutic drug are studied together to support their respective approvals, the clinical trial must meet both the IDE and investigational new drug application (IND) requirements. We expect that any IVD companion diagnostic device developed for use with drug products will utilize the PMA pathway and that a clinical trial performed under an IDE will have to be completed before the PMA application may be submitted.

We are developing companion diagnostic tests for use with drug products in development by pharmaceutical companies, such as our collaborations with pharmaceutical companies on PARP inhibitors for the treatment of ovarian, breast and other cancers. The FDA has also introduced the concept of a complementary diagnostic that it defines as a test that is not required but which provides significant information about the use of a drug. A complementary test can help guide treatment strategy and identify which patients are likely to derive the greatest benefit from therapy, and if approved by the FDA, information regarding the IVD will be included in the therapeutic product labeling. Although the FDA has not yet issued any written guidance regarding complementary diagnostics, it has approved some complementary diagnostics, including a supplementary premarket approval for BRACAnalysis CDx and MyChoice CDx as complementary diagnostic tests in ovarian cancer patients associated with enhanced progression-free survival (PFS) when used with the PARP inhibitor Zejula™ (niraparib).

In December 2014, we first obtained premarket approval for BRACAnalysis CDx, which is used as a companion diagnostic test to identify ovarian cancer patients who may benefit from AstraZeneca's PARP inhibitor Lynparza™ (olaparib). Since then, other indications for BRACAnalysis CDx in ovarian, breast, prostate and pancreatic cancer have received supplemental PMA approval as a companion diagnostic for Lynparza. The MyChoice CDx test has also received approvals as a companion diagnostic test. The premarket approval process for companion or complementary diagnostics is a complex, costly and time-consuming procedure. Approvals must be supported by valid scientific evidence, submitted as part of a PMA application, which typically requires extensive data, including quality technical, preclinical, clinical and manufacturing data to demonstrate to the FDA's satisfaction the safety and effectiveness of the companion diagnostic. We are currently collaborating with several bio-pharmaceutical companies for additional indications and geographical commercialization opportunities for BRACAnalysis CDx and MyChoice CDx as companion diagnostics with other drugs.

Ongoing Post-Market Regulatory Requirements in the United States

Any products sold by us pursuant to FDA clearances or approvals will be subject to pervasive and continuing regulation by the FDA. In particular, after a medical device is placed on the market, applicable regulatory requirements include:

- compliance with the FDA's Quality System Regulation (QSR), which requires manufacturers to follow stringent design, testing, control, documentation, record maintenance, including maintenance of complaint and related investigation files, and other quality assurance controls during the manufacturing process;
- labeling and advertising regulations, which prohibit the promotion of FDA-regulated medical products for uncleared, or unapproved uses, or "off-label" uses, and impose other restrictions on labeling; and
- medical device reporting obligations, which require that manufacturers investigate and report to the FDA adverse events, including deaths, or serious injuries that may have been or were caused by a medical device and malfunctions in the device that would likely cause or contribute to a death or serious injury if it were to recur.

In addition, device manufacturers are required to register their establishments and list their devices with the FDA and are subject to periodic inspections by the FDA and certain state agencies. Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA and other enforcement agencies, which may include sanctions, including but not limited to, warning letters; fines, injunctions and civil penalties; recall or seizure of the device; operating restrictions, partial suspension or total shutdown of production; refusal to grant 510(k) clearance or approval of PMAs of new devices; withdrawal of clearance or approval; and civil or criminal prosecution.

Regulation of In Vitro Diagnostics and Companion Diagnostic Devices Outside the United States

Products intended for use in IVD applications require regulatory approvals in many other countries and geographic areas, some of which also provide for approval of companion diagnostics.

European Union

In the European Union (EU), IVD medical devices historically were regulated under the EU Directive 98/79/EC of the European Parliament and of the Council on in vitro diagnostic medical devices (the Directive). IVDs were not subject to pre-market authorization by a National Competent Authority (NCA) under the Directive, but instead had to comply with essential requirements based on conformity with harmonized standards. For certain IVDs, compliance with the essential requirements was subject to assessment by a Notified Body. Notified bodies are entities designated by the relevant NCAs and are responsible for assessing the conformity of IVDs before they are placed on the EU market. Under the Directive, the majority of IVDs could be placed on the market as a result of the manufacturer self-certifying the IVD as being in conformity with the essential requirements, without the involvement of a Notified Body.

The Directive was replaced by the Regulation (EU) 2017/746 of the European Parliament and of the Council on *in vitro* diagnostic medical devices (IVDR) that entered into force in May 2017, and which initially included a 5-year period until its original effective date of May 26, 2022, plus some transition provisions for IVDs already on the market. Unlike the Directive, which specifies certain requirements that must be achieved by each Member State and permits each Member State to decide how to transpose the Directive into national law to meet those requirements, the IVDR has direct binding legal force throughout every Member State without the need for national implementation. The major goals of the IVDR are to standardize diagnostic procedures within the EU, increase reliability of diagnostic analysis and enhance patient safety. Under the IVDR, IVDs are subject to additional legal regulatory requirements as compared to the Directive. Among other things, the IVDR introduces a new risk-based classification for IVDs and specifies CDx and genetic tests as Class C products (second highest risk). Under the IVDR, Class C IVDs require assessment by a Notified Body for certification and audit of the manufacturer's quality management system (QMS) before they can be placed on the market. The IVDR also obligates laboratories located outside the EU to comply with the IVDR if testing specimens from European citizens. Compliance with the IVDR may be expensive and time-consuming. Manufacturers will need to provide significant evidence to demonstrate that a device performs safely and effectively. Performance data may require the conduct of additional clinical investigations or performance studies, with additional and more strict requirements under the IVDR. As noted above, the vast majority of IVDs under the Directive are self-certified, so many device manufacturers have not previously been subject to the Notified Body audits that will occur under the IVDR and will have to revise their QMS and Technical Documentation which will now be reviewed by the Notified Bodies. Companion diagnostic IVDs may also be reviewed by the competent medicinal product authorities, usually the European Medicines Agency, as part of a consultation process that will be part of the conformity assessment procedure. There will also be a greater emphasis on post-market surveillance and submission of post-market performance follow-up reports.

Due to multiple challenges to IVD manufacturers being ready for full application by the May 2022 implementation date, Regulation (EU) 2022/112 of the Parliament and of the Council was published on January 25, 2022 allowing for a delay to the application of the IVDR by amending the transition provision for certain *in vitro* diagnostic medical devices. For products classified as Class C under the IVDR, the transition period allows for legacy devices with a valid declaration of conformity drawn up prior to May 26, 2022 to continue to be placed on the market until May 26, 2026. On January 23, 2024, the European Commission announced proposals to further extend the IVDR transition provisions in order to ensure availability of IVDs. Under the proposal, the transition period in the IVDR will be extended to December 2028 for Class C high individual and/or moderate public health risk devices. Medical devices certified under the Directive may benefit from the extension provided they meet certain conditions (i.e., continue to comply with the Directive, not be the subject of significant changes on design or intended purpose, etc.). The proposal needs to be adopted by the European Parliament and Council before it enters into force. Certain IVDR requirements, including post-market surveillance, market surveillance, vigilance, and registration of economic operators and devices remained effective on the May 26, 2022 implementation date.

United Kingdom

The withdrawal of the United Kingdom (UK) from the EU has had ramifications for IVD manufacturers.

The UK Medicine and Healthcare products Regulatory Agency (MHRA) issued guidance on the regulation of IVDs in the UK following Brexit, and changed the applicable legislation in the UK to take account of the fact that the UK is now a free-standing regulatory regime. However, the UK remains broadly aligned with the EU Directive.

As described in these provisions, MHRA will continue to recognize CE marks within Great Britain, which is defined as England, Scotland and Wales, up to July 2030 for certain devices in order to align with EU transition periods. Companies wishing to place IVDs on the UK market are also required to register with MHRA and have to appoint a UK Responsible Person to manage their compliance efforts in the UK, but are still able to sell CE-IVD marked products in Great Britain. From approximately July 2025, new legislation will apply in the UK to better align with the IVDR and other international requirements, including requirements for the new marking called a UK Conformity Assessed mark (UKCA). This mark, which can be obtained now, is not recognized in EU countries, meaning that companies that wish to sell in the UK and the EU will have to seek both a UKCA and CE-IVD mark in the future. The EU legislative framework applies in Northern Ireland, meaning that companies can still, and will still be able to, sell tests in Northern Ireland under applicable EU IVD regulations including the current IVDR.

Japan

IVDs are regulated in Japan by the Pharmaceutical and Medical Devices Agency (PMDA) and are assigned to one of three classes depending on the perceived level of risk. Those in the least risky class may be registered and marketed after filing a pre-market submission, while those in the middle class are subject to pre-market certification by a registered certification body. The riskiest IVDs must be approved. Submissions may be made only by marketing authorization holders, which must satisfy specific requirements.

Significant revisions to Japanese regulations of medical devices, IVDs and other health care products are ongoing. The first round of changes to Japan's Pharmaceuticals and Medical Devices Act took effect September 1, 2020 and August 2021. The revision in May 2022 created the fast track approval of IVDs conditional or time-limited approval in emergency situations when the efficacy of medical product is presumed, subject to safety confirmation. The Ministry of Health, Labour and Welfare will start discussion in May 2024 on the upcoming revision of the Pharmaceuticals and Medical Devices Act, which includes a reform of sales system of the medical products which may include IVDs.

Additional International Regulation

We market, directly or through distributors, some of our tests outside of the United States and are subject to foreign regulatory requirements governing laboratory licensure, human clinical testing, use of tissue, privacy and data security, and marketing approval for our tests. These requirements vary by jurisdiction, differ from those in the United States and may require us to implement additional compliance measures or perform additional pre-clinical or clinical testing. In many countries outside of the United States, coverage, pricing and reimbursement approvals are also required. We are also required to maintain accurate information on and control over sales and distributors' activities that may fall within the purview of the Foreign Corrupt Practices Act, its books and records provisions and its anti-bribery provisions, as well the UK Bribery Act and other anti-corruption laws.

HIPAA and Other Privacy Laws

The Health Insurance Portability and Accountability Act of 1996 (HIPAA), which applies to health plans, healthcare clearing houses, and healthcare providers that conduct certain health care transactions electronically (Covered Entities) contains provisions that address the privacy and security of individually identifiable health information (called "protected health information" under HIPAA), the standardization of identifying numbers used in the healthcare system and the standardization of certain health care transactions. HIPAA's privacy regulations protect health information by limiting its use and disclosure to certain purposes, such as treatment or payment, without patient authorization. HIPAA also gives patients certain rights including the right to access their medical records and the right to an accounting of certain disclosures of protected health information. HIPAA's privacy rule also limits many disclosures of protected health information to the minimum amount necessary to accomplish an intended purpose. The HIPAA security standards require the adoption of administrative, physical, and technical safeguards for the protection of protected health information and the adoption of written security policies and procedures.

The Health Information Technology for Economic and Clinical Health Act (HITECH) expanded and strengthened HIPAA, created new targets for enforcement, imposed new penalties for noncompliance and established new breach notification requirements for Covered Entities. Under HITECH's breach notification requirements, Covered Entities must report breaches of protected health information that has not been encrypted or otherwise secured in accordance with guidance from the Secretary of the U.S. Department of Health and Human Services. Required breach notices must be made as soon as is reasonably practicable, but no later than 60 days following discovery of the breach. Reports must be made to affected individuals and to the Secretary and, in some cases depending on the size and impact of the breach, they must be reported through local and national media. Breach reports can lead to investigation, enforcement, civil monetary penalties and civil litigation, including class action lawsuits and enforcement by state authorities as well as significant reputational harm.

We are currently subject to the HIPAA regulations and maintain an active compliance program that is designed to meet requirements of the privacy and security rules and to identify privacy and security incidents and other issues in a timely fashion so that we may remediate, mitigate harm and report if required by law. However, even if we take steps to comply with HIPAA, we may be subject to breaches caused by human error or external threat actors, complaints and investigation at the federal and/or state level. In the event of a breach, even if we mitigate harm and make required reports on a timely basis, we may still be subject to penalties for the underlying breach.

In addition to the federal privacy and security regulations, there are a number of state laws regarding the privacy and security of health information and personal data that can be applicable to our clinical laboratories, as further discussed in the "Risk Factor" section below. Many states have also implemented genetic testing laws imposing specific patient consent requirements and protecting genetic information by limiting the use and disclosure of such information. State requirements are particularly stringent regarding predictive genetic tests, due to the risk of genetic discrimination against healthy patients identified through testing as being at risk for disease. Compliance with health information privacy and security statutes and regulations, including genetic testing and genetic information privacy laws in all jurisdictions, both state and federal, can be challenging as these laws often change, and we may not be able to maintain compliance in all jurisdictions where we do business.

Transparency Laws and Regulations

A federal law known as the Physician Payments Sunshine Act requires medical device manufacturers to track and report to CMS certain payments and other transfers of value made to covered recipients, which include physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse-midwives who are not bona fide employees of the manufacturer, as well as teaching hospitals, and ownership or investment interests held by physicians and their immediate family members. Manufacturers must report data for the previous calendar year by the 90th day of the then-current calendar year. CMS then publishes the data on a publicly available website no later than June 30. There are also state “sunshine” laws that require manufacturers to provide reports to state governments on pricing and marketing information. Several states have enacted legislation requiring medical device manufacturers to, among other things, establish marketing compliance programs, file periodic reports with the state, and make periodic public disclosures on sales and marketing activities, and such laws may also prohibit or limit certain other sales and marketing practices. These laws may adversely affect our sales, marketing, and other activities by imposing administrative and compliance burdens on us. If we fail to track and report as required by these laws or to otherwise comply with these laws, we could be subject to the penalty provisions of the pertinent state and federal authorities.

Reimbursement and Billing

Reimbursement and billing for diagnostic services is highly complex. Laboratories must bill various payors, such as private third-party payors, including managed care organizations (MCOs), and state and federal health care programs, such as Medicare and Medicaid, and each may have different billing requirements. Additionally, the audit requirements imposed by these payors, as well as our internal compliance policies and procedures, add further complexity to the billing process. Other factors that complicate billing include:

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

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

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

Presently, approximately 62% of our revenue comes from private third-party payors.

In April 2014, Congress passed the Protecting Access to Medicare Act of 2014 (PAMA), which included substantial changes to the way in which CMS pays for clinical laboratory services under Medicare's Clinical Laboratory Fee Schedule (CLFS). PAMA took effect on January 1, 2018 and requires applicable laboratories to report to CMS private insurer payment rates and volumes for their tests. CMS uses the data reported and the Healthcare Common Procedure Coding System code associated with the test to calculate a weighted median payment rate for each test, which is used to establish revised Medicare CLFS reimbursement rates for tests that are considered to be clinical diagnostic laboratory tests (CDLTs), subject to certain phase-in limits. For tests furnished on or after January 1, 2019, Medicare payments for CDLTs are based on reported private payor rates. For a CDLT that is assigned a new or substantially revised current procedural terminology (CPT) code, the initial payment rate is assigned using the gap-fill methodology, as under prior law.

If the test falls into the category of new advanced diagnostic laboratory test (ADLT) instead of a CDLT, the test will be paid based on an actual list charge for an initial period of three quarters before being shifted to the weighted median private payor rate reported by the laboratory performing the ADLT. Laboratories offering ADLTs are subject to recoupment if the actual list charge exceeds the weighted median private payor rate by a certain amount. Accordingly, if newly developed tests receive Medicare coverage in the future, the reimbursement rate we receive for such tests may be affected by payment rates made by private payors for such tests.

Since December 2019, Congress has passed a series of laws to modify PAMA's statutory requirements related to the data reporting period and phase-in of payment reductions under the CLFS for CDLTs that are not ADLTs. Most recently, the Further Continuing Appropriations and Other Extensions Act of 2024 (Pub.L. 118-22, enacted on November, 16, 2023) further delayed the reporting requirement as well as the application of the 15% phase-in reduction. Under these statutory provisions, the next data reporting period for CDLTs that are not ADLTs will be January 1, 2025 through March 31, 2025, and will be based on the most recent data collection period of January 1, 2019 through June 30, 2019. After this data reporting period, the three-year data reporting cycle for these tests will resume (e.g., 2028, 2031, etc.).

CMS's methodology under PAMA (as well as the willingness of commercial insurers to recognize the value of diagnostic testing and pay for that testing accordingly) renders commercial insurer payment levels even more significant. This calculation methodology has resulted in significant reductions in reimbursement, even though CMS imposed caps on those reductions. For example, PAMA (as amended) includes provisions that limit the amount by which payment for testing may be reduced. For example, for 2018 through 2020, a test price could not be reduced by more than 10% per year. The same series of laws modified the phase-in of payment reductions resulting from private payor rate implementation so that a 0.0 percent reduction limit was applied for calendar years 2021 through 2023, as compared to the payment amounts for a test the preceding year. The Further Continuing Appropriations and Other Extensions Act of 2024 further applied a 0.0 percent reduction limit for calendar year 2024. Consequently, payment may not be reduced by more than 15 percent per year for calendar years 2025 through 2027 as compared to payment amount established for a test the prior year.

The subsequent data reporting period for CDLTs that are not ADLTs will occur in three-year cycles, with the next cycle beginning in 2025. Given the many uncertainties built into PAMA's price-setting process, we cannot predict how payments we receive under the CLFS, and thus our revenue, may change from year to year.

The No Surprises Act was signed into law on December 27, 2020, as part of the Consolidated Appropriations Act, 2021. The Department of Health and Human Services, the Department of Treasury, and the Department of Labor have since released "Tri-Agency" regulations to implement the No Surprises Act, which became effective on January 1, 2022. The law and regulations generally apply to group health plans and health insurance issuers offering group or individual health insurance coverage for plan years starting January 1, 2022, and to certain health care providers and facilities. For non-emergency services provided by an out-of-network provider (such as a laboratory) during a visit at an in-network facility (which includes a hospital but not a physician office), the No Surprises Act requires the non-emergency services provider to hold a patient harmless for amounts beyond the in-network cost-sharing requirement. In other words, balance billing generally is prohibited. Because these billing requirements do not apply to patient specimens collected in a physician office, Myriad is impacted primarily when a patient's specimen is collected at an in-network hospital, and Myriad is an out-of-network provider under the patient's insurance plan. Out-of-network rates for covered services are determined by a state All-Payer Model Agreement, a specified state law, an agreed-upon amount, or, if none apply, an amount determined by an independent dispute resolution entity. The cost-sharing amount is limited to an amount determined by an All-Payor Model Agreement, a specified state law, or, if neither applies, the lesser of the billed charge or the "qualifying payment amount," which is generally the plan or issuer's median contracted rate for the same or similar service in the specific geographic area. Non-covered services are not impacted by these rules. In addition, providers, including Myriad, must post consumer notices on their website about the applicability of the law. Providers, including physician offices, must provide a good faith estimate of the cost of the service when requested by a patient who is uninsured or seeking to forgo insurance and pay cash instead.

Federal and State Fraud and Abuse Laws

A variety of state and federal laws prohibit fraud and abuse involving state and federal health care programs, such as Medicare and Medicaid. These laws are interpreted broadly and enforced aggressively by various state and federal agencies, including CMS, the Department of Justice, the Office of Inspector General for the Department of Health and Human Services (OIG), and various state agencies. In addition, the Medicare and Medicaid programs increasingly use a variety of contractors to review claims data and to identify improper payments as well as fraud and abuse. Any overpayments must be repaid within 60 days of identification unless a favorable decision is obtained on appeal. In some cases, these overpayments can be used as the basis for an extrapolation by which the error rate is applied to a larger set of claims, which can result in even higher repayments.

Anti-Kickback Laws

The Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing, arranging for or recommending of an item or service that is reimbursable, in whole or in part, by a federal health care program. "Remuneration" is broadly interpreted to include anything of monetary value, such as, for example, cash payments, gifts or gift certificates, discounts, or the furnishing of services, supplies or equipment.

Recognizing the potential breadth of interpretation of the Anti-Kickback Statute and the fact that it may technically prohibit many innocuous or beneficial arrangements within the healthcare industry, the OIG has promulgated safe harbors intended to protect such arrangements. Compliance with all requirements of a safe harbor immunizes the parties to the business arrangement from prosecution under the Anti-Kickback Statute. The failure of a business arrangement to fit within a safe harbor does not necessarily mean that the arrangement is illegal or that enforcement agencies will pursue prosecution. Still, in the absence of an applicable safe harbor, a violation of the Anti-Kickback Statute may occur even if only one purpose of an arrangement is to induce referrals. The penalties for violating the Anti-Kickback Statute can be severe. These sanctions include criminal and civil penalties, imprisonment and possible exclusion from federal health care programs. Many states have adopted laws similar to the Anti-Kickback Statute, and some apply to items and services reimbursable by any payor, including private third-party payors.

In addition, in October 2018, the Eliminating Kickbacks in Recovery Act of 2018 (EKRA), was enacted as part of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (the SUPPORT Act). EKRA is an all-payor anti-kickback law that makes it a criminal offense to pay any remuneration to induce referrals to, or in exchange for, patients using the services of a recovery home, a substance use clinical treatment facility, or laboratory. Although it appears that EKRA was intended to reach patient brokering and similar arrangements to induce patronage of substance use recovery and treatment, the language in EKRA is broadly written. Further, certain of EKRA's exceptions are inconsistent with the Anti-Kickback Statute regulations. Significantly, EKRA permits the U.S. Department of Justice to issue regulations clarifying EKRA's exceptions or adding additional exceptions, but such regulations have not yet been issued. Further, there is no agency guidance and little court precedent to indicate how and to what extent EKRA will be applied and enforced.

Physician Self-Referral Bans

The federal ban on physician self-referrals, commonly known as the Stark Law, prohibits, subject to certain exceptions, physician referrals of Medicare patients to an entity providing certain designated health services, which include laboratory services, if the physician or an immediate family member of the physician has any financial relationship with the entity. Several Stark Law exceptions are relevant to arrangements involving clinical laboratories, including but not limited to: (1) fair market value compensation for the provision of items or services; (2) payments by physicians to a laboratory for clinical laboratory services; (3) space and equipment rental arrangements that satisfy certain requirements; and (4) personal services arrangements. 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 to the Stark Law, many states have their own self-referral bans, which may extend to all self-referrals, regardless of the payor.

State and Federal Prohibitions on False Claims

The federal False Claims Act 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. Under the False Claims Act, 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. The qui tam provisions of the False Claims Act allow a private individual to bring an action on behalf of the federal government and to share in any amounts paid by the defendant to the government in connection with the action. Penalties include payment of up to three times the actual damages sustained by the government, plus significant civil penalties for each false claim, as well as possible exclusion from federal health care programs. In addition, various states have enacted similar laws modeled after the False Claims Act that apply to items and services reimbursed under Medicaid and other state health care programs, and, in several states, such laws apply to claims submitted to any payor.

Civil Monetary Penalties Law

The federal Civil Monetary Penalties Law (the CMP Law), prohibits, among other things, (1) the offering or transfer of remuneration to a Medicare or state health care 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 health care program, unless an exception applies; (2) employing or contracting with an individual or entity that the provider knows or should know is excluded from participation in a federal health care program; (3) billing for services requested by an unlicensed physician or an excluded provider; and (4) billing for medically unnecessary services. The penalties for violating the CMP Law include exclusion, substantial fines, and payment of up to three times the amount billed, depending on the nature of the offense.

Other U.S. 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 medical specimens, infectious and hazardous waste 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 United States. This includes requirements to develop and implement multi-faceted programs to protect workers from exposure to blood-borne pathogens, including preventing or minimizing any exposure through needle stick injuries. This also includes requirements to ensure employees are informed of hazardous chemicals in the workplace and provide expectations for the safe handling of hazardous chemicals. 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 agencies: 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.

Our laboratories are subject to federal, state and local regulations relating to the handling and disposal of regulated medical waste, radioactive materials, hazardous waste and biohazardous waste, including chemical and biological agents and compounds, blood and bone marrow samples, and other human tissue. Typically, we use outside vendors who are contractually obligated to comply with applicable laws and regulations to dispose of such waste. These vendors are licensed or otherwise qualified to handle and dispose of such waste.

In addition, our advertising for laboratory services using FDA-cleared or approved IVDs as well as services using LDTs that are not FDA-approved is subject to federal truth-in-advertising laws enforced by the Federal Trade Commission (FTC), as well as certain state laws. Under the Federal Trade Commission Act, or FTC Act, the FTC is empowered, among other things, to prevent unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce. The FTC has very broad enforcement authority, and failure to abide by the substantive requirements of the FTC Act and other consumer protection laws can result in administrative or judicial penalties, including civil penalties, injunctions affecting the manner in which we would be able to market services or certain products in the future, or criminal prosecution.

Available Information

We are a Delaware corporation with our principal executive offices located at 322 North 2200 West, Salt Lake City, Utah 84116. Our telephone number is (801) 584-3600 and our website address is *www.myriad.com*. We make available free of charge through the Investor Relations section of our website our Code of Conduct, our Audit and Finance Committee and other committee charters and our other corporate governance policies, as well as our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all amendments to those reports as soon as reasonably practicable after such material is electronically filed with or furnished to the Securities and Exchange Commission. The Securities and Exchange Commission maintains an internet site (*http://www.sec.gov*) that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the Securities and Exchange Commission. We include our website address in this Annual Report on Form 10-K only as an inactive textual reference and do not intend it to be an active link to our website.

Item 1A. RISK FACTORS

The following is a summary of the principal risks that could adversely affect our business, operations, and financial results:

Risks Related to Our Business and Our Strategy

- We may not be able to generate sufficient revenue from our existing tests or develop new tests to be profitable.
- Our strategic growth plan may not achieve the anticipated results, and we may not be able to achieve or maintain revenue growth or operate our business on a profitable basis.
- If the government and other third-party payors fail to provide coverage and adequate payment for our existing and future tests, if any, our revenue and prospects for profitability will be harmed.
- If we do not generate sufficient cash flow from operations and are unable to secure additional funding, we may have to reduce our operations.
- We are subject to debt covenants that impose operating and financial restrictions on us and if we are not able to comply with them, it could have a material adverse impact on our operations and liquidity.
- If our existing capital resources and expected net cash to be generated from sales of our tests is not sufficient for us to maintain our currently planned operations, we may find it necessary to raise additional funding, which may not be available on favorable terms, or at all.
- We have been subject to, and in the future may be subject to, securities class action lawsuits and stockholder derivative actions, as well as product or professional liability claims. These, and potential similar or related litigation, could result in substantial losses and have a material adverse effect on our business, cash position, operating results or financial condition.
- An inability to attract and retain experienced and qualified personnel, including key management personnel, could adversely affect our business.
- We have acquired and we may continue to acquire technologies, assets or other businesses that could cause us to incur significant expense and expose us to a number of unanticipated operational and financial risks, which could adversely affect our financial condition, results of operations and business prospects.
- Failure to comply with laws and regulations related to submission of claims for our services could result in significant monetary damages and penalties and exclusion from the Medicare and Medicaid programs and corresponding foreign reimbursement programs.
- Our financial condition and results of operations could be adversely affected by adverse public health developments.
- If our SneakPeek Early Gender DNA Test does not perform as expected, we may not realize the expected benefits of our acquisition of Gateway (as defined below).
- Security breaches, loss of data and other disruptions, including from cyberattacks, could compromise sensitive information related to our business, prevent us from accessing critical information or expose us to liability, which could adversely affect our business and our reputation.
- If we experience a significant disruption in our information technology systems, our business operations and financial condition could be adversely affected.
- Each of our tests is processed in a single one of our laboratory facilities, and any loss or prolonged interruption of our ability to use these laboratories or failure to maintain their operation in compliance with applicable regulations would seriously harm our business.
- Our inability to, or delay in, transitioning certain of our laboratory operations to new laboratory facilities in west Salt Lake City, Utah and South San Francisco, California could adversely affect our business.
- We depend on a limited number of third parties, or, in some cases, single-source suppliers, for equipment, reagents and other supplies. If these supplies become unavailable or are disrupted, then we may not be able to successfully perform our research or operate our business on a timely basis or at all.
- Our international business exposes us to business, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States.
- Ethical, legal and social concerns related to the use of genetic information could reduce demand for our tests.
- We rely on commercial courier delivery services to transport biological materials to our facilities in a timely and cost-efficient manner and if these delivery services are disrupted, our business will be harmed.
- We face risks associated with currency exchange rate fluctuations, which could adversely affect our operating results.
- Impairment in the value of our goodwill or other intangible assets could have a material adverse effect on our operating results and financial condition.
- Our estimates of actionable market size and forecasts of market growth may prove to be inaccurate, and even if the market in which we compete achieves the forecasted growth, our business could fail to grow at similar rates.
- Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

Risks Related to the Development and Commercialization of Our Tests and Test Candidates

- Our tests in development may not be clinically effective or may never achieve significant commercial market acceptance and our test offerings that we have recently launched or acquired may not be commercially successful.
- If we do not compete effectively with scientific and commercial competitors, we may not be able to successfully commercialize our tests, increase our revenue or achieve and sustain profitability.
- If our current research collaborators or scientific advisors terminate their relationships with us or develop relationships with a competitor, our ability to discover genes, proteins, and biomarkers, and to validate and commercialize tests could be adversely affected.

Risks Related to Our Intellectual Property

- If we fail to protect our proprietary technology, others could compete against us more directly, which would harm our business.
- If we are subject to litigation or other proceedings arising from a claim of infringement of the intellectual property of a third party, we might incur significant costs and delays in test introduction or we could be prevented from using technologies incorporated in our tests.
- If we fail to comply with our obligations under license or technology agreements with third parties, we could lose license rights that are critical to our business.
- We may be subject to claims that we or our employees have wrongfully used or disclosed alleged trade secrets.
- If we fail to adequately protect our trademarks, service marks, trade names and trade dress, we may lose goodwill and brand equity associated with our business.

Risks Related to Government Regulation

- If we fail to comply with the complex federal, state, local and foreign laws and regulations that apply to our business, we could suffer consequences that could materially and adversely affect our operating results and financial condition.
- Our actual or perceived failure to comply with data protection laws and regulations could lead to government enforcement actions, private litigation, and/or adverse publicity and could negatively affect our business.
- We may from time to time be subject to government investigation(s), the unfavorable outcome of which may have a material adverse effect on our financial condition, results of operations and cash flows.
- Changes in health care policy could increase our costs, decrease our revenues and impact sales of and reimbursement for our tests.
- Our business could be harmed by the loss, suspension, or other restriction on a license, certification, or accreditation, or by the imposition of a fine or penalties, under CLIA, its implementing regulations, or other state, federal and foreign laws and regulations affecting licensure or certification, or by future changes in these laws or regulations.
- Changes in the way that the FDA regulates tests performed by laboratories like ours could result in delay or additional expense in offering our tests and tests that we may develop in the future.
- FDA regulation of our GeneSight Psychotropic test could be disruptive to our business.
- Companion and complementary diagnostic tests require FDA approval, and we may not be able to secure such approval in a timely manner or at all.
- Our companion diagnostic tests are subject to ongoing regulatory compliance obligations and continued regulatory review and the failure to comply with such obligations could result in regulatory enforcement and/or penalties.
- Our business involves environmental risks that may result in liability for us.

General Risks and Risks Related to Our Common Stock

- Our stock price is highly volatile, and our stock may lose all or a significant part of its value.
- If we are unable to achieve and maintain effective disclosure controls and procedures and internal control over financial reporting, our results of operations, our stock price and investor confidence in us could be adversely affected.
- Anti-takeover provisions of Delaware law, provisions in our charter and bylaws and re-adoption of our stockholders' rights plan, or poison pill, could make a third-party acquisition of us difficult.
- Future sales and issuances of our common stock would result in dilution of the percentage ownership of our stockholders and could cause the price of our common stock to decline.
- We do not intend to pay dividends so any returns will be limited to changes in the value of our common stock.
- If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.
- Increasing scrutiny and evolving expectations from regulators, business partners, investors, and other stakeholders with respect to our ESG practices may impose additional costs on us or expose us to new or additional risks.
- Our restated certificate of incorporation and our restated bylaws designate specific state or federal courts as the exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Risks Related to Our Business and Our Strategy

We may not be able to generate sufficient revenue from our existing tests or develop new tests to be profitable.

We believe our future success is dependent upon our ability to successfully market our existing tests to additional patients within the United States, to expand into new markets, to develop and commercialize new tests and to maintain or obtain reimbursement for our tests. However, we may not be able to generate sufficient revenue, from our existing tests and launching and commercializing new tests, to be profitable. The demand for our existing tests may decrease or may not continue to increase at historical rates due to sales of new tests that may replace or cannibalize our existing product portfolio, or for other reasons such as the introduction of competing testing products by competitors. For example, because most of our tests are only utilized once per patient, we will need to sell our products to new patients or develop new tests in order to continue to generate revenue. Our average reimbursement rate per test may also decline, which may cause our revenues to decrease. Our pipeline of new test candidates, such as FirstGene and Precise MRD, are in various stages of development, some of which may take many more years to develop and must undergo extensive clinical validation. We may be unable to discover or develop any additional tests through the utilization of our technologies or technologies we license or acquire from others. Even if we develop tests for commercial use, we may not be able to develop tests that:

- meet applicable regulatory standards, in a timely manner or at all;
- successfully compete with other technologies and tests;
- avoid infringing the proprietary rights of others;
- are adequately reimbursed by third-party payors;
- can be performed at commercial levels or at reasonable cost; or
- can be successfully marketed.

We must generate significant revenue to achieve profitability. Even if we succeed in marketing our existing tests to physicians for use in new patients and in developing and commercializing any additional tests, we may not be able to generate sufficient revenue to be profitable.

Our strategic growth plan may not achieve the anticipated results, and we may not be able to achieve or maintain revenue growth or operate our business on a profitable basis.

We are currently executing upon a multi-year strategic growth plan in which we intend to continue growing by articulating our clinical differentiation, raising awareness with patients who we believe would benefit from our testing products, and innovation that improves clinical outcomes, ease of use, and access. Our future performance and growth depend on the success of our growth plan, including management's ability to execute upon that plan and the ability of our employees to respond quickly and effectively to strategic projects and changes in our operations and business practices. The implementation of our strategic growth plan has resulted, and is expected to continue to result, in changes to business priorities and operations, capital allocation priorities, operational and organizational structures, and increased demands on management. The execution of our strategic growth plan may take longer than anticipated, and we may not realize, in full or part, our anticipated growth targets in our testing volumes and revenue, or such growth may be realized more slowly than anticipated.

In recent years we have not operated our business profitably, and we may not be able to achieve or maintain profitability in the future. Potential events or factors that may have a significant impact on our ability to achieve our growth targets and achieve and/or maintain revenue growth and profitability for our business include the following:

- the efforts of third-party payors to limit or decrease the amounts that they are willing to pay for our tests, recoup amounts already paid, not cover our tests, or institute burdensome administrative requirements for reimbursement, such as prior authorization requirements;
- our ability to execute on our strategic growth plan;
- increased costs of reagents and other consumables required for testing;
- increased personnel and facility costs;
- our inability to hire competent, trained staff, including laboratory directors required to review and approve all reports we issue in our business, and sales personnel;
- our inability to obtain necessary equipment or reagents to perform testing;
- our inability to increase production capacity to meet demand increases;
- our inability to expand into new markets;
- increased licensing or royalty costs, and our ability to maintain and enforce the intellectual property rights underlying our tests and services;
- changes in intellectual propriety law applicable to our patents or enforcement in the United States and foreign countries;
- the expiration of the patents covering our products;
- the outcome of outstanding or new litigation;
- potential obsolescence of our tests;
- our inability to obtain or increase commercial acceptance of our tests;
- increased competition and loss of market share;
- global or local economic conditions;
- increased regulatory requirements; and
- material litigation costs, settlements, and judgments.

The failure to achieve our growth targets and achieve and/or maintain revenue growth and profitability for our business could have a material adverse effect on our business, prospects, financial condition, results of operations, cash flows, as well as the trading price of our common stock.

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

In both domestic and foreign markets, sales of our tests or any future tests will depend in large part upon the availability of reimbursement from third-party payors. Such third-party payors include state and federal health care programs such as Medicare, managed care organizations, other private health insurers and other organizations. These third-party payors are increasingly attempting to contain health care costs by demanding price discounts and limiting both coverage regarding which tests they will pay for and the amounts that they will pay for existing and new tests. We have experienced coverage limitations and price reductions for many of our products, including for our GeneSight Psychotropic Mental Health Medication Test, and we may continue to experience future coverage limitations and price reductions from CMS, managed care organizations, and other third-party payors. The fact that a test has been approved for reimbursement in the past, for any particular indication or in any particular jurisdiction, does not guarantee that such a test will be approved or remain approved for reimbursement, that the reimbursement amount approved for such test will not be reduced in the future, or that similar or additional tests will be approved for reimbursement in the future. Historically, we have not received reimbursement from third-party payors or payment from patients for many of our tests. Moreover, there can be no assurance that any new tests we have launched or may launch will be reimbursed at rates that are comparable to the rates that we historically obtained for our existing product portfolio. As a result, third-party payors may not cover or provide adequate payment for our current or future tests to enable us to maintain past levels of revenue or profitability with respect to such tests. Further, third-party reimbursement might not be available to enable us to maintain price levels sufficient to realize an appropriate return on investment in product development.

In addition, under PAMA, Medicare reimbursement for any given test is based on the weighted-median of the payments made by private payors for such test, rendering private payor payment levels even more significant. As a result, future Medicare payments may fluctuate more often and become subject to the willingness of private payors to recognize the value of tests generally and any given test individually. Since December 2019, Congress has passed a series of laws to modify PAMA's statutory requirements related to the data reporting period and phase-in of payment reductions under the CLFS for CDLTs that are not ADLTs. Most recently, the Further Continuing Appropriations and Other Extensions Act of 2024 (Pub.L. 118-22, enacted on November, 16, 2023) further delayed the reporting requirement as well as the application of the 15% phase-in reduction. Under these statutory provisions, the next data reporting period for CDLTs that are not ADLTs will be January 1, 2025 through March 31, 2025. The same series of laws modified the phase-in of payment reductions resulting from private payor rate implementation so that a 0.0 percent reduction limit was applied for calendar years 2021 through 2023, as compared to the payment amounts for a test the preceding year. The Further Continuing Appropriations and Other Extensions Act of 2024 further applied a 0.0 percent reduction limit for calendar year 2024. Consequently, payment may not be reduced by more than 15 percent per year for calendar years 2025 through 2027 as compared to payment amount established for a test the prior year. Any declines in average selling prices of our products due to pricing pressures may have an adverse impact on our business, results of operations and financial condition.

Third-party payors may also impose prior authorization requirements, dispute our billing or coding and may decide to deny payment or recoup payment for testing that they contend to have been not medically necessary, against their coverage determinations, or for which they have otherwise overpaid, and we may be required to refund reimbursements already received. We have also experienced delays or denials of coverage for failure to adequately comply with procedural requirements imposed by third-party payors to obtain reimbursement. We also periodically receive and respond to requests for recoupment from third-party payors in the ordinary course of business. When a third-party payor denies payment for testing, we often are not able to collect payment from the patient, and therefore, we do not receive any revenue from our testing. In addition, if a third-party payor successfully proves that payment for prior testing was in breach of contract or otherwise contrary to law, they may recoup payment, which amounts could be significant and would impact our results of operations. We may also continue to negotiate and settle with third-party payers in order to resolve allegations of overpayment.

Third-party payors, such as commercial health insurers and government payors and programs, may also adopt requirements, programs or policies that may restrict or adversely affect our business. For example, in September 2022, the California Department of Public Health (CDPH) promulgated certain regulatory amendments to the California Prenatal Screening (PNS) Program that made the PNS Program the exclusive means of obtaining cfDNA trisomy screening in California. These regulatory amendments set a price that participating laboratories would receive for each cfDNA test that was substantially lower than laboratories had previously charged, and prohibited laboratories that did not contract with CDPH from participating in the PNS Program and from offering or performing cfDNA trisomy screening in California. As we are not a participating laboratory under the PNS Program, we would have been prohibited from offering or performing our Prequel screening test in California. On September 16, 2022, we filed jointly with Laboratory Corporation of America Holdings (Labcorp) a writ petition in the Superior Court of the State of California, County of San Francisco, against the CDPH and its Director challenging CDPH's ability to make the PNS Program the exclusive means of obtaining cfDNA trisomy screening in California. On September 16, 2022, we also moved jointly with Labcorp for a preliminary injunction to enjoin the implementation and enforcement of the new exclusivity regulation. On November 2, 2022, the Superior Court granted our motion for a preliminary injunction, which allowed us to continue to offer our Prequel screening test in California. On December 17, 2022, we filed jointly with Labcorp a motion for judgment on our writ, through which we sought a permanent injunction to enjoin the implementation and enforcement of the new exclusivity regulation. On April 28, 2023, the Superior Court issued an order granting our motion for a permanent injunction to enjoin the implementation and enforcement of the new exclusivity regulation. On June 1, 2023, the Superior Court issued a final judgment and writ of mandate enjoining the implementation and enforcement of the new exclusivity regulation. The CDPH did not file a notice of appeal. As a result of the foregoing, we expect to continue to be able to offer and perform our Prequel screening test in California. However, the possibility that we might not be able to continue to offer our Prequel screening test in California had a chilling effect on sales of our Prequel screening test in California.

U.S. and foreign governments continue to propose and pass legislation designed to reduce the cost of health care. For example, in some foreign markets, the government controls the pricing of many health care products. We expect that there will continue to be federal and state proposals to implement governmental controls or impose health care requirements. In addition, the Medicare program and increasing emphasis on managed care in the United States will continue to put pressure on product pricing. Cost control initiatives could decrease the price that we would receive for any tests in the future, which would limit our revenue and profitability.

If we do not generate sufficient cash flow from operations and are unable to secure additional funding, we may have to reduce our operations.

While we believe that our existing cash, cash equivalents and marketable securities, future cash flow from operations, and amounts available for borrowing under our ABL Facility (as defined below) will be sufficient to meet our anticipated cash requirements for at least the next 12 months, changes could occur that would consume available capital resources more quickly than we currently expect and we may need or want to raise additional financing.

On June 30, 2023, we entered into an asset-based revolving credit facility (the "ABL Facility") with an initial maximum principal amount of $90.0 million with JPMorgan Chase Bank, N.A. as administrative agent and issuing bank, and the other lender parties thereto. On October 31, 2023, we entered into an amendment to the ABL Facility to increase the maximum principal amount of the available revolving line of credit under the ABL Facility by $25.0 million for a total maximum principal commitment under the ABL Facility of $115.0 million. As of December 31, 2023, we had $40.0 million of outstanding borrowings under the ABL Facility. The ABL Facility limits our ability to incur additional indebtedness and requires us to comply with certain minimum liquidity and minimum availability covenants.

In addition, during November 2023, we completed an underwritten public offering of our common stock in which we sold 7,441,176 shares of our common stock at a price of $17.00 per share for proceeds of $117.6 million, net of offering expenses and underwriting discounts.

If we do not generate sufficient cash from operations, if our capital resources are consumed more rapidly than expected, or if we no longer have access to additional funds under our ABL Facility and are unable to secure additional funding, on acceptable terms or at all, we may be forced to delay, scale back or eliminate some of our sales and marketing activities, research and development activities, or other operations, and potentially delay development of our tests in an effort to provide sufficient funds to continue our operations. If any of these events occur, our ability to achieve our development and commercialization goals could be adversely affected.

Our future capital requirements will depend on many factors that are currently unknown to us, including:

- the scope, progress, results and cost of development, clinical testing and pre-market studies of any new tests that we may develop or acquire;
- the progress, results, and costs to develop additional tests;
- our ability to operate our business on a profitable basis;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our current issued patents, and defending intellectual property-related claims;
- our ability to enter into collaborations, licensing or other arrangements favorable to us;
- the costs of acquiring technologies or businesses, and our ability to successfully integrate and achieve the expected benefits of our business development activities and acquisitions;
- the progress, cost and results of our international efforts;
- the costs of expanding our sales and marketing functions and commercial operation facilities in the United States and in new markets;
- the costs, timing and outcome of any litigation against us; and
- the costs to satisfy our current and future obligations.

We are subject to debt covenants that impose operating and financial restrictions on us and if we are not able to comply with them, it could have a material adverse impact on our operations and liquidity.

Covenants in the ABL Facility impose operating and financial restrictions on us. These restrictions may prohibit or place limitations on, among other things, our ability to incur liens, incur indebtedness, dispose of assets, make investments, make certain restricted payments, merge or consolidate and enter into certain speculative hedging arrangements. We are also required to maintain minimum liquidity of $60.0 million and minimum availability of $25.0 million at all times before achieving a fixed charge coverage ratio of 1.0 to 1.0 and thereafter, to maintain a fixed charge coverage ratio of 1.0 to 1.0 until achieving availability under the ABL Facility of greater than the greater of (a) $10.6 million and (b) 12.5% of the lesser of the maximum commitment amount and the borrowing base for a period of 30 consecutive days. In addition, the ABL Facility includes a number of customary events of default. If any event of default occurs (subject, in certain instances, to specified grace periods), the principal, premium, if any, interest and any other monetary obligations on all the then outstanding amounts under the ABL Facility may become due and payable immediately, which could have a material adverse impact on our operations and liquidity.

If our existing capital resources and expected net cash to be generated from sales of our tests is not sufficient for us to maintain our currently planned operations, we may find it necessary to raise additional funding, which may not be available on favorable terms, or at all.

We believe that our existing cash, cash equivalents and marketable securities of $140.9 million as of December 31, 2023, our expected cash flow from operations, and our availability to borrow will be sufficient to meet our anticipated cash requirements for at least the next 12 months. However, we base this expectation on our current operating plan, which may change. We have incurred, and may continue to incur, significant losses. We may not be able to generate sufficient revenue from our existing tests and launching and commercializing new tests, to be profitable. In addition, our ongoing efforts to develop tests and expand our business, which may be through internally developed products, partnerships, in-licensing and mergers and acquisitions, will continue to require substantial cash resources. In addition, we have incurred, and may continue to incur, substantial costs in defending and settling legal proceedings. In connection with the settlement of the Ravgen (as defined below) litigation, we may be required to pay Ravgen $21.25 million in five annual installments beginning no earlier than January 1, 2026 if certain conditions are satisfied. We may also be required to pay an additional $25.0 million to the former equity and vested incentive unit holders of Gateway, if certain revenue, volume and earnings targets set forth in the acquisition agreement are achieved. If adequate funds are not available, we may be required to raise additional funds. Sources of potential additional capital resources may include, but are not limited to, public or private equity financings, or selling convertible or non-convertible debt securities. Any additional funding, if necessary, may not be available to us on reasonable terms, or at all.

Because of our potential long-term capital requirements, we may access the public or private equity or debt markets whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time. Under Securities and Exchange Commission rules, we currently qualify as a well-known seasoned issuer (WKSI), and can at any time file a registration statement registering securities to be sold to the public which would become effective and available for use upon filing. If additional funds are raised by issuing equity or equity-based securities, existing stockholders may suffer significant dilution. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances, partnerships and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or tests or grant licenses on terms that are not favorable to us.

We have been subject to, and in the future may be subject to, securities class action lawsuits and stockholder derivative actions, as well as product or professional liability claims. These, and potential similar or related litigation, could result in substantial losses and have a material adverse effect on our business, cash position, operating results or financial condition.

We have been subject to a variety of litigation, including a securities class action lawsuit filed in the United States District Court for the District of Utah, and stockholder derivative actions filed in the Delaware Court of Chancery and the United States District Court for the District of Delaware. On August 2, 2023, we entered into a stipulation and agreement of settlement to resolve the securities class action lawsuit, which was subsequently approved by the United States District Court for the District of Utah on December 15, 2023. Pursuant to the terms of the settlement, we paid a settlement amount of $77.5 million in cash. We also may be subject to future securities class action and stockholder derivative claims. Such litigation may adversely impact our business, cash position, results of operations or financial condition and divert management's time and attention from our business.

In addition, the marketing, sale and use of our tests could subject us to liability for errors in, misunderstandings of, or inappropriate reliance on, information we provide to clinicians, geneticists or patients, and lead to claims against us if someone were to allege that a test failed to perform as it was designed or marketed, if we failed to provide a correct test result to a patient, if we failed to correctly interpret the test results, if we failed to update the test results due to a reclassification of the variants according to new published guidelines, or if the ordering physician or patient were to misinterpret test results or improperly rely on them when making a clinical decision. We could also be subject to claims, lawsuits or liability if the biological materials we receive for analysis were not properly attributed to the correct patient or if we failed to maintain custody of or properly track the biological materials. A product liability or professional liability claim could result in substantial damages and be costly and time-consuming for us to defend.

Although we maintain liability insurance for certain claims, including director and officer's insurance and insurance for errors and omissions, we cannot assure you that such insurance would fully protect us from the financial impact of defending against outstanding or future claims or any judgments, fines or settlement costs arising out of any outstanding or future claims. Any claim brought against us, with or without merit, could increase our insurance rates or prevent us from securing insurance coverage in the future. If we were successfully sued for product or professional liability claims or in connection with future securities class action and stockholder derivative claims, we could face substantial losses that exceed our insurance coverage and our other resources. For example, we depleted our director and officer's insurance coverage for the recently settled securities class action lawsuit and no insurance proceeds were available to us to pay the settlement amount. If we are not successful in our defense of any future litigation, we could be forced to make significant payments to or other settlements with our stockholders and their lawyers outside of our insurance coverage, and such payments or settlement arrangements could have a material adverse effect on our business, cash position, operating results or financial condition. Additionally, any lawsuit could cause injury to our reputation or cause us to suspend sales of our tests. The occurrence of any of these events could have a materially adverse effect on our reputation, cash position, and results of operations.

An inability to attract and retain experienced and qualified personnel, including key management personnel, could adversely affect our business.

Because of the specialized scientific nature of our business, we are highly dependent upon our ability to attract and retain highly qualified and experienced personnel, including key management personnel. Competition for these personnel is intense, especially for management, sales, scientific, medical, information technology, research and development and other technical personnel. 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. We have from time to time experienced, and we expect to continue to experience, difficulty in hiring and retaining employees with appropriate qualifications. Our compensation arrangements, such as our short-term incentive and equity award programs, may not be successful in attracting new employees and retaining and motivating our existing employees. Our agreements with our employees generally provide for employment that can be terminated by either party without cause at any time, subject to specified notice requirements. Further, the non-competition provision that certain key employees are subject to may not be enforceable under certain state laws, particularly California, or federal laws or such provisions may be prohibitively expensive to enforce. Our growth and commercial activities have placed a greater workload and strain on our existing employees, increasing the risk that our employees experience fatigue or burnout or terminate their employment with us. In addition, inflation has had an impact on the costs that we incur to attract and retain qualified personnel and may make it more difficult for us to attract and retain such personnel.

Our success also depends on the skills, experience and performance of key members of our senior management team, who are critical to directing and managing our growth and development in the future. The loss of any member of our senior management team may cause us to experience difficulties in competing effectively, developing our technologies, and implementing our business strategies. Furthermore, the loss of the services of or failure to recruit key scientific and technical personnel and other qualified personnel who are necessary to operate our business would adversely affect our business and it may have a material adverse effect on our business as a whole.

We have acquired and we may continue to acquire technologies, assets or other businesses that could cause us to incur significant expense and expose us to a number of unanticipated operational and financial risks, which could adversely affect our financial condition, results of operations and business prospects.

In addition to organic growth, we intend to continue to pursue growth through the acquisition of technology, assets or other businesses that may enable us to enhance our technologies and capabilities, expand our geographic market and sales channels, add experienced management personnel and increase our test offerings. For example, on February 1, 2024, we acquired the Precise Tumor Test, the Precise Liquid Test, and a CLIA certified laboratory from Intermountain Healthcare. However, these acquisitions may not generate a positive return on our investment. Additionally, we may be unable to implement our growth strategy if we cannot identify suitable acquisition candidates, reach agreement on potential acquisitions on acceptable terms, successfully integrate personnel or assets that we acquire or for other reasons. We may also experience increased expenses, distraction of our management, and personnel and customer uncertainty as a result of our acquisition activities. Our acquisition efforts may involve certain risks, including:

- we may have difficulty integrating products, operations and systems of any acquired business;
- key personnel and customers of the acquired company may terminate their relationships with the acquired company as a result of the acquisition;
- we may not be successful in launching newly acquired tests, or if those tests are launched, they may not prove successful in the marketplace;
- we may experience additional financial and accounting challenges and complexities in areas such as tax planning and financial reporting;
- we may assume or be held liable for risks and liabilities as a result of our acquisitions, including for legal, compliance, recoupment, and environmental-related costs and liabilities, some of which we may not discover during our due diligence;
- we may incur significant additional operating expenses and such acquisition may not be profitable;
- we may experience inconsistencies in standards, controls, procedures, policies and compensation structures;
- we may encounter risks and limitations on our ability to consolidate our corporate and administrative infrastructures;
- our ongoing business may be disrupted or receive insufficient management attention; and
- we may not be able to realize synergies, the cost savings or other financial and operational benefits we anticipated, or such synergies, savings or benefits may take longer than we expected.

The process of negotiating acquisitions and integrating acquired tests, services, technologies, personnel or businesses might result in operating difficulties and expenditures and might require significant management attention that would otherwise be available for ongoing development of our business, whether or not any such transaction is ever consummated. Moreover, we might never realize the anticipated benefits of any acquisition such as increase in our scale, diversification, cash flows and operational efficiency and meaningful accretion to our diluted earnings per share. Future acquisitions could result in the use of our available cash and marketable securities, potentially dilutive issuances of equity securities, the need to incur additional debt, contingent liabilities, or impairment expenses related to goodwill, and impairment or amortization expenses related to other intangible assets, which could harm our financial condition. In addition, if we are unable to integrate any acquired businesses, tests or technologies effectively, our business, financial condition and results of operations may be adversely affected.

We may also seek to divest assets from time to time, including but not limited to, large capital equipment, diagnostic tests, intellectual property, business units, or corporate affiliates. For example, we divested Myriad RBM, Inc., which provided pharmaceutical and clinical services, on July 1, 2021, and we completed the sale of select operating assets and intellectual property, including the Vectra test, from the Myriad Autoimmune business unit, on September 13, 2021. The prices that we receive for such assets may not be high and, in some cases, have been and may be lower than the amount we invested in or paid for such assets.

Failure to comply with laws and regulations related to submission of claims for our services could result in significant monetary damages and penalties and exclusion from the Medicare and Medicaid programs and corresponding foreign reimbursement programs.

We are subject to laws and regulations governing the submission of claims for payment for our services, such as those relating to: coverage of our services under Medicare, Medicaid and other state, federal and foreign health care programs; the amounts that we may bill for our services; and the party to which we must submit claims. Our failure to comply with applicable laws and regulations could result in our inability to receive payment for our services or in attempts by state and federal health care programs, such as Medicare and Medicaid, to recover payments already made. Submission of claims in violation of these laws and regulations can result in recoupment of payments already received, substantial civil monetary penalties, and exclusion from state and federal health care programs, and can subject us to liability under the federal False Claims Act and similar laws. The failure to report and return an overpayment to the Medicare or Medicaid program within 60 days of identifying its existence can give rise to liability under the False Claims Act. Further, a government agency could attempt to hold us liable for causing the improper submission of claims by another entity for services that we performed if we were found to have knowingly participated in the arrangement at issue.

Our financial condition and results of operations could be adversely affected by adverse public health developments.

Any outbreak of contagious disease or adverse public health development could have a material and adverse effect on our business operations, financial condition, or results of operations. Such adverse effects have included, and may in the future include, diversion or prioritization of health care resources away from the conduct of testing, limitations on patients' access to our products, and disruptions or restrictions affecting the ability of our laboratories to process our tests. Future surges in COVID-19 cases or any other outbreak of contagious disease and related employee absences may strain our workforce and impact our ability to process tests in a timely way due to reduced staff availability.

To the extent that any disease affects individuals and businesses around the globe, we may experience disruptions from time to time that could severely impact our business, including:

- decreased volume of testing as a result of disruptions to health care providers and limitations on the ability of providers to administer tests, including the suspension of non-emergency appointments and services;
- disruptions or restrictions on the ability of our customers, our collaborators', or our suppliers' personnel to travel, including as a result of shelter-in-place or stay-at-home orders from state and local governments, and temporary closures of our facilities or the facilities of our collaborators or suppliers;
- limitations on employee resources that would otherwise be focused on the development of our products, processing our tests, and the conduct of our clinical trials, including because of sickness of employees or their families or requirements imposed on employees to avoid contact with large groups of people; and
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or access.

In addition, the continued spread of COVID-19 or the spread of another disease globally could continue to adversely affect our manufacturing and supply chain. Parts of our direct and indirect supply chain are located overseas and both international and domestic components have been, and may in the future be, subject to disruption as a result of COVID-19 or another disease and responses to it. If the supplies and components necessary to manufacture our products become unavailable or are disrupted as a result of a disease and responses to it, then we may not be able to successfully perform our research, sell our tests, or operate our business on a timely basis or at all.

If our SneakPeek Early Gender DNA Test does not perform as expected, we may not realize the expected benefits of our acquisition of Gateway.

On November 1, 2022, we acquired Gateway Genomics, LLC ("Gateway"), a personal genomics company and developer of consumer genetic tests that gives families insight into their future children. Gateway offers and sells the SneakPeek Early Gender DNA Test in the U.S. direct to consumers via sneakpeektest.com and Amazon.com, through various clinical channels, such as OBGYN offices, midwives, birth centers and ultrasound clinics and laboratories, and in certain retail locations. The SneakPeek Early Gender DNA Test is also sold internationally through distributors in the United Kingdom, Canada, Australia and certain other countries.

The SneakPeek Early Gender DNA Test competes against other gender DNA tests and other methods of determining fetal sex (such as non-invasive prenatal testing and ultrasounds) based on a variety of factors, including accuracy, how early the sex of the fetus can be determined, price, ease of use, convenience, and the speed in which test results are delivered. We believe that the SneakPeek Early Gender DNA Test currently outperforms competing tests and methods of fetal sex determination on a number of these factors, including accuracy, ease of sample collection with the at-home SNAP blood collection device, and the test's ability to reveal a baby's sex at six weeks into pregnancy, the earliest method available. However, there can be no guarantee that the SneakPeek Early Gender DNA Test will continue to outperform other early fetal sex determination tests in these areas or that we will be able to continue to enhance and improve the SneakPeek Early Gender DNA Test in ways that would allow it to remain the market-leading early fetal sex determination test.

The success of our acquisition of Gateway depends in part on the continued growth of the SneakPeek Early Gender DNA Test, including our ability to sell the SneakPeek Early Gender DNA Test in retail stores while continuing to increase sales volumes in existing channels, and our ability to cross-sell our Prequel prenatal screening test to SneakPeek Early Gender DNA Test customers. Historically, we have limited experience with marketing non-clinical, consumer products directly to consumers or with retail-based marketing strategies, and there can be no guarantee that we will be successful in doing so. In addition, we may not be able to continue to grow the SneakPeek Early Gender DNA Test at the rate at which it was growing prior to our acquisition of Gateway, and we may not be successful at selling the SneakPeek Early Gender DNA Test in retail stores. We may also face a number of obstacles to cross-sell our Prequel prenatal screening test to SneakPeek Early Gender DNA Test customers, including persuading physicians of our SneakPeek Early Gender DNA Test customers to use our Prequel prenatal screening test and navigating patient consent and data privacy laws.

Security breaches, loss of data and other disruptions, including from cyberattacks, could compromise sensitive information related to our business, prevent us from accessing critical information or expose us to liability, which could adversely affect our business and our reputation.

In the ordinary course of our business, we collect and store sensitive data, including legally protected patient health information, credit card information, personally identifiable information about our employees and customers, intellectual property, and proprietary business information, including that of our customers, payors and collaboration partners. We manage and maintain our applications and data utilizing on-site, remote, or cloud-based systems. These applications and data encompass a wide variety of business-critical information including research and development information, commercial information and business and financial information.

The secure processing, storage, maintenance and transmission of this critical information is vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure has been, and may continue to be, vulnerable to attacks by hackers, or viruses, malware, including ransomware, breaches or interruptions due to employee error, malfeasance or other disruptions, or lapses in compliance with privacy and security mandates. Any such malicious cyberattack, virus, breach or interruption could compromise our networks and the information stored there could be accessed by unauthorized parties, publicly disclosed, held for ransom, altered, lost or stolen. We have measures in place that are designed to prevent, and if necessary, to detect and respond to such cybersecurity incidents and breaches of privacy and security mandates. While we have experienced unauthorized accesses to our information technology systems and infrastructure in the past, which may occur again in the future, our security measures have been able to detect, respond to and prevent any material adverse effect to our information systems and business operations from such breaches. However, in the future, any such access, disclosure or other loss, or alteration of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, such as HIPAA, government enforcement actions and civil or even criminal penalties. Unauthorized access, loss, alteration, or dissemination could also disrupt our operations, including our ability to process samples, provide test results, bill payors or patients, provide customer support services, conduct research and development activities, process and prepare company financial information, and manage various general and administrative aspects of our business, and may damage our reputation, any of which could adversely affect our business, financial condition and results of operations.

In addition, we face increased cybersecurity risks and potential disruption to our technology infrastructure due to the number of employees that are working remotely as a result of remote work policies and other hybrid work arrangements. Increased levels of remote access create additional opportunities for cybercriminals to exploit vulnerabilities, and employees may be more susceptible to phishing and social engineering attempts.

If we experience a significant disruption in our information technology systems, our business operations and financial condition could be adversely affected.

Information technology (IT) and communication systems are an important part of our business operations. These IT and communications systems support a variety of functions, including sample processing, tracking, quality control, customer service and support, billing, research and development activities, and various general and administrative activities. The availability of our products and services and fulfillment of our customer contracts depends on the continuing operation of our IT and communication systems. Our IT and communication systems may be susceptible to damage, disruptions or shutdowns due to power outages, hardware failures, computer viruses, attacks by computer hackers, telecommunication failures, user errors, catastrophes or other unforeseen events. Our IT and communication systems also may experience interruptions, delays or cessations of service or produce errors in connection with system implementation, integration, upgrades or system migration work that takes place from time to time. In addition, we may not be able to maintain operational effectiveness of our IT and communication systems due to insufficient technology infrastructure, aging components, accumulated technical debt and gaps in our software release processes. If we were to experience a prolonged system disruption in the IT and communication systems that involve our interactions with customers, providers or suppliers, it could result in the loss of sales and customers and significant incremental costs, which could adversely affect our business. In addition, security breaches of our IT systems could result in the misappropriation or unauthorized disclosure of confidential information belonging to us or to our employees, partners, customers or suppliers, which could result in our suffering significant financial or reputational damage.

Each of our tests is processed in a single one of our laboratory facilities, and any loss or prolonged interruption of our ability to use these laboratories or failure to maintain their operation in compliance with applicable regulations would seriously harm our business.

We rely on a CLIA-certified facility in Salt Lake City, Utah to perform most of our tests; a CLIA-certified laboratory in South San Francisco, California to perform our Foresight and Prequel tests; a CLIA-certified laboratory in St. George to perform our Precise Tumor test; a single laboratory facility in Cologne, Germany to perform and produce our EndoPredict test kits; a CLIA-certified laboratory in Mason, Ohio to perform our GeneSight test; and a laboratory in San Diego, California to perform our SneakPeek Early Gender DNA test. Our laboratories and the equipment we use to perform our tests would be difficult to replace and may require significant lead time to replace and qualify for use if they become inoperable. Some of our laboratories are located near active earthquake fault lines and in a region affected by wildfires and flooding. We currently have no backup or redundant facility to perform each of our tests. In the event any of our testing facilities were to lose its CLIA certification or other required certifications or licenses or were affected by a pandemic or man-made or natural disaster, such as an earthquake, severe weather, flooding, rising sea levels, other physical effects of climate change, power outages or contamination, we would be unable to continue our business, with respect to the tests performed at the particular facility or overall, at current levels to meet customer demands for a significant period of time. According to the U.S. Environmental Protection Agency, heat waves and large storms are likely to become more frequent or more intense with human-induced climate change, which could impact our operations. Although we maintain insurance on these facilities, including business interruption insurance, it may not be adequate to protect us from all potential losses if these facilities were damaged or destroyed. In addition, any interruption in our business would result in a loss of goodwill, including damage to our reputation. If our business were interrupted, it would seriously harm our business.

Our inability to, or delay in, transitioning certain of our laboratory operations to new laboratory facilities in west Salt Lake City, Utah and South San Francisco, California could adversely affect our business.

We are in the process of transitioning our laboratory operations in Salt Lake City, Utah, where most of our tests are performed, and South San Francisco, California, where our Foresight and Prequel tests are performed, to new laboratory facilities in west Salt Lake City, Utah, and South San Francisco, California, respectively. The inability to transition our existing laboratory operations to our new laboratories in South San Francisco, California and west Salt Lake City, Utah, delays in transitioning our laboratory operations to such facilities or the failure to obtain any required permits, licenses, or certifications could result in increased costs, limit our ability to keep up with the demand for our products, and prevent us from realizing the intended benefits of these new facilities and our future laboratories.

We depend on a limited number of third parties, or, in some cases, single-source suppliers, for equipment, reagents and other supplies. If these supplies become unavailable or are disrupted, then we may not be able to successfully perform our research or operate our business on a timely basis or at all.

We currently rely on a small number of suppliers, or, in some cases, single-source suppliers, to provide our gene sequencing equipment, content enrichment equipment, multiplex protein analysis equipment, robots, and specialty reagents and other laboratory supplies required in connection with our testing and research and development activities. We believe that currently there are limited alternative suppliers of the equipment, robots, reagents and certain other supplies that we use in our business. The equipment, robots, reagents or other supplies may not remain available in commercial quantities at acceptable costs. In addition, we rely upon a limited number of commercial delivery services to provide us with laboratory supplies, and the disruption of such delivery services could adversely impact our business. If we are unable to obtain when needed additional or alternative equipment or robots, or an adequate supply of reagents or other ingredients or supplies at commercially reasonable rates, our ability to continue to identify genes and perform testing would be adversely affected. In addition, the loss of a single-source supplier or the failure to perform by a single-source supplier could have a disruptive effect on our business, including our ability to perform testing, and could adversely affect our results of operations.

In addition, the spread of disease globally could further adversely affect our manufacturing and supply chain. Parts of our direct and indirect supply chain are located overseas and both international and domestic components have been subject to disruption as a result of COVID-19 and responses to it. We have experienced and may in the future experience a shortage of certain laboratory supplies and equipment, and we may experience a suspension of services from other laboratories or third parties as a result of a global pandemic and responses to it. Political, administrative, legislative, legal or regulatory actions in response to a global pandemic could create additional supply shortages, disruptions or other uncertainties affecting our research and business. If the supplies and components necessary to manufacture our products become unavailable or are disrupted, then we may not be able to successfully perform our research or operate our business on a timely basis or at all.

Further, disruption in the global supply chain related to hostilities in Ukraine and the Middle East could impact our supply chain. For example, Houthi forces have recently begun attacking freighters in the Red Sea due to the ongoing conflict between Israel and Gaza. While we have not experienced material supply chain disruptions related to these global hostilities to date, we are unable to predict how these conflicts will develop or guarantee that we will not experience material supply chain disruptions in the future.

Our international business exposes us to business, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States.

As part of our business strategy, we operate in international markets and have active sales operations in Germany, France, and Japan and production operations in Germany. We also distribute our SneakPeek Early Gender DNA Test through distributors in the United Kingdom, Australia, Canada and certain other countries. We may establish additional operations or acquire additional properties outside the United States in order to advance our international sales. Doing business internationally involves a number of risks, including:

- multiple, conflicting and changing laws and regulations such as tax laws, export and import restrictions, employment laws, data privacy laws such as the EU GDPR, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us to obtain regulatory approvals or adequate reimbursement for the use of our tests in various countries;
- ineffective marketing campaigns leading to failure in establishing a viable, profitable, and sustainable presence in our international markets;
- difficulty in staffing and managing foreign operations;
- managing multiple payor reimbursement regimes, government payors and self-pay systems;
- complexities and difficulties in obtaining protection and enforcing our intellectual property;
- logistics and regulations associated with shipping patient samples, including infrastructure conditions, customs and transportation delays, including compliance with the Office of Foreign Assets Control and other international trade sanctions;
- limits in our ability to penetrate international markets if we are not able to process tests locally;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable and exposure to foreign currency exchange rate fluctuations;
- political and economic instability, including wars, terrorism, and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions;
- 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 U.S. Foreign Corrupt Practice Act, UK Bribery Act, anti-boycott laws and other anti-corruption laws; and
- risks related to the disruptions caused by COVID-19 or another disease and responses to it.

Any of these factors could significantly harm our international operations and, consequently, our revenues and results of operations. In addition, any failure to comply with applicable legal and regulatory obligations could impact us in a variety of ways that include, but are not limited to, significant criminal, civil and administrative penalties, including imprisonment of individuals, fines and penalties, denial of export privileges, seizure of shipments, and restrictions on certain business activities. Also, the failure to comply with applicable legal and regulatory obligations could result in the disruption of our distribution and sales activities.

Our international operations could be affected by changes in laws, trade regulations, labor and employment regulations, and procedures and actions affecting approval, production, pricing, reimbursement and marketing of tests, as well as by inter-governmental disputes. Any of these changes could adversely affect our business. Our success internationally will depend, in part, on our ability to develop and implement policies and strategies that are effective in anticipating and managing these and other risks in the countries in which we do business. Failure to manage these and other risks may have a material adverse effect on our operations in any particular country and on our business as a whole.

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

Genetic testing has raised ethical, legal and social issues regarding privacy rights and the appropriate uses of the resulting information. Governmental authorities could, for social or other purposes, limit or regulate the use of genetic information or genetic testing or prohibit testing for 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 even if permissible; they may also refuse genetic testing due to concerns regarding eligibility for life or other insurance. Ethical and social concerns may also influence U.S. and foreign patent offices and courts with regard to patent protection for technology relevant to our business. Although the Genetic Information Non-discrimination Act has criminalized the disallowance of health insurance on the basis of genetic information, modification or retraction of this federal law could reduce public demand for genetic testing. These and other ethical, legal and social concerns may limit market acceptance of our tests or reduce the potential markets for our tests, either of which could have an adverse effect on our business, financial condition or results of operations.

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

Our core business depends on our ability to quickly and reliably deliver test results to our customers. We typically receive biological material for analysis at our laboratory facilities within days of collection from the patient. Disruptions in delivery service, whether due to errors by the courier service, labor disruptions, bad weather, natural disasters, terrorist acts or threats or other reasons, some of which we have experienced in the past, 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. We also rely on commercial courier delivery services to transport some of our tests directly to customers and any disruptions in delivery service could adversely affect our ability obtain and process samples in a timely manner and to service our customers.

We face risks associated with currency exchange rate fluctuations, which could adversely affect our operating results.

We receive a portion of our revenues and pay a portion of our expenses in currencies other than the U.S. dollar, such as the Japanese Yen, Euro, the Swiss franc, and the British pound. As a result, we are at risk for exchange rate fluctuations between such foreign currencies and the U.S. dollar, which could affect the results of our operations. If the U.S. dollar strengthens against foreign currencies, the translation of these foreign currency denominated transactions will result in decreased revenues and operating expenses. During the year ended December 31, 2023, our revenues were not materially impacted due to foreign currency fluctuations, but may be in the future. We may not be able to offset adverse foreign currency impact with increased revenues. We do not currently utilize hedging strategies to mitigate foreign currency risk and even if we were to implement hedging strategies to mitigate foreign currency risk, these strategies might not eliminate our exposure to foreign exchange rate fluctuations and would involve costs and risks of their own, such as ongoing management time and expertise, external costs to implement the strategies and potential accounting implications.

Impairment in the value of our goodwill or other intangible assets could have a material adverse effect on our operating results and financial condition.

We record goodwill and intangible assets at fair value upon the acquisition of a business. Goodwill represents the excess of amounts paid for acquiring businesses over the fair value of the net assets acquired. Goodwill and indefinite-lived intangible assets are evaluated for impairment annually, or more frequently if conditions warrant, by comparing the carrying value of a reporting unit to its estimated fair value. Intangible assets with definite lives are reviewed for impairment when events or circumstances indicate that their carrying value may not be recoverable. Declines in operating results, divestitures, sustained market declines and other factors that impact the fair value of our reporting unit could result in an impairment of goodwill or intangible assets and, in turn, a charge to net income. Any such charges could have a material adverse effect on our results of operations or financial condition.

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

Our actionable market size opportunity estimates and growth forecasts for our products are subject to significant uncertainty and are based on assumptions and estimates that may not prove to be accurate. Our publicly announced estimates and forecasts relating to the size and expected growth of the market for our products may prove to be inaccurate. Even if the markets in which we compete meet our size estimates and forecasted growth for such markets, our business could fail to grow at similar rates.

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

As of December 31, 2023, we have substantial deferred tax assets related to net operating loss (“NOLs”) and tax credit carryforwards. Pursuant to the Tax Cuts and Jobs Act (H.R.1) of 2017, federal NOLs arising in tax years beginning after December 31, 2017 have an indefinite carryover period and may only be used to offset 80% of current year taxable income. Federal NOLs prior to this enactment were subject to a 20-year carry-forward limitation. Further, under Section 382 of the Internal Revenue Code of 1986, as amended (the "Code"), if a corporation undergoes an “ownership change” (generally defined as a greater than 50% change, by value, in equity ownership over any three-year period), the corporation’s ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. Given the Code’s broad definition, an ownership change could be the unintended consequence of otherwise normal market trading in our stock that is outside our control. An ownership change under Section 382 of the Code could also be triggered by certain strategic transactions. These limitations may result in our NOLs, tax credits, or other similar tax attributes expiring before we have the ability to use them.

Risks Related to the Development and Commercialization of Our Tests and Test Candidates

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

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

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

These factors present obstacles to commercial acceptance of our tests, which we would have to spend substantial time and money to overcome, if we can do so at all. Our inability to successfully do so would harm our business.

In addition, we may experience research and development and regulatory challenges that could delay or prevent the development and commercialization of new test offerings, such as FirstGene and Precise MRD. The tests we enhance or develop may not be clinically effective in clinical trials or commercially, or may not ultimately meet our desired target product profile, be offered at acceptable cost and with the test performance metrics necessary to address the relevant clinical need or commercial opportunity. We also may experience difficulties completing the clinical development of any new or enhanced product, or establishing or maintaining the collaborative relations that may be essential to our clinical development and commercialization efforts. Clinical development requires large numbers of patient specimens and, for certain products, require large, prospective, and controlled clinical trials. We may not be able to enroll patients or collect a sufficient number of appropriate specimens in a timely manner, or we may experience delays during clinical development due to slower than anticipated enrollment, or due to changes in study design or other unforeseen circumstances, or we may be unable to afford or manage the large-sized clinical trials that some of our planned future products may require.

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

If we do not compete effectively with scientific and commercial competitors, we may not be able to successfully commercialize our tests, increase our revenue or achieve and sustain profitability.

The clinical laboratory and genetics testing fields are intense, highly competitive and characterized by rapid technological change, frequent new product introductions, reimbursement challenges, emerging competition, intellectual property disputes and litigation, price competition, aggressive marketing practices, evolving industry standards, and changing customer preferences. Our competitors in the United States and abroad are numerous and include, among others, major diagnostic companies, reference laboratories, molecular diagnostic firms, direct-to-consumer genetic companies, low-priced competitors, clinical laboratories, universities and other research institutions. Some of our competitors and potential competitors have larger customer bases, greater brand recognition and market penetration, better selling and marketing capabilities, more experience with third-party payors and considerably greater financial, technical, marketing and other resources than we do, which has allowed and may continue to allow these competitors to discover important genes and determine their function before we do, respond more quickly to changes in customer preferences, devote greater resources to the development, promotion and sale of their tests than we do, sell their tests at prices designed to win significant levels of market share, or obtain reimbursement from more third-party payors and at higher prices than we do. We could be adversely affected if we do not discover genes, proteins or biomarkers and characterize their function, develop tests based on these discoveries, obtain required regulatory and other approvals and launch these tests and their related services before our competitors. We may also not be able to keep pace with the rapid technological changes in our industry, or properly leverage new technologies to achieve or sustain competitive advantages in our tests, systems and processes. We also expect to encounter significant competition with respect to any tests that we may develop or commercialize. Those companies that bring to market new tests before we do may achieve a significant competitive advantage in marketing and commercializing their tests. We may not be able to develop additional tests successfully and we or our licensors may not obtain or enforce patents covering these tests that provide protection against our competitors. Moreover, our competitors may succeed in developing tests that circumvent our technologies or tests. Furthermore, our competitors may succeed in developing technologies or tests that are more effective or less costly than those developed by us or that would render our technologies or tests less competitive or obsolete. Increased competition and cost-saving initiatives on the part of governmental entities and third-party payors are likely to result in pricing pressures, which could harm our sales, profitability or ability to gain market share. We expect competition to intensify in the fields in which we are involved as technical advances in these fields occur and become more widely known and changes in intellectual property laws generate challenges to our intellectual property position.

If our current research collaborators or scientific advisors terminate their relationships with us or develop relationships with a competitor, our ability to discover genes, proteins, and biomarkers, and to validate and commercialize tests could be adversely affected.

We have relationships with research collaborators at academic and other institutions who conduct research at our request. These research collaborators are not our employees. As a result, we have limited control over their activities and, except as otherwise required by our collaboration agreements, can expect only limited amounts of their time to be dedicated to our activities. Our ability to discover genes, proteins, and biomarkers involved in human disease and validate and commercialize tests will depend in part on the continuation of these collaborations. If any of these collaborations are terminated, we may not be able to enter into other acceptable collaborations. In addition, our existing collaborations may not be successful.

Our research collaborators and scientific advisors may have relationships with other commercial entities, some of which could compete with us. Our research collaborators and scientific advisors sign agreements which provide for the confidentiality of our proprietary information. We may not, however, be able to maintain the confidentiality of our technology and other confidential information related to all collaborations. The dissemination of our confidential information to third parties could have a material adverse effect on our business.

Risks Related to Our Intellectual Property

If we fail to protect our proprietary technology, others could compete against us more directly, which would harm our business.

As of December 31, 2023, our patent portfolio included issued patents owned or licensed by us and numerous patent applications in the United States and other countries with claims protecting our intellectual property rights. Our commercial success will depend, in part, on our ability to obtain additional patents and licenses and protect our existing patent position, both in the United States and in other countries, for compositions, processes, methods and other inventions that we believe are patentable. Our ability to preserve our trade secrets, proprietary data bases and other intellectual property is also important to our long-term success. If our intellectual property is not adequately protected, competitors may be able to use our technologies and erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. Patents may also issue to third parties which could interfere with our ability to bring our tests to market. The laws of some foreign countries do not protect our proprietary rights to the same extent as U.S. laws, and we may encounter significant problems in protecting our proprietary rights in these countries.

The patent positions of diagnostic companies, including our patent position, are generally highly uncertain and involve complex legal and factual questions, and, therefore, any patents issued to us may be challenged, deemed unenforceable, invalidated or circumvented. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies and any future tests are covered by valid and enforceable patents or are effectively maintained as trade secrets. Our patent applications may never issue as patents, and the claims of any issued patents may not afford meaningful protection for our technology or tests. In addition, any patents issued to us or our licensors may be challenged, and subsequently narrowed, invalidated or circumvented.

Where necessary, we may initiate litigation to enforce our patent or other intellectual property rights. Any such litigation may require us to spend a substantial amount of time and money and could distract management from our day-to-day operations. Moreover, there is no assurance that we will be successful in any such litigation.

The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that:

- we or our licensors were the first to make the inventions covered by each of our patent applications;
- we or our licensors were the first to file patent applications for these inventions;
- others will not independently develop similar or alternative technologies or duplicate any of our technologies;
- any of our or our licensors' patent applications will result in issued patents;
- any of our or our licensors' patents will be valid or enforceable;
- any patents issued to us or our licensors and collaborators will provide a basis for commercially viable tests, will provide us with any competitive advantages or will not be challenged by third parties;
- we will develop additional proprietary technologies or tests that are patentable;
- the patents of others will not have an adverse effect on our business; or
- our patents or patents that we license from others will survive legal challenges and remain valid and enforceable.

If a third party files a patent application with claims to subject matter we have invented, the U.S. Patent and Trademark Office (USPTO) may declare interference between competing patent applications. If an interference is declared, we may not prevail in the interference. If the other party prevails in the interference, we may be precluded from commercializing services or tests based on the invention or may be required to seek a license. A license may not be available to us on commercially acceptable terms, if at all.

We also rely on trade secrets to protect our proprietary technologies and databases, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and others to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy if unauthorized disclosure of confidential information occurs. In addition, others may independently discover our trade secrets and proprietary information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive position.

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

Our tests may conflict with patents that have been or may be granted to others. Our industry includes many organizations that have or are seeking to discern biomarkers and develop genomic, proteomic and other technologies. To the extent any patents are issued or have been issued to those organizations, the risk increases that the sale of our tests currently being marketed or under development may give rise to claims of patent infringement. Others may have filed and in the future are likely to file patent applications covering biomarkers that are similar or identical to our tests. Any of these patent applications may have priority over our patent applications and these entities or persons could bring legal proceedings against us seeking damages or seeking to enjoin us from testing or marketing our tests. Patent litigation is costly, and even if we prevail, the cost of such litigation could have a material adverse effect on us. If the other parties in any such actions are successful, in addition to any liability for damages, we could be required to cease the infringing activity or obtain a license. Any license required may not be available to us on commercially acceptable terms, if at all. Our failure to obtain a license to any technology that we may require to commercialize our tests could have a material adverse effect on our business. In addition, we could experience delays in product introductions or sales growth while we attempt to develop non-infringing alternatives.

We believe that there has been, and may continue to be, significant litigation in the industry regarding patent and other intellectual property rights. On December 21, 2020, Ravgen, Inc. ("Ravgen") filed a lawsuit against us and our wholly owned subsidiary, Myriad Women's Health, Inc., in the U.S. District Court for the District of Delaware, alleging infringement of two patents relating to blood collection tubes and non-invasive prenatal testing analysis. On October 23, 2023, we and Ravgen entered into a settlement agreement pursuant to which the parties agreed to settle the lawsuit. Pursuant to the terms of the settlement agreement, we agreed to pay Ravgen a minimum of $12.75 million in three installment payments of $5 million, $5 million, and $2.75 million on or before October 31, 2023, October 31, 2024, and October 31, 2025, respectively. We may also be required to pay Ravgen $21.25 million in five annual installments beginning no earlier than January 1, 2026 if certain conditions are satisfied. Any intellectual property litigation that we may become involved with in the future could consume a substantial portion of our managerial and financial resources. If any such litigation is resolved adversely to us, we could be required to pay damages, cease the infringing activity or pay an ongoing licensing fee, each of which could have a material adverse effect on our financial condition, results of operations or cash flows.

Additionally, third parties may claim that the branding of our products infringes the trademarks, service marks, trade names or otherwise misappropriates or dilutes those third parties' rights. If we are found to be liable or to have infringed upon those third parties' rights, we may be required to pay damages and rebrand the infringing products. Rebranding can be expensive and time-consuming and may lead to the loss of brand equity or goodwill associated with the rebranded products.

If we fail to comply with our obligations under license or technology agreements with third parties, we could lose license rights that are critical to our business.

We license intellectual property that is important to our business, including licenses underlying the technology in our tests, and in the future, we may enter into additional agreements that provide us with licenses to valuable intellectual property or technology. These licenses impose various royalty payments, milestones, and other obligations on us. If we fail to comply with any of these obligations, the licensor may have the right to terminate the license. Termination by the licensor would cause us to lose valuable rights, and could prevent us from distributing our current tests, or inhibit our ability to commercialize future test candidates. Our business would suffer if any current or future licenses terminate, if the licensors fail to abide by the terms of the license, if the licensors fail to prevent infringement by third parties, if the licensed patents or other rights are found to be invalid, unenforceable or infringe upon third party patents, or if we are unable to enter into necessary licenses on acceptable terms.

We may be subject to claims that we or our employees have wrongfully used or disclosed alleged trade secrets.

As is commonplace in our industry, we employ individuals who were previously employed at universities or genetic testing, diagnostic, biotechnology or other health care companies, including our competitors or potential competitors. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees or consultants have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of a former employer or other third parties. Litigation may be necessary to defend against these claims, and if we are unsuccessful, we could be required to pay substantial damages and could lose rights to important intellectual property. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

If we fail to adequately protect our trademarks, service marks, trade names and trade dress, we may lose goodwill and brand equity associated with our business.

Our registered and unregistered trademarks, service marks, or trade names could be infringed by third parties. Enforcing our rights against such third parties can be expensive and distracting. If we fail to effectively enforce such rights against third parties, our trademark, service mark or trade name rights, and the associated goodwill and brand equity, could be lost.

We file applications for registration of various marks associated with our brands in the United States and foreign jurisdictions. We may fail to successfully register these marks. Additionally, once a mark is registered, we may fail to pay all fees and attend to all formalities required to maintain the registration. Failure to obtain or maintain registration of our marks could make those marks harder to enforce and reduce the liability of an infringer even if we are able to successfully enforce such rights.

Risks Related to Government Regulation

If we fail to comply with the complex federal, state, local and foreign laws and regulations that apply to our business, we could suffer consequences that could materially and adversely affect our operating results and financial condition.

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

- Clinical Laboratory Improvement Amendments of 1988 and the implementing regulations, which requires that laboratories obtain certification from the federal government, and state licensure laws and regulations;
- U.S. Food and Drug Administration laws and regulations that apply to medical devices such as our companion diagnostics and other IVDs;
- Health Insurance Portability and Accountability Act of 1996 (HIPAA), which imposes 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 strengthened and expanded HIPAA privacy and security compliance requirements, increased penalties for violators, extended enforcement authority to state attorneys general and imposed requirements for breach notification;
- state laws regulating genetic testing and protecting the privacy of genetic test results, as well as state laws protecting the privacy and security of health information and personal data and mandating reporting of breaches to affected individuals and state regulators;
- the federal Anti-Kickback Statute, which prohibits knowingly and willfully offering, paying, soliciting, or receiving remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing, arranging for, or recommending of an item or service that is reimbursable, in whole or in part, by a federal health care program;
- the Eliminating Kickbacks in Recovery Act of 2018 (EKRA), which is an all-payor anti-kickback prohibition on, among other things, knowingly and willfully paying or offering any remuneration directly or indirectly to induce a referral of an individual to a clinical laboratory;
- the federal physician self-referral prohibition (Stark Law or the Physician Self-Referral Law), which, absent an exception, prohibits a physician from making a Medicare referral for certain designated health services, including clinical laboratory services, if the physician or an immediate family member of the physician has an applicable financial relationship with the entity providing the designated health services;
- 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 Medicaid 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 Medicaid, unless an exception applies;
- other federal and state fraud and abuse laws, such as anti-kickback laws, prohibitions on self-referral and fee-splitting, and false claims acts, which may extend to services reimbursable by any third-party payor, including private insurers;
- the federal Physician Payments Sunshine Act, which requires medical device manufactures to track and report to the federal government certain payments and other transfers of value made to physicians, other health care professionals, and teaching hospitals and ownership or investment interests held by physicians and their immediate family members;

- Section 216 of the federal Protecting Access to Medicare Act of 2014, which requires the Centers for Medicare & Medicaid Services (CMS) to set Medicare rates for clinical laboratory testing based on private payor data reported by applicable laboratories;
- the U.S. Foreign Corrupt Practices Act of 1977, as amended, which prohibits companies and their intermediaries from making payments in violation of law to non-U.S. government officials for the purpose of obtaining or retaining business or securing any other improper advantage;
- state laws that impose reporting and other compliance-related requirements; and
- similar foreign laws and regulations that apply to us in the countries in which we operate.

We may also be subject to or affected by current or future federal, state, local and foreign laws and regulations, including laws relating to reproductive health care, which could restrict our business, reduce demand for our products, and adversely affect our operations, revenue, and results of operations.

As a clinical laboratory, our business practices may face heightened scrutiny from government enforcement agencies such as the Department of Justice, the Office of Inspector General for the Department of Health and Human Services (OIG), and CMS. The OIG has issued fraud alerts in recent years, including a fraud alert relating to speaker programs in November 2020, that identify certain arrangements between medical device and drug companies and referring physicians as implicating the Anti-Kickback Statute. Moreover, the provision of payments or other items of value by a clinical laboratory to a referral source could be prohibited under the federal self-referral prohibition, commonly known as the Stark Law or the Physician Self-Referral Law, unless the arrangement meets all criteria of an applicable exception. The government has actively enforced these laws, as well as the federal False Claims Act, against clinical laboratories in recent years.

These laws and regulations are complex and are subject to interpretation by the courts and by government agencies. Our failure to comply could lead to civil or criminal penalties, exclusion from participation in state and federal health care programs, or prohibitions or restrictions on our laboratories' ability to provide or receive payment for our services. We believe that we are in material compliance with all statutory and regulatory requirements, but there is a risk that one or more government agencies could take a contrary position, or that a private party could file suit under the qui tam provisions of the federal False Claims Act or a similar state law. Such occurrences, regardless of their outcome, could damage our reputation and adversely affect important business relationships with third parties, including managed care organizations, and other private third-party payors.

The growth of our business and our continued business outside of the United States may increase the potential of violating similar foreign 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. Any of the foregoing consequences could seriously harm our business and our financial results.

Our actual or perceived failure to comply with data protection laws and regulations could lead to government enforcement actions, private litigation and/or adverse publicity and could negatively affect our business.

We are subject to domestic and international data protection laws and regulations that address privacy and data security and may affect our collection, use, storage, and transfer of personal information. The legislative and regulatory landscape for data protection continues to evolve, and in recent years there has been an increasing focus on privacy and data security issues with the potential to affect our business. In the U.S., numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws and federal and state consumer protection laws govern the collection, use, disclosure and protection of health-related and other personal information. Failure to comply with data protection laws and regulations, where applicable, could result in government enforcement actions, which could include civil or criminal penalties, private litigation and/or adverse publicity and could negatively affect our operating results and business. For example, California has enacted the California Consumer Privacy Act, or CCPA, which went into effect in January of 2020. The CCPA established a new privacy framework for covered businesses by creating an expanded definition of personal information, establishing new data privacy rights for California residents, requiring covered businesses to provide new disclosures to California residents, and creating a new and potentially severe statutory damages framework for violations of the CCPA and for businesses that fail to implement reasonable security procedures and practices to prevent data breaches. Additionally in 2020, California voters passed the California Privacy Rights Act, or CPRA, which went into effect on January 1, 2023. The CPRA significantly amends the CCPA, potentially resulting in further uncertainty, additional costs and expenses in an effort to comply and additional potential for harm and liability for failure to comply. Among other things, the CPRA established a new regulatory authority, the California Privacy Protection Agency, which is tasked with enacting new regulations under the CPRA and will have expanded enforcement authority. In addition to California, more U.S. states are enacting similar legislation, increasing compliance complexity and increasing risks of failures to comply. In 2023, comprehensive privacy laws in Virginia, Colorado, Connecticut, and Utah all took effect, and laws in Montana, Oregon, and Texas will take effect in 2024. In addition, laws in other U.S. states are set to take effect beyond 2024, and additional U.S. states have proposals under consideration, all of which are likely to increase our regulatory compliance costs and risks, exposure to regulatory enforcement action and other liabilities.

Numerous other countries have, or are developing, laws governing the collection, use and transmission of personal information as well. For example, the European Union's General Data Protection Regulation (GDPR), became effective in 2018 and imposed a broad data protection framework that expanded the scope of EU data protection law, including to non-EU entities meeting the jurisdictional requirements that process, or control the processing of, personal data relating to individuals located in the EU, including clinical trial data. The GDPR sets out a number of requirements for controllers and/or processors, as applicable, that must be complied with when handling the personal data of EU based data subjects, including: providing expanded disclosures about how their personal data will be used; higher standards for organizations to demonstrate that they have obtained valid consent or have another legal basis in place to justify their data processing activities; the obligation to appoint data protection officers in certain circumstances; new rights for individuals to be "forgotten" and rights to data portability, as well as enhanced current rights (e.g., access requests); the principal of accountability and demonstrating compliance through policies, procedures, training and audit; and a new mandatory data breach regime. In particular, medical or health data, genetic data and biometric data are all classified as "special category" data under the GDPR and afford greater protection and require additional compliance obligations. Further, EU member states have a broad right to impose additional conditions—including restrictions—on these data categories. This is because the GDPR allows EU member states to derogate from the requirements of the GDPR mainly in regard to specific processing situations (including special category data and processing for scientific or statistical purposes).

The GDPR is applicable to part of our business and has increased our responsibility and liability in relation to personal data that we process, and we may be required to put in place additional procedures to comply. The GDPR is complex and regulatory guidance continues to evolve. Furthermore, national GDPR variations, including the fields of clinical study and other health-related information may raise our costs of compliance and result in greater legal risks.

We are also subject to evolving GDPR requirements on data export, because we transfer data to third countries outside of the EU that are not deemed "adequate." The GDPR only permits exports of personal data outside of the EU to "non-adequate" countries where there is a suitable data transfer mechanism in place to safeguard personal data (e.g., the EU Commission approved Standard Contractual Clauses or certification under the newly-adopted Data Privacy Framework). On July 16, 2020, the Court of Justice of the EU, or the CJEU, issued a landmark opinion in the case Maximilian Schrems vs. Facebook (Case C-311/18) (Schrems II). This decision calls into question certain data transfer mechanisms as between the EU member states and the U.S. The CJEU is the highest court in Europe and the Schrems II decision heightened the burden to assess U.S. national security laws on their business, and future actions of EU data protection authorities are difficult to predict at this time. While the newly-adopted Data Privacy Framework was meant to address the concerns raised by the CJEU in Schrems II, it will likely be subject to future legal challenges. Consequently, there is some risk of any data transfers from the EU being halted. If we have to rely on third parties to carry out services for us, including processing personal data on our behalf, we are required under GDPR to enter into contractual arrangements to flow down or help ensure that these third parties only process such data according to our instructions and have sufficient security measures in place. Any security breach or non-compliance with our contractual terms or breach of applicable law by such third parties could result in enforcement actions, litigation, fines and penalties or adverse publicity and could cause customers to lose trust in us, which would have an adverse impact on our reputation and business. Any contractual arrangements requiring the processing of personal data from the EU to us in the U.S. will require greater scrutiny and assessments as required under Schrems II and may have an adverse impact on cross-border transfers of personal data or increase costs of compliance. The GDPR provides an enforcement authority to impose large penalties for noncompliance, including the potential for fines of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater.

Applicable data privacy and data protection laws may conflict with each other, and by complying with the laws or regulations of one jurisdiction, we may find that we are violating the laws or regulations of another jurisdiction. Despite our efforts, we may not have fully complied in the past and may not in the future. That could require us to incur significant expenses, which could significantly affect our business. Failure to comply with data protection laws may expose us to risk of enforcement actions taken by data protection authorities or other regulatory agencies, private rights of action in some jurisdictions, and potential significant penalties if we are found to be non-compliant. Furthermore, the number of government investigations related to data security incidents and privacy violations continue to increase and government investigations typically require significant resources and generate negative publicity, which could harm our business and reputation.

We may from time to time be subject to government investigation(s), the unfavorable outcome of which may have a material adverse effect on our financial condition, results of operations and cash flows.

We may from time to time be subject to government investigations, which may divert management resources and attention, cause us to incur substantial costs, and/or result in negative publicity, and any unfavorable outcome arising from such investigation may have a material adverse effect on our financial condition, results of operations and cash flows. For example, in June 2016, our wholly-owned subsidiary, Crescendo Bioscience, LLC (formerly known as Crescendo Bioscience, Inc.) (CBI), received a subpoena from the Office of Inspector General of the Department of Health and Human Services requesting that CBI produce documents relating to entities that received payment from CBI for the collection and processing of blood specimens for testing, including a named unrelated company, healthcare providers and other third-party entities. On January 30, 2020, the U.S. District Court for the Northern District of California unsealed a qui tam complaint, filed on April 16, 2016 against CBI, alleging violations of the federal and California False Claims Acts and the California Insurance Fraud Prevention Act (CIFPA). On January 22, 2020, after a multi-year investigation into CBI's and the Company's alleged conduct, the United States declined to intervene. On January 27, 2020, the State of California likewise filed its notice of declination. On April 1, 2022, we settled the qui tam lawsuit pursuant to which we paid a total of $45.25 million to the United States and the State of California and $2.75 million to relator's counsel. The qui tam lawsuit was formally dismissed by the U.S. District Court for the Northern District of California on May 4, 2022. We may be subject to future claims or investigations under the Federal False Claims Act or a similar state law, and any unfavorable outcome arising from such claims or investigation could have a material adverse effect on our financial condition, results of operations and cash flows.

Changes in health care policy could increase our costs, decrease our revenues and impact sales of and reimbursement for our tests.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, collectively called the ACA, became law. This law substantially changed the way health care is financed by both government and private third-party payors and continues to significantly impact our business and operations in ways we may not be able to predict. Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, and as a result, certain sections of the ACA have not been fully implemented or were effectively repealed. However, following several years of litigation in the federal courts, in June 2021, the U.S. Supreme Court upheld the ACA when it dismissed a legal challenge to the ACA's constitutionality. Further legislative and regulatory changes under the ACA remain possible. The federal administration under President Biden has signaled that it plans to build on the ACA and expand the number of people who are eligible for health insurance subsidies under it. Future changes or additions to the ACA or the Medicare and Medicaid programs, such as changes stemming from other health care reform measures, especially with regard to health care access, financing or other legislation in individual states, could have a material adverse effect on the health care industry in the United States. The uncertainty around the future of the ACA, and in particular the impact to reimbursement levels and the number of insured individuals, may lead to delay in the purchasing decisions of our customers, which may in turn negatively impact our product sales. Further, if reimbursement levels are inadequate, our business and results of operations could be adversely affected.

In addition to the ACA, there will continue to be proposals by legislators at both the federal and state levels, regulators and private third-party payors to reduce costs while expanding individual health care benefits. Certain of these changes could impose additional limitations on the prices we will be able to charge for our tests or the amounts of reimbursement available for our tests from governmental agencies or private third-party payors. Any future changes to legal or regulatory requirements or new cost containment initiatives could have a materially adverse effect on our business, financial condition, results of operation, and cash flows.

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

The diagnostic testing industry is subject to extensive laws and regulations, many of which have not been interpreted by the courts. CLIA requires virtually all laboratories to be certified by the federal government and mandates compliance with various operational, personnel, facilities administration, quality and proficiency testing requirements intended to ensure that testing services are accurate, reliable and timely. CLIA certification is also a prerequisite to be eligible to bill state and federal health care programs, as well as many private third-party payors, for laboratory testing services. As a condition of CLIA certification, each of our laboratories is subject to survey and inspection every other year, in addition to being subject to additional random inspections. The biennial survey is conducted by CMS, a CMS agent (typically a state agency), or, if the laboratory holds a CLIA certificate of accreditation, a CMS-approved accreditation organization. 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 fines or criminal penalties. In addition, we are subject to regulation under state laws and regulations governing laboratory licensure. Some states have enacted state licensure laws that are more stringent than CLIA. We are also subject to laws and regulations governing our reference laboratory in Germany. Changes in state or foreign licensure laws that affect our ability to offer and provide diagnostic services across state or foreign country lines could materially and adversely affect our business. In addition, state and foreign requirements for laboratory certification may be costly or difficult to meet and could affect our ability to receive specimens from certain states or foreign countries.

Any sanction imposed under CLIA, its implementing regulations, or state or foreign laws or regulations governing licensure, or our failure to renew a CLIA certificate, a state or foreign license, or accreditation, could have a material adverse effect on our business. If the CLIA certificate of any one of our laboratories is revoked, CMS could seek revocation of the CLIA certificates of our other laboratories based on their common ownership or operation, even though they are separately certified.

Changes in the way that the FDA regulates tests performed by laboratories like ours could result in delay or additional expense in offering our tests and tests that we may develop in the future.

Historically, the FDA has exercised enforcement discretion with respect to most laboratory developed tests (LDTs) and has generally not required laboratories that furnish LDTs to comply with the agency's requirements for medical devices (e.g., establishment registration, device listing, quality systems regulations, premarket clearance or premarket approval, and post-market controls). As of December 31, 2023, none of our products other than MyChoice CDx and BRACAnalysis CDx are marketed by us under the FDA's requirements for medical devices. In recent years, the FDA publicly announced its intention to regulate certain LDTs and issued two draft guidance documents that set forth a proposed phased-in risk-based regulatory framework that would apply varying levels of FDA oversight to LDTs. However, these guidance documents were not finalized, and in 2017, the FDA issued an informal discussion paper reflecting some of the feedback that FDA had received on the proposed LDT regulatory system.

Subsequently, in October 2023, FDA issued a proposed rule to regulate LDTs under the current medical device framework and proposed to phase out the current enforcement discretion policy; the public comment period ended in early December 2023. The proposal envisions that the LDT enforcement policy phase-out process would occur in gradual stages over a total period of four years, with premarket approval applications for high-risk tests to be submitted by the 3.5-year mark, although more details are expected to be provided with the upcoming final rule. The likelihood of the FDA finalizing the proposed rule in April 2024 (as currently projected), as well as potential litigation challenging its authority to take such action, is uncertain at this time. Affected stakeholders continue to press for a comprehensive legislative solution to create a harmonized paradigm for oversight of LDTs by both the FDA and CMS, instead of implementation of the proposed administrative agency action, which may be disruptive to the industry and to patient access to certain diagnostic tests. Until any administrative rulemaking is finalized and regulatory changes become effective, the FDA is expected to continue to exercise enforcement discretion; although it may attempt to regulate certain LDTs on a case-by-case basis at any time, which could result in delay or additional expense in offering our tests and tests that we may develop in the future.

In addition, for several years bipartisan members of Congress have been negotiating legislation with the FDA and industry stakeholders to regulate in vitro clinical tests including LDTs under a shared FDA/CMS framework. Most recently, reform legislation entitled the Verifying Accurate, Leading-edge IVCT Development (VALID) Act received increasing congressional support. As drafted and re-introduced for consideration by the current Congress, the VALID Act would codify into law the term "in vitro clinical test" (IVCT) to create a new medical product category separate from medical devices that includes products currently regulated as in vitro diagnostics (IVDs) as well as LDTs. If enacted, the VALID Act's regulatory framework would give the FDA the authority to ensure IVCTs are both analytically and clinically valid. While CMS would retain the authority to ensure the quality of operations within laboratories. All LDTs on the market prior to enactment of the legislation would be grandfathered and not subject to the new regulation. The FDA's recent publication of an LDT proposed rule that would apply the existing medical device framework to laboratory-developed products may renew stakeholder calls for a more targeted approach to modernizing federal oversight of clinical diagnostic tests. It remains possible that congressional action in this area could displace the need for the FDA to complete its recently proposed rulemaking.

It is unclear whether the VALID Act or other diagnostic reform legislation will be passed by Congress or signed into law by the President. Until the FDA finalizes its regulatory position regarding LDTs through formal notice-and-comment rulemaking, or the VALID Act or other legislation is passed reforming the federal government's regulation of LDTs, it is unknown how the FDA may attempt to regulate our tests in the future and what testing and data may be required to support any required clearance or approval of our tests by the agency. If the VALID Act is implemented as drafted, or if the FDA were to finalize the proposed rule to regulate most LDTs as medical devices, it could have a materially adverse impact on our results of operations.

FDA regulation of our GeneSight Psychotropic test could be disruptive to our business.

As described further above, the FDA has long claimed authority to regulate laboratory-developed tests but has exercised its "enforcement discretion" to limit enforcement of in vitro diagnostic regulatory requirements on this category of products. In October 2023, FDA issued a proposed rule to regulate LDTs under the current medical device framework and proposed to phase out the current enforcement discretion policy. Further, the FDA has from time to time appeared to increase its attention to the marketing of pharmacogenetic tests. For example, in late 2018, the FDA issued a safety communication regarding "genetic tests that claim results can be used to help physicians identify which antidepressant medication would have increased effectiveness or side effects compared to other antidepressant medications." This safety communication explained that the FDA had reached out to several firms marketing such pharmacogenetic tests where the FDA believed the relationship between genetic variations and a medication's effects had not been established, including a warning letter to Inova Genomics Laboratory.

In early 2019, we provided the FDA with clinical evidence and other information to support our GeneSight Psychotropic test. Later that year, the FDA requested changes to the GeneSight test offering. Although we disagreed that changes to the test were required, we submitted a proposal regarding the reporting of GeneSight test results to healthcare providers that we believed addressed the FDA's principal concerns and would not affect the benefits that we believe are provided by the GeneSight test.

Since submitting our proposal to the FDA, we engaged with our trade association in their efforts to defend the offering of pharmacogenomic tests as LDTs and to monitor broader developments across the stakeholder community. In response to public letters from the national laboratory trade association and patient groups, on February 20, 2020, the FDA announced a new "collaboration between FDA's Center for Devices and Radiological Health and Center for Drug Evaluation and Research intended to provide the agency's view of the state of the current science in pharmacogenetics." Although the announcement again asserted that some pharmacogenetic test offerings may be potentially dangerous, the agency also acknowledged that pharmacogenetic testing "offers promise for informing the selection or dosing of some medications for certain individuals" when there is sufficient evidence demonstrating a relationship between how a person's genes may impact their metabolism of a drug or how they may respond to the drug. In conjunction with the announcement, the FDA also released an updated "Table of Pharmacogenetic Associations," which lists gene-drug interactions that the agency believes are supported by FDA-approved drug labeling and/or "sufficient scientific evidence based on published literature." The Table has been updated periodically since that time. Based on our discussions with the agency and these developments, we have not implemented our proposal to the FDA regarding the GeneSight test. While we see these developments as signaling a positive shift in the FDA's approach to regulating pharmacogenetic tests, we cannot predict with certainty the outcome of this matter or its timing, or whether the ultimate form of the GeneSight Psychotropic Mental Health Medication test offering, if it must be changed, will have an adverse effect on our revenues from the test.

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

Our companion and complementary diagnostic products, marketing, sales and development activities and manufacturing processes are subject to extensive and rigorous regulation by the FDA pursuant to the federal Food, Drug, and Cosmetic Act (FDCA), by comparable agencies in foreign countries, and by other regulatory agencies and governing bodies. Under the FDCA, companion diagnostics must receive FDA clearance or approval before they can be commercially marketed in the U.S. The process of obtaining marketing approval or clearance from the FDA or by comparable agencies in foreign countries for new products could:

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

Although we have successfully received FDA approval for some tests (e.g., our BRACAnalysis CDx and MyChoice CDx tests), we cannot predict whether or when we will be able to obtain FDA approval for other companion diagnostics that we are developing.

Our companion diagnostic tests are subject to ongoing regulatory compliance obligations and continued regulatory review and the failure to comply with such obligations could result in regulatory enforcement and/or penalties.

Companion diagnostic tests such as BRACAnalysis CDx and MyChoice CDx are subject to ongoing FDA and comparable foreign regulatory authority requirements for manufacturing, labeling, packaging, storage, distribution, quality, safety, sale, marketing, advertising, promotion, sampling, record-keeping, export, import, conduct of post-marketing studies and submission of safety, efficacy or other post-market information. In addition, we are subject to continued compliance with regulatory requirements applicable to medical devices and in vitro diagnostics. The FDA or other regulatory authorities may take regulatory enforcement or other legal action or may impose consent decrees or withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur with our marketed products. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and be subject to financial penalties or administrative action.

Our business involves environmental risks that may result in liability for us.

In connection with our laboratory operations and research and development activities, we are subject to federal, state and local laws, rules, regulations and policies governing the use, generation, manufacture, storage, air emission, effluent discharge, handling and disposal of certain materials, including hazardous materials, biological specimens, chemicals and waste. The cost of compliance with these laws and regulations may become significant and could negatively affect our operating results. Although we believe that we have complied with the applicable laws, regulations and policies in all material respects and have not been required to correct any material noncompliance, we may be required to incur significant costs to comply with environmental and health and safety regulations in the future. Although we believe that our safety procedures for handling and disposing of controlled materials comply with the standards prescribed by state and federal regulations, accidental contamination or injury to employees or third parties from the use, storage, handling or disposal of these materials may occur. In the event of such an occurrence, we could be held liable for any damages that result and any such liability could exceed our resources or any applicable insurance coverage we may have.

Risks Related to Our Common Stock

Our stock price is highly volatile, and our stock may lose all or a significant part of its value.

The market prices for securities of relevant testing companies have been volatile. This volatility has significantly affected the market prices for these securities for reasons frequently unrelated to the operating performance of the specific companies. These broad market fluctuations may adversely affect the market price of our common stock. The market price for our common stock has fluctuated significantly since public trading commenced in October 1995, and it is likely that the market price will continue to fluctuate in the future. In the year ended December 31, 2023, our stock price ranged from $13.82 per share to $24.21 per share. In addition, the stock market in general has experienced extreme price and volume fluctuations. Events or factors that may have a significant impact on our business and on the market price of our common stock include the following:

- failure to achieve and sustain revenue growth or margins in our business;
- major market events, such as the market's reaction to the COVID-19 pandemic generally and its specific impact on the Company;
- failure of any of our recently launched tests and any new test candidates to achieve commercial success;
- changes in the structure of healthcare payment systems and changes in governmental or private insurer reimbursement levels for our tests;
- introduction of new commercial tests or technological innovations by competitors;
- termination of the licenses underlying our tests;
- delays or other problems with operating our laboratory facilities;
- failure of any of our research and development programs;
- changes in intellectual property laws or the enforcement, validity or expiration of our patents in the United States and foreign countries;
- developments or disputes concerning patents or other proprietary rights involving us directly or otherwise affecting the industry as a whole;
- missing or changing the financial guidance we provide;
- failure of analysts to initiate or maintain coverage of our company;
- negative publicity, including misinformation, about our company, our tests or the industry in which we operate;
- changes in the government regulatory approval process for our existing and new tests;
- failure to meet estimates or recommendations by securities analysts that cover our common stock;
- issuance of new securities analysts reports or changes in estimates or recommendations by securities analysts relating to our common stock or the securities of our competitors;
- public concern over our approved tests and any test candidates;
- litigation, including the outcome of existing and new litigation against us;
- government and regulatory investigations;
- our ability to raise additional funds if and when needed;
- future sales or anticipated sales of our common stock by us or our stockholders;
- the timing and amount of any repurchases of our common stock;
- general market conditions, including as a result of changes in the rate of inflation and interest rates;
- potential seasonal slowness in sales, particularly in the quarters ending September 30 and March 31, the effects of which may be difficult to understand during periods of growth;
- general perception of the industry and our products;
- economic, health care and diagnostic trends, disasters or crises and other external factors; and
- period-to-period fluctuations in our financial results.

These and other external factors may cause the market price and demand for our common stock to fluctuate substantially, which may limit or prevent investors from readily selling their shares of common stock and may otherwise negatively affect the liquidity of our common stock.

If we are unable to achieve and maintain effective disclosure controls and procedures and internal control over financial reporting, our results of operations, our stock price and investor confidence in us could be adversely affected.

Section 404 of the Sarbanes-Oxley Act of 2002 requires that companies evaluate and report on the effectiveness of their internal control over financial reporting. Failure to have effective internal control over financial reporting and disclosure controls and procedures could impair our ability to produce accurate financial statements on a timely basis and could lead to a restatement of our financial statements. If as a result of the ineffectiveness of our internal control over financial reporting and disclosure controls and procedures, we cannot provide reliable financial statements, our business decision processes may be adversely affected, our business and results of operations could be harmed, investors could lose confidence in our reported financial information, and our ability to obtain additional financing, or additional financing on favorable terms, could be adversely affected.

Although we determined that our internal controls over financing reporting were effective as of December 31, 2023, we may in the future identify internal control deficiencies that could rise to the level of a material weakness or uncover other errors in financial reporting. During the course of our evaluation of these material weaknesses, we may identify areas requiring improvement and may be required to design additional enhanced processes and controls to address issues identified through this review. There can be no assurance that such remediation efforts will be successful, that our internal control over financial reporting will be effective as a result of these efforts or that any such future deficiencies identified may not be material weaknesses that would be required to be reported in future periods. In addition, we cannot assure you that our independent registered public accounting firm will be able to attest that such internal controls are effective when they are required to do so.

If we fail to maintain effective disclosure controls and procedures or internal control over financial reporting or remediate any future material weaknesses, you may not be able to rely on the integrity of our financial results, which could result in inaccurate or late reporting of our financial results, as well as delays or the inability to meet our reporting obligations or to comply with the rules and regulations of the Securities and Exchange Commission. Any of these events could result in delisting actions by the Nasdaq Stock Market, investigation and sanctions by regulatory authorities, and stockholder investigations and lawsuits, in addition to adversely affecting our business and the trading price of our common stock.

Anti-takeover provisions of Delaware law, provisions in our charter and bylaws and re-adoption of our stockholders' rights plan, or poison pill, could make a third-party acquisition of us difficult.

Because we are a Delaware corporation, the anti-takeover provisions of Delaware law could make it more difficult for a third party to acquire control of us, even if the change in control would be beneficial to stockholders. We are subject to the provisions of Section 203 of the General Corporation Law of Delaware, which prohibits us from engaging in certain business combinations, unless the business combination is approved in a prescribed manner. In addition, our restated certificate of incorporation and restated bylaws also contain certain provisions that may make a third-party acquisition of us difficult, including:

- a classified Board of Directors, with three classes of directors each serving a staggered three-year term;
- the ability of the Board of Directors to issue preferred stock;
- a 70% super-majority stockholder vote to amend our bylaws and certain provisions of our certificate of incorporation;
- the inability of our stockholders to call a special meeting or act by written consent; and
- only our Board of Directors can fill vacancies on the Board.

In the past, we implemented a stockholders' rights plan, also called a poison pill, which could make it uneconomical for a third party to acquire the Company on a hostile basis. Although the plan expired in July 2011, our Board of Directors could adopt a new plan at any time. The provisions in a stockholders' rights plan, as well as Section 203, may discourage certain types of transactions in which our stockholders might otherwise receive a premium for their shares over the then-current market price, and may limit the ability of our stockholders to approve transactions that they think may be in their best interests.

Future sales and issuances of our common stock would result in dilution of the percentage ownership of our stockholders and could cause the price of our common stock to decline.

From time to time, we may issue additional securities or sell common stock, convertible securities or other securities in one or more transactions at prices and in a manner we determine. For example, in November 2023, we sold approximately 7.4 million shares of our common stock in an underwritten public offering. We also plan to continue to grant equity awards that convert into shares of our common stock to employees and directors pursuant to our equity incentive plan. If we sell or issue common stock, convertible securities or other equity securities, or common stock is issued pursuant to equity incentive plans, holders of our common stock may be materially diluted. In addition, we may issue common stock or other equity securities in connection with an acquisition or other strategic transaction, which would cause dilution to our existing stockholders. New investors in such transactions could gain rights, preferences and privileges senior to those of holders of our common stock.

We do not intend to pay dividends so any returns will be limited to changes in the value of our common stock.

We currently intend to retain any future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, the terms of our ABL Facility restrict our ability to pay dividends. Any determination to pay dividends in the future will be at the discretion of our Board of Directors and will depend on our financial condition, operating results, capital requirements, general business conditions and other factors that our Board of Directors may deem relevant. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for the foreseeable future.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. If few analysts continue coverage of us, the trading of our stock would likely decrease. Even if we do maintain sufficient analyst coverage, there can be no assurance that analysts will provide favorable coverage. If one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

Increasing scrutiny and evolving expectations from regulators, business partners, investors, and other stakeholders with respect to our environmental, social, and governance ("ESG") practices may impose additional costs on us or expose us to new or additional risks.

Companies across many industries are facing increasing scrutiny related to their ESG practices and disclosure. With this increased focus, public reporting regarding ESG practices is becoming more broadly expected. Any failure or perceived failure to accomplish or accurately track and report on our ESG initiatives on a timely basis or to meet stakeholder expectations could adversely affect our business, the willingness of our partners to do business with us, employee retention efforts, and our brand and reputation.

In addition, we expect there will likely be increasing levels of regulation, disclosure-related and otherwise, with respect to ESG matters. For example, during 2022, the SEC proposed rules that require companies to provide significantly expanded climate-related disclosures in their periodic reporting, which may require us to incur significant additional costs to comply, including the implementation of significant additional internal controls processes and procedures regarding matters that have not been subject to such controls in the past, and impose increased oversight obligations on our management and Board of Directors. Furthermore, changing laws and regulations and evolving stakeholder expectations may further increase our compliance and other costs necessary to meet those expectations. In addition, California has recently enacted climate disclosure laws that may require us to report on our greenhouse gas emissions, climate-related financial risks, and other climate-related matters. Furthermore, industry and market practices, as well as requirements of our business partners, may further develop to become even more robust than what is required under any new laws and regulations, and we may have to expend significant efforts and resources to keep up with market trends, stay competitive among our peers, and comply with such requirements, which could result in higher associated compliance costs and penalties for failure to comply with such laws and regulations.

Our restated certificate of incorporation and our restated bylaws designate specific state or federal courts as the exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our restated bylaws provide that a state court located within the State of Delaware (or, if no state court located within the State of Delaware has jurisdiction, the federal district court for the District of Delaware) is the sole and exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a claim of breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our restated certificate of incorporation or our restated bylaws, or any action asserting a claim against us governed by the internal affairs doctrine. Our restated certificate of incorporation provides that the federal district courts of the United States of America are the exclusive forum for the resolution of any claims under the Securities Act of 1933, as amended. These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees and may discourage these types of lawsuits. Alternatively, if a court were to find these exclusive forum provisions to be inapplicable or unenforceable in an action, we might incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, financial condition and results of operations.

Item 1B. UNRESOLVED STAFF COMMENTS

None.

Item 1C. CYBERSECURITY

Cybersecurity Risk Management and Strategy

We recognize the critical importance of maintaining the trust and confidence of patients, business partners, payors, clinical trial participants, and employees toward our business and are committed to protecting the confidentiality, integrity and availability of our business operations and systems. Our Board of Directors is actively involved in oversight of our risk management activities, and cybersecurity represents an important element of our overall approach to risk management. In general, we seek to address cybersecurity risks through a comprehensive, cross-functional approach that is focused on preserving the confidentiality, security, and availability of the information that we collect and store by identifying, preventing, and mitigating cybersecurity threats and effectively responding to cybersecurity incidents when they occur. We generally follow the HITRUST Common Security Framework in our cybersecurity policies, standards, processes, and practices.

To identify and assess material risks from cybersecurity threats, we maintain a cybersecurity risk management program that includes the identification, prioritization, and management of technical and non-technical risk to the confidentiality, integrity, or availability of patient, employee, clinical trial participant, payor, business partner, and company information. This program considers the risks associated with our industry and the technical and regulatory requirements related to the information systems and data involved. We consider risks from cybersecurity threats alongside other company risks as part of our overall risk assessment process.

We have developed policies, standards, processes, and practices designed to protect our information systems and data from unauthorized access, cybersecurity attacks and other security incidents. The policies, standards, processes, and practices are implemented and enforced by dedicated IT and cybersecurity professionals. We utilize a variety of control measures and cybersecurity technologies that are designed to protect our availability of critical information systems and data, maintain regulatory compliance, assess, identify, and manage our material risks from cybersecurity threats, and protect against and respond to security incidents.

These controls and processes are reviewed periodically and include the following activities:

- we monitor emerging data protection laws and implement changes to our processes that are designed to comply with such laws;
- through our policies, practices, and contracts (as applicable), we require employees, as well as third parties that provide services on our behalf, to treat confidential information and data with care;
- we utilize technical safeguards that are designed to protect our information systems from cybersecurity threats, including firewalls, virtual private networks (VPN), Web Application Firewalls (WAF), intrusion detection systems, antivirus and endpoint detection and response software, multi-factor authentication (MFA), data encryption, encrypted backups, vulnerability scanning and patching, email anti-phishing technology, malicious URL and IP filtering, application controls, USB control and threat intelligence services;
- our cybersecurity personnel include certified security professionals who are experienced in networks, computer systems, cloud cybersecurity, cybersecurity risk management, incident response, and security awareness training;
- we regularly test and monitor our cybersecurity defenses to ensure that they are effective; and
- we also conduct security awareness training for all employees to help them identify and mitigate cybersecurity risks.

We describe whether and how risks from identified cybersecurity threats, including as a result of any previous cybersecurity incidents, have materially affected or are reasonably likely to materially affect us, including our business strategy, results of operations, or financial condition, under the heading "***Security breaches, loss of data and other disruptions, including from cyberattacks, could compromise sensitive information related to our business, prevent us from accessing critical information or expose us to liability, which could adversely affect our business and our reputation***" which disclosures are incorporated by reference herein.

We did not experience any material cybersecurity incidents during the last fiscal year.

We have an incident response plan and processes in place for responding to cybersecurity incidents. The process includes steps to identify, contain, investigate, and remediate the impacts of the incident, as well as to comply with potentially applicable legal obligations and mitigate damage to our business and reputation. The plan involves the participation of a security incident response team that includes our Chief Legal Officer, our Privacy Officer, and other senior leaders in finance, communication, human resources, and legal. The plan includes procedures to communicate the incident to management and customers as appropriate and to provide information as required to state and federal law enforcement and regulatory bodies.

Our processes also address cybersecurity threat risks associated with our use of third-party service providers, including our suppliers and manufacturers or who have access to patient, payor, business partner, and employee data or our systems. In addition, cybersecurity considerations affect the selection and oversight of our third-party service providers. We perform diligence on third parties that have access to our systems, our data, or our facilities that house such systems or data, and continually monitor cybersecurity threat risks identified through such diligence. Additionally, we generally require those third parties that could introduce significant cybersecurity risk to us to agree by contract to manage their cybersecurity risks in specified ways, and to agree to be subject to cybersecurity audits, which we conduct as appropriate.

Cybersecurity Governance; Management

Role of the Board

Cybersecurity is an important part of our risk management processes and an area of focus for our Board of Directors and management. In general, our Audit and Finance Committee of our Board of Directors has primary responsibility for and oversight over cybersecurity threats and our information security management program and considers specific risks, including, for example, risk associated with our strategic plan and business operations. The Audit and Finance Committee receives regular reports from our Chief Technology Officer and Senior Vice President, Technology - Enterprise IT and Engineering, on, among other things, material cybersecurity threat risks or incidents and developments, assessments of our security program and overall security posture, our incident response plan, and initiatives to strengthen our information security systems and mitigate cybersecurity risks. The Audit and Finance Committee, including Rashmi Kumar, provides insights and guidance to management on cybersecurity related matters. Ms. Kumar, who currently serves as Senior Vice President, Chief Information Officer, of Medtronic plc, is a seasoned technology leader with extensive experience in cybersecurity and information technology matters. Management, along with the chair of the Audit and Finance Committee and Ms. Kumar, regularly report to the Board of Directors on cybersecurity risks and other related matters reviewed by the Audit and Finance Committee.

Role of Management

Our cybersecurity risk management and strategy processes, which are discussed in greater detail above, are led by our Chief Technology Officer, who is supported by our leaders in Information Technology, Information Security, and IT Security Compliance. These management team members are informed about and monitor the prevention, mitigation, detection, and remediation of cybersecurity incidents through their management of, and participation in, the cybersecurity risk management and strategy processes described above, including the operation of our incident response plan. As discussed above, our Chief Technology Officer and Senior Vice President, Technology - Enterprise IT and Engineering regularly report to our Audit and Finance Committee about cybersecurity threat risks, among other cybersecurity related matters.

Item 2. PROPERTIES

Our corporate headquarters is located in west Salt Lake City, Utah. We lease approximately 137,000 square feet of laboratory space in Salt Lake City where our Oncology and Women's Health businesses are performed. We plan to transition these operations to our new west Salt Lake City facility, which has approximately 234,000 square feet of laboratory and office space, by the second half of 2025. The leases on our existing Salt Lake City facilities have remaining terms of two to fifteen years, expiring from 2025 through 2038, and provide for renewal options for up to ten additional years. In December 2023, we entered into certain lease termination agreements in which we and the landlord agreed, subject to certain conditions, to terminate or shorten the term of the leases for our laboratory facilities in Salt Lake City.

In South San Francisco, California, we currently lease a total of approximately 112,000 square feet. Of that amount, we lease approximately 49,000 square feet of laboratory space to perform testing for our Women's Health business. We plan to transition all of our operations from this legacy leased facility to our new building, the Walter Gilbert Research and Innovation Center, which has approximately 63,000 square feet of building space dedicated to administration, research and development, and a laboratory for our Women’s Health business. The lease on our legacy facility expires in 2025, by which time we expect to be fully transitioned into our new building. The leases on our South San Francisco facilities have remaining terms of two to ten years, expiring from 2025 through 2033, and provide for renewal options for up to ten additional years.

We also lease a space in Mason, Ohio, with approximately 24,000 total square feet, which will expire in August 2024. Our GeneSight test is performed at this location in a CLIA-certified laboratory.

We also lease several small office locations, including our manufacturing facility located in Cologne, Germany.

We believe that our existing facilities and equipment are well maintained and in good working condition. We continue to move our testing products to our next-generation sequencing platforms and our new laboratories in South San Francisco, California, and west Salt Lake City, Utah. We believe our current facilities will provide adequate testing capacity for the foreseeable future. For more information on our leased properties, see "Note 13-Leases in the Notes to Consolidated Financial Statements."

Item 3. LEGAL PROCEEDINGS

For information regarding certain current legal proceedings, see "Note 12--Commitments and Contingencies in the Notes to Consolidated Financial Statements."

Item 4. MINE SAFETY DISCLOSURES

None.

PART II

Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock is traded on the Nasdaq Global Select Market under the symbol "MYGN."

Stockholders

As of February 21, 2024, there were approximately 95 holders of record of our common stock. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees on their behalf.

Dividend Policy

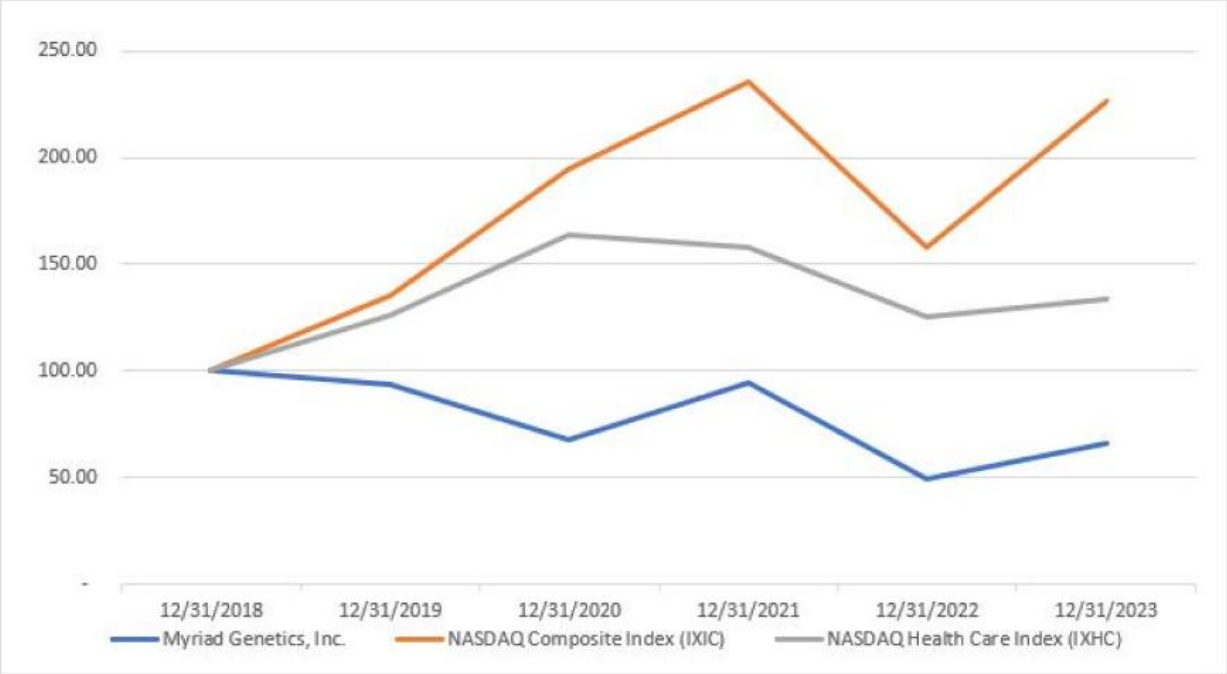
We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business. We do not intend to pay cash dividends on our common stock for the foreseeable future. In addition, the terms of our ABL Facility restrict our ability to pay dividends. Any future determination related to our dividend policy will be made at the discretion of our Board of Directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects and other factors our Board of Directors may deem relevant.

Unregistered Sales of Securities

None.

Stock Performance Graph

The graph set forth below compares the annual percentage change in our cumulative total stockholder return on our common stock during a period commencing on December 31, 2018 and ending on December 31, 2023 (as measured by dividing (A) the difference between our share price at the end and the beginning of the measurement period by (B) our share price at the beginning of the measurement period) with the cumulative total return of the Nasdaq Composite Index (IXIC) and the Nasdaq Health Care Index (IXHC) during such period. We have not paid any cash dividends on our common stock, and we do not include cash dividends in the representation of our performance. The price of a share of common stock is based upon the closing price per share as quoted on the Nasdaq Global Select Market on the last trading day of the year shown. The graph lines merely connect year-end values and do not reflect fluctuations between those dates. The comparison assumes $100 was invested on December 31, 2018 in our common stock and in each of the foregoing indices. The comparisons shown in the graph below are based upon historical data. We caution that the stock price performance shown in the graph below is not necessarily indicative of, nor is it intended to forecast, the potential future performance of our common stock.



	12/31/2018	12/31/2019	12/31/2020	12/31/2021	12/31/2022	12/31/2023
Myriad Genetics, Inc.	100.00	93.67	68.01	94.94	49.91	65.84
NASDAQ Composite Index (IXIC)	100.00	135.23	194.24	235.78	157.74	226.24
NASDAQ Health Care Index (IXHC)	100.00	125.83	163.63	157.82	125.58	133.80

Note: Information used on the graph was obtained from the CRSP Total Return Indexes, a source believed to be reliable, but we are not responsible for any errors or omission in such information.

The performance graph shall not be deemed to be incorporated by reference by means of any general statement incorporating by reference this Annual Report on Form 10-K into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except to the extent that we specifically incorporate such information by reference, and shall not otherwise be deemed filed under such acts.

Item 6. [RESERVED]

Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This section of Management's Discussion and Analysis discusses year-to-year comparisons between the year ended December 31, 2023 and the year ended December 31, 2022. Discussions of comparisons between the year ended December 31, 2022 and the year ended December 31, 2021 that are not included in this Annual Report on Form 10-K can be found in "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Item 7 of Part II of our Annual Report on Form 10-K for the year ended December 31, 2022, filed with the Securities and Exchange Commission on March 1, 2023. The following discussion and analysis should be read in conjunction with the audited Consolidated Financial Statements and accompanying notes thereto included elsewhere in this Annual Report on Form 10-K. Unless otherwise noted, all of the financial information in this Annual Report on Form 10-K is consolidated financial information of the Company.

Overview

We are a leading genetic testing and precision medicine company dedicated to advancing health and well-being for all. We develop and offer genetic tests that help assess the risk of developing disease or disease progression and guide treatment decisions across medical specialties where genetic insights can significantly improve patient care and lower health care costs. Our genetic tests provide insights that help people take control of their health and enable healthcare providers to better detect, treat and prevent disease.

Personalized genetic data, digital, and virtual consumer trends are converging to change traditional models of care. We believe significant growth opportunities exist to help patient populations with pressing health care needs through innovative genetic and precision medicine solutions and services. Our focus is on innovation and growth in three key areas where we have specialized products, capabilities, and expertise: Oncology, Women's Health, and Pharmacogenomics. The pillars of our long-term growth strategy are founded on investments in science and innovation, technology-enabled operations, an elevated customer experience, strong commercial execution, and scalable operations. We believe our path to continued growth is driven by articulating our clinical differentiation, raising awareness with patients who we believe would benefit from our testing products, and innovation that improves clinical outcomes, ease of use, and access. By investing in tech-enabled commercial tools, new laboratory facilities, advanced automation, and standardized processes and technology, we believe we will be able to reduce complexity and cost while enhancing our ability to scale and grow. We plan to expand some of our current products, such as our Foresight Universal Plus Test, which is an expanded carrier screening test that we anticipate launching in the second half of 2024. We also plan to launch new products, such as FirstGene, Precise Liquid, and Precise minimal residual disease, which we expect will help accelerate our growth. We intend to develop and enhance our products to support growth, improve patient and provider experience, and reach more patients of all backgrounds. We are committed to disciplined management of a key set of initiatives to fulfill our mission and drive long-term growth and profitability.

Our consolidated revenues consist primarily of sales of tests through our wholly-owned subsidiaries. During the year ended December 31, 2023, we reported total revenues of $753.2 million, net loss attributable to our stockholders of $263.3 million and basic and diluted loss per share of $3.18.

Business Updates

During the year ended December 31, 2023, our significant business updates and financial highlights include the following:

- Testing volumes grew 35% year-over-year and 18% year-over-year excluding the contribution from our SneakPeek Early Gender DNA Test, driven by 24% growth in Pharmacogenomics, 17% growth in Hereditary Cancer, 15% growth in Prenatal, excluding the contribution from SneakPeek, and 2% growth in Tumor Profiling.

- Revenue growth of 11% year-over-year.

- Completed an underwritten public offering of our common stock in November 2023 in which we sold 7,441,176 shares of our common stock at a price of $17.00 per share, with proceeds of $117.6 million, net of offering expenses of $1.3 million and underwriting discounts.

- Achieved additional improvements amongst our tests and offerings, including an enhancement to the GeneSight test to personalize mental health medication treatment decisions based on smoking status, the addition of Folate Receptor Alpha test to Precise Oncology Solutions to expand treatment options for women living with ovarian cancer, the inclusion of breast density to MyRisk with RiskScore breast cancer risk treatment, and advancements in prostate cancer care with the addition of absolute risk reduction to Prolaris.

- Ranked among Best Large Workplaces in Health Care by Fortune and achieved a Great Place to Work® Certification for 2023.

- Entered into and announced partnerships and collaborations that we believe will provide additional value, insights, and opportunities, including (1) an expanded partnership with Illumina, Inc. to broaden access to, and availability of, oncology HRD testing in the United States, (2) a collaboration with Memorial Sloan Kettering Cancer Center to study the use of minimal residual disease testing in breast cancer, (3) a research collaboration with the University of Texas MD Anderson Cancer Center related to our minimal residual disease testing platform, (4) a collaboration with SimonMed® Imaging to launch a new hereditary cancer assessment program that combines diagnostic imaging, genetic risk assessment utilizing MyRisk with RiskScore and patient education, and (5) a partnership with Onsite Women's Health to help more women understand breast cancer risk.

Seasonality

We have historically experienced seasonality in our testing business. In the quarter ended March 31 we typically experience a decrease in volumes due to the annual reset of patient deductibles. Additionally, the volume of testing is typically negatively impacted by the summer season, which is generally reflected in the quarter ended September 30. Conversely, the quarter ended December 31 is generally strong as we typically experience an increase in volumes from patients who have met their annual insurance deductible. In the fiscal year ended December 31, 2023, we did not experience seasonality to the same extent we have in prior years. For example, in the quarter ended September 30, 2023, we did not see the customary impact from the summer season as volumes decreased less than one percent in comparison to the quarter ended June 30, 2023. Historical patterns of seasonality may not continue in future years.

Components of Consolidated Operations

Revenue

Testing. Our tests are designed to analyze genes and their expression levels to assess an individual's risk for developing disease, determine a patient's likelihood of responding to a particular drug, assess a patient's risk of disease progression, identify factors which could lead to serious conditions in pregnancy, or provide other prenatal insights. Revenue is recognized when the communication of test results has occurred.

Other. On July 1, 2021, we divested Myriad RBM, Inc., which provided biomarker discovery, pharmaceutical and clinical services to the pharmaceutical, biotechnology, and medical research industries utilizing multiplexed immunoassay technology. As a result, we ceased providing pharmaceutical and clinical services as of that date and no longer generate revenue from these services. Revenue for these services was recognized at the completion of the pharmaceutical and clinical services.

Costs and Expenses

Expenses. Personnel-related costs for each category of Costs and expenses include salaries, bonuses, employee benefit costs, employer payroll taxes, and stock-based compensation.

Cost of Testing Revenue. Cost of testing revenue consists primarily of costs related to laboratory supplies, personnel-related costs, and overhead costs.

Cost of Other Revenue. Cost of other revenue consists primarily of costs related to laboratory supplies and personnel-related costs.

Research and Development Expense. Research and development expenses consist primarily of personnel-related costs and laboratory supplies, which includes costs incurred in formulating, improving, validating and creating alternative or modified processes related to and expanding the use of our current test offerings and costs incurred in the discovery, development and validation of our pipeline of test candidates.

Selling, General, and Administrative Expense. Selling, general, and administrative expenses include costs associated with managing and growing our businesses. Selling, general, and administrative expenses consist primarily of personnel-related costs and third-party costs for sales, marketing, customer service, billing and collection, legal, finance and accounting, information technology, and human resources.

Legal Settlements. Legal settlements related to litigation. For more information, see "Note 12–Commitments and Contingencies in the Notes to Consolidated Financial Statements."

Goodwill and Long-Lived Asset Impairment Charges. Goodwill and long-lived asset impairment charges include the impairment loss recognized on our goodwill or long-lived assets, including impairments recognized on intangible assets and right-of-use (ROU) lease assets.

Other Income (Expense). Other income (expense) includes interest income earned on our cash, cash equivalents, and restricted cash held in short-term interest-bearing accounts; interest expense associated with our debt and amortization of deferred financing costs and original issue discount costs; gains or losses on the sale of assets or businesses; and foreign currency gains and losses, realized gain or loss on marketable securities, and other nonrecurring income and expenses.

Results of Operations

Revenue

	Years Ended December 31,			% of Total Revenue	
(In millions)	2023	2022	Change	2023	2022
Testing revenue:					
Hereditary Cancer	$ 327.8	$ 305.5	$ 22.3	44 %	45 %
Tumor Profiling	135.6	128.6	7.0	18 %	19 %
Prenatal	151.3	116.4	34.9	20 %	17 %
Pharmacogenomics	138.5	127.6	10.9	18 %	18 %
Other	—	0.3	(0.3)	— %	— %
Total revenue	$ 753.2	$ 678.4	$ 74.8	100 %	100 %

Test revenues for the year ended December 31, 2023 increased $74.8 million compared to the prior year due to an increase in testing volume across the majority of our products, partially offset by a decline in the average revenue per test. For the year ended December 31, 2023, we recorded $7.2 million of revenue as a result of a change of estimate related to previously delivered tests, as compared to the year ended December 31, 2022, in which we recorded $22.1 million of revenue as a result of a change of estimate related to previously delivered tests.

Prenatal revenues increased $34.9 million due primarily to a 15% increase in volumes excluding SneakPeek, and additional revenue from SneakPeek of $17.8 million. As the Gateway acquisition occurred on November 1, 2022, there were no corresponding SneakPeek revenues for the majority of the prior year. Hereditary Cancer revenues increased $22.3 million due to a 17% increase in testing volume, partially offset by a 8% decrease in the average revenue per test. Revenue from Pharmacogenomics increased $10.9 million compared to the prior year due primarily to a 24% increase in volume, partially offset by a 12% decrease in the average revenue per test. Tumor Profiling revenues increased $7.0 million primarily due to an increase of $12.8 million in revenue for Prolaris, partially offset by a $7.3 million decrease in revenue from MyChoice CDx. These changes were driven by an increase in testing volume of 11% and an increase in average revenue per test of 8% for Prolaris and a 19% decrease in volume for MyChoice CDx, respectively.

Cost of Sales

	Years Ended December 31,		
(in millions)	2023	2022	Change
Cost of testing revenue	$ 236.2	$ 202.0	$ 34.2
Cost of testing revenue as a % of revenue	31.4 %	29.8 %	

Cost of testing revenue for the year ended December 31, 2023 increased $34.2 million compared to the prior year due primarily to an increase in volumes, with the most significant increases in Hereditary Cancer and Pharmacogenomics. In addition, cost of testing revenue increased $10.2 million as compared to the prior year due to the acquisition of Gateway and the associated SneakPeek product. The cost of testing revenue as a percentage of revenue increased from 29.8% to 31.4% during the year ended December 31, 2023 compared to the year ended December 31, 2022. The increase was due in part to the decline in revenue per unit exceeding the decline in the cost per unit.

Research and Development Expense

	Years Ended December 31,		
(in millions)	2023	2022	Change
Research and development expense	$ 88.7	$ 85.4	$ 3.3
Research and development expense as a % of total revenue	11.8 %	12.6 %	

Research and development expense for the year ended December 31, 2023 increased by $3.3 million compared to the prior year primarily due to an increase in the average compensation expense per employee and clinical trial expenses, partially offset by a decrease in information technology related costs and certain laboratory expenses, such as a decrease in the consumption of reagents, as compared to the prior year.

Selling, General, and Administrative Expense

	Years Ended December 31,		
(in millions)	2023	2022	Change
Selling, general, and administrative expense	$ 572.9	$ 514.7	$ 58.2
Selling, general, and administrative expense as a % of total revenue	76.1 %	75.9 %	

Selling, general, and administrative expense increased by $58.2 million for the year ended December 31, 2023 compared to the prior year due primarily to a $38.8 million increase in compensation costs driven by increases in the average cost per employee, commission expense due to increases in testing volume, and bonus expense, a $16.2 million increase in general legal expenses due in part to the previous year's legal expenses being offset by the receipt of $12.0 million from insurers in the prior year to offset certain legal expenses, and a $5.7 million increase in facility costs, partially offset by a $16.4 million decrease in consulting costs in the current year. In addition, in connection with the decision to cease the use of our previous corporate headquarters, we recognized a $7.7 million loss on termination of the lease and $5.7 million of accelerated depreciation for certain leasehold improvements and equipment.

Legal Settlements

	Years Ended December 31,		
(in millions)	2023	2022	Change
Legal settlements	$ 112.8	$ —	$ 112.8
Legal settlements as a % of total revenue	15.0 %	— %	

Legal settlements increased for the year ended December 31, 2023 compared to the prior year due to $112.8 million accruals related to legal settlements, including $77.5 million related to the class action settlement and $34.0 million in connection with the Ravgen settlement. For more information, see "Note 12–Commitments and Contingencies in the Notes to Consolidated Financial Statements." There were no corresponding legal settlement amounts incurred in the prior year.

Goodwill and Long-lived Asset Impairment Charges

	Years Ended December 31,		
(in millions)	2023	2022	Change
Goodwill and long-lived asset impairment charges	$ —	$ 16.9	$ (16.9)
Goodwill and long-lived asset impairment charges as a % of total revenue	— %	2.5 %	

Goodwill and long-lived asset impairment charges decreased for the year ended December 31, 2023 compared to the prior year primarily due to the Company recognizing a $13.0 million impairment to ROU assets and a $3.9 million impairment to the related leasehold improvements in the prior year as a result of our decision to no longer use certain leased facilities in order to consolidate space. There were no corresponding impairment charges in the current year.

Other Income (Expense)

	Years Ended December 31,		
(in millions)	2023	2022	Change
Interest income	$ 2.5	$ 2.6	$ (0.1)
Interest expense	(2.9)	(3.2)	0.3
Other	(4.4)	0.6	(5.0)
Other income (expense)	$ (4.8)	$ —	$ (4.8)

Other income (expense) decreased for the year ended December 31, 2023 compared to the prior year due primarily to a foreign currency loss of $3.4 million and a $1.5 million loss on the sale of investment securities in the current year. Losses on foreign currency and sales of investment securities were insignificant in the prior year.

Income Tax Expense (Benefit)

(in millions)	Years Ended December 31, 2023	2022	Change
Income tax expense (benefit)	$ 1.1	$ (28.6)	$ 29.7
Effective tax rate	0.4 %	(20.3)%	

Our tax rate is the product of a U.S. federal effective rate of 21.0% and a blended state income tax rate of approximately 3.4%. Certain significant or unusual items are separately recognized during the period in which they occur and can be a source of variability in the effective tax rates from period to period.

Income tax expense for the year ended December 31, 2023 was $1.1 million, and our effective tax rate was 0.4%. For the year ended December 31, 2023, our effective tax rate differs from the U.S. federal statutory rate primarily due to the change in valuation allowance. For the year ended December 31, 2022, our effective tax rate differs from the U.S. federal statutory rate primarily due to disallowed executive compensation expenses, stock compensation, change in valuation allowance, and research and development credits.

Liquidity and Capital Resources

Our primary sources of liquidity are our cash, cash equivalents and marketable investment securities, our cash flows from operations, and, in certain circumstances as discussed below, amounts available for borrowing under our ABL Facility. As of December 31, 2023, we had cash, cash equivalents and marketable investment securities of $140.9 million and availability under the ABL Facility was $40.7 million, subject to the minimum availability requirement under the ABL Facility. In 2023, our sources of liquidity also included $117.6 million from an underwritten public offering of our common stock, as further discussed below. Our capital deployment strategy focuses on use of resources in the key areas of research and development, technology and acquisitions. We believe that investing organically through research and development and new product development or acquisitively to support our business strategy provides the best return on invested capital.

Our ABL Facility has a total maximum principal commitment of $115.0 million. The ABL Facility requires that we and our subsidiaries guaranteeing the indebtedness, on a consolidated basis, maintain minimum liquidity of $60.0 million and minimum availability of $25.0 million at all times before achieving a fixed charge coverage ratio of 1.0 to 1.0 and thereafter, to maintain a fixed charge coverage ratio of 1.0 to 1.0 until achieving availability under the ABL Facility of greater of (a) $10.6 million and (b) 12.5% of the lesser of the maximum commitment amount and the borrowing base for a period of 30 consecutive days. As of December 31, 2023, we had $40.0 million outstanding under the ABL Facility and availability under the ABL Facility was $40.7 million, subject to the minimum availability requirement under the ABL Facility.

During November 2023, we completed an underwritten public offering of our common stock in which we sold 7,441,176 shares of our common stock at a price of $17.00 per share for proceeds of $117.6 million, net of offering expenses of $1.3 million and underwriting discounts. The proceeds from the offering were utilized to pay the remaining $57.5 million of the securities class action settlement, with the remainder being used for working capital and general corporate purposes.

We believe that our existing capital resources will be sufficient to meet our projected operating requirements for at least the next 12 months. Our available capital resources, however, may be consumed more rapidly than currently expected, or may be insufficient for our business needs for many reasons, including as a result of our operational cash needs, capital expenditures, and litigation related costs not covered by, or above the limits set forth in, our insurance. In addition, we are subject to covenants under our ABL Facility which could limit our ability to incur additional indebtedness or impact our ability to pursue other financing. If we do not generate sufficient cash from operations, if our capital resources are consumed more rapidly than expected, or if we no longer have access to additional funds under our ABL Facility and we are unable to secure additional funds on acceptable terms, or at all, we may be forced to delay, scale back or eliminate some of our sales and marketing efforts, research and development activities, or other operations; or delay development of our tests in an effort to provide sufficient funds to continue our operations. If any of these events occurs, our ability to achieve our development and commercialization goals could be adversely affected.

From time to time, we enter into purchase commitments or other agreements that may materially impact our liquidity position in future periods. In February 2022, we entered into a non-cancelable operating lease for approximately 230,000 square feet in west Salt Lake City, Utah. The lease has a term of 15 years, which commenced in the fourth quarter of 2023. Total future rent payments under the lease are approximately $79.6 million. We also entered into a non-cancelable operating lease for approximately 63,000 square feet of leased space in South San Francisco, California. The lease has a term of 10 years and, along with rent payments, commenced in the second quarter of 2023. Total future rent payments under the lease are approximately $56.7 million.

Because of the technical nature of our business and our focus on science, research, and development, we are highly dependent upon our ability to attract and retain highly qualified and experienced management, scientific, and technical personnel. Loss of the services of or failure to recruit additional key management, scientific, and technical personnel and other qualified personnel who are necessary to operate our business would adversely affect our business, and it may have a material adverse effect on our business as a whole. Additionally, disruptions to our supply chain could cause shortages of critical materials required to conduct our business, which may have a material adverse effect on our business as a whole. In addition, inflation has had, and may continue to have, an impact on the costs we incur to attract and retain qualified personnel, costs to generate sales and produce testing results, and costs of laboratory supplies.

The following table represents the balances of cash, cash equivalents, and marketable investment securities as of December 31, 2023 and 2022:

	December 31,	
(in millions)	**2023**	**2022**
Cash and cash equivalents	$ 132.1	$ 56.9
Marketable investment securities	8.8	58.0
Long-term marketable investment securities	—	54.8
Cash, cash equivalents and marketable investment securities	$ 140.9	$ 169.7

The decrease in cash, cash equivalents, and marketable investment securities as of December 31, 2023 compared to December 31, 2022 was primarily driven by $110.9 million in cash used by operations, which included legal settlement payments of $82.8 million, as well as $63.2 million in cash used for capital expenditures, and $2.8 million in cash used for the payment of withholding tax in connection with the issuance of common stock, net of proceeds from the issuance of common stock, which were partially offset by $117.6 million in proceeds from our underwritten public offering of common stock in November 2023, net of offering expenses, and proceeds from the ABL Facility of $38.3 million in the current year. The decrease in marketable investment securities as of December 31, 2023 as compared to the prior year was primarily driven by sales of marketable investment securities to fund operations in the current year, with total proceeds from maturities and sales of marketable investment securities in the current year of $105.2 million.

The following table represents the condensed cash flow statement:

	Years Ended December 31,	
(in millions)	**2023**	**2022**
Cash flows used in operating activities	$ (110.9)	$ (106.3)
Cash flows provided by (used in) investing activities	31.9	(77.5)
Cash flows provided by (used in) financing activities	152.9	(8.0)
Effect of foreign exchange rates on cash, cash equivalents, and restricted cash	0.6	(0.6)
Net increase (decrease) in cash, cash equivalents, and restricted cash	74.5	(192.4)
Cash, cash equivalents, and restricted cash at the beginning of the period	66.4	258.8
Cash, cash equivalents, and restricted cash at the end of the period	$ 140.9	$ 66.4

Cash Flows from Operating Activities

The amount of cash flows used in operating activities was largely consistent for the years ended December 31, 2023 and December 31, 2022. For the year ended December 31, 2023, we paid approximately $32.8 million more in legal settlements compared to the prior year. This change was largely offset by an improvement in core operations driven by an increase in revenues due to the growth in volumes and a decrease in expenses as a percentage of revenue when excluding the legal settlement costs.

Cash Flows from Investing Activities

The increase in cash flows provided by investing activities for the year ended December 31, 2023 as compared to the prior year was primarily due to an $80.2 million increase in net proceeds from marketable investment securities in the current year and the acquisition of Gateway, net of cash acquired, for $57.2 million in the prior year, partially offset by a $28.0 million increase in capital expenditures and capitalization of internal-use software costs in the current period.

Cash Flows from Financing Activities

The increase in cash flows provided by financing activities as compared to the prior year was primarily due to proceeds from an underwritten public offering of common stock of $117.6 million, net of offering expenses and underwriting discounts, and net proceeds from the ABL Facility of $38.3 million in the current year.

Effects of Inflation

Inflation has had, and may continue to have, an impact on the labor costs we incur to attract and retain qualified personnel, costs to generate sales and produce testing results, and costs of laboratory supplies. Inflationary costs have impacted our profitability and may continue to adversely affect our business, financial condition and results of operations. In addition, increased inflation has had, and may continue to have, an effect on interest rates. Increased interest rates may adversely affect our borrowing rate and our ability to obtain, or the terms under which we can obtain, additional funding.

Critical Accounting Estimates

Critical accounting estimates are those policies which are both important to the portrayal of a company's financial condition and results and require management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. Our critical accounting estimates are as follows:

- revenue recognition;
- goodwill; and
- income taxes.

Revenue Recognition. Revenue is recognized when, or as, performance obligations under the terms of a contract are satisfied, which occurs when control of the promised products or services is transferred to a customer. We exclude sales, use, value-added, and other taxes we collect on behalf of third parties from revenue. Revenue is measured as the amount of consideration we expect to receive in exchange for transferring products or services to a customer.

We generate revenue primarily by performing genetic testing. We perform our obligation under a contract with a customer by processing those tests and communicating the test results to customers, in exchange for consideration from the customer. Revenue from the sale of tests is recorded at the estimated transaction price. We have determined that the communication of test results indicates transfer of control for revenue recognition purposes. We have the right to bill our customers upon the completion of performance obligations and thus do not record contract assets. Occasionally customers make payments prior to our performance of our contractual obligations. When this occurs, we record a contract liability as deferred revenue.

Significant judgments are required in determining the transaction price in connection with satisfying performance obligations under the revenue standard. In determining the transaction price, we estimate the expected amount of consideration as revenue. We apply this method consistently for similar contracts when estimating the effect of any uncertainty on an amount of variable consideration to which we will be entitled. An estimate of transaction price does not include any estimated amount of variable consideration that is constrained. We consider all the information (historical, current, and forecast) that is reasonably available to identify possible consideration amounts. To determine our estimated transaction price, we apply the expected value method for sales where we have a large number of contracts with similar characteristics. We then consider the probability of the variable consideration for each possible scenario. We have significant experience with historical collection patterns and use this experience to estimate transaction prices.

The estimate of revenue is affected by assumptions in payor mix and in payor behavior such as changes in payor collections, current customer contractual requirements, and experience with ultimate collection from third-party payors. When assessing the total consideration for insurance carriers and patients, revenues are further constrained for estimated refunds. We reserve certain amounts in accrued liabilities in the Consolidated Balance Sheets in anticipation of request for refunds of payments made previously by insurance carriers, which are accounted for as reductions in revenues in the Consolidated Statements of Operations and Comprehensive Loss.

Cash collections for certain tests delivered may differ from rates estimated, primarily driven by changes in the estimated transaction price due to contractual adjustments, obtaining updated information from payors and patients that was unknown at the time the performance obligation was met and settlements with third-party payors. As a result of this new information, we update our estimate of the amounts to be recognized for previously delivered tests. During the year ended December 31, 2023, we recognized $7.2 million in revenue, which resulted in a $0.07 impact to loss per share for tests in which the performance obligation of delivering the test results was met in prior periods. The changes were primarily driven by changes in the estimated transaction price. During the year ended December 31, 2022, we recognized $22.1 million in revenue, which resulted in a $0.21 impact to loss per share for tests in which the performance obligation of delivering the test results was met in prior periods.

Goodwill. We test goodwill for impairment on an annual basis and in the interim by reporting unit if events and circumstances indicate that goodwill may be impaired. The events and circumstances that are considered include business climate and market conditions, legal factors, operating performance indicators and competition. Impairment of goodwill is evaluated on a qualitative basis before calculating the fair value of the reporting unit. If the qualitative assessment suggests that impairment is more likely than not, a quantitative impairment analysis is performed. The quantitative analysis involves comparison of the fair value of a reporting unit with its carrying amount. The valuation of a reporting unit requires judgment in estimating future cash flows, discount rates, residual growth rates and other factors. In making these judgments, we evaluate the financial health of our business, including such factors as industry performance, market saturation and opportunity, changes in technology and operating cash flows, and other relevant entity-specific events. Goodwill impairment testing requires us to make a number of assumptions and estimates concerning future levels of revenue growth, operating margins, and other financial assumptions, which are based upon our long-term plan. The discount rate is an estimate of the overall after-tax rate of return required by a market participant whose weighted average cost of capital includes both debt and equity, including a risk premium. While we use the best available information to prepare our cash flows and discount rate assumptions, actual future cash flows and/or market conditions could differ significantly resulting in future impairment charges related to recorded goodwill balances. While there are always changes in assumptions to reflect changing business and market conditions, our overall methodology used has remained unchanged. Changes in our forecasts or decreases in the value of our common stock could cause book value of reporting units to exceed their fair values. If the carrying amount of a reporting unit exceeds its fair value, an impairment loss is recognized in an amount equal to that excess, limited to the total amount of goodwill allocated to that reporting unit. If an event occurs that would cause a revision to the estimates and assumptions used in analyzing the value of the goodwill, the revision could result in a non-cash impairment charge that could have a material impact on the financial results.

As of December 31, 2023, we have recorded goodwill of $287.4 million on our Consolidated Balance Sheets. This goodwill is attributable to the Pharmacogenomics, Myriad International, Myriad Women's Health, and Gateway reporting units. We qualitatively evaluated our reporting units for impairment. The factors that are considered in the qualitative analysis include macroeconomic conditions, industry and market considerations, revenue growth rates, current and financial performance, other factors that would have a negative effect on earnings and cash flows, and other relevant entity-specific events and information. Significant judgment is required in assessing the weight of the qualitative factors. We noted no indicators of impairment during the year ended December 31, 2023.

Income Taxes. Our income tax provision is based on income before taxes and is computed using the liability method in accordance with ASC 740 – *Income Taxes*. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax basis of assets and liabilities using tax rates projected to be in effect for the year in which the differences are expected to reverse. Significant estimates are required in determining our provision for income taxes. Some of these estimates are based on interpretations of existing tax laws or regulations, or the expected results from any future tax examinations. Various internal and external factors may have favorable or unfavorable effects on our future provision for income taxes. Those factors include, but are not limited to, changes in tax laws, regulations and/or rates, the results of any future tax examinations, changing interpretations of existing tax laws or regulations, changes in estimates of prior years' items, past levels of research and development spending, acquisitions, changes in our corporate structure, and changes in overall levels of income before taxes all of which may result in periodic revisions to our provision for income taxes.

Developing our provision for income taxes, including our effective tax rate and analysis of potential uncertain tax positions, if any, requires significant judgment and expertise in federal and state income tax laws, regulations and strategies, including the determination of deferred tax assets and liabilities and any estimated valuation allowance we deem necessary to offset deferred tax assets. Our judgment and tax strategies are subject to audit by various taxing authorities. While we believe we have provided adequately for our uncertain income tax positions in our consolidated financial statements, an adverse determination by these taxing authorities could have a material adverse effect on our consolidated financial condition, results of operations or cash flows. Interest and penalties on income tax items are included as a component of overall income tax expense.

Recent Accounting Pronouncements

See Note 1 to the Consolidated Financial Statements included in Item 8 of this Annual Report on Form 10-K for a description of recent accounting pronouncements.

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 and foreign currency exchange risks.

We are exposed to interest rate risk primarily through borrowings under our ABL Facility. Our ABL Facility has a variable interest rate based on either the Prime Rate, the NYFRB Rate, or the Secured Overnight Financing Rate ("SOFR"). An incremental change in the borrowing rate of 100 basis points would increase or decrease our annual interest expense by $0.4 million based on our $40.0 million debt outstanding on our ABL Facility as of December 31, 2023.

We have been and may continue to be exposed to fluctuations in foreign currencies with regard to certain agreements with service providers. While our expenses are predominantly denominated in U.S. dollars, approximately 10% of our revenues are denominated in other currencies, primarily in Japanese yen. A hypothetical 10% change in the value of the Japanese yen relative to the U.S. dollar would result in a 1% change in our revenues. Although we also have certain operations denominated in Euros, Swiss francs, and British pounds, among other currencies, those operations are subject to less overall market risk due to the revenue and expenses being denominated in the same currency. During the year ended December 31, 2023, our revenues were not materially impacted by foreign currency fluctuations but may be in the future. We do not currently utilize hedging strategies to mitigate foreign currency risk.

We maintain an investment portfolio in accordance with our written investment policy. Our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure to any single issue, issuer or type of investment. Our investments consist of debt securities of various types and maturities of one year or less and are classified as available-for-sale.

Although our investment policy guidelines are intended to ensure the preservation of principal, market conditions can result in high levels of uncertainty. Our ability to trade or redeem the securities in which we invest, including certain corporate bonds, may become difficult. Valuation and pricing of these securities can also become variable and subject to uncertainty. As of December 31, 2023, the unrealized losses in our investment portfolio were determined to be immaterial. We do not utilize derivative financial instruments to manage our interest rate risks.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

MYRIAD GENETICS, INC.

Index to Financial Statements

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of Myriad Genetics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Myriad Genetics, Inc. and subsidiaries (the Company) as of December 31, 2023 and 2022, the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2023, 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, 2023 and 2022, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2023, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2023, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), and our report dated February 28, 2024 expressed an unqualified opinion thereon.

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 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. 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.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Measurement of testing revenue

Description of the Matter	During the year ended December 31, 2023, the Company's testing revenue was $753.2 million. As discussed in Note 1 of the consolidated financial statements, management estimates the expected amount of consideration to be received as testing revenue and revenue is recognized when the performance obligation is complete. Auditing the measurement of the Company's testing revenue was complex and judgmental due to the significant estimation required in determining the amount that will be collected for each test. In particular, the estimate of revenue is affected by assumptions related to payors such as changes in payor mix, payor collections, current customer contractual requirements, and experience with ultimate collection from third-party payors.

How We Addressed the Matter in Our Audit	We obtained an understanding, evaluated the design and tested the operating effectiveness of controls over the Company's revenue recognition process. For example, we tested controls over management's review of the significant assumptions above and inputs used in calculating the estimated amount that would be collected for each test and tested management's controls to compare actual payments received to previously forecasted activity. We also tested controls used by management to compare the current and historical data used in making the estimates for completeness and accuracy. Our audit procedures over the Company's testing revenue included, among others, assessing valuation methodologies and models and testing the significant assumptions above and the underlying data used by the Company in its analysis. We agreed transactions selected for testing back to the actual customer contract terms. We compared the significant assumptions above and inputs used by management to changes in the Company's contracted rates, third-party payor collection trends, and other relevant factors. We assessed the historical accuracy of the cash collections used in the Company's revenue models, and assessed the completeness of adjustments to estimates of future cash collections as a result of significant contract amendments, changes in collection trends and changes in payor behavior.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2006.

Salt Lake City, UT
February 28, 2024

MYRIAD GENETICS, INC.
AND SUBSIDIARIES
Consolidated Balance Sheets
(in millions, except per share amounts)

	December 31,	
	2023	2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 132.1	$ 56.9
Marketable investment securities	8.8	58.0
Trade accounts receivable	114.3	101.6
Inventory	22.0	20.1
Prepaid taxes	17.0	17.6
Prepaid expenses and other current assets	19.4	20.4
Total current assets	313.6	274.6
Operating lease right-of-use assets	61.6	103.9
Long-term marketable investment securities	—	54.8
Property, plant and equipment, net	119.0	83.4
Intangibles, net	349.5	379.7
Goodwill	287.4	286.8
Other assets	15.4	15.5
Total assets	$ 1,146.5	$ 1,198.7
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 25.8	$ 28.8
Accrued liabilities	113.9	94.3
Current maturities of operating lease liabilities	16.2	14.1
Total current liabilities	155.9	137.2
Unrecognized tax benefits	30.2	26.8
Long-term debt	38.5	—
Noncurrent operating lease liabilities	97.4	130.9
Other long-term liabilities	41.3	18.0
Total liabilities	363.3	312.9
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.01 par value, 89.9 and 81.2 shares outstanding at December 31, 2023 and 2022, respectively	0.9	0.8
Additional paid-in capital	1,415.5	1,260.1
Accumulated other comprehensive loss	(3.7)	(8.9)
Accumulated deficit	(629.5)	(366.2)
Total stockholders' equity	783.2	885.8
Total liabilities and stockholders' equity	$ 1,146.5	$ 1,198.7

See accompanying notes to consolidated financial statements.

MYRIAD GENETICS, INC.
AND SUBSIDIARIES
Consolidated Statements of Operations
(in millions, except per share amounts)

	Years Ended December 31,		
	2023	2022	2021
Testing revenue	$ 753.2	$ 678.4	$ 666.4
Other revenue	—	—	24.2
Total revenue	753.2	678.4	690.6
Costs and expenses:			
Cost of testing revenue	236.2	202.0	185.7
Cost of other revenue	—	—	11.9
Research and development expense	88.7	85.4	81.9
Selling, general, and administrative expense	572.9	514.7	537.8
Legal settlements	112.8	—	62.0
Goodwill and long-lived asset impairment charges	—	16.9	1.8
Total costs and expenses	1,010.6	819.0	881.1
Operating loss	(257.4)	(140.6)	(190.5)
Other income (expense):			
Interest income	2.5	2.6	0.7
Interest expense	(2.9)	(3.2)	(6.6)
Other	(4.4)	0.6	139.3
Total other income (expense)	(4.8)	—	133.4
Loss before income tax	(262.2)	(140.6)	(57.1)
Income tax expense (benefit)	1.1	(28.6)	(29.9)
Net loss	$ (263.3)	$ (112.0)	$ (27.2)
Net loss per share:			
Basic and diluted	$ (3.18)	$ (1.39)	$ (0.35)
Weighted average shares outstanding:			
Basic and diluted	82.8	80.6	78.0

See accompanying notes to consolidated financial statements.

MYRIAD GENETICS, INC.
AND SUBSIDIARIES
Consolidated Statements of Comprehensive Loss
(in millions)

	Years Ended December 31,		
	2023	2022	2021
Net loss attributable to Myriad Genetics, Inc. stockholders	$ (263.3)	$ (112.0)	$ (27.2)
Change in unrealized loss on available-for-sale securities, net of tax	1.2	(2.5)	(1.0)
Change in foreign currency translation adjustment, net of tax	2.1	(1.3)	(1.8)
Reclassification adjustments for losses included in net loss, net of tax	1.5	—	—
Reclassification of cumulative translation adjustment to income upon liquidation of an investment in a foreign entity, net of tax	0.4	—	—
Comprehensive loss	$ (258.1)	$ (115.8)	$ (30.0)

See accompanying notes to consolidated financial statements.

MYRIAD GENETICS, INC.
AND SUBSIDIARIES
Consolidated Statements of Stockholders' Equity
(in millions)

	Common stock	Additional paid-in capital	Accumulated other comprehensive loss	Accumulated deficit	Myriad Genetics, Inc. Stockholders' equity
BALANCES AT DECEMBER 31, 2020	**$ 0.8**	**$ 1,109.5**	**$ (2.3)**	**$ (227.0)**	**$ 881.0**
Issuance of common stock under stock-based compensation plans, net of shares exchanged for withholding tax	—	80.3	—	—	80.3
Stock-based payment expense	—	36.5	—	—	36.5
Net loss	—	—	—	(27.2)	(27.2)
Other comprehensive loss, net of tax	—	—	(2.8)	—	(2.8)
BALANCES AT DECEMBER 31, 2021	**$ 0.8**	**$ 1,226.3**	**$ (5.1)**	**$ (254.2)**	**$ 967.8**
Issuance of common stock under stock-based compensation plans, net of shares exchanged for withholding tax	—	(4.3)	—	—	(4.3)
Stock-based payment expense	—	38.1	—	—	38.1
Net loss	—	—	—	(112.0)	(112.0)
Other comprehensive loss, net of tax	—	—	(3.8)	—	(3.8)
BALANCES AT DECEMBER 31, 2022	**$ 0.8**	**$ 1,260.1**	**$ (8.9)**	**$ (366.2)**	**$ 885.8**
Issuance of common stock under stock-based compensation plans, net of shares exchanged for withholding tax	—	(2.8)	—	—	(2.8)
Issuance of common stock for public offering, net	0.1	117.5	—	—	117.6
Stock-based payment expense	—	40.7	—	—	40.7
Net loss	—	—	—	(263.3)	(263.3)
Other comprehensive income, net of tax	—	—	5.2	—	5.2
BALANCES AT DECEMBER 31, 2023	**$ 0.9**	**$ 1,415.5**	**$ (3.7)**	**$ (629.5)**	**$ 783.2**

See accompanying notes to consolidated financial statements.

MYRIAD GENETICS, INC.
AND SUBSIDIARIES
Consolidated Statements of Cash Flows
(in millions)

	Years Ended December 31,		
	2023	2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss attributable to Myriad Genetics, Inc. stockholders	$ (263.3)	$ (112.0)	$ (27.2)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Depreciation and amortization	61.9	52.7	62.8
Non-cash lease expense	11.3	11.7	12.8
Loss on termination of lease	7.7	—	—
Stock-based compensation expense	40.7	38.1	36.3
Deferred income taxes	(4.0)	(30.8)	(32.1)
Unrecognized tax benefits	3.4	(1.1)	(2.6)
Net realized losses on marketable investment securities	1.5	—	—
Loss on inventory	—	—	6.5
Impairment of goodwill and long-lived assets	—	16.9	1.8
Gain on sale of businesses and assets	—	—	(162.0)
Other non-cash adjustments	2.9	1.7	1.5
Changes in assets and liabilities:			
Prepaid expenses and other current assets	0.2	1.6	(6.6)
Trade accounts receivable	(12.5)	(10.3)	(8.8)
Inventory	(1.8)	(2.9)	1.6
Prepaid taxes	0.7	0.7	89.9
Other assets	0.6	(0.9)	(3.6)
Tenant improvement allowance received	16.3	18.0	—
Accounts payable	(3.7)	(3.5)	9.2
Accrued liabilities	27.4	(81.2)	65.7
Deferred revenue	(0.2)	(5.0)	(26.6)
Net cash provided by (used in) operating activities	(110.9)	(106.3)	18.6
CASH FLOWS FROM INVESTING ACTIVITIES:			
Capital expenditures	(63.2)	(45.3)	(18.0)
Capitalization of internal-use software costs	(10.1)	—	—
Acquisitions, net of cash acquired	—	(57.2)	—
Proceeds from sale of business and assets	—	—	379.1
Purchases of marketable investment securities	—	(103.2)	(147.8)
Proceeds from maturities and sales of marketable investment securities	105.2	128.2	61.1
Net cash provided by (used in) investing activities	31.9	(77.5)	274.4
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from common stock issued under stock-based compensation plans	6.0	6.3	91.8
Payment of tax withheld for common stock issued under stock-based compensation plans	(8.8)	(10.6)	(11.5)
Proceeds from underwritten public offering, net of costs and discounts	117.6	—	—
Proceeds from revolving credit facility	80.0	—	—
Fees associated with issuance and refinancing of revolving credit facility	(1.7)	(0.7)	(1.2)
Repayment of revolving credit facility	(40.0)	—	(226.4)
Payment of contingent consideration recognized at acquisition	—	(3.0)	(3.3)
Payment on finance leases	(0.2)	—	—
Net cash provided by (used in) financing activities	152.9	(8.0)	(150.6)
Effect of foreign exchange rates on cash, cash equivalents, and restricted cash	0.6	(0.6)	(0.6)
Net increase (decrease) in cash, cash equivalents, and restricted cash	74.5	(192.4)	141.8
Cash, cash equivalents, and restricted cash at beginning of the period	66.4	258.8	117.0
Cash, cash equivalents, and restricted cash at end of the period	$ 140.9	$ 66.4	$ 258.8

See accompanying notes to consolidated financial statements.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(in millions, except per share data)

1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Financial Statement Presentation

Myriad Genetics, Inc. (together with its subsidiaries, the "Company" or "Myriad") is a leading genetic testing and precision medicine company dedicated to advancing health and well-being for all. Myriad provides insights that help people take control of their health and enable healthcare providers to better detect, treat, and prevent disease. Myriad develops and offers genetic tests that help assess the risk of developing disease or disease progression and guide treatment decisions across medical specialties where genetic insights can significantly improve patient care and lower health care costs. The Company generates revenue by performing tests and, prior to the sale of Myriad RBM, Inc. on July 1, 2021 as described in Note 17, by providing pharmaceutical and clinical services to the pharmaceutical and biotechnology industries and medical research institutions utilizing its multiplexed immunoassay technology. The Company currently operates as a single reporting segment. The Company's principal executive office is located in Salt Lake City, Utah.

The accompanying consolidated financial statements for the Company have been prepared in accordance with United States ("U.S.") generally accepted accounting principles ("GAAP") for financial information and pursuant to the applicable rules and regulations of the Securities and Exchange Commission ("SEC"). All intercompany accounts and transactions have been eliminated in consolidation. In the opinion of management, the accompanying financial statements contain all adjustments (consisting of normal and recurring accruals) necessary to present fairly all financial statements in accordance with GAAP.

Use of Estimates

The preparation of the consolidated financial statements in accordance with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the consolidated financial statements, as well as the reported amounts of revenue and expenses during the reporting period. Significant items subject to such estimates and assumptions include revenue recognition estimates for the average expected reimbursement per test, valuation allowances for deferred income tax assets, our incremental borrowing rates used to calculate our lease balances, certain accrued liabilities, stock-based compensation, purchase accounting, and impairment analysis of goodwill and long-lived assets. Actual results could differ from those estimates.

Reclassifications

Certain prior period amounts have been reclassified to conform with the current period presentation. The reclassifications have no impact on the total assets, total liabilities, stockholders' equity, or cash flows from operations.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents and accounts receivable. Substantially all of the Company's accounts receivable are with companies in the healthcare industry, U.S. and state governmental agencies, and individuals. The Company does not believe that receivables due from U.S. and state governmental agencies, such as Medicare, represent a credit risk since the related health care programs are funded by the U.S. and state governments. The Company only has one payor, Medicare, that represents greater than 10% of its revenues. Revenues received from Medicare represented approximately 12%, 14%, and 17% of total revenue for the years ended December 31, 2023, 2022, and 2021, respectively. Concentrations of credit risk are mitigated due to the number of the Company's customers as well as their dispersion across many geographic regions. The Company has only one payor that accounted for more than 10% of accounts receivable at December 31, 2023. The balance of accounts receivable from the payor represented 12% of the total accounts receivable balance as of December 31, 2023. No payor accounted for more than 10% of accounts receivable at December 31, 2022. The Company does not require collateral from its customers.

Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less to be cash equivalents. Cash and cash equivalents primarily consist of cash and money market deposits with financial institutions.

Restricted Cash

In certain circumstances, the Company is required to maintain cash deposits with certain banks with respect to contractual or other legal obligations, and therefore the use of these cash deposits for general operational purposes is restricted. As of December 31, 2023, restricted cash was approximately $8.8 million, of which $1.2 million was recognized as a current asset and $7.6 million was recognized as a long-term asset. As of December 31, 2022, restricted cash was approximately $9.5 million, of which $2.0 million was recognized as a current asset and $7.5 million was recognized as a long-term asset. The restricted cash amounts are largely comprised of cash held in escrow related to the Company's acquisition of Gateway Genomics, LLC ("Gateway"), which occurred during the year ended December 31, 2022. The current and long-term portions are included in Prepaid expenses and other current assets and Other assets, respectively, on the Consolidated Balance Sheets.

The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported on the Consolidated Balance Sheets that agrees to the amounts included in the Consolidated Statement of Cash Flows.

	December 31,		
(in millions)	**2023**	**2022**	**2021**
Cash and cash equivalents	$ 132.1	$ 56.9	$ 257.4
Restricted cash	8.8	9.5	1.4
Total cash, cash equivalents, and restricted cash	$ 140.9	$ 66.4	$ 258.8

Marketable Investment Securities

The Company has classified its marketable investment securities, all of which are debt securities, as available-for-sale securities. These securities are carried at estimated fair value with unrealized holding gains and losses, net of the related tax effect, included in Accumulated other comprehensive loss in Stockholders' equity until realized. Gains and losses on investment security transactions are reported on the specific-identification method. Dividend and interest income are recognized when earned. The Company's cash equivalents consist of short-term, highly liquid investments that are readily convertible to known amounts of cash.

A decline in the market value of any available-for-sale security below cost that is deemed other than temporary results in a charge to earnings and establishes a new cost basis for the security. Losses are charged against Other income (expense) when a decline in fair value is determined to be other than temporary. The Company reviews several factors to determine whether a loss is other than temporary. These factors include but are not limited to: (i) the extent to which the fair value is less than cost and the cause for the fair value decline, (ii) the financial condition and near term prospects of the issuer, (iii) the length of time a security is in an unrealized loss position and (iv) the Company's ability to hold the security for a period of time sufficient to allow for any anticipated recovery in fair value. There were no other-than-temporary impairments recognized during the years ended December 31, 2023, 2022, and 2021.

Inventory

Inventories consist of supplies such as reagents, plates and testing kits, which are consumed when providing test results, and therefore the Company does not maintain finished goods inventory. Inventories are stated at the lower of cost or market and costs are determined on a first-in, first-out basis.

The Company evaluates its inventories for excess quantities and obsolescence. Inventories that are considered excess or obsolete are expensed. In order to assess the ultimate realization of inventories, the Company is required to make judgments as to future demand requirements compared to current or committed inventory levels. The valuation of inventories requires the use of estimates as to the amounts of current inventories that will be sold. These estimates are dependent on management's assessment of current and expected orders from the Company's customers.

Trade Accounts Receivable

Trade accounts receivable represents estimated receivables from customers for revenue recognized related to genetic tests. The Company does not have any off-balance-sheet credit exposure related to its customers and does not require collateral.

Property, Plant and Equipment

Equipment and leasehold improvements are stated at cost less accumulated depreciation. Depreciation and amortization are computed using the straight-line method based on the lesser of estimated useful lives of the related assets or lease terms. Equipment items have depreciable lives of five to seven years. Leasehold improvements are depreciated over the shorter of the estimated useful lives or the associated lease terms, which range from one to fifteen years. Repairs and maintenance costs are charged to expense as incurred.

Leases

The Company acts as the lessee in its lease agreements, which primarily include operating leases for corporate offices, laboratory space, warehouse space, vehicles and certain laboratory and office equipment.

The Company determines whether an arrangement is, or contains, a lease at inception and whether the lease should be classified as a finance or operating lease. For all leases, the Company records the present value of lease payments as right-of-use ("ROU") assets and lease liabilities on the Consolidated Balance Sheets. ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent an obligation to make lease payments based on the present value of lease payments over the lease term. Classification of lease liabilities as either current or non-current is based on the expected timing of payments due under the Company's obligations.

As most of the Company's leases do not provide an implicit interest rate, the Company uses its incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments. The ROU asset also consists of any lease incentives received. The lease terms used to calculate the ROU asset and related lease liability include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. The leases have remaining lease terms of 1 year to 15 years, some of which include options to extend the lease term for up to 10 years.

The Company has taken advantage of certain practical expedients offered to registrants at adoption of Accounting Standards Codification ("ASC") 842, *Leases*. Lease expense for leases with a term of twelve months or less is recognized on a straight-line basis and is not included in the recognized ROU assets and lease liabilities. Further, as a practical expedient, all lease contracts are accounted for as one single lease component, as opposed to separating lease and non-lease components to allocate the consideration within a single lease contract.

Operating leases are included in Operating lease right-of-use assets, Current maturities of operating lease liabilities, and Noncurrent operating lease liabilities in the Consolidated Balance Sheets. Finance leases are included in Other assets, Accrued liabilities, and Other long-term liabilities in the Consolidated Balance Sheets.

Intangible Assets

Intangible assets are comprised of acquired licenses and technology. Acquired intangible assets are recorded at fair value and amortized over the shorter of the contractual life or the estimated useful life. The Company capitalizes certain costs incurred to develop internal-use software. Implementation and development costs for internal-use software are capitalized as part of Intangible Assets in the Consolidated Balance Sheets. After the implementation of the internal-use software, the capitalized costs are amortized on a straight-line basis over the estimated useful life of the asset. Costs incurred during the post implementation stage of the project are expensed as incurred. As of December 31, 2023, the Company had unamortized internal-use software costs of $11.9 million. For the years ended December 31, 2023, 2022, and 2021 amortization expense for these capitalized software costs was insignificant.

Other Long-Lived Assets

The Company continually reviews and monitors long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated future undiscounted cash flows, an impairment charge is recognized in the amount by which the carrying amount of the asset exceeds the fair value of the asset. Assets to be disposed of are reported at the lower of the carrying amount or fair value less costs to sell. The Company capitalizes certain costs incurred to develop internal-use technology, including certain implementation costs incurred in cloud computing arrangements and hosting arrangements. The Company's cloud computing arrangements or hosting arrangements are primarily service contracts related to information technology. Implementation and development costs for internal-use technology are capitalized as part of Other assets in the Consolidated Balance Sheets. As of December 31, 2023 and 2022, the Company had unamortized internal-use technology costs of $4.6 million and $7.1 million, respectively, within Other assets. For the years ended December 31, 2023, 2022 and 2021, amortization expense for these capitalized internal-use technology was insignificant.

Goodwill

Goodwill is tested for impairment by reporting unit on an annual basis as of October 1 and in the interim if events and circumstances indicate that goodwill may be impaired. The events and circumstances that are considered include business climate and market conditions, legal factors, operating performance indicators and competition. Impairment of goodwill is first assessed using a qualitative approach. If the qualitative assessment suggests that impairment is more likely than not, a quantitative analysis is performed. The quantitative analysis involves a comparison of the fair value of the reporting unit with its carrying amount. If the carrying amount of a reporting unit exceeds its fair value, an impairment loss is recognized in an amount equal to that excess, limited to the total amount of goodwill allocated to that reporting unit. If an event occurs that would cause a revision to the estimates and assumptions used in analyzing the value of the goodwill, the revision could result in a non-cash impairment charge that could have a material impact on the financial results.

Business Acquisitions

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 the Company's 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 to 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.

In circumstances where an acquisition involves a contingent consideration arrangement that meets the definition of a liability under ASC 480, *Distinguishing Liabilities from Equity*, the Company recognizes a liability equal to the fair value of the contingent payments expected to be made as of the acquisition date. This liability is remeasured each reporting period and the changes in the fair value are recognized in Selling, general, and administrative expenses in the Consolidated Statements of Operations.

Transaction costs associated with acquisitions are expensed as incurred in Selling, general, and administrative expenses in the Consolidated Statements of Operations. Results of operations and cash flows of acquired companies are included in the operating results from the date of acquisition.

Revenue Recognition

The Company primarily generates revenue by performing genetic testing. Testing revenues are primarily derived from the following categories of products: Hereditary Cancer (MyRisk, BRACAnalysis, BRACAnalysis CDx), Tumor Profiling (MyChoice CDx, Prolaris, and EndoPredict), Prenatal (Foresight, Prequel, and SneakPeek), and Pharmacogenomics (GeneSight). The Company previously provided pharmaceutical and clinical services prior to the sale of Myriad RBM, Inc. in July 2021. Prior to the sale of the Myriad myPath, LLC laboratory in May 2021 and the Myriad Autoimmune business in September 2021, the associated revenue from such businesses was included within Testing revenues. See Note 17 for a discussion of these divestitures. Revenue is recorded at the estimated transaction price. The Company has determined that the communication of test results or the completion of pharmaceutical and clinical services indicates transfer of control for revenue recognition purposes.

The following table presents detail regarding the composition of the Company's total revenue by product type for the years ended December 31, 2023, 2022, and 2021:

	Years Ended December 31,		
(In millions)	**2023**	**2022**	**2021**
Testing revenues:			
Hereditary Cancer	$ 327.8	$ 305.5	$ 316.3
Tumor Profiling	135.6	128.6	120.9
Prenatal	151.3	116.4	106.8
Pharmacogenomics	138.5	127.6	93.7
Autoimmune	—	0.3	28.2
Other	—	—	0.5
Total testing revenue	753.2	678.4	666.4
Other revenue	—	—	24.2
Total revenue	$ 753.2	$ 678.4	$ 690.6

In addition, the following tables reconcile revenue by geographical region, either U.S. or rest of world ("RoW"), to total revenue:

	Years Ended December 31,								
	2023			**2022**			**2021**		
(in millions)	**U.S.**	**RoW**	**Total**	**U.S.**	**RoW**	**Total**	**U.S.**	**RoW**	**Total**
Testing revenues:									
Hereditary Cancer	$ 280.5	$ 47.3	$ 327.8	$ 263.5	$ 42.0	$ 305.5	$ 271.0	$ 45.3	$ 316.3
Tumor Profiling	102.1	33.5	135.6	84.5	44.1	128.6	80.4	40.5	120.9
Prenatal	150.6	0.7	151.3	115.6	0.8	116.4	106.2	0.6	106.8
Pharmacogenomics	138.5	—	138.5	127.6	—	127.6	93.7	—	93.7
Autoimmune	—	—	—	0.3	—	0.3	28.2	—	28.2
Other	—	—	—	—	—	—	—	0.5	0.5
Total testing revenue	671.7	81.5	753.2	591.5	86.9	678.4	579.5	86.9	666.4
Other revenue	—	—	—	—	—	—	24.2	—	24.2
Total revenue	$ 671.7	$ 81.5	$ 753.2	$ 591.5	$ 86.9	$ 678.4	$ 603.7	$ 86.9	$ 690.6

Under ASC 606, *Revenue from Contracts with Customers* ("ASC 606"), an entity recognizes revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The Company performs its obligation under a contract with a customer by processing tests and communicating the test results to customers, in exchange for consideration from the customer. The Company has the right to bill its customers upon the completion of performance obligations and thus does not record contract assets. Occasionally, customers make payments prior to the Company's performance of its contractual obligations. When this occurs, the Company records a contract liability as Deferred revenue, which is included in Accrued liabilities in the Consolidated Balance Sheets. A reconciliation of the beginning and ending balances of deferred revenue is shown in the table below:

	Years Ended December 31,		
(in millions)	2023	2022	2021
Deferred revenue - beginning balance	$ 0.6	$ 5.2	$ 32.7
Revenue recognized	(0.5)	(4.9)	(40.5)
Prepayments	0.4	0.3	14.0
Divestitures	—	—	(1.0)
Deferred revenue - ending balance	$ 0.5	$ 0.6	$ 5.2

In accordance with ASC 606, the Company has elected not to disclose the aggregate amount of the transaction price allocated to remaining performance obligations for its contracts that are one year or less, as the revenue is expected to be recognized within the next year. Furthermore, the Company has elected not to disclose the aggregate amount of the transaction price allocated to remaining performance obligations for its agreements wherein the Company's right to payment is in an amount that directly corresponds with the value of the Company's performance to date. In determining the transaction price, the Company includes an estimate of the expected amount of consideration as revenue. The Company applies this method consistently for similar contracts when estimating the effect of any uncertainty on an amount of variable consideration to which it will be entitled. An estimate of transaction price does not include any estimated amount of variable consideration that is constrained. In addition, the Company considers all the information (historical, current, and forecast) that is reasonably available to identify possible consideration amounts. In determining the expected value, the Company considers the probability of the variable consideration for each possible scenario. The Company also has significant experience with historical discount patterns and uses this experience to estimate transaction prices.

The estimate of revenue is affected by assumptions in payor behavior such as changes in payor mix, payor collections, current customer contractual requirements, and experience with collections from third-party payors. When assessing the total consideration for insurance carriers and patients, revenues are further constrained for estimated refunds. The Company reserves certain amounts in Accrued liabilities in the Consolidated Balance Sheets in anticipation of requests for refunds of payments made previously by insurance carriers, which are accounted for as reductions in revenues in the Consolidated Statements of Operations and Comprehensive Loss.

Cash collections for certain tests delivered may differ from rates estimated, primarily driven by changes in the estimated transaction price due to contractual adjustments, obtaining updated information from payors and patients that was unknown at the time the performance obligation was met and settlements with third-party payors. As a result of this new information, the Company updates its estimate of the amounts to be recognized for previously delivered tests. During the year ended December 31, 2023, the Company recognized $7.2 million in revenue, which resulted in a $0.07 impact to loss per share for tests in which the performance obligation of delivering the test results was met in prior periods. During the year ended December 31, 2022, the Company recognized $22.1 million in revenue which resulted in a $0.21 impact to loss per share for tests in which the performance obligation of delivering the test results was met in prior periods. During the year ended December 31, 2021, the Company recognized $15.9 million in revenue which resulted in a $0.15 impact to loss per share for tests in which the performance obligation of delivering the test results was met in prior periods. Additionally, during the year ended December 31, 2021, revenue of $6.8 million was recognized due to expanded coverage for the Company's Prolaris test, for which revenue was fully constrained in a prior period. The changes for all periods presented were primarily driven by changes in the estimated transaction price.

In accordance with ASC 606, the Company has elected to exclude from the measurement of transaction price all taxes assessed by a governmental authority that are both imposed on and concurrent with a specific revenue-producing transaction and collected by the Company from a customer for sales tax, value added tax, and certain other taxes.

The Company applies the practical expedient related to costs to obtain or fulfill a contract since the amortization period for such costs will be one year or less. Accordingly, no costs incurred to obtain or fulfill a contract have been capitalized. The Company also applies the practical expedient for not adjusting revenue recognized for the effects of the time value of money. This practical expedient has been elected because the Company collects very little cash from customers under payment terms and the vast majority of payment terms have a payback period of less than one year.

Stock-based Payment Expense

We recognize the fair value compensation cost relating to stock-based payment transactions in accordance with ASC 718, *Compensation – Stock Compensation* ("ASC 718"). Under the provisions of ASC 718, stock-based compensation cost is measured at the grant date, based on the fair value of the award, and is recognized over the employee's requisite service period, which is generally the vesting period. Compensation cost for awards with only service conditions are recognized on a straight-line basis over the requisite service period. The fair value of restricted stock units (RSUs) and performance restricted stock units (PSUs) that do not have market conditions is based on the number of shares granted and the quoted price of the Company's common stock on the grant date. The fair value of PSU awards that have market conditions is determined using the Monte Carlo Method. For PSUs, the Company estimates the likelihood of achievement of the performance conditions at the end of each period. Forfeitures are recognized as a reduction of compensation expense in earnings in the period in which they occur. The fair value of shares issued under the Company's Employee Stock Purchase Plan is calculated using the Black-Scholes option-pricing model, based on assumptions including the risk-free interest rate, expected life, expected dividend yield and expected volatility. The average risk-free interest rate is determined using the U.S. Treasury rate. We determine the expected life based on the offering period of the Employee Stock Purchase Plan. The expected volatility is determined using the weighted average of daily historical volatility of the price of the Company's common stock.

Other Income (Expense)

The Company recognizes the gain or loss on its divestitures as Other income (expense) in the Consolidated Statement of Operations. See Note 17 for additional information regarding these divestitures.

Income Taxes

The Company recognizes income taxes under the asset and liability method. This approach requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the carrying amounts and the tax bases of assets and liabilities.

The provision for income taxes, including the effective tax rate and analysis of potential tax exposure items, if any, requires significant judgment and expertise in federal, state, and foreign income tax laws, regulations and strategies, including the determination of deferred tax assets and liabilities and any estimated valuation allowances deemed necessary to recognize deferred tax assets at an amount that is more likely than not to be realized. The Company's filings, including the positions taken therein, are subject to audit by various taxing authorities. While the Company believes it has provided adequately for its income tax liabilities in the consolidated financial statements, adverse determinations by these taxing authorities could have a material adverse effect on the Company's consolidated financial condition, results of operations or cash flows.

Earnings Per Share

Basic earnings per share (EPS) is computed based on the weighted-average number of shares of common stock outstanding. Diluted earnings per share is computed based on the weighted-average number of shares of common stock, including the dilutive effect of common stock equivalents, outstanding.

The following is a reconciliation of the denominators of the basic and diluted earnings per share computations:

	Years Ended December 31,		
(in millions)	2023	2022	2021
Denominator:			
Weighted-average shares outstanding used to compute basic EPS	82.8	80.6	78.0
Effect of dilutive stock options and RSUs	—	—	—
Weighted-average shares outstanding and dilutive securities used to compute diluted EPS	82.8	80.6	78.0

Certain outstanding options and RSUs were excluded from the computation of diluted earnings per share because the effect would have been anti-dilutive. These potential dilutive shares of common stock, which may be dilutive to future diluted earnings per share, are as follows:

	Years Ended December 31,		
(in millions)	2023	2022	2021
Anti-dilutive options and RSUs excluded from EPS computation	5.1	4.4	4.5

Foreign Currency

The functional currency of the Company's international subsidiaries is the local currency. For those subsidiaries, expenses denominated in the functional currency are translated into U.S. dollars using average exchange rates in effect during the period and assets and liabilities are translated using period-end exchange rates. The foreign currency translation adjustments are included in Accumulated other comprehensive loss as a separate component of Stockholders' equity.

The following table shows the cumulative translation adjustments included in Accumulated other comprehensive loss (in millions):

Ending balance December 31, 2022	$	(6.2)
Period translation adjustments		2.1
Reclassification of cumulative translation adjustment to income upon liquidation of an investment in a foreign entity		0.4
Ending balance December 31, 2023	$	(3.7)

During the years ended December 31, 2023 and 2022, the Company recognized a gain (loss) related to foreign currency of $(3.4) million and $0.2 million, respectively, which is included in Other in the Consolidated Statements of Operations.

Recent Accounting Pronouncements

In November 2023, the FASB issued accounting standards update ("ASU") 2023-07, which enhances the disclosures required for reportable segments in annual and interim consolidated financial statements. ASU 2023-07 is effective for the Company for annual reporting periods beginning after December 15, 2023 and for interim periods within fiscal years December 15, 2024. Early adoption is permitted. The Company is currently evaluating the impact of ASU 2023-07 on its segment disclosures.

In December 2023, the FASB issued ASU 2023-09, which requires enhanced income tax disclosures, including disaggregation of information on the rate reconciliation table and disaggregated information related to income taxes paid. The amendments in ASU 2023-09 are effective for annual periods beginning after December 15, 2024. The Company is currently evaluating the impact of ASU 2023-09 on its income tax disclosures.

2. MARKETABLE INVESTMENT SECURITIES

The amortized cost, gross unrealized holding gains, gross unrealized holding losses, and fair value for debt securities classified as available-for-sale securities by major security type and class of security at December 31, 2023 and December 31, 2022 were as follows:

(in millions)	Amortized cost	Gross unrealized holding gains	Gross unrealized holding losses	Estimated fair value
December 31, 2023:				
Cash and cash equivalents:				
Cash	$ 129.9	$ —	$ —	$ 129.9
Cash equivalents	2.2	—	—	2.2
Total cash and cash equivalents	132.1	—	—	132.1
Available-for-sale:				
Corporate bonds and notes	8.4	—	(0.1)	8.3
Municipal bonds	0.5	—	—	0.5
Total	$ 141.0	$ —	$ (0.1)	$ 140.9

(in millions)	Amortized cost	Gross unrealized holding gains	Gross unrealized holding losses	Estimated fair value
December 31, 2022:				
Cash and cash equivalents:				
Cash	$ 53.6	$ —	$ —	$ 53.6
Cash equivalents	3.3	—	—	3.3
Total cash and cash equivalents	56.9	—	—	56.9
Available-for-sale:				
Corporate bonds and notes	66.7	—	(1.6)	65.1
Municipal bonds	16.3	—	(0.3)	16.0
Federal agency issues	20.7	—	(0.7)	20.0
U.S. government securities	11.8	—	(0.1)	11.7
Total	$ 172.4	$ —	$ (2.7)	$ 169.7

Cash, cash equivalents, and maturities of debt securities classified as available-for-sale were as follows at December 31, 2023:

(in millions)	Amortized cost	Estimated fair value
Cash	$ 129.9	$ 129.9
Cash equivalents	2.2	2.2
Available-for-sale:		
Due within one year	8.9	8.8
Total	$ 141.0	$ 140.9

During the years ended December 31, 2023, 2022, and 2021, the Company sold $90.4 million, $28.4 million, and $8.3 million of investments, respectively. The cost of the available for sale security sold was determined using the specific-identification method. The amount of gross realized gains and realized losses upon sales of investments was $1.5 million for the year ended December 31, 2023 and was insignificant for the years ended December 31, 2022 and 2021. As of December 31, 2023, the Company had 7 available-for-sale debt securities in a gross unrealized loss position of $0.1 million, with a fair market value of $8.8 million. As of December 31, 2022, the Company had 118 available-for-sale debt securities in a gross unrealized loss position of $2.7 million, with a fair market value of $111.6 million. As of December 31, 2023 and 2022, the expected losses were determined to be immaterial and as such, the Company did not record an allowance for credit losses. The Company does not intend to sell these available-for-sale debt securities, and it is not more likely than not that it will be required to sell these securities prior to recovery of their amortized cost basis. Additional information relating to fair value of marketable investment securities can be found in Note 3.

3. FAIR VALUE MEASUREMENTS

The fair value of the Company's financial instruments reflects the amounts that the Company estimates it will receive in connection with the sale of an asset or pay in connection with the transfer of a liability in an orderly transaction between market participants at the measurement date (exit price). The fair value hierarchy prioritizes the use of inputs used in valuation techniques into the following three levels:

Level 1—quoted prices in active markets for identical assets and liabilities.

Level 2—observable inputs other than quoted prices in active markets for identical assets and liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities. Some of the Company's marketable securities primarily utilize broker quotes in a non-active market for valuation of these securities.

Level 3—unobservable inputs.

All of the Company's financial instruments are valued using quoted prices in active markets or based on other observable inputs. For Level 2 securities, the Company uses a third-party pricing service which provides documentation on an ongoing basis that includes, among other things, pricing information with respect to reference data, methodology, inputs summarized by asset class, pricing application and corroborative information. For Level 3 contingent consideration related to the acquisitions of Sividon Diagnostics GmbH ("Sividon") and Gateway, the Company reassesses the fair value of each expected contingent consideration and the corresponding liability each reporting period using the Monte Carlo Method, which is consistent with the initial measurement of the expected contingent consideration liability. This fair value measurement is considered a Level 3 measurement because the Company estimates projections during the expected measurement periods of approximately 11.5 and 1.3 years for Sividon and Gateway, respectively, utilizing various potential pay-out scenarios. During the year ended December 31, 2023, the previously recognized contingent consideration liability related to the acquisition of Gateway, which was $2.1 million as of December 31, 2022, was released due to the revised forecasts and the results of the Monte Carlo valuation. Probabilities were applied to each potential scenario and the resulting values were discounted using a rate that considers weighted average cost of capital as well as a specific risk premium associated with the riskiness of the contingent consideration itself, the related projections, and the overall business. The contingent consideration liabilities are classified as components of Accrued liabilities and Other long-term liabilities in the Consolidated Balance Sheets. Changes to contingent consideration liabilities are reflected in Selling, general, and administrative expense in the Consolidated Statements of Operations. Changes to the unobservable inputs could have a material impact on the Company's financial statements.

The fair value of the Company's long-term debt, which it considers a Level 2 measurement, is estimated using discounted cash flow analyses, based on the Company's current estimated incremental borrowing rates for similar borrowing arrangements. The fair value of the Company's long-term debt is estimated to be $39.7 million at December 31, 2023.

The following table sets forth the fair value of the financial assets and liabilities that the Company re-measures on a regular basis:

(in millions)	Level 1	Level 2	Level 3	Total
December 31, 2023				
Money market funds (a)	$ 2.2	$ —	$ —	$ 2.2
Corporate bonds and notes	—	8.3	—	8.3
Municipal bonds	—	0.5	—	0.5
Contingent consideration	—	—	(5.4)	(5.4)
Total	$ 2.2	$ 8.8	$ (5.4)	$ 5.6

(in millions)	Level 1	Level 2	Level 3	Total
December 31, 2022				
Money market funds (a)	$ 3.3	$ —	$ —	$ 3.3
Corporate bonds and notes	—	65.1	—	65.1
Municipal bonds	—	16.0	—	16.0
Federal agency issues	—	20.0	—	20.0
U.S. government securities	—	11.7	—	11.7
Contingent consideration	—	—	(6.8)	(6.8)
Total	$ 3.3	$ 112.8	$ (6.8)	$ 109.3

(a) Money market funds are primarily comprised of exchange traded funds and accrued interest.

The following table reconciles the change in the fair value of the contingent consideration during the periods presented:

(in millions)	Years Ended December 31,		
	2023	2022	2021
Carrying amount at beginning of period	$ 6.8	$ 8.6	$ 10.9
Payment of contingent consideration	—	(3.0)	(3.3)
Consideration recognized at acquisition	—	2.1	—
Change in fair value recognized in the statement of operations	(1.5)	(0.4)	1.8
Translation adjustments recognized in other comprehensive income (loss)	0.1	(0.5)	(0.8)
Carrying amount at end of period	$ 5.4	$ 6.8	$ 8.6

4. PROPERTY, PLANT AND EQUIPMENT, NET

The property, plant and equipment at December 31, 2023 and December 31, 2022 were as follows:

	December 31,	
(in millions)	2023	2022
Leasehold improvements	$ 91.3	$ 67.9
Equipment	147.6	124.7
Property, plant and equipment, gross	238.9	192.6
Less accumulated depreciation	(119.9)	(109.2)
Property, plant and equipment, net	$ 119.0	$ 83.4

During the year ended December 31, 2023, the Company incurred $5.7 million of accelerated depreciation of leasehold improvements and equipment in connection with the Company's decision to cease the use of its corporate headquarters in Salt Lake City and transition corporate support operations to its new facility in west Salt Lake City. The Company formally assigned the previous corporate headquarter lease to a third party as of December 31, 2023. See Note 13 for further discussion.

During the year ended December 31, 2022, the Company ceased the use of certain leased Salt Lake City facilities and one of its South San Francisco facilities. As a result, the Company recognized a $3.9 million impairment on the property, plant and equipment associated with the leases, which consisted primarily of leasehold improvements. See Note 13 for further discussion.

The Company recorded depreciation during the respective periods as follows:

	Years Ended December 31,		
(in millions)	2023	2022	2021
Depreciation expense	$ 19.1	$ 11.6	$ 12.1

5. GOODWILL AND INTANGIBLE ASSETS

Goodwill

The changes in the carrying amount of goodwill for the year ended December 31, 2023 are as follows:

(in millions)	Year Ended December 31, 2023
Beginning balance	$ 286.8
Translation adjustments	0.6
Carrying amount at end of period	$ 287.4

The Company assessed goodwill for impairment as part of its annual goodwill testing in accordance with the appropriate guidance (see Note 1) and determined none of its reporting units were impaired as of the annual testing date. The Company did not record an impairment of goodwill for the years ended December 31, 2023, 2022 and 2021.

Intangible Assets

The following tables summarize the amounts reported as intangible assets (in millions):

At December 31, 2023:	Gross Carrying Amount	Accumulated Amortization	Net	Weighted-Average Useful Life (in Years)	Weighted-Average Remaining Useful Life (in Years)
Developed technologies	$ 626.1	$ (295.3)	$ 330.8	14.4	8.1
Internal-use software	0.8	(0.1)	0.7	3.0	2.5
Internal-use software (in-process)	11.2	—	11.2	3.0	3.0
Customer relationships	1.6	(0.2)	1.4	10.0	8.8
Trademarks	6.1	(0.7)	5.4	10.0	8.8
Total intangible assets	$ 645.8	$ (296.3)	$ 349.5	13.9	7.9

At December 31, 2022:	Gross Carrying Amount	Accumulated Amortization	Net	Weighted-Average Useful Life (in Years)	Weighted-Average Remaining Useful Life (in Years)
Developed technologies	$ 625.0	$ (252.9)	$ 372.1	14.4	9.1
Customer relationships	1.6	—	1.6	10.0	9.8
Trademarks	6.1	(0.1)	6.0	10.0	9.8
Total intangible assets	$ 632.7	$ (253.0)	$ 379.7	14.4	9.1

As of December 31, 2023, the Company's developed technologies have estimated remaining useful lives ranging between 7 and 12 years. The Company's trademarks and customer relationships acquired as of December 31, 2023 have an estimated remaining useful life of approximately nine years. The Company's internal-use software assets are amortized over the estimated useful life of the software, which is generally three years. The Company concluded there was no impairment of long-lived intangible assets for the years ended December 31, 2023, 2022 and 2021.

The Company recorded amortization during the respective periods for these intangible assets as follows:

	Years Ended December 31,		
(in millions)	2023	2022	2021
Amortization of intangible assets	$ 42.8	$ 41.1	$ 50.7

Future amortization expense of intangible assets as of December 31, 2023 is estimated to be as follows (in millions):

Years Ended December 31,	Amortization Expense
2024	$ 45.0
2025	46.3
2026	46.5
2027	44.7
2028	43.4
Thereafter	123.6
Total	$ 349.5

6. ACCRUED LIABILITIES

The Company's accrued liabilities at December 31, 2023 and December 31, 2022 were as follows:

	December 31,	
(in millions)	2023	2022
Employee compensation and benefits	$ 49.7	$ 41.2
Accrued taxes payable	4.6	4.8
Refunds payable and reserves	20.1	19.3
Short-term contingent consideration	3.1	—
Accrued royalties	5.3	4.8
Legal settlement	6.0	—
Lease termination accrual	4.4	—
Other accrued liabilities	20.7	24.2
Total accrued liabilities	$ 113.9	$ 94.3

7. LONG-TERM DEBT

On June 30, 2023, the Company entered into an asset-based revolving credit facility (the “ABL Facility”) with an initial maximum principal amount of $90.0 million, with JPMorgan Chase Bank, N.A. as administrative agent and issuing bank, the other lender parties thereto, and certain of the Company's domestic subsidiaries (the "Guarantors"). On October 31, 2023, the Company entered into an amendment to the ABL Facility to increase the maximum principal amount of the available revolving line of credit by $25.0 million for a total maximum principal commitment of $115.0 million under the ABL Facility, which was effected through a new commitment provided by a new lender, Goldman Sachs Bank USA. The ABL Facility replaced the Company's previous credit facility and matures on June 30, 2026. The obligations of the Company are guaranteed by the Guarantors, and the ABL Facility is secured by substantially all of the assets of the Company and the Guarantors. The Company had long-term debt of $38.5 million under the ABL Facility at December 31, 2023, net of $1.5 million of debt issuance costs. The proceeds of the ABL Facility were or will be used for the working capital needs and general corporate purposes of the Company and its subsidiaries, including, without limitation, consummating permitted acquisitions and refinancing existing indebtedness.

Availability under the ABL Facility is subject to a borrowing base, which is the lesser of (a) 85% of the Company's and the Guarantor's eligible accounts receivable plus certain cash held in a segregated and fully-blocked account with the administrative agent in an amount up to $20.0 million ("Eligible Cash") minus any reserves established by the administrative agent in accordance with the ABL Facility, and (b) the aggregate amount of cash collections from eligible accounts of the Company and the Guarantors for the 60 consecutive days most recently ended. Subject to certain conditions, the Company can freely withdraw cash from the Eligible Cash account, provided that any reduction in the Eligible Cash amount will have a corresponding reduction in the borrowing base.

Loans outstanding under the ABL Facility will bear interest at a rate per annum equal to, at the option of the Company, either (a) the greatest of (i) the daily Prime Rate, (ii) the daily NYFRB Rate plus 0.50%, and (iii) the monthly Adjusted Term SOFR Rate (as defined below) plus 1.00% (the “ABR”) plus an applicable margin ranging from 1.00% to 1.50% depending on the aggregate average unused availability under the ABL Facility during the prior quarter or (b) term SOFR for a tenor of one, three or six months (at the Company’s election) plus 0.10% (the “Adjusted Term SOFR Rate”) plus an applicable margin ranging from 2.00% to 2.50% depending on the average unused availability under the ABL Facility during the prior quarter, with an ABR floor of 1.00% and an Adjusted Term SOFR Rate floor of 0.00%. Under the ABL Facility the undrawn fee ranges from 37.5 to 50 basis points based on the daily amount of the available revolving commitment. The interest rate for borrowings under the ABL Facility as of December 31, 2023 was 9.75%.

The Company may elect to prepay all or any portion of the amounts owed prior to the maturity date without premium or penalty. The ABL Facility is also subject to customary mandatory prepayments with the proceeds of unpermitted indebtedness and upon the occurrence of an over-advance. Voluntary and mandatory prepayments and all other payments of the ABL Facility must be accompanied by payment of accrued interest on the principal amount repaid or prepaid.

The ABL Facility contains customary loan terms, interest rates, representations and warranties and affirmative and negative covenants, in each case, subject to customary limitations, exceptions and exclusions. Covenants under the ABL Facility limit or restrict the Company and its subsidiaries' ability to incur liens, incur indebtedness, dispose of assets, make investments, make certain restricted payments, merge or consolidate and enter into certain speculative hedging arrangements. The ABL Facility requires the Company and the Guarantors, on a consolidated basis, to maintain minimum liquidity of $60.0 million and minimum availability of $25.0 million at all times before achieving a fixed charge coverage ratio of 1.0 to 1.0 and thereafter, to maintain a fixed charge coverage ratio of 1.0 to 1.0 until achieving availability under the ABL Facility of greater than the greater of (a) $10.6 million and (b) 12.5% of the lesser of the maximum commitment amount and the borrowing base for a period of 30 consecutive days. As of December 31, 2023, availability under the ABL Facility was $40.7 million. In addition, the ABL Facility includes a number of customary events of default. If any event of default occurs (subject, in certain instances, to specified grace periods), the principal, premium, if any, interest and any other monetary obligations on all the then-outstanding amounts under the ABL Facility may become due and payable immediately.

Under the terms of the ABL Facility, if (i) an event of default has occurred and is continuing or (ii) availability under the ABL Facility is less than the greater of (a) $12.5 million and (b) 15% of the lesser of the maximum commitment amount and the borrowing base, the Company will become subject to cash dominion, upon which the administrative agent will apply funds credited to a collection account to first prepay any outstanding protective advances, second to prepay any revolving loans and third, to cash collateralize any outstanding letter of credit exposure. Such cash dominion period will end when availability has remained in excess of the greater of (i) $12.5 million and (ii) 15% of the lesser of the maximum commitment amount and the borrowing base for a period of 45 consecutive days and no event of default is continuing.

The Company had no outstanding balances under the previous credit facility, which was replaced with the ABL Facility, as of December 31, 2022.

8. OTHER LONG-TERM LIABILITIES

The Company's other long-term liabilities at December 31, 2023 and December 31, 2022 were as follows:

	December 31,	
(in millions)	2023	2022
Contingent consideration	$ 2.3	$ 6.8
Escrow liability	7.5	7.5
Legal settlements	24.0	—
Other	7.5	3.7
Total other long-term liabilities	$ 41.3	$ 18.0

Contingent consideration as of December 31, 2023 consisted of the long-term portion of contingent consideration related to the acquisition of Sividon. As of December 31, 2022, contingent consideration consisted of the long-term portion of contingent consideration related to the acquisitions of Sividon and Gateway. The previously recognized contingent consideration liability related to the acquisition of Gateway is not included in the balance as of December 31, 2023, as it is not probable that the required metrics will be met. Additionally, a corresponding amount of cash to the escrow liability of $7.5 million has been restricted for the potential payment under the indemnity and escrow provisions of the Gateway acquisition agreement. See Note 16 for additional information on the Gateway acquisition. The Company has also accrued $24.0 million in connection with pending legal settlements. See Note 12 for additional information on Commitments and Contingencies.

9. PREFERRED AND COMMON STOCKHOLDERS' EQUITY

The Company is authorized to issue up to 5.0 million shares of preferred stock, par value $0.01 per share. There were no shares of preferred stock outstanding at December 31, 2023 and December 31, 2022.

The Company is authorized to issue up to 150.0 million shares of common stock, par value $0.01 per share.

In November 2023, the Company completed an underwritten public offering in which it sold 7.4 million shares of its common stock at a price of $17.00 per share, for gross proceeds of $126.5 million and net proceeds of $117.6 million.

There were 89.9 million and 81.2 million shares of common stock issued and outstanding at December 31, 2023 and 2022, respectively.

Shares of common stock issued and outstanding

	Years Ended December 31,		
(in millions)	2023	2022	2021
Beginning common stock issued and outstanding	81.2	80.0	75.4
Common stock issued upon exercise of options, vesting of restricted stock units, and purchases under employee stock purchase plans	1.3	1.2	4.6
Common stock issued for public offering	7.4	—	—
Common stock issued and outstanding at end of period	89.9	81.2	80.0

10. STOCK-BASED COMPENSATION

On November 30, 2017, the Company's stockholders approved the adoption of the 2017 Employee, Director and Consultant Equity Incentive Plan (as amended, the "2017 Plan"). The 2017 Plan allows the Company, under the direction of the Compensation and Human Capital Committee of the Board of Directors (the "CHCC"), to make grants of restricted and unrestricted stock and stock unit awards to employees, consultants and directors. Stockholders have subsequently approved amendments to the 2017 Plan increasing the shares available to grant thereunder, including most recently at the Company's annual meeting of stockholders held on June 1, 2023, when stockholders approved an amendment to the 2017 Plan to increase the aggregate number of shares of common stock available thereunder for the granting of awards by an additional 4.8 million shares. As of December 31, 2023, the Company had 4.7 million shares of common stock available for grant under the 2017 Plan. If an RSU awarded under the 2017 Plan is cancelled or forfeited without the issuance of shares of common stock, the unissued or reacquired shares that were subject to the RSU will again be available for issuance pursuant to the 2017 Plan.

The number of shares, terms, and vesting periods are generally determined by the Company's Board of Directors or the CHCC on an award-by-award basis. RSUs granted to employees generally vest either ratably over three or four years or as a cliff vesting after three years either on the anniversary of the date on which the RSUs were granted or during the month in which such anniversary dates occur. The number of PSUs awarded to certain employees may be increased or may be reduced based on certain additional performance and market metrics. RSUs granted to non-employee directors vest in full upon the earlier of the completion of one year of service following the date of the grant or the date of the next annual meeting of stockholders following such grant. Options granted to the Company's President and Chief Executive Officer as an inducement to his employment expire on August 13, 2027.

The performance and market conditions associated with PSU awards granted during the year ended December 31, 2023 include vesting that is based on revenue targets (34% weighting), adjusted earnings per share targets (33% weighting), and relative total stockholder return (33% weighting) measured against the Nasdaq Health Care Index (IXHC) using the 20-trading day averages at the beginning and end of the measurement period. The measurement period for the relative total stockholder return metric is January 1, 2023 to December 31, 2025, and the revenue and adjusted earnings per share metrics will be measured based on fiscal year 2025 results. The Company estimates the likelihood of achievement of performance conditions at the end of each period. To the extent those awards or portions thereof are considered probable of being achieved, such awards or portions thereof are expensed over the performance period. The portion of the awards pertaining to relative total stockholder return represent market conditions and, accordingly, the estimated fair value of such awards are recognized over the performance period.

Stock Options

A summary of the stock option activity under the Company's equity plans, and inducement awards for the year ended December 31, 2023 is as follows:

(number of shares in millions)	Number of shares	Weighted average exercise price	Weighted average remaining contractual life (years)
Options outstanding at December 31, 2022	0.7	$ 13.38	
Options outstanding at December 31, 2023	0.7	13.38	3.62
Options exercisable at December 31, 2023	0.5	13.38	3.62
Options vested and expected to vest	0.7	$ 13.38	3.62

There were no options granted during the years ended December 31, 2023, 2022 and 2021.

Restricted Stock Units

A summary of the RSU awards activity under the Company's equity plans and inducement awards, including PSU awards, for the year ended December 31, 2023 is as follows:

	2023	
(number of shares in millions)	Number of shares	Weighted average grant date fair value
RSUs unvested and outstanding at December 31, 2022	3.7	$ 25.08
RSUs granted	2.4	23.02
Less:		
RSUs vested	(1.3)	23.55
RSUs canceled	(0.4)	24.38
RSUs unvested and outstanding at December 31, 2023	4.4	$ 24.37

The weighted average grant-date fair value of RSUs granted during the years ended December 31, 2023, 2022, and 2021 was $23.02, $25.78, and $29.83, respectively.

The fair value of RSUs that vested during the years ended December 31, 2023, 2022, and 2021 was $30.5 million, $31.0 million, and $22.6 million, respectively.

Stock-based compensation expense recognized and included in the Consolidated Statements of Operations was allocated as follows:

	Years Ended December 31,		
(in millions)	2023	2022	2021
Cost of testing revenue	$ 1.4	$ 1.7	$ 1.5
Cost of other revenue	—	—	0.1
Research and development expense	4.0	5.2	4.2
Selling, general, and administrative expense	35.3	31.2	30.5
Total stock-based compensation expense	$ 40.7	$ 38.1	$ 36.3

As of December 31, 2023, there was $66.2 million of total unrecognized stock-based compensation expense that will be recognized over a weighted-average period of 1.9 years. The Company recognizes forfeitures as they occur.

The aggregate intrinsic value of options outstanding, aggregate intrinsic value of options that are fully vested and aggregate intrinsic value of RSUs vested and expected to vest is as follows:

(in millions)	As of December 31, 2023
Aggregate intrinsic value of options outstanding	$ 3.9
Aggregate intrinsic value of options fully vested	2.6
Aggregate intrinsic value of RSUs outstanding	84.1

The total intrinsic value of options exercised was as follows:

	Years Ended December 31,		
(in millions)	2023	2022	2021
Total intrinsic value of options exercised	$ —	$ —	$ 29.2

Employee Stock Purchase Plan

The Company also has an Employee Stock Purchase Plan that was initially approved by stockholders in 2012 and was amended and approved by the Board of Directors of the Company on September 23, 2021 and the stockholders on June 2, 2022 (the "Amended and Restated 2012 Purchase Plan"), under which 4.0 million shares of common stock were authorized. Shares are issued under the Amended and Restated 2012 Purchase Plan twice yearly at the end of each offering period and the number of shares that may be purchased by any participant during an offering period is limited to 5,000 shares. The first offering period of 2023 started on December 1, 2022 and ended on May 31, 2023. The second offering period of 2023 began on June 1, 2023 and ended on November 30, 2023. As of December 31, 2023, 1.3 million shares of common stock were available for issuance under the Amended and Restated Purchase Plan. Shares purchased under, and compensation expense associated with, the Amended and Restated 2012 Purchase Plan for the periods reported are as follows:

	Years Ended December 31,		
(in millions)	2023	2022	2021
Shares purchased under the plans	0.4	0.3	0.2
Plan compensation expense	$ 2.2	$ 1.9	$ 1.5

The fair value of shares issued under the Amended and Restated 2012 Purchase Plan that was in effect for each period reported was calculated using the Black-Scholes option-pricing model using the weighted-average assumptions below. Each of these inputs is subjective and its determination generally requires significant judgment.

	Years Ended December 31,		
	2023	2022	2021
Risk-free interest rate	5.1%	1.4%	0.1%
Expected dividend yield	—%	—%	—%
Expected life (in years)	0.5	0.5	0.5
Expected volatility	56%	53%	60%

11. INCOME TAXES

Income tax expense (benefit) consists of the following:

	Years Ended December 31,		
(in millions)	2023	2022	2021
Current:			
Federal	$ 3.4	$ (0.5)	$ (1.9)
State	1.8	1.9	3.6
Foreign	0.2	0.5	0.1
Total current	5.4	1.9	1.8
Deferred:			
Federal	(51.8)	(25.8)	(33.7)
State	(5.2)	(4.8)	5.1
Foreign	0.1	(2.9)	0.1
Change in valuation allowance	52.6	3.0	(3.2)
Total deferred	(4.3)	(30.5)	(31.7)
Total income tax expense (benefit)	$ 1.1	$ (28.6)	$ (29.9)

Loss before income taxes consists of the following:

	Years Ended December 31,		
(in millions)	2023	2022	2021
United States	$ (263.2)	$ (141.3)	$ (53.8)
Foreign	1.0	0.7	(3.3)
Total	$ (262.2)	$ (140.6)	$ (57.1)

The differences between income taxes at the statutory federal income tax rate and income taxes reported in the Consolidated Statements of Operations were as follows:

	Years Ended December 31,					
(in millions)	2023		2022		2021	
Federal income tax expense at the statutory rate	$ (54.9)	*21.0 %*	$ (29.5)	*21.0 %*	$ (12.0)	*21.0 %*
State income taxes, net of federal benefit	(4.1)	*1.6 %*	(3.3)	*2.3 %*	(1.8)	*3.2 %*
Research and development credits	(1.6)	*0.6 %*	(3.5)	*2.5 %*	2.5	*(4.4)%*
Uncertain tax positions	3.7	*(1.4)%*	0.6	*(0.4)%*	(3.0)	*5.3 %*
Incentive stock option and employee stock purchase plan expense	1.2	*(0.5)%*	2.5	*(1.8)%*	0.7	*(1.2)%*
Foreign rate differential	(0.4)	*0.2 %*	—	*— %*	0.5	*(0.9)%*
Change in valuation allowance	52.6	*(20.1)%*	2.6	*(1.8)%*	(3.2)	*5.6 %*
CARES Act	—	*— %*	—	*— %*	2.7	*(4.7)%*
Non-deductible meals and entertainment	—	*— %*	—	*— %*	0.1	*(0.2)%*
Non-deductible officer compensation	3.0	*(1.1)%*	3.5	*(2.5)%*	3.3	*(5.8)%*
Non-deductible legal settlement	—	*— %*	—	*— %*	2.5	*(4.5)%*
Acquisitions, dispositions, and contingent consideration	0.1	*— %*	(0.1)	*0.1 %*	(23.0)	*40.3 %*
Other, net	1.5	*(0.7)%*	(1.4)	*0.9 %*	0.8	*(1.4)%*
Total income tax expense (benefit)	$ 1.1	*-0.4 %*	$ (28.6)	*20.3 %*	$ (29.9)	*52.3 %*

The significant components of the Company's deferred tax assets and liabilities were comprised of the following:

	December 31,	
(in millions)	2023	2022
Deferred tax assets:		
Net operating loss carryforwards	$ 77.1	$ 66.6
Stock compensation expense	5.0	3.6
Research and development credits	20.8	19.9
Lease liability	28.0	35.2
Section 174 capitalized costs	38.4	21.2
Accrued expenses and liabilities	22.5	10.8
Other, net	3.2	3.6
Total gross deferred tax assets	195.0	160.9
Less valuation allowance	(95.0)	(42.4)
Total deferred tax assets	100.0	118.5
Deferred tax liabilities:		
Intangible assets	84.2	93.8
Lease right-of-use assets	15.5	25.4
Property, plant and equipment	1.9	2.8
Total deferred tax liabilities	101.6	122.0
Net deferred tax liability	$ (1.6)	$ (3.5)

The Tax Cuts and Jobs Act (TCJA), passed in 2017, amended Section 174 of the Internal Revenue Code to require that specific research and experimental (R&E) expenditures be capitalized and amortized over five years for U.S. R&E expenditures or 15 years for non-U.S. R&E expenditures beginning in the Company's fiscal year ended December 31, 2022. Although Congress has considered legislation that would defer, modify or repeal the capitalization and amortization requirement, there is no assurance that the provision will be deferred, repealed or otherwise modified. If the requirement is not modified, the Company may be required to utilize some of its federal and state tax attributes and there may be increases to state cash taxes or tax expense.

The Company has incurred a cumulative three-year loss. Pursuant to ASC 740, *Income Taxes* ("ASC 740"), the negative evidence of a cumulative loss may be difficult to overcome. Due to cumulative book losses and the lack of sufficient positive evidence, the Company has applied a valuation allowance to all applicable deferred tax assets, leaving a remaining deferred tax liability balance of $1.6 million.

At December 31, 2023, the Company had the following net operating loss and research credit carryforwards (tax effected), with their respective expiration periods. Certain carryforwards are subject to the limitations of Section 382 and 383 of the Internal Revenue Code as indicated (in millions):

Carryforwards	Amount	Subject to sections 382, 383	Expires beginning in year	Through
Federal net operating loss	$ 38.5	Yes	2033	Indefinite
Federal capital loss	13.8	No	2026	2028
Utah net operating loss	0.8	No	2024	Indefinite
California net operating loss	4.4	Yes	2029	2043
Other state net operating loss	8.6	Yes	Various	Various
Foreign net operating losses (various jurisdictions)	10.8	No	Various	Various
Federal research credit	10.5	Yes	2027	2043
Utah research credit	5.4	No	2024	2037
California research credit	4.8	No	Indefinite	Indefinite

Due to the cumulative losses that have been incurred to date in foreign operations, the changes of the Tax Cuts and Jobs Act and the election to treat its foreign subsidiaries as disregarded entities, no deferred taxes related to the Company's foreign operations have been recorded. For those foreign entities for which an election has been made to be treated as disregarded for U.S. tax purposes, the appropriate U.S. jurisdiction deferred tax assets and liabilities have been recorded.

The Company provides for uncertain tax positions when such tax positions do not meet the recognition thresholds or measurement criteria as set forth in ASC 740. As of December 31, 2023, the Company had net unrecognized tax benefits of $48.1 million. The Company's gross unrecognized tax benefits as of the years ended December 31, 2023, 2022, and 2021 and the changes in those balances are as follows:

	Years Ended December 31,		
(in millions)	2023	2022	2021
Unrecognized tax benefits at the beginning of period	$ 43.9	$ 32.1	$ 37.6
Gross increases - current year tax positions	0.8	12.9	1.4
Gross increases - prior year tax positions	3.6	1.6	1.1
Gross decreases - prior year tax positions	(0.2)	(2.0)	(2.8)
Gross decreases - settlements	—	(0.7)	(5.1)
Gross decreases - statute lapse	—	—	(0.1)
Unrecognized tax benefits at end of year	$ 48.1	$ 43.9	$ 32.1
Interest and penalties in year-end balance	$ 6.4	$ 4.1	$ 3.3

In 2022, the Company filed a U.S. federal tax return taking an uncertain tax position that was not recorded as a benefit or deferred tax asset in the financial statements but for which the $12.0 million unrecognized tax benefit has been included in the table above. Interest and penalties related to uncertain tax positions are included as a component of Income tax benefit and all other interest and penalties are included as a component of Other income (expense) in the Consolidated Statements of Operations. For the years ended December 31, 2023 and December 31, 2022, $30.2 million and $26.8 million of the unrecognized tax benefits, if recognized, would affect the effective tax rate, respectively.

The Company files U.S. federal, foreign and state income tax returns in jurisdictions with various statutes of limitations. The Company is currently under audit by Switzerland for the years ended June 30, 2017 through December 31, 2021 Annual tax provisions include amounts considered necessary to pay assessments that may result from examination of prior year tax returns; however, the amount ultimately paid upon resolution of issues may differ materially from the amount accrued.

12. COMMITMENTS AND CONTINGENCIES

The Company is involved from time to time in various disputes, claims and legal actions, including class actions and other litigation, including the matters described below, arising in the ordinary course of business. Such actions may include allegations of negligence, product or professional liability or other legal claims, and could involve claims for substantial compensatory and punitive damages or claims for indeterminate amounts of damages. The Company is also involved, from time to time, in investigations by governmental agencies regarding its business which may result in adverse judgments, settlements, fines, penalties, injunctions or other relief. In addition, certain federal and state statutes, including the qui tam provisions of the federal False Claims Act, allow private individuals to bring lawsuits against healthcare companies on behalf of the government or private payors. The Company has received subpoenas from time to time related to billing or other practices based on the False Claims Act or other federal and state statutes, regulations or other laws.

The Company intends to defend its current litigation matters but cannot provide any assurance as to the ultimate outcome or that an adverse resolution would not have a material adverse effect on its financial condition, results of operations or cash flows.

The Company assesses legal contingencies to determine the degree of probability and range of possible loss for potential accrual in its financial statements. When evaluating legal contingencies, the Company may be unable to provide a meaningful estimate due to a number of factors, including the proceedings may be in early stages, there may be uncertainty as to the outcome of pending appeals or motions, there may be significant factual issues to be resolved, and there may be complex or novel legal theories to be presented. In addition, damages may not be specified or the damage amounts claimed may be unsupported, exaggerated or unrelated to possible outcomes, and therefore, such amounts are not a reliable indicator of potential liability.

As of December 31, 2023, except as noted below, the Company has not recorded any material accrual for loss contingencies associated with legal proceedings or other matters or determined that an unfavorable outcome is probable and reasonably estimable in accordance with ASC 450, *Contingencies*. However, it is possible that the ultimate resolution of legal proceedings or other matters, if unfavorable, may be material to the Company's results of operations, financial condition or cash flows. Further, in the event that damages from an unfavorable resolution of one or more of these proceedings exceed the aggregate amount of the coverage limits of the Company’s insurance, or if the Company’s insurance carriers disclaim coverage, the amounts payable by the Company could also have a material adverse impact on the Company’s results of operations, financial condition or cash flows.

Securities Class Action

On September 27, 2019, a class action complaint was filed in the U.S. District Court for the District of Utah, against the Company, its former President and Chief Executive Officer, Mark C. Capone, and its Chief Financial Officer, R. Bryan Riggsbee (Defendants). On February 21, 2020, the plaintiff filed an amended class action complaint, which added the Company's former Executive Vice President of Clinical Development, Bryan M. Dechairo, as an additional Defendant. This action, captioned In re Myriad Genetics, Inc. Securities Litigation (No. 2:19-cv-00707-DBB), is premised upon allegations that the Defendants made false and misleading statements regarding the Company's business, operations, and acquisitions. The lead plaintiff sought the payment of damages allegedly sustained by it and the class by reason of the allegations set forth in the amended complaint, plus interest, and legal and other costs and fees. On March 16, 2021, the U.S. District Court for the District of Utah denied the Company's motion to dismiss. On December 1, 2021, the U.S. District Court for the District of Utah granted plaintiff's motion for class certification. On August 3, 2023, the Company entered into a stipulation and agreement of settlement to resolve this lawsuit (the "Settlement") and the parties filed a motion seeking court approval of the Settlement. The Settlement was approved by the court on December 15, 2023, and the case was subsequently dismissed. Pursuant to the terms of the Settlement, the Company paid an aggregate settlement amount of $77.5 million in cash. As part of the terms of the Settlement, the settlement class agreed to release the Company, the other defendants named in the lawsuit, and certain of their respective related parties from any and all claims, suits, causes of action, damages, demands, liabilities, or losses that are based upon, arise from, or relate to (a) the purchase, acquisition or trading of any common stock during the class period from August 9, 2017 until February 6, 2020; and (b) the allegations, transactions, facts, matters or occurrences, representations, or omissions involved, set forth, or referred to in the class action. The Settlement also contained no admission of liability, wrongdoing or responsibility by any of the parties.

Stockholder Derivative Actions

On August 9, 2021, a stockholder derivative complaint was filed in the Delaware Court of Chancery against the Company's former President and Chief Executive Officer, Mark C. Capone, its Chief Financial Officer, R. Bryan Riggsbee, its former Executive Vice President of Clinical Development, Bryan M. Dechairo, and certain of the Company's current and former directors, Lawrence C. Best, Walter Gilbert, John T. Henderson, Heiner Dreismann, Dennis Langer, Lee N. Newcomer, S. Louise Phanstiel, and Colleen F. Reitan (collectively, the Individual Defendants), and the Company, as nominal defendant. The complaint is premised upon similar allegations as set forth in the securities class action, including that the Individual Defendants made false and misleading statements regarding the Company's business and operations. The plaintiff, Donna Hickock, asserts breach of fiduciary duty and unjust enrichment claims against the Individual Defendants and seeks, on behalf of the Company, damages allegedly sustained by the Company as a result of the alleged breaches, or disgorgement or restitution, from each of the Individual Defendants, plus interest. Plaintiff Hickock also seeks legal and other costs and fees relating to this action. On November 19, 2021, this action was stayed by the Delaware Court of Chancery pending the resolution of the securities class action lawsuit.

On January 18, 2022, a stockholder derivative complaint was filed in the Delaware Court of Chancery against the Individual Defendants, and the Company, as nominal defendant. The action is premised upon similar allegations as set forth in the securities class action and the Hickock stockholder derivative action. The plaintiff, Esther Kogus, asserts that the Individual Defendants breached their fiduciary duties and also asserts unjust enrichment and aiding and abetting breaches of fiduciary duty claims against the Individual Defendants. Plaintiff Kogus seeks, on behalf of the Company, damages allegedly sustained by the Company as a result of the alleged breaches and claims, and restitution from the Individual Defendants. On behalf of herself, plaintiff Kogus seeks legal and other costs and fees relating to this action.

On March 3, 2022, the Delaware Court of Chancery consolidated the Hickock and Kogus derivative actions and stayed the consolidated action. This consolidated action currently remains stayed.

On September 17, 2021, a stockholder derivative complaint was filed in the U.S. District Court in the District of Delaware against the Individual Defendants, and the Company, as nominal defendant. The action is premised upon similar allegations as set forth in the securities class action and Hickock stockholder derivative action. The plaintiff, Karen Marcey, asserts that the Individual Defendants violated U.S. securities laws and breached their fiduciary duties, and also asserts unjust enrichment, waste of corporate assets and insider trading claims against all or some of the Individual Defendants. Plaintiff Marcey seeks, on behalf of the Company, damages allegedly sustained by the Company as a result of the alleged violations and restitution from the Individual Defendants, plus interest and, on behalf of herself, legal and other costs and fees relating to this action. On January 4, 2022, this action was stayed by the U.S. District Court for the District of Delaware pending the resolution of the securities class action lawsuit. This action currently remains stayed.

Other Legal Proceedings

On December 21, 2020, Ravgen, Inc. ("Ravgen") filed a lawsuit against the Company and its wholly owned subsidiary, Myriad Women's Health, Inc., in the U.S. District Court for the District of Delaware, alleging infringement of two Ravgen-owned patents. The lawsuit sought monetary damages, enhancement of those damages for willfulness, injunctive relief, and recovery of attorney's fees and costs. Various third parties have filed challenges to the validity of the asserted patents with the U.S. Patent and Trademark Office, which challenges have been instituted for review. On March 14, 2022, the case was stayed pending the outcome of the first of these validity challenges. On February 13, 2023, the court lifted the stay and litigation of the case resumed. On October 23, 2023 (the "Effective Date"), the Company and Ravgen entered into a settlement agreement pursuant to which the parties agreed to settle the lawsuit. As part of the settlement, the Company agreed to pay Ravgen a minimum of $12.75 million in three installment payments as follows: (1) the first installment of $5.0 million on or before October 31, 2023, (2) the second installment of $5.0 million on or before October 31, 2024, and (3) the third installment of $2.75 million on or before October 31, 2025. Subject to the terms of the settlement agreement, the Company also agreed to pay Ravgen an additional contingent payment of $21.25 million payable in five annual installments, with (1) the first installment of $5.0 million payable on the later of (a) 30 days after notification in writing by Ravgen of the successful conclusion in favor of Ravgen of all of Ravgen's litigations and patent reexaminations pending as of the Effective Date and (b) January 1, 2026 (the "Contingent Payment Date"); (2) the second installment of $5.0 million on the first anniversary of the Contingent Payment Date; (3) the third installment of $5.0 million on the second anniversary of the Contingent Payment Date; (4) the fourth installment of $5.0 million on the third anniversary of the Contingent Payment Date; and (5) $1.25 million on the fourth anniversary of the Contingent Payment Date. As of December 31, 2023, the Company has accrued $29.0 million for this action, of which $24.0 million is included in Other long-term liabilities and $5.0 million is included in Accrued liabilities in the Company's Consolidated Balance Sheets as of December 31, 2023.

On February 3, 2022, a purported class action lawsuit was filed against the Company in the U.S. District Court in the Northern District of California by Ashley Carroll. Plaintiff alleged, among other things, that the Company made false statements about the accuracy of its Prequel prenatal screening test. The complaint sought unspecified monetary damages, as well as punitive damages and injunctive relief. On April 1, 2022, the Company filed a motion to dismiss the lawsuit. On May 2, 2022, the plaintiff amended her complaint. On June 2, 2022, the Company filed a motion to dismiss the amended complaint. On July 26, 2022, the court granted and denied in part the Company's motion to dismiss the amended complaint. As part of the court's order, plaintiff was granted leave to file a second amended complaint. The plaintiff filed a second amended complaint on August 16, 2022. On September 6, 2022, the Company filed a motion to dismiss the second amended complaint. On November 9, 2022, the Court granted and denied in part the Company's motion to dismiss the second amended complaint. On October 6, 2023, the Company and the plaintiff agreed to settle the lawsuit for an immaterial amount. The settlement agreement contains no admission of liability, wrongdoing or responsibility on the part of the Company.

From time to time, the Company receives recoupment requests from third-party payors for alleged overpayments. The Company disagrees with the contentions of the pending requests or has recorded an estimated reserve for the alleged overpayments.

13. LEASES

The Company leases certain office spaces and research and development laboratory facilities, vehicles, and office equipment with remaining lease terms ranging from approximately one to fifteen years. These leases require monthly lease payments that may be subject to annual increases throughout the lease term. Certain of these leases also include renewal options, which allows the Company to, at its election, renew or extend the lease for a fixed period of time. These optional periods have not been considered in the determination of the ROU assets or lease liabilities associated with these leases as the Company did not consider it reasonably certain it would exercise the options.

Due to the increase in remote and hybrid work and the Company's need to ensure its facilities are designed to handle future growth, the Company has been executing on a multi-year strategy to reset its real estate footprint. As part of that strategy, in the first quarter of 2022, the Company entered into a non-cancelable operating lease for approximately 234,000 square feet in west Salt Lake City, Utah. The Company took possession of this leased facility in phases, beginning in the three months ended June 30, 2022. During the twelve months ended December 31, 2023, the Company took possession of the remaining phases of the west Salt Lake City facility and recognized $5.9 million of ROU asset and corresponding lease liability, net of tenant improvement allowance not yet received. The lease has a term of 15 years and total future rent payments under the lease are approximately $79.6 million. Also during the twelve months ended December 31, 2023, the Company assigned the lease for its previous corporate headquarters to a third party and transitioned its headquarters to the west Salt Lake City facility. As a result of the lease assignment, the operating lease ROU asset and operating lease liability associated with the previous headquarters of $33.3 million and $39.6 million, respectively, were removed from the Company's Consolidated Balance Sheets. In connection with the assignment of the lease, the Company recorded an accrual of $8.5 million for future payments under the lease assignment agreement, which is included in Accrued liabilities and Other long-term liabilities in the Company's Consolidated Balance Sheets as of December 31, 2023. The total net loss recognized associated with the assignment of the lease agreement was $7.7 million, which is included in Selling, general, and administrative expense in the Company's Consolidated Statements of Operations. In addition, the Company modified the remaining lease term of certain other Salt Lake City facilities reducing the associated ROU asset and lease liability by $6.4 million.

In connection with the Company's multi-year real-estate strategy, the Company also entered into a non-cancelable operating lease for approximately 63,000 square feet in South San Francisco, California with a term of 10 years, which commenced in the second half of fiscal year 2023. The Company took possession of the lease during fiscal year 2022 and recognized the related ROU asset and lease liability, net of tenant improvement allowance not yet received, of $30.7 million. Total future rent payments under the lease are approximately $56.7 million. The Company plans to transition all of the operations from the current South San Francisco facility, which has approximately 49,000 square feet of laboratory space utilized to perform testing for the Women's Health business, to the new South San Francisco facility.

During the twelve months ended December 31, 2022, the Company ceased the use of certain of its leased Salt Lake City facilities and one of its South San Francisco facilities. As a result, the Company recorded an impairment charge on ROU assets of $13.0 million and an impairment charge of $3.9 million on the related property, plant and equipment, which consisted primarily of leasehold improvements. The total $16.9 million impairment is included in Goodwill and long-lived asset impairment charges in the Consolidated Statement of Operations.

The Company performed evaluations of its contracts and determined the majority of its identified leases are operating leases. For the year ended December 31, 2023, the Company incurred $25.9 million in operating lease costs which are included in operating expenses in the Consolidated Statements of Operations in relation to these operating leases. Of such lease costs, $3.5 million was variable lease expense, which was not included in the measurement of the Company's operating ROU assets and lease liabilities. The variable rent expense is comprised primarily of the Company's proportionate share of operating expenses, property taxes, and insurance and is classified as lease expense due to the Company's election to not separate lease and non-lease components. For the year ended December 31, 2022, the Company incurred $22.1 million in lease costs which are included in operating expenses in the Consolidated Statements of Operations in relation to these operating leases. Of such lease costs, $3.2 million was variable lease expense, which was not included in the measurement of the Company's operating ROU assets and lease liabilities. The Company's finance leases are immaterial.

As of December 31, 2023, the maturities of the Company's operating lease liabilities were as follows (in millions):

Year Ended:		
2024	$	22.5
2025		17.9
2026		11.6
2027		11.7
2028		11.8
Thereafter		85.7
Total future lease payments		161.2
Less: amounts representing interest		(47.6)
Present value of future lease payments		113.6
Less: current maturities of operating lease liabilities		(16.2)
Noncurrent operating lease liabilities	$	97.4

As of December 31, 2023, the weighted average remaining lease term is 9.4 years and the weighted average discount rate used to determine the operating lease liability was 6.34%.

As the implicit rate in the Company's leases is generally unknown, the Company uses its incremental borrowing rate based on the information available at the lease commencement date in determining the present value of future lease payments. When calculating the Company's incremental borrowing rates, the Company gives consideration to its credit risk, term of the lease, total lease payments and adjusts for the impacts of collateral, as necessary. The lease term used may reflect any option to extend or terminate the lease when it is reasonably certain the Company will exercise such options. Lease expenses for the Company's operating leases are recognized on a straight-line basis over the lease term.

14. EMPLOYEE DEFERRED SAVINGS PLAN

The Company has a deferred savings plan which qualifies under Section 401(k) of the Internal Revenue Code. Substantially all of the Company's U.S. employees are covered by the plan. The Company makes matching contributions of 50% of each employee's contribution with the employer's contribution not to exceed 4% of the employee's compensation.

The Company's recorded contributions to the plan are as follows:

	Years Ended December 31,		
(in millions)	2023	2022	2021
Deferred savings plan contributions	$ 10.0	$ 9.0	$ 8.4

15. SEGMENT AND RELATED INFORMATION

The Company's business is aligned with how the chief operating decision maker ("CODM") reviews performance and makes decisions in managing the Company. Management prepares budgets at the operating segment level, and the CODM approves the budget, reviews the business, makes investing and resource allocation decisions and assesses operating performance at both the operating segment level and on an aggregate basis. As the Company's operating segments have similar economic and other characteristics, including the nature of the products and production processes, types of customers, distribution methods, and regulatory environment, they have been aggregated into a single reporting segment, which primarily provides testing that helps assess an individual's risk for developing disease or disease progression and guides treatment decisions across medical specialties where genetic insights can significantly improve patient health care and lower health care costs, and includes corporate services such as finance, human resources, legal and information technology.

The following table reconciles assets by geographical region to total assets:

(in millions)	December 31, 2023	December 31, 2022
Net equipment, leasehold improvements and property:		
United States	$ 117.7	$ 81.9
Rest of world	1.3	1.5
Total	$ 119.0	$ 83.4
Total assets:		
United States	$ 961.6	$ 983.4
Rest of world	44.0	45.6
Total	$ 1,005.6	$ 1,029.0
Cash, cash equivalents, and marketable investment securities	140.9	169.7
Total	$ 1,146.5	$ 1,198.7

16. BUSINESS ACQUISITION

On November 1, 2022, the Company acquired all of the membership interests of Gateway, a San Diego-based personal genomics company and developer of consumer genetic tests that give families insight into their future children.

The acquisition date fair value of the consideration transferred was $68.7 million. The following table summarizes the estimated fair value of identified assets acquired and liabilities assumed at the date of acquisition.

(in thousands)	Estimated fair value
Identifiable assets acquired	
Current assets	$ 1,053
Inventory	1,900
Intangible assets	
Developed technology	10,100
Trademarks	6,100
Customer relationships	1,600
Total intangible assets	17,800
Other non-current assets	161
Total identifiable assets acquired	20,914
Liabilities assumed	
Accounts payable	(246)
Accrued liabilities	(693)
Total liabilities assumed	(939)
Net identifiable assets acquired	19,975
Goodwill	48,723
Total fair value of Purchase Price	$ 68,698

Pro Forma Information (Unaudited)

The unaudited pro forma results presented below include the effects of Gateway acquisition as if it had been consummated as of January 1, 2021, with adjustments to give effect to pro forma events that are directly attributable to the acquisition, which includes adjustments related to the amortization of acquired intangible assets, interest income and expense, and depreciation.

The unaudited pro forma results do not reflect any operating efficiency or potential cost savings that may result from the consolidation of Gateway with the Company. Accordingly, these unaudited pro forma results are presented for informational purposes only and are not necessarily indicative of what the actual results of operation of the combined company would have been if the acquisition had occurred at the beginning of the period presented, nor are they indicative of future results of operations and are not necessarily indicative of results that might have been achieved had the acquisition been consummated as of January 1, 2021. The Company did not have any material, nonrecurring pro forma adjustments directly attributable to the business acquisition included in the reported pro forma earnings.

	Years Ended December 31,	
(in thousands)	2022	2021
Revenue	$ 695,632	$ 709,132
Net loss	(112,185)	(28,686)

Revenue and net loss from Gateway included in the Company's Consolidated Statements of Operations for the year ended December 31, 2023 is $21.1 million and $4.0 million, respectively.

Revenue and net loss from Gateway included in the Company's Consolidated Statements of Operations from the acquisition date through December 31, 2022 is $3.3 million and $2.8 million, respectively.

17. DIVESTITURES

On May 28, 2021, the Company completed the sale of the Myriad myPath, LLC laboratory to Castle Biosciences, Inc. for cash consideration of $32.5 million. The transaction was accounted for as a sale of assets and the Company recognized a gain of $31.2 million, net of transaction costs of $1.3 million, in Other income (expense) in the Consolidated Statements of Operations.

On July 1, 2021, the Company completed the sale of Myriad RBM, Inc., then a wholly owned subsidiary of the Company, to IQVIA RDS, Inc., for cash consideration of $197.0 million. The transaction was accounted for as a sale of a business and the Company recognized a gain of $121.0 million, net of transaction costs of $4.8 million, in Other income (expense) in the Consolidated Statements of Operations.

On September 13, 2021, the Company completed the sale of select operating assets and intellectual property, including the Vectra test, from the Myriad Autoimmune business unit to Laboratory Corporation of America Holdings for cash consideration of $150.0 million. The transaction was accounted for as a sale of a business and the Company recognized a loss of $0.6 million, net of transaction costs of $4.4 million, in Other income (expense) in the Consolidated Statements of Operations.

The operating results of these businesses do not qualify for reporting as discontinued operations.

Inventory

In connection with the divestiture transactions, the Company recognized losses of $5.2 million and $6.5 million for a non-cancelable inventory purchase commitment and inventory, respectively, during the year ended December 31, 2021, as the Company no longer had use for the goods. Both of these losses are included in Other income (expense) in the Consolidated Statements of Operations for the year ended December, 2021.

The following table details the amounts recognized in Other income (expense) for the year ended December 31, 2021:

(in millions)	Year Ended December 31, 2021
Gain on sale of Myriad RBM, Inc.	$ 121.0
Gain on sale of the Myriad myPath, LLC laboratory	31.2
Loss on inventory	(11.7)
Loss on sale of Myriad Autoimmune assets	(0.6)
Other	(0.6)
Total other income (expense)	$ 139.3

18. SUPPLEMENTAL CASH FLOW INFORMATION

The Company's supplemental cash flow information for the respective periods are as follows:

	Years Ended December 31,		
(in millions)	2023	2022	2021
Cash paid for income taxes	$ 1.9	$ 1.8	$ 4.6
Cash paid for interest	1.4	—	4.4
Cash received for income tax receivables	—	—	90.0
Non-cash investing and financing activities:			
Change in operating lease right-of-use assets and lease liabilities			
Operating lease right-of-use assets	$ (31.0)	$ 46.9	$ 41.8
Operating lease liabilities	36.7	(46.9)	(48.1)
Tenant improvement allowance not yet received	—	22.9	—
Purchases of property, plant and equipment and capitalization of internal-use software in accounts payable and accrued liabilities	6.9	10.0	—

19. SUBSEQUENT EVENTS

On February 1, 2024, the Company acquired from Intermountain Health select assets for an immaterial amount from its Intermountain Precision Genomics (IPG) laboratory business, including the Precise Tumor Test, the Precise Liquid Test, and IPG's CLIA-certified laboratory in St. George, Utah.

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

Item 9A. CONTROLS AND PROCEDURES

1. Disclosure Controls and Procedures

We maintain disclosure controls and procedures (Disclosure Controls) within the meaning of Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Our Disclosure Controls are designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act, such as this Annual Report on Form 10-K, is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms. Our Disclosure Controls are also designed to ensure that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating our Disclosure Controls, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management necessarily applied its judgment in evaluating and implementing possible controls and procedures.

As of the end of the period covered by this Annual Report on Form 10-K, we evaluated the effectiveness of the design and operation of our Disclosure Controls, which was done under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer. Based on the evaluation of our Disclosure Controls, our Chief Executive Officer and Chief Financial Officer have concluded that, as of December 31, 2023, our Disclosure Controls were effective to provide reasonable assurance that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time period specified in the Securities and Exchange Commission's rules and forms and is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

2. Management's Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our internal control over financial reporting is designed 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.

Our management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2023, using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in *Internal Control - Integrated Framework (2013).* We have evaluated the effectiveness of our internal control over financial reporting as of the end of the period covered by this Annual Report on Form 10-K, with the participation of our Chief Executive Officer and Chief Financial Officer, as well as other key members of our management. Based on this assessment, management concluded that, as of December 31, 2023, the Company's internal control over financial reporting was effective.

The effectiveness of our internal control over financial reporting as of December 31, 2023 has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their report included elsewhere herein.

3. Change in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the quarter or year ended December 31, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

4. Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of Myriad Genetics, Inc.

Opinion on Internal Control Over Financial Reporting

We have audited Myriad Genetics, Inc. and subsidiaries' internal control over financial reporting as of December 31, 2023, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Myriad Genetics, Inc. and subsidiaries (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2023, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2023 and 2022, and the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2023, and the related notes and our report dated February 28, 2024 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

Salt Lake City, UT
February 28, 2024

Item 9B. OTHER INFORMATION

(b)

Rule 10b5-1 Trading Plans

On November 22, 2023, Dan Spiegelman, a member of the Company's Board of Directors, adopted a trading plan intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act. The plan provides for the sale in multiple transactions of 50% of the shares to be acquired upon the vesting of Mr. Spiegelman's award of 15,151 restricted stock units granted on June 1, 2023. The plan expires on the earlier of (i) the date all of the shares under the plan have been sold and (ii) November 14, 2024.

Except as disclosed above, none of our directors or officers adopted or terminated any contract, instruction or written plan for the purchase or sale of our securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) or any "non-Rule 10b5-1 trading arrangement" as such term is defined in Item 408(a) of Regulation S-K.

Item 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The response to this item is incorporated by reference from the discussion responsive thereto under the captions “Management and Corporate Governance,” “Corporate Code of Conduct” and "Insider Trading Policies" in our Proxy Statement for the 2024 Annual Meeting of Stockholders expected to be held on June 6, 2024.

Item 11. EXECUTIVE COMPENSATION

The response to this item is incorporated by reference from the discussion responsive thereto under the captions “Compensation Discussion and Analysis,” "Pay Versus Performance," “Management and Corporate Governance – Committees of the Board of Directors and Meetings – Compensation and Human Capital Committee Interlocks and Insider Participation,” “Compensation and Human Capital Committee Report” and “Management and Corporate Governance – Board’s Role in the Oversight of Risk Management” in our Proxy Statement for the 2024 Annual Meeting of Stockholders expected to be held on June 6, 2024.

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

The response to this item is incorporated by reference from the discussion responsive thereto under the captions “Security Ownership of Certain Beneficial Owners and Management” and “Compensation Discussion and Analysis - Equity Compensation Plan Information” in our Proxy Statement for the 2024 Annual Meeting of Stockholders expected to be held on June 6, 2024.

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

The response to this item is incorporated by reference from the discussion responsive thereto under the caption “Certain Relationships and Related Person Transactions” and “Management and Corporate Governance – Director Independence” in our Proxy Statement for the 2024 Annual Meeting of Stockholders expected to be held on June 6, 2024.

Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The response to this item is incorporated by reference from the discussion responsive thereto in the proposal entitled “Selection of Independent Registered Public Accounting Firm” in our Proxy Statement for the 2024 Annual Meeting of the Stockholders expected to be held on June 6, 2024.

PART IV

Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) The following documents are included as part of this Annual Report on Form 10-K.

1. Financial Statements

See "Index to Consolidated Financial Statements" under Part II, Item 8 to this Annual Report on Form 10-K.

2. Financial Statement Schedules

Financial statement schedules have not been included because they are not applicable, or the information is included in financial statements or notes thereto.

3. Exhibits

Exhibit Number		Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/ Registration Number
3.1		Restated Certificate of Incorporation, as amended		10-Q (Exhibit 3.1)	8/4/2023	000-26642
3.2		Restated By-Laws		8-K (Exhibit 3.1)	10/15/2020	000-26642
4.1		Specimen Common Stock Certificate		10-K (Exhibit 4.1)	8/15/2011	000-26642
4.2		Description of Securities		10-KT (Exhibit 4.2)	3/16/2021	000-26642
Lease Agreements						
10.1	.1	Lease Agreement, dated October 12, 1995, between the Registrant and Boyer Research Park Associates V, by its general partner, the Boyer Company		10-Q (Exhibit 10.2)	11/8/1996	000-26642
	.2	Amendment to Phase I Lease Agreement, dated February 3, 2016, between the Registrant and HCPI/UTAH II, LLC.		10-Q (Exhibit 10.1)	5/4/2016	000-26642
	.3	Lease Termination Agreement, dated December 18, 2023, between the Registrant and HCPI/ Utah II, LLC	X			
10.2	.1	Lease Agreement-Research Park Building Phase II, dated March 6, 1998, between the Registrant and Research Park Associated VI, by its general partner, the Boyer Company, L.C.		10-K (Exhibit 10.44)	9/24/1998	000-26642
	.2	Amendment to Phase II Lease Agreement, dated February 3, 2016, between Myriad Genetics, Inc. and HCPI/UTAH II, LLC.		10-Q (Exhibit 10.2)	5/4/2016	000-26642
	.3	Lease Termination Agreement, dated December 18, 2023, between Myriad Genetics, Inc. and HCPI/Utah II, LLC.	X			
10.3	.1	Lease Agreement, dated March 31, 2001, between the Registrant and Boyer Research Park Associates VI, by its general partner, The Boyer Company, L.C.		10-Q (Exhibit 10.1)	5/15/2001	000-26642
	.2	Amendment to Phase III Lease Agreement, dated February 3, 2016, between Myriad Genetics, Inc. and HCPI/UTAH II, LLC.		10-Q (Exhibit 10.3)	5/4/2016	000-26642

Exhibit Number	Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/ Registration Number
.3	Lease Termination Agreement, dated December 18, 2023, between Myriad Genetics, Inc. and HCPI/Utah II, LLC	X			
10.4	Lease Agreement, dated February 9, 2022, between Myriad Genetics, Inc. and Bay Bridge/ Corporate, LLC.	X			
10.5	Lease, effective December 7, 2021, between Myriad Women's Health, Inc. and Bayside Area Development, LLC.	X			
Agreements with Executive Officers and Directors					
10.6	Non-Employee Director Compensation Policy (effective June 2023)+		10-Q (Exhibit 10.4)	8/4/2023	000-26642
10.7	Form of director and executive officer indemnification agreement+		10-K (Exhibit 10.34)	8/25/2009	000-26642
10.8	Form of Severance and Change in Control Agreement+		8-K (Exhibit 10.1)	10/15/2020	000-26642
10.9	Executive Employment Agreement between the Registrant and Paul J. Diaz dated July 24, 2020+		10-Q (Exhibit 10.1)	11/9/2020	000-26642
10.10	Performance-Based Restricted Stock Unit Agreement between Registrant and Paul J. Diaz dated October 8, 2020+		10-Q (Exhibit 10.2)	11/9/2020	000-26642
10.11	Restricted Stock Unit Agreement between the Registrant and Paul J. Diaz dated August 13, 2020+		10-Q (Exhibit 10.3)	11/9/2020	000-26642
10.12	Performance-Based Non-Qualified Stock Option Agreement between the Registrant and Paul J. Diaz dated August 13, 2020+		10-Q (Exhibit 10.4)	11/9/2020	000-26642
10.13	Non-Qualified Stock Option Agreement between the Registrant and Paul J. Diaz dated August 13, 2020+		10-Q (Exhibit 10.5)	11/9/2020	000-26642
10.14	Form of Separation and Release Agreement between the Registrant and Paul J. Diaz+		10-Q (Exhibit 10.6)	11/9/2020	000-26642
10.15	Executive Employment Agreement, dated October 17, 2023, between Myriad Genetics, Inc. and Samraat S. Raha+		10-Q (Exhibit 10.2)	11/7/2023	000-26642
10.16	Severance and Change of Control Agreement, dated December 11, 2023, by and between Myriad Genetics, Inc. and Samraat S. Raha+	X			
10.17	Executive Employment Agreement, dated December 15, 2023, between Myriad Genetics, Inc. and Scott Leffler+	X			
10.18	Separation and Consulting Agreement and Release of Claims, dated December 15, 2023, between Myriad Genetics, Inc. and R. Bryan Riggsbee+	X			

Exhibit Number	Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/ Registration Number
10.19	Separation and Consulting Agreement and Release of Claims, dated October 4, 2023, by and between Myriad Genetics, Inc. and Nicole Lambert+	X			
Equity Compensation Plans					
10.20	2017 Employee, Director and Consultant Equity Incentive Plan, as amended (June 1, 2023)+		8-K (Exhibit 10.1+)	6/2/2023	000-26642
10.21	Form of Restricted Stock Unit Agreement under the 2017 Equity Incentive Plan+		10-K (Exhibit 10.11)	8/13/2020	000-26642
10.22	Amended and Restated 2012 Employee Stock Purchase Plan +		8-K (Exhibit 10.1)	6/2/2022	000-26642
10.23	Form of Restricted Stock Unit Agreement under the 2017 Equity Incentive Plan (Employee)+		10-Q (Exhibit 10.1)	5/4/2023	000-26642
10.24	2013 Executive Incentive Plan, as amended+		8-K (Exhibit 10.2)	12/1/2017	000-26642
Credit Agreement					
10.25	Credit Agreement dated June 30, 2023, among Myriad Genetics, Inc., the other loan parties from time to time party thereto, the lenders from time to time party thereto, and JPMorgan Chase Bank, N.A., as the administrative agent and issuing bank.		8-K (Exhibit 10.1)	7/6/2023	000-26642
10.26	Pledge and Security Agreement dated June 30, 2023, among Myriad Genetics, Inc., each of the other Guarantors and JPMorgan Chase Bank, N.A., as administrative agent for the secured parties.		8-K (Exhibit 10.2)	7/6/2023	000-26642
10.27	First Amendment to Credit Agreement and Pledge and Security Agreement, dated as of October 31, 2023, among Myriad Genetics, Inc., the other loan parties party thereto, the lenders party thereto, and JPMorgan Chase Bank, N.A., as administrative agent.		8-K (Exhibit 10.1)	10/31/2023	000-26642
Other Exhibits					
21.1	List of Subsidiaries of the Registrant	X			
23.1	Consent of Independent Registered Public Accounting Firm (Ernst & Young LLP)	X			
24.1	Power of Attorney (included in the signature page hereto)	X			

Exhibit Number	Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/ Registration Number
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X			
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X			
32	Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X			
97.1	Clawback Policy	X			
101	The following materials from Myriad Genetics, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2022, formatted in XBRL (eXtensible Business Reporting Language): (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations (iii) Consolidated Statements of Comprehensive Loss, (iv) Consolidated Statements of Stockholders' Equity, (v) Consolidated Statements of Cash Flows, and (vi) Notes to Consolidated Financial Statements. Inline XBRL Instance Document – Instance Document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.	X			
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)	X			

(+) Management contract or compensatory plan arrangement.

Item 16. FORM 10-K SUMMARY

None.

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, on February 28, 2024.

MYRIAD GENETICS, INC.

By: /s/ Paul J. Diaz

Paul J. Diaz

President and Chief Executive Officer

Power of Attorney

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Paul J. Diaz and Scott J. Leffler and each of them, as his or her true and lawful attorneys-in-fact and agents, each with the full power of substitution, for him or her and in his or her name, place or 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 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 and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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

Signatures	Title	Date
By: /s/ Paul J. Diaz **Paul J. Diaz**	President, Chief Executive Officer and Director (Principal Executive Officer)	February 28, 2024
By: /s/ Scott J. Leffler **Scott J. Leffler**	Chief Financial Officer (Principal Financial Officer)	February 28, 2024
By: /s/ Natalie Munk **Natalie Munk**	Chief Accounting Officer (Principal Accounting Officer)	February 28, 2024
By: /s/ S. Louise Phanstiel **S. Louise Phanstiel**	Chair of the Board	February 28, 2024
By: /s/ Paul Bisaro **Paul Bisaro**	Director	February 28, 2024
By: /s/ Heiner Dreismann **Heiner Dreismann, Ph.D.**	Director	February 28, 2024
By: /s/ Rashmi Kumar **Rashmi Kumar**	Director	February 28, 2024
By: /s/ Lee N. Newcomer **Lee N. Newcomer, M.D.**	Director	February 28, 2024
By: /s/ Colleen F. Reitan **Colleen F. Reitan**	Director	February 28, 2024
By: /s/ Daniel M. Skovronsky **Daniel M. Skovronsky, M.D., Ph.D.**	Director	February 28, 2024
By: /s/ Daniel K. Spiegelman **Daniel K. Spiegelman**	Director	February 28, 2024

Corporate Information

Board of Directors

S. Louise Phanstiel, Chair
Former Senior Executive, Elevance Health, Inc. (formerly WellPoint, Inc.)

Paul M. Bisaro, Director
Former Executive Chairman, Amneal Pharmaceuticals, Inc. and President and Chief Executive Officer, Impax Laboratories, Inc.

Paul J. Diaz
President and CEO of Myriad Genetics, Inc.

Heiner Dreismann, Ph.D.
Former Senior Executive, the Roche Group

Rashmi Kumar
Senior Vice President, Chief Information Officer, Medtronic plc

Lee N. Newcomer, M.D.
Former Senior Vice President for Oncology and Genetics, Chief Medical Officer, UnitedHealth Group

Colleen F. Reitan
Former Executive Vice President and President of Plan Operations and Chief Operating Officer, Health Care Services Corporation

Daniel M. Skovronsky, M.D., Ph.D.
President, Lilly Research Laboratories, Chief Scientific Officer at Eli Lilly and Company

Daniel K. Spiegelman
Former Executive Vice President and Chief Financial Officer at BioMarin Pharmaceuticals, Inc.

Executive Officers

Paul J. Diaz
President and CEO

Margaret Ancona
Senior Vice President, Chief of Staff

Kevin R. Haas
Chief Technology Officer

Scott J. Leffler
Chief Financial Officer

Dale Muzzey
Chief Scientific Officer

Sam S. Raha
Chief Operating Officer

Shereen Solaiman
Chief People Officer

Mark Verratti
Chief Commercial Officer

Shareholder Information

Stockholders and Stock Listing
Our common stock is traded on Nasdaq Global Select Market under the symbol MYGN. On April 11, 2024, the closing price of our common stock was $20.50 per share and our common stock was held by 95 stockholders of record.

Investor Information
You may obtain a copy of any of the exhibits to our Annual Report on Form 10-K free of charge. These documents are available on our website at www.myriad.com or by contacting Investor Relations department at (801) 584-3532. Requests for information about Myriad Genetics, Inc. should be directed to our Investor Relations department.

Annual Meeting
Our 2024 Annual Meeting of Stockholders will be held on Thursday, June 6, 2025, at 8:00 a.m. MDT, via live webcast on the Internet at the following URL: www.virtualshareholdermeeting.com/MYGN2024

Internet Website
www.myriad.com

Independent Registered Public Accounting Firm
Ernst & Young LLP
Salt Lake City, Utah

Transfer Agent and Registrar
Equiniti Trust Company, LLC
55 Challenger Road 2nd floor
Ridgefield Park, New Jersey
076601
1 800 937-5449