

**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, 2021

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

(State or other jurisdiction
of incorporation or organization)

320 Wakara Way, Salt Lake City, UT
(Address of principal executive offices)

87-0494517
(I.R.S. Employer
Identification No.)

84108
(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	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

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.

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, 2021 was \$2,376,886,737.

As of February 18, 2022 the registrant had 80,022,885 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, 2021, for the Annual Meeting of Stockholders to be held on June 2, 2022.

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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 risks and uncertainties that could cause actual results to differ materially and adversely from those described in the forward-looking statements. These risks include, but are not limited to:

- uncertainties associated with COVID-19, including its possible effects on our operations and the demand for our products and services;
- risks related to our ability to efficiently and flexibly manage our business amid uncertainties associated with COVID-19;
- the risk that sales and profit margins of our existing molecular diagnostic tests may decline or that we may not be able to operate our business on a profitable basis;
- risks related to our ability to generate sufficient revenue from our existing product portfolio or in launching and commercializing new tests;
- 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 and services;
- the risk that we may be unable to develop or achieve commercial success for additional molecular diagnostic tests in a timely manner, or at all;
- the risk that we may not successfully develop new markets for our molecular diagnostic tests, including our ability to successfully generate revenue outside the United States;
- the risk that licenses to the technology underlying our molecular diagnostic tests and any future tests are terminated or cannot be maintained on satisfactory terms;
- risks related to delays or other problems with operating and constructing our 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;
- risks related to our projections 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 molecular diagnostic 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 and regulations in the United States and internationally;
- the risk that we may be unable to comply with financial operating covenants under our credit or lending agreements;
- risks related to the material weaknesses related to our quarterly income tax provision process and general information technology controls, including the impact thereof and our remediation plan, and our inability to achieve and maintain effective disclosure controls and procedures and internal control over financial reporting;
- risks related to current and future lawsuits, including product or professional liability claims; and
- other factors discussed under the heading "Risk Factors" contained in Item 1A of this Annual Report.

In light of these assumptions, risks and uncertainties, the results and events discussed in the forward-looking statements contained in this Annual Report 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. 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. All forward-looking statements in this Annual Report 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, Precise, FirstGene, 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, projections and other information concerning our industry, our business and relevant molecular diagnostics markets, including data regarding the estimated size of relevant molecular diagnostic 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 do 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 provide insights that help people take control of their health and enable healthcare providers to better detect, treat, and prevent disease. We discover and commercialize genetic tests that determine the risk of developing disease, assess the risk of disease progression, or guide treatment decisions across medical specialties where critical genetic insights can significantly improve patient care and lower health care costs.

Change in Fiscal Year

Effective January 1, 2021, we changed our fiscal year end from the last day of June to a calendar fiscal year. Our calendar fiscal year commenced on January 1, 2021 and ended on December 31, 2021. The six month period that commenced on July 1, 2020 and ended on December 31, 2020 was a transition period (the "transition period"). In this Annual Report, references to "fiscal year" refer to years ended June 30th or December 31st, as applicable. References in this report to the "transition period" refer to the six-month period ended December 31, 2020.

Business Updates

During the year ended December 31, 2021, we took meaningful steps to fulfill our mission and execute our strategic transformation and growth plan. Our announcements in 2021 included the following:

- Launched a new version of the MyRisk Hereditary Cancer Test with RiskScore, which allows, for the first time, women of all ancestries to receive a personalized polygenic breast cancer risk assessment.
- Entered into a collaboration with Illumina, Inc. ("Illumina") and Intermountain Precision Genomics for a comprehensive offering of germline and somatic tumor testing services. The strategic collaboration combines germline genetic testing, next-generation tumor sequencing and world-class testing capabilities to improve precision oncology care.
- Completed the sales of Myriad RBM, Inc., select operating assets and intellectual property, including the Vectra® test, from the Myriad Autoimmune business unit, and the Myriad myPath, LLC laboratory.
- Announced the hiring of several new Company leaders, including a new Chief Growth Officer, Diversity, Equity and Inclusion Leader, Chief Medical Officer, and Chief Legal Officer, as well as the new appointment of our Chief Marketing Officer, Chief Technology Officer, President of Myriad Oncology, President of Myriad Women's Health and Chief Operating Officer. In January 2022, we also announced the retirement of our Chief Scientific Officer.
- Peer-reviewed journal Psychiatry Research published a new analysis showing that the combinatorial approach available in the GeneSight® Psychotropic test is better than single-gene testing at predicting patient outcomes and medication blood levels.
- Presented new data at the American Society of Clinical Oncology Genitourinary Conference demonstrating that the Prolaris test can accurately predict which patients will benefit from multi-modality therapy. Using the newly established threshold, an estimated 27% of men with newly diagnosed high-risk disease and 73% with unfavorable intermediate-risk disease could avoid multi-modality therapy.
- Received the first reimbursement decision for MyChoice® Diagnostic System in Japan, enabling women with ovarian cancer to benefit from treatment with the PARP inhibitor Zejula® (niraparib). MyChoice is the only companion diagnostic test of its kind to be approved for reimbursement in Japan.

Our Business Strategy

Personalized genetic data, digital, and virtual consumer trends are converging to change traditional models of care. Significant growth opportunities exist to help patient populations with pressing health care needs through innovative solutions and services. We are currently executing a strategic transformation and growth plan that aims to capitalize on those trends by focusing on the following strategic priorities:

- Innovation that improves clinical outcomes, ease of use, and access;

- Enterprise capabilities to accelerate growth and scale to market opportunity; and
- Focus on execution and delivery of consistent results.

In connection with these strategic priorities, we are focusing our efforts in three key areas where we have specialized products, capabilities, and expertise: Oncology, Women's Health, and Mental Health. In each of these areas, we intend to develop and enhance best-in-class products to support growth, improve patient and provider experience, and reach more patients of all backgrounds. By investing in tech-enabled commercial tools, we believe we will be able to drive increased engagement, improve revenue cycle management, and reduce complexity and cost. We are committed to disciplined management of a key set of initiatives to fulfill our mission and drive long-term growth and profitability. With a foundation of financial, commercial, operational and technological strength, we expect to accelerate growth as we launch a new enterprise commercial model, launch a unified ordering portal, invest in new sequencing technologies, further develop direct-to-consumer channels, and build commercial capabilities to support new products and offerings.

Molecular Diagnostic Testing

Our molecular diagnostic 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, or assess a patient's risk of disease progression.

Oncology: Genetic testing for cancer patients and companion diagnostic tests that work with corresponding drugs and treatments.

Women's Health: Serves women of all ancestries, assesses risk of cancer, and offers prenatal testing solutions.

Mental Health: Genetic testing to help physicians understand how genetic alterations impact patient response to anti-depressants and other drugs.

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

<u>Oncology</u>	<u>Women's Health</u>	<u>Mental Health</u>
MyRisk Precise Tumor MyChoice CDx BRACAnalysis CDx EndoPredict Prolaris	MyRisk Prequel Foresight	GeneSight

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, colorectal, endometrial, melanoma, pancreatic, prostate, and gastric cancers. The test analyzes 35 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 35 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 and provides a personalized five-year and lifetime risk of developing breast cancer—regardless of ancestry.

BRCAAnalysis CDx® Germline Companion Diagnostic Test: *DNA sequencing test to help determine the most beneficial therapy for patients with metastatic breast, ovarian, metastatic pancreatic, or metastatic prostate cancer with deleterious or suspected deleterious germline BRCA variants.* Results of the 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. This 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: *the most comprehensive 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. 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 Conformité Européenne ("CE") marked, which signifies European certification for clinical use.

Precise™ Tumor: *a comprehensive solution for advanced precision oncology.* Precise™ Oncology Solutions, which we expect to launch in the first quarter of 2022, combines our leading germline hereditary cancer test (MyRisk/BRCAAnalysis CDx), our HRD companion diagnostic test (MyChoice CDx), and a comprehensive genetic tumor panel powered by Intermountain Precision Genomics, a service of Intermountain Healthcare. 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 screening 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 the only 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 test screens for carrier status of up to 175 serious and clinically actionable conditions in parents. The test has been shown to have a detection rate of 99% across all ethnicities. Studies have 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.

GeneSight® Psychotropic Mental Health Medication Test: *DNA genotyping test to aid psychotropic drug selection for patients suffering from depression, anxiety, 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 61 medications commonly prescribed for depression, anxiety, ADHD, and 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 with 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, patients were more likely to respond to treatment compared to standard of care.

Sales and Marketing

We sell our tests through our own direct sales force and marketing efforts in the United States, France, Germany and Japan, and service additional global accounts through indirect sales channels. Our United States sales force is comprised of approximately 500 individuals across our dedicated sales channels. Our inside sales team focuses on a broader base of leads, freeing up the field sales team to target high potential, high revenue clinical leads. 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. As we elevate our existing products to their full potential and further differentiate our products, we intend to increase awareness and access while we reinforce clinical utility data, and maximize cross-selling and synergies across the enterprise.

Research and Development

Our molecular diagnostic 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 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 numerous product opportunities. For the year ended December 31, 2021, the transition period ended December 31, 2020, and the years ended June 30, 2020 and 2019, we incurred research and development expense of \$81.9 million, \$35.8 million, \$77.2 million and \$85.9 million, respectively.

Industry and Competition

Patients, healthcare providers, payors and health systems are looking to apply the power of genetic insights, molecular diagnostics and precision medicine to achieve improved clinical outcomes and lower cost. 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;
- disruption in the way outpatient care is delivered in the midst of the COVID-19 pandemic, coupled with broadened awareness of the vital role of diagnostic testing;
- 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; 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.

These market trends create new opportunities to position Myriad for growth and commercial success through enhanced customer service levels and a stronger alignment of our value proposition with physicians and payors. Our focus is on innovative science that improves health outcomes, access for all, and ease of experience in the genetic 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 so that we can adapt quickly to customer preferences and market dynamics.

Oncology

In oncology, we offer genetic 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, Quest Diagnostics Incorporated, Laboratory Corporation of America Holdings, Exact Sciences Corporation, Foundation Medicine, Inc. and other commercial and academic laboratories.

We believe that the key opportunities to grow our business are our expansion of companion diagnostics, market expansion through new clinical guidelines, and providing new offerings. In the first quarter of 2022, we plan to launch Precise Tumor, part of a differentiated, comprehensive solution for advanced precision oncology, in partnership with Intermountain Precision Genomics and Illumina. In mid-2021, we launched our MyRisk Hereditary Cancer Test enhanced with RiskScore for all ancestries, creating the first and only hereditary cancer test that incorporates genetic markers for patients without a high-risk gene mutation. In early 2021, we partnered with Illumina to offer a MyChoice CDx kit as part of their Trusight oncology offering. This kit will be marketed to international markets and we expect it will increase global access to our MyChoice CDx solution. This partnership combines Illumina's expertise in next-generation sequencing with Myriad's proprietary MyChoice CDx assay technology to advance comprehensive genetic profiling of tumor samples and drive improved outcomes in oncology. These collaborations reflect our focus on partnering with high-caliber health care leaders to bring innovative solutions to the oncology market.

We currently offer our FDA-approved BRACAnalysis CDx test as a companion diagnostic for the prediction of response to PARP inhibitors. Currently, we are the only laboratory with an FDA-approved germline test for this indication and have received approvals from the FDA in ovarian cancer, metastatic breast cancer, pancreatic cancer, and advanced prostate cancer.

In May 2020, we received FDA approval for the MyChoice CDx® test for use as a companion diagnostic by healthcare professionals to identify advanced ovarian cancer patients with positive homologous recombination deficiency status, who are eligible or may become eligible, for treatment with Lynparza (olaparib) in combination with bevacizumab. We recently received additional approvals from U.S., European, and Japanese regulatory agencies for the use of MyChoice CDx® in predicting response to PARP-inhibitors in ovarian cancer. In addition, we plan to further expand MyChoice CDx® for use as a companion diagnostic indicator for additional cancer types, including pancreatic, prostate, and breast cancer.

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 compete with multiple companies including large national reference laboratories, specialty laboratories, academic/university laboratories, and kit-based products with our MyRisk, RiskScore, Foresight, and Prequel tests. Our competitors include Invitae Corporation, Natera, Inc., Ambry Genetics Corporation, Quest Diagnostics Incorporated, Laboratory Corporation of America Holdings, and Sema4 Holdings Corp. We compete mainly based on our test breadth and accuracy, commercial scale in the prenatal market, and the quality of our customer service and informatics tools.

We see opportunities to improve both our economics and the customer experience on these products. We remain focused on the reimbursement for carrier screening and finding streamlined patient payment models. As mentioned above, we recently launched our MyRisk Hereditary Cancer Test enhanced with RiskScore for all ancestries. This test provides a genetically informed breast cancer risk assessment as part of a comprehensive panel, with equity in care for all patients and expanded access to genetic insights for more ethnic groups. We are expanding new channels to interact with patients and for customers to have greater access to our products. We also plan to improve customer experience with a new online MyRisk portal to engage with patients and physicians, patient cost estimators across our product lines, and AI-based tools for interacting with patients.

The launch of our AMPLIFY™ technology in 2020 further increased the accuracy of the Prequel test, enabling more women to receive highly accurate test results regardless of BMI, race, or ethnicity, permitting them to make more informed choices about whether to pursue diagnostic testing. Moving forward we expect to further simplify and advance prenatal care with the launch of FirstGene™ for comprehensive prenatal screening. FirstGene combines the power of our Prequel NIPS with our Foresight Carrier Screen and provides insight into fetal recessive status. This new test, which is expected to launch in 2023, 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.

Mental Health

In mental health, we help physicians understand how genetic alterations impact patient response to antidepressants and other drugs. Our GeneSight 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. Our competitors in this market include Genomind, AltheaDx, Inc., and numerous other commercial and academic laboratories.

Key opportunities to grow our business in this market include primary care expansion, commercial payor reimbursement, and telehealth partnerships. 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 depression and anxiety patients, and through the expansion of sales and digital marketing capabilities. Moving forward we are exploring the extension of GeneSight in other potential areas including postpartum depression through our Women's Health channel. Separately, based on the market need, we are exploring new partnerships to develop tests for early detection and treatment of degenerative neurological conditions such as Alzheimer's disease and dementia.

Across the core specialties of our business – Women's Health, Oncology, and Mental Health – we have numerous opportunities to elevate our products. We have a respected portfolio and internationally recognized scientific know-how.

Seasonality

We have historically experienced seasonality in our testing business. The quarter ended December 31st is generally strong as we typically experience an increase in volumes from patients who have met their annual insurance deductible. Conversely, in the quarter ended March 31st we typically experience a decrease in volumes due to the annual reset of patient deductibles. Additionally, the volume of testing is negatively impacted by the summer season, which is generally reflected in the quarter ended September 30th. These seasonality patterns have generally continued during the COVID-19 pandemic, but due to the continued uncertainty surrounding the COVID-19 pandemic, we cannot predict if seasonality will follow the same pattern as in prior years.

Human Capital Management

Myriad's mission is to advance health and well-being for all, empower individuals with vital genetic insights and enable 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, competitive compensation and benefits programs.

As of December 31, 2021, we have approximately 2,400 full-time equivalent employees. Most of our employees are engaged directly in customer experience, research, technology, development, production, sales and marketing activities. Our employees are not covered by a collective bargaining agreement, and we consider our relations with our employees to be good.

Diversity, Equity and Inclusion (DE&I): Our DE&I objective is to make Myriad a place where all employees have a sense of belonging. To achieve this objective, we have adopted diversity, equity and inclusion goals into our human capital management strategy. Myriad has three employee-led resource groups (ERGs) that represent and support three diverse communities in our workforce: the Pride Alliance Group, the Black Employees at Myriad Group and the Women's Leadership Group. We plan to add more ERGs that serve other interest and cultural groups. 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, 2021, 61% of our employees are women and women hold 42% of leadership roles (vice president and above). One third of the members of our Board of Directors are women, including the chairperson.

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 enhanced 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, employee assistance programs, community outreach programs, training and development opportunities and wellness programs. We provide added work life balance to our employees through hybrid work arrangements. We also provide free mental health resources for employees and their dependents.

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 seek feedback from our employees on a variety of topics, including but not limited to, employee engagement, Company strengths and focus areas, and culture drivers. The results are reviewed by the 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.

Social Responsibility and Community: At Myriad, corporate responsibility plays an important role in our approach to discovering and delivering 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:

- *Philanthropy:* Myriad provides financial support to nonprofit organizations and shares the expertise of Myriad employees in the communities where we operate.
- *Advocacy:* Myriad collaborates with and supports 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.
- *Scholarship:* Myriad provides financial support for academic scholarship and education at both the undergraduate and post-graduate levels and contributes to advancing education and training for women and minorities in medicine and science.
- *Patient Assistance:* Myriad is 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.
- *Environmental:* As described further below, Myriad has created a Green Team to foster environmental and sustainability stewardship.

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 by adopting a Sustainability Strategy and Vision Statement 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, led by our President and Chief Executive Officer, and created a Green Team in an effort to reduce material waste, optimize energy and emissions usage, reduce water use, air pollution, and hazardous material use, perform community outreach, promote employee health and safety and manage other environmental projects.

We are committed to the health and safety of our employees and have formed a health and safety committee. During the COVID-19 pandemic, we have aligned with CDC guidelines to help protect our employees. In addition to requiring all employees to wear masks and adhere to social distancing guidelines, we have also made an effort to track and mitigate internal exposure to COVID-19 when we learn of employee exposure or infection. Additionally, we offer COVID-19 test kits to employees who may have come in contact with someone exposed to COVID-19 as an additional benefit to our employees and to limit disruption to our business operations. We have also postponed all non-essential and international business travel and encouraged all employees to get vaccinated against COVID-19, maintaining a voluntary count of employees that have been vaccinated.

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 patent assets relating to our tests that generate material revenue are described in the table below. 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
<i>Prolaris Prostate Cancer Prognostic Test</i>	We own or hold an exclusive license to one or more issued patents and pending patent applications in the U.S. and other jurisdictions relating to Prolaris® testing.	These issued U.S. 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.
<i>EndoPredict Breast Cancer Prognostic Test</i>	We own or hold an exclusive license to one or more issued patents and pending patent applications in the U.S., Europe and other jurisdictions relating to EndoPredict® testing.	These 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.
<i>MyChoice CDx Companion Diagnostic Test</i>	We own or hold an exclusive license to one or more issued patents and pending patent applications in the U.S. and other jurisdictions relating to MyChoice® CDx testing.	These 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.
<i>GeneSight Mental Health Medication Test</i>	We own or hold an exclusive license to one or more issued patents and pending patent applications in the U.S. and other jurisdictions relating to GeneSight® testing.	These issued patents have terms expected to begin expiring in 2024.	Claims relating to biomarkers, kits, systems and methods for detecting single nucleotide polymorphisms and selecting and/or optimizing therapy based on such detection.
<i>Foresight Carrier Screen</i>	We own or hold an exclusive 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 Foresight® testing.	These issued patents have terms expected to begin expiring in 2032.	Claims relating to systems and methods for detecting genetic sequences.
<i>Prequel Prenatal Screen</i>	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 issued patents have terms expected to begin expiring in 2032.	Claims relating to systems and methods for detecting genetic sequences.

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 diagnostic products. Should any other group obtain patent protection with respect to our discoveries, our commercialization of our molecular diagnostic tests could be limited or prohibited.

Others may offer clinical diagnostic 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 molecular diagnostic 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 molecular diagnostic 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. We have licenses with the following entities:

Entity	Subject	Royalties	Expiration
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.	We do not anticipate that this license will expire until 2024.
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 will pay UTMDACC a royalty based on net sales of our MyChoice® HRD test.	We do not anticipate that this license will expire until 2032.
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 expect to pay CMCC a royalty based on net sales of our MyChoice® HRD test.	We do not anticipate that this license will expire until 2032.
Institut Curie and INSERM (“INSERM”)	Exclusive world-wide right to certain rights of INSERM in intellectual property relating to our MyChoice® HRD testing.	We expect to pay INSERM a royalty based on net sales of our MyChoice® HRD test.	We do not anticipate that this license will expire until 2032.
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 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.

In addition, CLIA requires each of our certified laboratories to enroll in an approved proficiency testing program if performing testing in any category for which proficiency testing is required. Each of our 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 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 laboratories are accredited by the College of American Pathologists (“CAP”), which is a CMS-approved accreditation organization, they are typically subject to CAP 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 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 FDA has exercised enforcement discretion for LDTs, which means that 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. In 2020, the Verifying Accurate, Leading-edge IVCT Development (“VALID”) Act was introduced in both chambers of Congress, and it was reintroduced in revised form for the 117th Congress in July 2021. If enacted, clinical laboratories that develop and offer LDTs and traditional IVD medical device manufacturers would be subjected to the same regulatory oversight. The VALID Act defines both LDTs and IVDs as in vitro clinical tests (“IVCT”) and would establish a new regulatory framework separate and apart from the medical device framework under the Food, Drug and Cosmetic Act (“FDCA”) for the review and oversight of IVCTs. 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. 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. This system is aimed at reducing the amount of time that it takes for the agency to approve such tests, and it establishes 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 would be passed by Congress in its current form or signed into law by the President.

In Vitro Diagnostics

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 application ("PMA") 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.

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 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. In October 2021, the FDA issued a final rule to formally codify requirements for the procedures and criteria for product developers to follow when preparing a De Novo classification request; the new Do 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. The FDA issued a final rule in December 2018 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. 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 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 is submitted, the FDA has 45 days to make a threshold determination that the PMA is sufficiently complete to permit a substantive review. If the PMA is complete, the FDA will file the PMA. The FDA is subject to a performance goal review time for a PMA 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 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 issued a final guidance document in 2014 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 a 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 introduced in the 2014 guidance. 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 issued draft guidance in July 2016 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.

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 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 already 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 is a complex, costly and time consuming procedure. Approvals must be supported by valid scientific evidence, submitted as part of a PMA, 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 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.

Rest of World Regulation of In Vitro Diagnostics and Companion Diagnostic Devices

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

European Union

In the European Union ("EU"), in vitro diagnostic medical devices have been regulated under the European Union Directive 98/79/EC (the "Directive"), since 2003, and all products and kits used for in vitro diagnostic applications must be compliant with the Directive. IVDs have not been subject to pre-market authorization under the Directive, but instead they had to comply with essential requirements based on conformity with harmonized standards. The majority of IVDs have been self-certified by manufacturers which can place a CE mark on most products to show that they meet the conformity assessment. EU Member States must ensure that IVDs are only placed on the market if they conform to the requirements, and must ensure the free movement of such devices in the internal market. Member States will designate independent organizations, or Notified Bodies, that ensure that a conformity assessment is carried out for devices. These Notified Bodies may carry out inspections of certain manufacturers, and manufacturers must report any incident causing death to, or damaging the health of, a patient to the competent authorities.

In May 2022, the Directive will be replaced by the In Vitro Diagnostic Device Regulation (IVDR) European Union (EU) 2017/746 that was published in May 2017, and given a 5-year transition period until its implementation on May 27, 2022. Unlike the Directive that specifies certain results that must be achieved by each Member State and permits each Member State to decide how to transpose the Directive into national law, the IVDR has binding legal force throughout every Member State and it will become effective on a set date in all the Member States. 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, as enacted by the European Commission (EC), in vitro diagnostics will be subject to additional legal regulatory requirements after it comes into full effect. Among other things, the IVDR introduces a new risk classification system and requirements for conformity assessments. Products already certified by a Notified Body may remain on the market until May 25, 2024 under some conditions including fulfillment of specific requirements in the IVDR, but ultimately most products will have to be approved. Compliance with the IVDR may be expensive and time-consuming. Manufacturers will need to provide more data to demonstrate that a device performs safely and effectively. 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 Quality Management System (QMS) and Technical Documentation which will be reviewed. There will also be a greater emphasis on post-market surveillance and submission of post-market performance follow-up reports.

United Kingdom

The withdrawal of the United Kingdom (“UK”) from the EU has had significant ramifications for IVD manufacturers. Among other things, IVD manufacturers have to follow new procedures in the UK including appointment of UK Responsible Persons rather than relying on European Authorized Representatives to manage their compliance efforts in the UK.

The UK Medicine and Healthcare Products Regulatory Agency (“MHRA”) issued guidance on regulation of IVDs in the UK following January 1, 2021. After a transition period, IVDs will require certification in Great Britain, which is defined as England, Scotland and Wales, while companies will still be able to sell tests in Northern Ireland under existing EU IVD regulations.

As described in the guidance, MHRA will continue to recognize CE marks until June 30, 2023. Companies wishing to place IVDs on the UK market have been required to register with MHRA since January 1, 2021, but will still be able to sell CE-IVD marked products until June 30, 2023. Starting July 1, 2023, companies selling in the UK will have to obtain a new marking called a UK Conformity Assessed mark (“UKCA”) in order to place a diagnostic device into commerce in Great Britain. This mark will not be automatically 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.

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, with phased implementations of new and updated requirements planned through 2022. The first round of changes to Japan’s Pharmaceuticals and Medical Devices Act took effect September 1, 2020 and August 2021, with additional revisions coming into force in December 2022. Some of those changes will affect IVDs, including the ability to qualify for fast track designation.

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 and the adoption of written security policies and procedures.

On February 17, 2009, Congress enacted the Health Information Technology for Economic and Clinical Health Act (“HITECH”), which 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 (the “Secretary”). 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 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.

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 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 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 are applicable to our clinical laboratories. Many states have also implemented genetic testing and privacy laws imposing specific patient consent requirements and protecting test results by strictly limiting the disclosure of those results. 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. We believe that we have taken the steps required of us to comply with health information privacy and security statutes and regulations, including genetic testing and genetic information privacy laws in all jurisdictions, both state and federal. However, these laws often change, and we may not be able to maintain compliance in all jurisdictions where we do business. Failure to maintain compliance with state or federal laws regarding privacy or security could result in civil and/or criminal penalties and significant reputational damage and could have a material adverse effect on our business.

The General Data Protection Regulation (“GDPR”), which imposes requirements regarding the handling of personal data about EU residents, also applies to some of our operations. The GDPR is discussed in more detail under the heading “Risk Factors” contained in Item 1A of this report.

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 30th. 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 (“MCO”), 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 services 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 65% 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 HCPCS 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.

On December 20, 2019, the President signed the Further Consolidated Appropriations Act, which included the Laboratory Access for Beneficiaries Act (“LAB Act”). The LAB Act delayed until the first quarter of 2021 reporting of payment data under PAMA for CDLTs that are not ADLTs. The Coronavirus Aid, Relief, and Economic Security Act (“CARES Act”), which Congress passed in March 2020, again delayed the reporting by an additional year, this time until the first quarter of 2022. Then, on December 10, 2021, Congress passed the Protecting Medicare and American Farmers from Sequester Cuts Act, which included a provision that further delayed the next PAMA reporting period for CDLTs that are not ADLTs to January 1, 2023 through March 31, 2023. New CLFS rates for CDLTs will be established based on that data beginning in 2024, subject to phase-in limits.

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. Reductions for 2023 through 2025 are limited to 15%. (The CARES Act delayed for one year the 15% cut that was scheduled to take effect on January 1, 2021, and the Protecting Medicare and American Farmers from Sequester Cuts Act further delayed those cuts until 2023.)

The subsequent data reporting period for CDLTs that are not ADLTs will occur in three-year cycles, with the next cycle beginning in 2026. 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 out-of-network with 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-Payer 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 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 civil penalties of between \$5,500 and \$11,000 for each false claim, as well as possible exclusion from federal health care programs. However, the civil penalty amounts are adjusted annually for inflation. For civil penalties assessed after December 13, 2021, whose associated violations occurred after November 2, 2015, the civil penalty amount ranges between \$11,803 and \$23,607 per claim. 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. 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.

Available Information

We are a Delaware corporation with our principal executive offices located at 320 Wakara Way, Salt Lake City, Utah 84108. Our telephone number is (801) 584-3600 and our website address is www.myriad.com. We make available free of charge through the Investor Information 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 and Transition Reports 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

Risk Factors Summary

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

- Our financial condition and results of operations could be further adversely affected by the ongoing coronavirus pandemic.
- We may not be able to generate sufficient revenue from our existing tests or develop new tests to be profitable.
- We may not be able to maintain revenue growth or operate our business on a profitable basis, and our transformation plan may not achieve the anticipated results.
- If we do not continue to generate sufficient revenue from sales of our molecular diagnostic tests and are unable to secure additional funding, we may have to reduce our operations.
- An inability to attract and retain experienced and qualified personnel, including key management personnel, could adversely affect our business.
- 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 current operating plan changes and we find that our existing capital resources will not meet our needs, we may find it necessary to raise additional funding, which may not be available.
- We may 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.
- We are currently 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 damages and may divert management's time and attention from our business.
- 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, including security breaches, or if we fail to implement new systems and software successfully, our business operations and financial condition could be adversely affected.
- Our business involves environmental risks that may result in liability for us.
- Changes in health care policy could increase our costs, decrease our revenues and impact sales of and reimbursement for our tests.
- 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.

Risks Related to Commercialization of Our Tests, Our Services and Test Candidates

- Our molecular diagnostic and companion diagnostic tests in development may never achieve significant commercial market acceptance.
- 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.
- Our international business exposes us to business, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States.
- Foreign governments may impose reimbursement standards, which may adversely affect our future profitability.
- Domestic and international data protection laws and regulations may restrict our activities and increase our costs.
- Each of our molecular diagnostic 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 depend on a limited number of third parties for some of our supplies of equipment and reagents. If these supplies become unavailable or are disrupted, including as a result of COVID-19 and responses to it, then we may not be able to successfully perform our research or operate our business on a timely basis or at all.

- 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 molecular diagnostic and companion diagnostic tests could be adversely affected.

Risks Related to Our Intellectual Property

- If we are not able to protect our proprietary technology, others could compete against us more directly, which would harm our business.
- If we were sued for patent infringement by third parties, we might incur significant costs and delays in test introduction.
- We may be unable to adequately prevent disclosure of trade secrets, proprietary databases, and other proprietary information.
- 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 or consultants have wrongfully used or disclosed alleged trade secrets.

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 severe consequences that could materially and adversely affect our operating results and financial condition.
- If the government and 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.
- FDA regulation of our industry generally or our tests specifically could be disruptive to our business.
- 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 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.
- 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.
- 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.

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.
- We have identified two material weaknesses in our internal control over financial reporting related to our income tax provision process and our general information technology controls and such weaknesses led to a conclusion that our internal control over financial reporting and disclosure controls and procedures were not effective as of December 31, 2021. Our inability to remediate these material weaknesses, our discovery of any additional weaknesses, or our inability to achieve and maintain effective disclosure controls and procedures and internal control over financial reporting could adversely affect our results of operations, our stock price and investor confidence in us.
- 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.
- We do not intend to pay dividends on our common stock 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.
- Our restated bylaws provide that a state court located within the State of Delaware is the sole and 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

Our financial condition and results of operations could be further adversely affected by the ongoing coronavirus pandemic.

Any outbreaks of COVID-19 (including its variant strains, such as the highly transmissible Omicron and Delta variants) or any other outbreak of contagious disease or adverse public health development, could have a further material and adverse effect on our business operations, financial condition, or results of operations. For example, government public health officials have implemented, and may continue to implement restrictions to curb the spread of COVID-19, which has limited, and may continue to limit, patients' access to our services, and has caused, and may continue to cause, patients to elect to defer certain testing, each of which has impeded, and may continue to impede, our progress in returning to profitability and recovering from the earlier effects of the COVID-19 pandemic. Such adverse effects have included, and may continue to include, diversion or prioritization of health care resources away from the conduct of genetic testing, disruptions, or restrictions affecting the ability of laboratories to process our tests, and delays or difficulties in patients accessing our tests. Future surges in COVID-19 cases and related employee absences may strain our workforce and impact our ability to process tests in a timely way due to reduced staff availability. In addition, failure to comply with potential federal or state regulations requiring us to mandate COVID-19 vaccination for our employees could result in our losing access to government funding or facing monetary penalties.

As COVID-19 continues to affect individuals and businesses around the globe, we will likely experience further 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 diagnostic 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 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 continue to be, subject to disruption as a result of COVID-19 and ongoing responses to it. If the supplies and components necessary to manufacture our products become unavailable or are disrupted as a result of COVID-19 and ongoing responses to it, then we may not be able to successfully perform our research, sell our diagnostic tests, or operate our business on a timely basis or at all. Additionally, our results of operations could be adversely affected to the extent that the continued spread of COVID-19 or any other public health emergency harms our business or the economy in general either domestically or in any other region in which we do business.

The extent to which COVID-19 continues to affect our business, results of operations, financial condition and impede our recovery from the earlier effects of the COVID-19 pandemic will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration, spread and severity of COVID-19 outbreaks, the rate of vaccination and efficacy of approved vaccines against COVID-19 and its variant strains, actions taken to contain COVID-19 or treat its impact, new information that may emerge concerning the health effects of COVID-19, and how quickly and to what extent normal economic and operating conditions would resume if the pandemic subsided, any of which could have a further adverse effect on our business and financial condition. Even after the COVID-19 pandemic subsides, we may continue to experience an adverse impact to our business as a result of its global economic impact, including from increased inflation and the prospect that policy responses to inflation could delay economic recovery or lead to another recession.

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 molecular diagnostic tests to additional patients within the United States, to expand into new markets within and outside the United States, and to develop and commercialize new molecular diagnostic and companion diagnostic tests. However, we may not be able to generate sufficient revenue from our existing tests and launching and commercializing our new tests to be profitable. The demand for our existing molecular diagnostic 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 molecular diagnostic testing products by competitors. For example, because most of our molecular diagnostic tests are only utilized once per patient, we will need to sell our services through physicians to new patients or develop new molecular diagnostic 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 molecular diagnostic and companion diagnostic test candidates is 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 molecular diagnostic or companion diagnostic tests through the utilization of our technologies or technologies we license or acquire from others. Even if we develop tests or services for commercial use, we may not be able to develop tests or services 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 molecular diagnostic tests to physicians for use in new patients and in developing and commercializing any additional molecular diagnostic tests and companion diagnostic tests, we may not be able to generate sufficient revenue and we may not be profitable.

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

We may not be able to generate revenue growth or maintain existing revenue levels. Historically, our molecular diagnostic business has operated profitably providing a cash contribution to our funding and operational needs. We may not, however, be able to operate our molecular diagnostic business on a profitable basis in the future. Potential events or factors that may have a significant impact on our ability to sustain revenue growth and achieve or maintain profitability for our molecular diagnostic 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, or institute burdensome administrative requirements for reimbursement, such as prior authorization requirements;
- increased costs of reagents and other consumables required for molecular diagnostic 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 molecular diagnostic business, and sales personnel;
- our inability to obtain necessary equipment or reagents to perform molecular diagnostic testing;
- our inability to increase production capacity as demand increases;
- our inability to expand into new markets within or outside the United States;
- increased licensing or royalty costs, and our ability to maintain and enforce the intellectual property rights underlying our tests and services;
- changes in intellectual property law applicable to our patents or enforcement in the United States and foreign countries;
- potential obsolescence of our tests;
- our inability to increase commercial acceptance of our molecular diagnostic tests;
- increased competition and loss of market share;
- increased regulatory requirements; and
- material litigation costs and judgments.

We are currently executing upon a strategic transformation plan, which, among other things, is focused on developing and enhancing best-in-class products to support growth, improving the patient and provider experience, and reaching more patients of all backgrounds. In addition, as part of that transformation plan, we intend to accelerate growth through the launch of a new enterprise commercial model, the launch of a unified ordering portal, investment in new sequencing technologies, the development of direct-to-consumer channels, and building commercial capabilities to support new products and offerings. Our future performance and growth depends on the success of our transformation plan, including management's ability to execute upon that plan and the ability of our employees to respond quickly and effectively to transformational projects and rapid changes in our operations and business practices. The implementation of our transformation 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 transformation plan may take longer than anticipated, and once implemented, we may not realize, in full or part, the anticipated benefits, including growth in our testing volumes and revenue, or such benefits may be realized more slowly than anticipated. The failure to realize benefits, which may be due to our inability to execute plans, delays in the implementation of the transformation plan, global or local economic conditions, competition, changes in the molecular diagnostics industry, the ongoing COVID-19 pandemic, and the other risk factors described herein, 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 we do not continue to generate sufficient revenue from sales of our molecular diagnostic tests and are unable to secure additional funding, we may have to reduce our operations.

While we anticipate that our existing cash, cash equivalents and marketable securities, cash flow from operations, and in certain circumstances, amounts available for borrowing under our Amended Facility (as defined below) will be sufficient to fund our current operations for the foreseeable future, 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 December 23, 2016, we entered into a senior secured revolving credit facility as borrower, with the lenders from time to time party thereto, which was amended on July 31, 2018, May 1, 2020 and February 22, 2021 (the "Amended Facility"). On July 30, 2021, using cash generated from our recent divestitures, we repaid all outstanding borrowings under our Amended Facility.

The Amended Facility restricts our ability to make future borrowings if unrestricted cash, cash equivalents and marketable securities exceed \$150.0 million, unless such borrowings are used in connection with certain permitted acquisitions. Unrestricted cash, cash equivalents and marketable securities totaled \$398.8 million as of December 31, 2021. Our revolving commitment amount is \$250.0 million as of December 31, 2021. As our total unrestricted cash, cash equivalents, and marketable securities exceeded \$150.0 million as of December 31, 2021, we will be unable to make future borrowings unless related to a permitted acquisition. In addition, following the expiration of the waiver of the leverage ratio and interest coverage ratio covenants, which waiver is effective until March 31, 2022, our ability to borrow under the Amended Facility will be limited if we are unable to comply with those financial covenants.

We may not be able to secure additional financing in a timely manner or on favorable terms, if at all. In addition, we are subject to financial covenants as part of our Amended Facility that could limit our ability to incur additional indebtedness. Without additional funds, 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 diagnostic 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 molecular diagnostic tests that we may discover or acquire;
- the progress, results, and costs to develop additional molecular diagnostic 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.

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, particularly in the San Francisco Bay Area, where we have office and laboratory facilities. 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 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, particularly California, or federal laws or such provisions may be prohibitively expensive to enforce. Competition and compensation for highly qualified and experienced personnel increased as employment vacancies surged over the past year, which has increased the difficulty and cost of hiring and retaining qualified personnel. Our transformation 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. Potential federal or state regulations may require us to mandate COVID-19 vaccinations for our employees, or any future decision on our part to voluntarily require our employees to receive a COVID-19 vaccine, could also impact our ability to hire and retain employees. In addition, inflation has had, and we expect that it will continue to have, 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 molecular diagnostic business and it may have a material adverse effect on our business as a whole.

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 Amended Facility impose operating and financial restrictions on us. These restrictions may prohibit or place limitations on, among other things, our ability to incur additional indebtedness, create certain types of liens, and complete mergers, consolidations, or change in control transactions. Under the Amended Facility, a change in control of the Company, which means that a stockholder or a group of stockholders is or becomes the beneficial owner, directly or indirectly, of more than 35% of the total voting power of the voting stock of the Company, would require mandatory prepayment of any outstanding debt. The Amended Facility may also prohibit or place limitations on our ability to sell assets, pay dividends or provide other distributions to stockholders. These restrictions could also limit our ability to take advantage of business opportunities.

We must maintain specified leverage and interest ratios measured as of the end of each applicable quarter as financial covenants in the Amended Facility. The Amended Facility, through Amendment No. 2 entered into on May 1, 2020 and Amendment No. 3 entered into on February 22, 2021, modified compliance with the leverage covenant and the interest coverage ratio covenant, which were waived through March 31, 2022, and added a minimum liquidity covenant. If we are unable to improve our results of operations, it is possible that we could be in violation of certain financial covenants contained in the Amended Facility in the future. If we are unable to comply with the covenants and ratio in the Amended Facility, we may be in default under the agreement. A default would result in an increase in the rate of interest and limits on our ability to incur certain additional indebtedness and it could potentially cause any loan repayment to be accelerated, any of which could have a material adverse impact on our operations and liquidity.

If our current operating plan changes and we find that our existing capital resources will not meet our needs, we may find it necessary to raise additional funding, which may not be available.

We anticipate that our existing capital resources and expected net cash to be generated from sales of our molecular diagnostic tests will enable us to maintain our currently planned operations for the foreseeable future. However, we base this expectation on our current operating plan, which may change. We have incurred, and will continue to incur, significant costs in the discovery, development and marketing of current and prospective molecular diagnostic and companion diagnostic tests. 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 require substantial cash resources. If, due to changes in our current operating plan, 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, expanding or supplementing our Amended Facility, or selling convertible or non-convertible debt securities. This additional funding, if necessary, may not be available to us on reasonable terms, or at all. If we issue shares of stock or other securities to acquire new companies or technologies, the ownership interests of our existing stockholders may be significantly diluted.

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, or WKSI, and can at any time file a registration statement registering securities to be sold to the public which would become effective upon filing. If additional funds are raised by issuing equity 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 may 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. However, these acquisitions may not achieve profitability or 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. Our acquisition efforts may involve certain risks, including:

- we may have difficulty integrating operations and systems;
- 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 new molecular diagnostic tests or companion diagnostic 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;
- 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 materially 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. The prices that we receive we are able to command for such assets may not be high and, in some cases, may be lower than the amount we invested in or paid for such assets.

We are currently 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 damages and may divert management's time and attention from our business.

We are currently 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, each of which could result in substantial damages and may divert management's time and attention from our business. We also may be subject to future securities class action and stockholder derivative claims, which may adversely impact our business, results of operations, financial condition or cash flows and divert management's time and attention from our business.

In addition, the marketing, sale and use of our genetic 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 for errors and omissions, we cannot assure you that such insurance would fully protect us from the financial impact of defending against these types of claims or any judgments, fines or settlement costs arising out of any such claims. Any liability claim, including an errors and omissions liability 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, we could face substantial liabilities that exceed our insurance coverage and our other resources. Additionally, any liability 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 an adverse effect on our reputation and results of operations.

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, 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 may 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, 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 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 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, including security breaches, or if we fail to implement new systems and software successfully, our business operations and financial condition could be adversely affected.

Information technology 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 information technology and communication systems. Our information technology 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 information technology and communication systems also may experience interruptions, delays or cessations of service or produce errors in connection with system integration, upgrades or system migration work that takes place from time to time. If we were to experience a prolonged system disruption in the information technology 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 information technology 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.

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

In connection with our 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 from 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.

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 cannot currently 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, although 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 allowing the federal government to directly negotiate drug prices, or 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.

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 dramatically 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 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 United States dollar, such as the Euro, the Swiss franc, the Japanese yen, and the British pound. As a result, we are at risk for exchange rate fluctuations between such foreign currencies and the United States 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. 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.

Risks Related to Commercialization of Our Tests, Our Services and Test Candidates

Our molecular diagnostic and companion diagnostic tests in development may never achieve significant commercial market acceptance.

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

- our ability to convince the medical community of the clinical utility of our tests and their potential advantages over existing tests;
- 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
- the willingness of physicians to utilize our tests, which can be difficult to interpret. This difficulty is caused by the ability of our tests to predict only 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.

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 may 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 molecular diagnostic 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 molecular diagnostic and companion diagnostic tests that we may develop or commercialize. Those companies that bring to market new molecular diagnostic and companion tests before we do may achieve a significant competitive advantage in marketing and commercializing their tests. We may not be able to develop additional molecular diagnostic 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 molecular diagnostic and companion diagnostic 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.

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. Although we recently narrowed our international operations, we have active sales operations in Germany, France, and Japan and production operations in Germany. 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 and 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 and ongoing 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.

Foreign governments may impose reimbursement standards, which may adversely affect our future profitability.

We market our tests in foreign jurisdictions and as such may be subject to rules and regulations in those jurisdictions relating to our testing. In some foreign countries, the reimbursement of diagnostic tests is subject to governmental control. In these countries, reimbursement negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a test candidate. If reimbursement of our future tests is unavailable or limited in scope or amount, or if reimbursement rates are set at unsatisfactory levels, we may be unable to achieve or sustain profitability.

Domestic and international data protection laws and regulations may restrict our activities and increase our costs.

Domestic and international data protection laws and regulations may affect our collection, use, storage, and transfer of information obtained within and outside of the United States. State privacy and data security laws in the United States are becoming more stringent. For example, California adopted the California Consumer Privacy Act of 2018 (“CCPA”), which was effective in January 2020. The CCPA establishes a new privacy framework for covered businesses by creating an expanded definition of personal information, establishing new data privacy rights for consumers in the State of California, imposing special rules on the collection of consumer data from minors, 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. In addition to the CCPA, other states are introducing similar legislation which will impact compliance obligations and increase complexity and cost of compliance.

The European Union (“EU”) has adopted the GDPR, which applies to all EU member states. The GDPR requires us to meet new and more stringent requirements regarding the handling of personal data about European Union residents. Failure to meet GDPR requirements could result in penalties of up to \$20 million Euros or 4% of our worldwide revenue, whichever is higher.

The GDPR 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 ensure compliance with the new EU data protection rules. The GDPR is a complex law with still evolving regulatory guidance, including with respect to how the GDPR should be applied in the context of clinical studies or other transactions from which we may gain access to personal data. Furthermore, many of the countries within the European Union are still in the process of drafting supplementary data protection legislation in key fields where the GDPR allows for national variation, including the fields of clinical study and other health-related information. These variations in European data protection laws may raise our costs of compliance and result in greater legal risks. Failure to comply with data protection laws and regulations could result in government enforcement actions, which may involve civil and criminal penalties, private litigation and/or adverse publicity and could negatively affect our operating results and business. Claims that we have violated individuals’ privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

Each of our molecular diagnostic 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 molecular diagnostic tests; a CLIA-certified laboratory in South San Francisco, California to perform our Foresight and Prequel tests; a single laboratory facility in Cologne, Germany to perform and produce our EndoPredict test kits; and a CLIA-certified laboratory in Mason, Ohio to perform our GeneSight test. Our laboratory in South San Francisco is near major earthquake faults known for seismic activity and in a region affected by wildfires. These facilities and certain pieces of laboratory equipment would be difficult to replace and may require significant lead time to replace and qualify for use if they became inoperable. We currently have no backup or redundant facility to perform each of our molecular diagnostic tests. In the event any of our clinical 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 molecular diagnostic business at current levels to meet customer demands for a significant period of time. 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 molecular diagnostic business would result in a loss of goodwill, including damage to our reputation. If our molecular diagnostic business were interrupted, it would seriously harm our business.

We depend on a limited number of third parties for some of our supplies of equipment and reagents. If these supplies become unavailable or are disrupted, including as a result of COVID-19 and responses to it, 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 to provide our gene sequencing equipment, content enrichment equipment, multiplex protein analysis equipment, robots, and specialty reagents and laboratory supplies required in connection with our testing and research. We believe that currently there are limited alternative suppliers of the equipment, robots, and reagents. The equipment, robots, or reagents may not remain available in commercial quantities at acceptable costs. If we are unable to obtain when needed additional or alternative equipment or robots, or an adequate supply of reagents or other ingredients at commercially reasonable rates, our ability to continue to identify genes and perform molecular diagnostic testing would be adversely affected.

In addition, the continued spread of COVID-19 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 may continue to be subject to disruption as a result of COVID-19 and ongoing responses to it. We have experienced and may continue to 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 COVID-19 and ongoing responses to it. Political, administrative, legislative, legal or regulatory actions in response to COVID-19, including the possible use of the Defense Production Act in the United States to compel manufacturers to prioritize other products or customers over us, 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 as a result of COVID-19 and ongoing responses to it, then we may not be able to successfully perform our research or operate our business on a timely basis or at all.

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 molecular diagnostic and companion diagnostic 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 molecular diagnostic and companion diagnostic 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 are not able to protect our proprietary technology, others could compete against us more directly, which would harm our business.

As of December 31, 2021, 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 molecular diagnostic 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 United States 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 upon unpatented proprietary technologies and databases. Although we require employees, consultants and collaborators to sign confidentiality agreements, we may not be able to adequately protect our rights in such unpatented proprietary technologies and databases, which could have a material adverse effect on our business. For example, others may independently develop substantially equivalent proprietary information or techniques or otherwise gain access to our proprietary technologies or disclose our technologies to our competitors.

If we were sued for patent infringement by third parties, we might incur significant costs and delays in test introduction.

Our tests may also 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 molecular diagnostic and companion diagnostic 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 may be significant litigation in the industry regarding patent and other intellectual property rights. If we become involved in this litigation, it could consume a substantial portion of our managerial and financial resources.

We may be unable to adequately prevent disclosure of trade secrets, proprietary databases, and other proprietary information.

We 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 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 molecular diagnostic 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 or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms.

We may be subject to claims that we or our employees or consultants 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.

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 severe 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:

- CLIA, which requires that laboratories obtain certification from the federal government, and state licensure laws;
- FDA laws and regulations that apply to medical devices such as our in vitro diagnostics;
- 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), which, absent an exception, prohibits a physician from making a 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 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;

- other federal and state fraud and abuse laws, such as anti-kickback laws, prohibitions on self-referral, 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 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 (“PAMA”), which requires the Centers for Medicare & Medicaid Services 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.

As a clinical laboratory, our business practices may face heightened scrutiny from government enforcement agencies such as the Department of Justice, the 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 clinical laboratories and referring physicians as implicating the Anti-Kickback Statute. The OIG has stated that it is particularly concerned about these types of arrangements because the choice of laboratory, as well as the decision to order laboratory tests, typically are made or strongly influenced by the physician, with little or no input from the patient. 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 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 expansion 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.

If the government and 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 molecular diagnostic tests or any future diagnostic 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, 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 diagnostic tests they will pay for and the amounts that they will pay for existing and new molecular diagnostic tests. We have experienced price reductions from CMS for some of our products, including for our GeneSight® psychotropic test subsequent to the July 2020 release of the final pharmacogenomics LCD, and we may experience future price reductions from CMS, managed care organizations, and other third-party payors. The fact that a diagnostic test has been approved for reimbursement in the past, for any particular indication or in any particular jurisdiction, does not guarantee that such a diagnostic test will remain approved for reimbursement, that the reimbursement amount approved for such test will not be reduced in the future, or that similar or additional diagnostic tests will be approved in the future. 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 molecular diagnostic 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 diagnostic 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 diagnostic tests generally and any given test individually. On December 10, 2021, Congress passed the Protecting Medicare and American Farmers from Sequester Cuts Act, which included a provision that delays the next PAMA reporting period for clinical laboratory tests that are not advanced diagnostic tests to January 1, 2023 through March 31, 2023. In addition, the next round of rate cuts will not be implemented until 2023, with tests receiving cuts of up to 15 percent a year from 2023 through 2025. 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.

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.

FDA regulation of our industry generally or our tests specifically could be disruptive to our business.

As described further below, 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. 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 of these 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.” 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 recent developments, we have not implemented our earlier proposal. 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 test offering will have an adverse effect on our revenues from the test.

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.

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. 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 United States 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. 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. The Company was not aware of the complaint until after it was unsealed. On April 16, 2020, CBI filed a motion to dismiss the action with prejudice. On May 23, 2020, the court denied that motion. We have accrued \$48.0 million for a potential settlement of this qui tam lawsuit against CBI and the Company, which is included in Accrued liabilities in the Company’s Consolidated Balance Sheet. If no settlement is reached, we intend to continue to vigorously defend against this action, but we cannot predict with any degree of certainty the ultimate resolution of this matter or determine whether, or to what extent, any loss with respect to this matter may exceed the amount that we have accrued. 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.

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 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). In recent years, however, 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 the framework was abandoned and replaced by an informal discussion paper reflecting some of the feedback that FDA had received on LDT regulation. The FDA acknowledged that the January 2017 discussion paper does not represent the formal position of the FDA and is not enforceable. Nevertheless, the FDA wanted to share its synthesis of the feedback that it had received in the hope that it might advance public discussion on future LDT oversight. Notwithstanding the discussion paper, the FDA continues to exercise enforcement discretion and 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 to potential enforcement priority changes from the FDA, in December 2018, bipartisan members of Congress released a discussion draft of a legislation to regulate in vitro clinical tests including LDTs under a shared FDA/CMS framework, and provided opportunities for stakeholders to comment on the proposed legislation. In 2020, the Verifying Accurate, Leading-edge IVCT Development ("VALID") Act was formally introduced in both chambers of Congress, and it was reintroduced in revised form for the 117th Congress in July 2021. If enacted, 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. The framework would give the FDA the authority to ensure IVCTs are both analytically and clinically valid. 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.

It is unclear whether the VALID Act will be passed by Congress in its current form or signed into law by the President. Until the FDA finalizes its regulatory position regarding LDTs, 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 it could have an adverse material impact on our results of operations.

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 achieved 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.

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 molecular diagnostic 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, 2021, our stock price has ranged from \$19.92 per share to \$36.66 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:

- 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;
- failure to sustain revenue growth or margins in our molecular diagnostic business;
- changes in the structure of healthcare payment systems and changes in governmental or private insurer reimbursement levels for our molecular diagnostic tests;
- introduction of new commercial tests or technological innovations by competitors;
- termination of the licenses underlying our molecular diagnostic 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 or validity 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;
- changes in estimates or recommendations by securities analysts relating to our common stock or the securities of our competitors;
- 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;
- public concern over our approved tests and any test candidates;
- litigation;
- government and regulatory investigations;
- 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;
- seasonal slowness in sales, particularly in the quarters ending September 30th and March 31st, the effects of which may be difficult to understand during periods of growth;

- general perception of the molecular diagnostic 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. In addition, securities class action litigation such as the current stockholder suit pending against the Company discussed elsewhere in this section and certain related matters may affect the market price and demand for our common stock. If any of our other stockholders brought another lawsuit against us, we could incur substantial costs defending the lawsuit regardless of the outcome. Such a lawsuit could also divert the time and attention of our management.

We have identified two material weaknesses in our internal control over financial reporting related to our income tax provision process and our general information technology controls and such weaknesses led to a conclusion that our internal control over financial reporting and disclosure controls and procedures were not effective as of December 31, 2021. Our inability to remediate these material weaknesses, our discovery of any additional weaknesses, or our inability to achieve and maintain effective disclosure controls and procedures and internal control over financial reporting could adversely affect our results of operations, our stock price and investor confidence in us.

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. In addition, we regularly engage our independent registered public accounting firm to report on its evaluation of those controls. As disclosed in more detail under Item 9A, “Controls and Procedures” below, during the preparation of our condensed consolidated quarterly financial statements as of September 30, 2021, management concluded that a material weakness in internal control over financial reporting existed related to our income tax provision process. Specifically, we did not provide adequate review and control with respect to the completeness and accuracy of inputs used in the gain/loss calculation related to a divestiture within the interim consolidated income tax provision and related accrual. While we have taken steps to remediate the material weakness, including steps to design and implement enhanced controls over the review of information underlying discrete transactions in the income tax provision, and we plan to continue taking additional steps to remediate the material weakness, this material weakness has not been remediated as of December 31, 2021. Management also concluded that a material weakness in internal control over financial reporting exists related to general information technology controls for information systems that are relevant to the preparation of the financial statements. Specifically, the material weakness resulted from the aggregation of control deficiencies related to systems supporting our internal control processes. Due to the material weaknesses in our internal control over financial reporting, we have also concluded that our disclosure controls and procedures were not effective as of December 31, 2021.

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. In addition, failure to maintain effective internal control over financial reporting could result in investigations or sanctions by regulatory authorities.

Our management has taken steps to remediate the material weakness related to our income tax provision process and our management will take steps to remediate the material weaknesses, including continuing to take steps to design and implement enhanced controls over the review of information underlying discrete transactions in the income tax provision, implementing improved IT policies, procedures and control activities for key systems which impact our financial reporting, and increasing resources dedicated to monitoring general information technology controls related to financial reporting to ensure compliance with policies and procedures. We intend to remediate these material weaknesses as soon as possible, but we cannot be certain as to when remediation will be completed. Additional details regarding the remediation efforts are disclosed under Item 9A, “Controls and Procedures” below. In addition, we may in the future identify additional 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. In addition, 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 remediate the material weaknesses and maintain effective disclosure controls and procedures or internal control over financial reporting, 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 SEC rules and regulations. Any of these could result in delisting actions by the Nasdaq Stock Market, investigation and sanctions by regulatory authorities, stockholder investigations and lawsuits, and could adversely affect 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; and
- the inability of our stockholders to call a special meeting or act by written consent.

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.

We do not intend to pay dividends on our common stock 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 Amended 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 commence coverage of us, the trading of our stock would likely decrease. Even if we do obtain 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.

Our restated bylaws provide that a state court located within the State of Delaware is the sole and 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 certificate of incorporation or our restated bylaws, or any action asserting a claim against us governed by the internal affairs doctrine. This exclusive forum provision 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 the exclusive forum provision contained in our restated bylaws 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 2. PROPERTIES

Our corporate headquarters and facilities are located in Salt Lake City, Utah. We currently lease a total of approximately 343,000 square feet of building space in Salt Lake City dedicated to research and development, administration and our laboratory that has received federal certification under CLIA. Activities related to our oncology, urology, and women's health molecular diagnostic business are performed at this location. The leases on our existing Salt Lake City facilities have terms of five to fifteen years, expiring from 2025 through 2036, and provide for renewal options for up to ten additional years.

We also lease approximately 93,000 square feet in South San Francisco, California under two leases that expire in April 2025 and September 2025. This space is dedicated to administration, research and development and the CLIA-certified laboratory for our Women's Health business.

We also lease a space in Mason, Ohio, with approximately 24,000 total square feet, which will expire in August 2024.

In addition, in late 2021, we entered into a non-cancelable operating lease for approximately 63,000 square feet in South San Francisco, California, which will commence in 2023 and expire in 2033. In the first quarter of 2022, we entered into a non-cancelable operating lease for approximately 230,000 square feet in Salt Lake City, Utah, which will commence in 2022 and expire in 2038.

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 believe our current facilities and those planned will provide adequate capacity for the foreseeable future. We continue to make investments in capital equipment as needed to meet the anticipated demand for our molecular diagnostic tests.

Item 3. LEGAL PROCEEDINGS

Qui Tam Lawsuit

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. The Office of Inspector General subsequently requested additional documentation in December 2017. CBI provided to the Office of Inspector General the documents requested. On January 30, 2020, the United States District Court for the Northern District of California unsealed a qui tam complaint, filed on April 16, 2016 against CBI and the Company, alleging violations of the Federal and California False Claims Acts and the California Insurance Fraud Prevention Act. 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. The Company was not aware of the complaint until after it was unsealed. On May 23, 2020, the court denied CBI and the Company’s motion to dismiss. We have accrued \$48.0 million for a potential settlement of this qui tam lawsuit against CBI and the Company, which is included in Accrued liabilities in the Company’s Consolidated Balance Sheet. If no settlement is reached, we intend to continue to vigorously defend against this case, but we cannot predict with any degree of certainty the ultimate resolution of this matter or determine whether, or to what extent, any loss with respect to this matter may exceed the amount that we have accrued.

Securities Class Action

On September 27, 2019, a class action complaint was filed in the United States District Court for the District of Utah, against the Company, our former President and Chief Executive Officer, Mark C. Capone, and our Chief Financial Officer, R. Bryan Riggsbee (“Defendants”). On February 21, 2020, the plaintiff filed an amended class action complaint, which added our 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 our business, operations, and acquisitions. The lead plaintiff seeks the payment of damages allegedly sustained by it and the purported 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 United States District Court for the District of Utah denied the Company’s motion to dismiss. On December 1, 2021, the United States District Court for the District of Utah granted plaintiff’s motion for class certification. We intend to vigorously defend against this action. Due to the nature of this matter and inherent uncertainties, it is not possible to provide an evaluation of the likelihood of an unfavorable outcome or an estimate of the amount or range of potential loss, if any.

Stockholder Derivative Actions

On August 9, 2021, a stockholder derivative complaint was filed in the Delaware Court of Chancery against our former President and Chief Executive Officer, Mark C. Capone, our Chief Financial Officer, R. Bryan Riggsbee, our former Executive Vice President of Clinical Development, Bryan M. Dechairo, and certain of our 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 our 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. We intend to vigorously defend against this action. Due to the nature of this matter and inherent uncertainties, it is not possible to provide an evaluation of the likelihood of an unfavorable outcome or an estimate of the amount or range of potential loss, if any.

On September 17, 2021, a second stockholder derivative complaint was filed in the United States 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 United States District Court for the District of Delaware pending the resolution of the securities class action lawsuit. We intend to vigorously defend against this action. Due to the nature of this matter and inherent uncertainties, it is not possible to provide an evaluation of the likelihood of an unfavorable outcome or an estimate of the amount or range of potential loss, if any.

On January 18, 2022, a third 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 and Marcey stockholder derivative actions. 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. We intend to vigorously defend against this action. Due to the nature of this matter and inherent uncertainties, it is not possible to provide an evaluation of the likelihood of an unfavorable outcome or an estimate of the amount or range of potential loss, if any.

Other Legal Proceedings

On July 27, 2020, a lawsuit was filed against the Company in the Superior Court of Suffolk County, Massachusetts, by Heide Abelli and Victor Pricolo (the "Abelli lawsuit"). The plaintiffs claimed negligence, breach of contract and associated torts in connection with an alleged error in testing performed by the Company in 2004. The plaintiffs sought damages allegedly sustained by them by reason of the allegations set forth in their complaint, together with interest and costs. As of December 31, 2021, we accrued \$14.0 million for a potential settlement of this lawsuit, which is included in Accrued liabilities in the Company's Consolidated Balance Sheet as of December 31, 2021. On January 24, 2022, the Company entered into an agreement with the plaintiffs to settle the lawsuit. Pursuant to the terms of the settlement agreement, the Company agreed to pay \$14.0 million to the plaintiffs. The settlement agreement also provides for a full release by the plaintiffs of all claims against the Company and contains no admission of liability, wrongdoing or responsibility on the part of the Company.

On February 3, 2022, a purported class action lawsuit was filed against the Company in the United States District Court in the Northern District of California by Ashley Carroll. Plaintiff alleges, among other things, that the Company made false statements about the accuracy of its Prequel prenatal screening test. The complaint seeks unspecified monetary damages and injunctive relief. We intend to vigorously defend against this action. Due to the nature of this matter and inherent uncertainties, it is not possible to provide an evaluation of the likelihood of an unfavorable outcome or an estimate of the amount or range of potential loss, if any.

Other than as set forth above, we are not a party to any legal proceedings that we believe will have a material impact on our business, financial position or results of operations.

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 18, 2022, there were approximately 99 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.

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. 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.

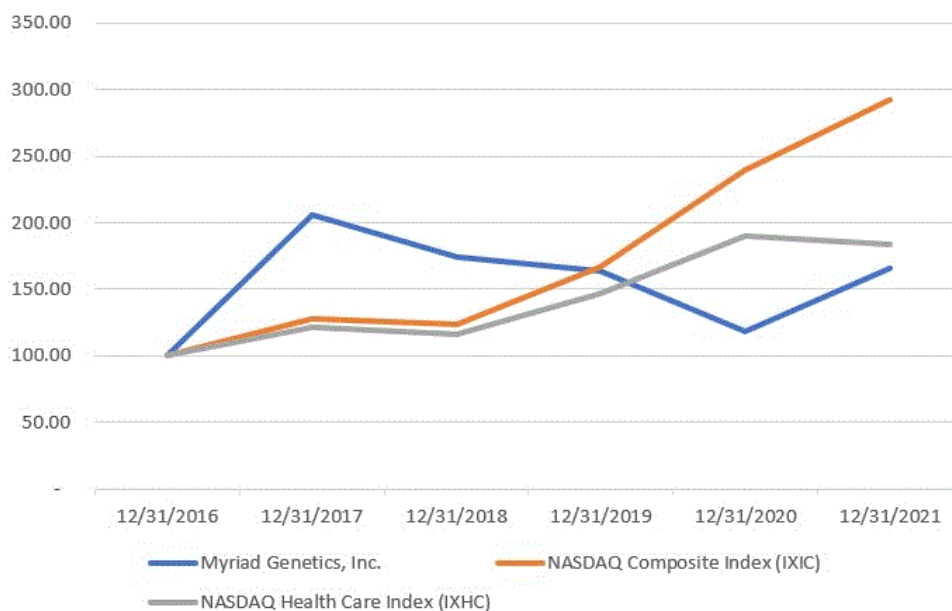
Issuer Purchases of Equity Securities

Our Board of Directors has previously authorized us to repurchase up to \$200.0 million of our outstanding common stock, of which \$110.7 million is still available to repurchase as of December 31, 2021. We are authorized to complete the repurchase through open market transactions or through an accelerated share repurchase program, in each case to be executed at management's discretion based on business and market conditions, stock price, trading restrictions, acquisition activity and other factors. The repurchase program may be suspended or discontinued at any time without prior notice.

No stock repurchases were made under our stock repurchase program during the year ended December 31, 2021.

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, 2016 and ending on December 31, 2021 (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, 2016 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.



	12/31/2016	12/31/2017	12/31/2018	12/31/2019	12/31/2020	12/31/2021
Myriad Genetics, Inc.	100.00	206.06	174.39	163.35	118.60	165.81
NASDAQ Composite Index (IXIC)	100.00	128.24	123.26	166.68	239.42	292.42
NASDAQ Health Care Index (IXHC)	100.00	121.30	116.25	146.27	190.21	183.47

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 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

The following discussion and analysis should be read in conjunction with the audited Consolidated Financial Statements and accompanying notes thereto included elsewhere in this Report. Unless otherwise noted, all of the financial information in this Report is consolidated financial information for the Company.

Overview

We discover and commercialize genetic tests that determine the risk of developing disease, assess the risk of disease progression, or guide treatment decisions across medical specialties where critical genetic insights can significantly improve patient care and lower health care costs. Our mission is to advance health and well-being for all, empower individuals with vital genetic insights and enable healthcare providers to better detect, treat and prevent disease.

We are currently executing upon a strategic transformation plan that is focused on the following strategic priorities: (1) innovation that improves clinical outcomes, ease of use, and access; (2) enterprise capabilities to accelerate growth and scale to market opportunity; and (3) focus on execution and delivery of consistent results. In connection with these strategic priorities, we are focusing our efforts on our Oncology, Women's Health, and Mental Health products. We intend to develop and enhance best-in-class products to support growth, improve patient and provider experience, and reach more patients of all backgrounds. By investing in tech-enabled commercial tools, we believe we will be able to drive increased engagement, improve revenue cycle management, and reduce complexity and cost. We are committed to disciplined management of our initiatives to fulfill our mission and drive long-term growth and profitability. With a foundation of financial, commercial, operational and technological strength, we expect to accelerate growth as we launch a new enterprise commercial model, launch a unified ordering portal, invest in new sequencing technologies, further develop direct-to-consumer channels, and build commercial capabilities to support new products and offerings.

Our consolidated revenues consist primarily of sales of molecular diagnostic tests through our wholly-owned subsidiaries. During the year ended December 31, 2021, we reported total revenues of \$690.6 million, net loss attributable to Myriad Genetics, Inc. stockholders of \$27.2 million and basic and diluted loss per share of \$0.35.

Industry and Competition

Patients, healthcare providers, payors and health systems are looking to apply the power of genetic insights, molecular diagnostics and precision medicine to achieve improved clinical outcomes and lower cost. 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;
- disruption in the way outpatient care is delivered in the midst of the COVID-19 pandemic, coupled with broadened awareness of the vital role of diagnostic testing;
- 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; 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.

These market trends create new opportunities to position us, and our products, for growth and commercial success through enhanced customer service levels and a stronger alignment of our value proposition with physicians and payors. Our focus is on innovative science that improves health outcomes, access for all, and ease of experience in the genetic 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 so that we can adapt quickly to customer preferences and market dynamics.

Seasonality

We have historically experienced seasonality in our testing business. The quarter ended December 31st is generally strong as we typically experience an increase in volumes from patients who have met their annual insurance deductible. Conversely, in the quarter ended March 31st we typically experience a decrease in volumes due to the annual reset of patient deductibles. Additionally, the volume of testing is negatively impacted by the summer season, which is generally reflected in the quarter ended September 30th. These seasonality patterns have generally continued during the COVID-19 pandemic, but due to the continued uncertainty surrounding the COVID-19 pandemic, we cannot predict if seasonality will follow the same pattern as in prior years.

Components of Consolidated Operations

Revenue

Molecular Diagnostic Testing. Our molecular diagnostic tests are designed to analyze genes and their expression levels to assess an individual's risk for developing disease later in life, determine a patient's likelihood of responding to a particular drug, or assess a patient's risk of disease progression. Provided with this valuable information, physicians may more effectively manage their patients' health care. Revenue is recognized when the communication of test results has occurred.

Pharmaceutical and Clinical Service. On July 1, 2021, we divested Myriad RBM, Inc., which provided pharmaceutical and clinical services. As a result, we ceased providing pharmaceutical and clinical services as of that date. We also divested of other clinical operations in February 2020. Through Myriad RBM, Inc., we provided biomarker discovery, pharmaceutical and clinical services to the pharmaceutical, biotechnology, and medical research industries utilizing our multiplexed immunoassay technology. 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 includes salaries, bonuses, employee benefit costs, employer payroll taxes, and stock-based compensation.

Cost of Molecular Diagnostic Testing. Cost of molecular diagnostic testing consists primarily of costs related to lab supplies, personnel-related costs, and overhead costs.

Cost of Pharmaceutical and Clinical Service. Cost of pharmaceutical and clinical service consists primarily of costs related to lab supplies and personnel-related costs.

Research and Development Expense. Research and development expenses consists primarily of personnel-related costs and lab supplies, which includes costs incurred in formulating, improving, validating and creating alternative or modified processes related to and expanding the use of our current molecular diagnostic test offerings and costs incurred for the discovery, development and validation of our pipeline of molecular diagnostic and companion diagnostic 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 salaries, commissions, related personnel costs, and third-party costs for sales, marketing, customer service, billing and collection, legal, finance and accounting, information technology, and human resources.

Goodwill and long-lived asset impairment charges. Goodwill and long-lived asset impairment charges includes the impairment loss recognized on the Company's goodwill or long-lived assets, including impairments recognized on intangible assets and right-of-use lease assets.

Other Income (Expense). Other income (expense) includes interest income earned on our cash and cash equivalents holdings 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

This section of Management's Discussion and Analysis generally discusses year-to-year comparisons between the year ended December 31, 2021 and the comparative year ended December 31, 2020. Due to our change in fiscal year from June 30th to December 31st, effective January 1, 2021, the comparative year ended December 31, 2020 was unaudited. Discussions of comparisons between (1) the transition period for the six months ended December 31, 2020 and the comparative period of the six months ended December 31, 2019 and (2) the years ended June 30, 2020 and June 30, 2019 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 Transition Report on Form 10-K for the transition period ended December 31, 2020, filed with the SEC on March 16, 2021.

Years Ended December 31, 2021 and 2020

Revenue

(In millions)	Years Ended December 31,			% of Total Revenue	
	2021	2020 (unaudited)	Change	2021	2020
Molecular diagnostic revenue:					
Hereditary Cancer	\$ 316.3	\$ 284.4	\$ 31.9	46 %	51 %
Tumor Profiling	120.9	58.4	62.5	18 %	10 %
Prenatal	106.8	74.5	32.3	15 %	13 %
Pharmacogenomics	93.7	58.7	35.0	14 %	11 %
Autoimmune	28.2	35.7	(7.5)	4 %	6 %
Other	0.5	1.8	(1.3)	— %	— %
Total molecular diagnostic revenue	666.4	513.5	152.9		
Pharmaceutical and clinical service revenue	24.2	43.6	(19.4)	4 %	8 %
Total revenue	\$ 690.6	\$ 557.1	\$ 133.5	100 %	100 %

Molecular diagnostic revenues for the year ended December 31, 2021 increased \$152.9 million compared to the same period in the prior year. Revenue for the year ended December 31, 2020 was negatively impacted by the pandemic as patients faced significant obstacles accessing healthcare professionals. Tumor Profiling revenues increased \$62.5 million compared to the same period in the prior year due to a \$31.9 million increase in revenue for Prolaris due to expanded coverage and the submission of claims for previously performed tests that were pending clarification of the coverage policy, as well as a \$25.3 million increase in revenues from MyChoice CDx due to expansion in Japan and other areas. Revenue from Pharmacogenomics increased \$35.0 million compared to the same period in the prior year due primarily to a 58% increase in volume. Prenatal revenues increased \$32.3 million compared to the same period in the prior year due primarily to an increase of 19% in the average reimbursement per test and an increase of 12% in volume, as well as a change in estimate related to revenues from prior periods. Hereditary Cancer revenues increased \$31.9 million compared to the same period in the prior year due primarily to a 13% increase in volume as well as a change in estimate related to revenues from prior periods. These increases were partially offset by a \$7.5 million decrease in Autoimmune compared to the same period in the prior year due primarily to the completion of the sale of select operating assets and intellectual property, including the Vectra test, from the Myriad Autoimmune business unit, on September 13, 2021.

Pharmaceutical and clinical service revenue for the year ended December 31, 2021 declined \$19.4 million compared to the year ended December 31, 2020, primarily due to the sale of Myriad RBM, Inc. on July 1, 2021 and the inclusion of revenue from Privatklinik Dr. Robert Schindlbeck GmbH & Co. KG (the "Clinic") for two months in the previous period prior to the sale of the Clinic in February 2020.

Cost of Sales

(in millions)	Years Ended December 31,		
	2021	2020 (unaudited)	Change
Cost of molecular diagnostic testing	\$ 185.7	\$ 157.9	\$ 27.8
Cost of molecular diagnostic testing as a % of revenue	26.9 %	28.3 %	
Cost of pharmaceutical and clinical services	\$ 11.9	\$ 20.3	\$ (8.4)
Cost of pharmaceutical and clinical services as a % of revenue	1.7 %	3.6 %	

The cost of molecular diagnostic testing as a percentage of revenue decreased from 28.3% to 26.9% during the year ended December 31, 2021 compared to the year ended December 31, 2020. The decrease was primarily driven by the increase in revenue from higher test volumes during the current period, as higher revenues were generated to cover fixed costs of performing the tests.

The cost of pharmaceutical and clinical services as a percentage of revenue decreased from 3.6% to 1.7% during the year ended December 31, 2021 compared to the year ended December 31, 2020 due to the sale of Myriad RBM, Inc. on July 1, 2021 and the inclusion of the costs related to the Clinic for two months in the previous period prior to the sale of the Clinic in February 2020.

Research and Development Expense

(in millions)	Years Ended December 31,		
	2021	2020 (unaudited)	Change
Research and development expense	\$ 81.9	\$ 73.3	\$ 8.6
Research and development expense as a % of total revenue	11.9 %	13.2 %	

Research and development expense for the year ended December 31, 2021 increased by \$8.6 million compared to the prior year due primarily to costs incurred in the current year as part of the Company's strategic transformation initiatives, increases in lab expenses, and increases in compensation costs as a result of employee bonus reductions in the prior period stemming from the significant impact of COVID-19 on our financial results.

Selling, General and Administrative Expense

(in millions)	Years Ended December 31,		
	2021	2020 (unaudited)	Change
Selling, general, and administrative expense	\$ 537.8	\$ 496.9	\$ 40.9
Selling, general, and administrative expense as a % of total revenue	77.9 %	89.2 %	

Selling, general and administrative expense increased by \$40.9 million for the year ended December 31, 2021 compared to the prior year due primarily to a \$12.6 million increase in stock-based compensation due to lower stock-based compensation in the prior period as a result of adjustments to stock-based compensation related to the departure of our former Chief Executive Officer, and a \$16.2 million increase in costs incurred in the current period as part of the Company's strategic transformation initiatives, as well as an \$8.2 million increase in bonus expense as a result of employee bonus reductions in the prior year stemming from the significant impact of the COVID-19 pandemic on our financial results, a \$6.3 million increase in legal expenses, a \$5.0 million increase in consulting fees, and a \$3.3 million increase in IT hardware costs. Increases were partially offset by a \$10.5 million decrease in amortization expense and a decrease in sales and marketing expenses of \$3.4 million due primarily to fewer in-person sales and marketing events and travel-related expenses.

Legal Charges Pending Settlement

(in millions)	Years Ended December 31,		
	2021	2020 (unaudited)	Change
Legal charges pending settlement	\$ 62.0	\$ —	\$ 62.0
Legal charges pending settlement as a % of total revenue	9.0 %	— %	

Legal charges pending settlement increased for the year ended December 31, 2021 compared to the prior year due to \$62.0 million of accruals related to potential legal settlements, including \$48.0 million in connection with the qui tam lawsuit against Crescendo Bioscience, LLC and the Company and \$14.0 million in connection with the Abelli lawsuit. There was no corresponding legal charges pending settlement in the prior year. The Abelli lawsuit was subsequently settled on January 24, 2022, pursuant to which the Company agreed to pay \$14.0 million to the plaintiffs.

Goodwill and Long-lived Asset Impairment Charges

(in millions)	Years Ended December 31,		
	2021	2020 (unaudited)	Change
Goodwill and long-lived asset impairment charges	\$ 1.8	\$ 98.4	\$ (96.6)
Goodwill and long-lived asset impairment charges as a % of total revenue	0.3 %	17.7 %	

Goodwill and long-lived asset impairment charges decreased for the year ended December 31, 2021 compared to the prior year due primarily to the Company recognizing goodwill impairment charges in the prior year related to the Autoimmune reporting unit, as well as additional charges related to the abandonment of in-process research and development intangible assets. In the current year, we recognized a \$1.8 million impairment to right-of-use assets as a result of the voluntary early termination of certain lease agreements to consolidate space.

Other Income (Expense)

(in millions)	Years Ended December 31,		
	2021	2020 (unaudited)	Change
Interest income	\$ 0.7	\$ 2.0	\$ (1.3)
Interest expense	\$ (6.6)	\$ (11.2)	\$ 4.6
Other	\$ 139.3	\$ 15.3	\$ 124.0
Other income (expense)	\$ 133.4	\$ 6.1	\$ 127.3

Other income (expense) increased for the year ended December 31, 2021 due primarily to the combined \$152.2 million net gain recognized on the sales of Myriad RBM, Inc. and the Myriad myPath, LLC laboratory in the current period, partially offset by expenses or losses in the current period, including the \$0.6 million net loss recognized on the sale of the Myriad Autoimmune business unit and losses of \$5.2 million and \$6.5 million for a non-cancelable purchase commitment and inventory, respectively, recognized in connection with the divestiture transactions. The increase in Other income (expenses) was partially offset by the receipt of \$14.6 million in stimulus funds from the CARES Act in the prior period. Interest expense decreased due primarily to the repayment of the Company's Amended Facility in full on July 30, 2021.

Income Tax Benefit

(in millions)	Years Ended December 31,		
	2021	2020 (unaudited)	Change
Income tax benefit	\$ (29.9)	\$ (59.9)	\$ 30.0
Effective tax rate	(52.4)%	(21.1)%	

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 benefit for the year ended December 31, 2021 was \$(29.9) million, and our effective tax rate was 52.4%. The change in the effective tax rate for the year ended December 31, 2021 as compared to the prior year is due primarily to the tax benefit recorded in the prior year related to the CARES Act, tax expense recorded in the prior year related to asset impairments, tax benefit recorded in the current year related to the differences between the book and tax basis of assets divested, disallowed executive compensation expenses, the release of a valuation allowance, and stock compensation expense.

Liquidity and Capital Resources

Our primary sources of liquidity are our cash, cash equivalents and marketable investment securities, our cash flows from operations, our cash flows from investing activities, and, in certain circumstances as discussed below, amounts available for borrowing under our Amended Facility. 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 or acquisitively to support business strategy provides the best return on invested capital. During the year ended December 31, 2021, our liquidity increased by \$379.1 million from the combined proceeds from the sales of Myriad RBM, Inc., the Myriad Autoimmune business, and the Myriad myPath, LLC laboratory. The cash generated from these divestitures provides us with additional liquidity as we seek out strategic opportunities for capital deployment.

We believe that our existing capital resources will be sufficient to meet our projected operating requirements for the foreseeable future. In addition, our capital resources and cash on hand may be used for acquisitions or other strategic investments.

All remaining borrowings under our Amended Facility, which matures on July 31, 2023, were repaid on July 30, 2021 using cash generated from our recent divestitures. Our available capital resources, however, may be consumed more rapidly than currently expected, and we may need or want to raise additional financing. We may not be able to secure such financing in a timely manner or on favorable terms, if at all. In addition, we are subject to financial covenants as part of our outstanding Amended Facility that could limit our ability to incur additional indebtedness. Without additional funds, we may be forced to delay, scale back or eliminate some of our sales and marketing efforts, research and development activities, or other operations, and potentially delay development of our diagnostic 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.

The Amended Facility restricts our ability to make future borrowings if unrestricted cash, cash equivalents and marketable securities exceed \$150.0 million, unless such borrowings are in connection with certain permitted acquisitions. Unrestricted cash, cash equivalents, and marketable securities totaled \$398.8 million as of December 31, 2021. Our revolving commitment amount is \$250.0 million as of December 31, 2021. As the Company's total unrestricted cash, cash equivalents, and marketable securities exceeded \$150.0 million as of December 31, 2021, we will be unable to make future borrowings unless related to a permitted acquisition. In addition, following the expiration of the waiver of the leverage ratio and interest coverage ratio covenants, which waiver is effective until March 31, 2022, our ability to borrow under the Amended Facility will be limited if we are unable to comply with those financial covenants.

From time to time, we enter into purchase commitments or other agreements that may materially impact our liquidity position in future periods. In April 2021, a non-cancelable operating lease for our new corporate headquarters in Salt Lake City, Utah, commenced with a lease term of 15 years and total future lease payments of approximately \$66.0 million as of December 31, 2021. In addition, in late 2021, we entered into two non-cancelable operating leases, one for approximately 7,500 square feet in Durham, North Carolina, which expires in 2029, and one for approximately 63,000 square feet in South San Francisco, California, which expires in 2033. The total future lease payments of the new North Carolina and California leases are approximately \$2.3 million and \$58.8 million, respectively, as of December 31, 2021. As of December 31, 2021, the Company had approximately \$4.0 million of non-cancelable contractual purchase obligations with varying terms over the next two years. In the first quarter of 2022, we entered into a non-cancelable operating lease for approximately 230,000 square feet in Salt Lake City, Utah, which will commence in 2022, with a lease term of 15 years and total future lease payments of approximately \$77.8 million.

Due to the continually evolving global situation from the COVID-19 pandemic, including the emergence of the more highly transmissible Delta and Omicron coronavirus variants and their impact on the ongoing recovery from the earlier effects of the COVID-19 pandemic, it is not possible to predict whether ongoing consequences of the pandemic are reasonably likely to materially affect our liquidity and capital resources in the future. 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. Competition and compensation for such personnel and other qualified personnel increased as employment vacancies surged during the year ended December 31, 2021, which has increased the difficulty and cost of hiring and retaining qualified personnel. In addition, potential federal or state regulations that require us to mandate COVID-19 vaccinations for our employees, or any future decision on our part to voluntarily require our employees to receive a COVID-19 vaccine, could impact our ability to hire and retain employees. 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 molecular diagnostic business, and it may have a material adverse effect on our business as a whole. Additionally, disruptions to our supply chain as a result of the COVID-19 pandemic 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 we expect it will continue to have, an impact on the costs we incur to attract and retain qualified personnel, costs to generate sales and produce diagnostic testing results, and costs of lab supplies.

The following table represents the balances of cash, cash equivalents and marketable investment securities:

<i>(in millions)</i>	December 31,	
	2021	2020
Cash and cash equivalents	\$ 258.4	\$ 117.0
Marketable investment securities	81.4	33.7
Long-term marketable investment securities	59.0	21.0
Cash, cash equivalents and marketable investment securities	\$ 398.8	\$ 171.7

The increase in cash, cash equivalents, and marketable investments securities for the year ended December 31, 2021 was primarily driven by \$379.1 million in total cash consideration from the sale of Myriad RBM, Inc., the Myriad Autoimmune business, and the Myriad myPath, LLC laboratory, the receipt of a U.S. federal tax refund of \$89.6 million, and proceeds of \$91.8 million from the exercise of stock options, partially offset by \$226.4 million in repayments of our Amended Facility and \$10.5 million in transaction expenses related to the foregoing divestitures, as well as by cash used in operating activities as part of our normal course of business.

During the transition period ended December 31, 2020, the decrease in cash, cash equivalents and marketable investment securities was primarily driven by the Company using \$73.7 million in cash for operating activities.

The following table represents the condensed cash flow statement:

<i>(in millions)</i>	Year Ended December 31,	
	2021	2020
		<i>(unaudited)</i>
Cash flows from operating activities	\$ 18.2	\$ (26.9)
Cash flows from investing activities	274.4	61.6
Cash flows from financing activities	(150.6)	(1.0)
Effect of foreign exchange rates on cash and cash equivalents	(0.6)	0.6
Change in cash and cash equivalents classified as held for sale	—	1.5
Net increase (decrease) in cash and cash equivalents	141.4	35.8
Cash and cash equivalents at the beginning of the period	117.0	81.2
Cash and cash equivalents at the end of the period	\$ 258.4	\$ 117.0

Cash Flows from Operating Activities

In the year ended December 31, 2021, the increase in cash flows was primarily due to the change in the balance of prepaid taxes due to the receipt of a \$89.6 million U.S. federal tax refund, partially offset by a decrease in cash flows from operating activities primarily driven by a \$37.7 million change in trade accounts receivable in the current period compared to the prior period due to the change in sales volumes and cash collections as a result of the significant impact of the COVID-19 pandemic on our financial results during the prior period.

Cash Flows from Investing Activities

In the year ended December 31, 2021, the increase in cash flows from investing activities as compared to the same period in the prior year was primarily due to incremental cash proceeds of \$357.8 million from divestitures in the current period as compared to the prior period. This increase is partially offset by an increase of \$132.0 million of purchases of marketable investment securities in the current period as compared to the prior period, a decrease of \$8.2 million in proceeds from marketable investment securities during the current period, and an increase of \$4.8 million in capital expenditures in the current period.

Cash Flows from Financing Activities

In the year ended December 31, 2021, the decrease in cash flows from financing activities as compared to the same period in the prior year was primarily due to the use of \$226.4 million in cash for repayments of the Amended Facility during the current year. The decrease was partially offset by an increase of \$80.2 million in proceeds from the exercise of stock options, net of shares exchanged for payroll withholding tax in the current year as compared to the prior year.

Effects of Inflation

We do not believe that inflation has had a material impact on our business, sales, or operating results during the periods presented. However, inflation has had, and we expect that it will continue to have, an impact on the labor costs we incur to attract and retain qualified personnel, costs to generate sales and produce diagnostic testing results, and costs of lab supplies. Inflationary costs may impact our profitability and could adversely affect our business, financial condition and results of operations.

Share Repurchase Program

Our Board of Directors has previously authorized us to repurchase up to \$200.0 million of our outstanding common stock. We may repurchase our common stock from time to time or on an accelerated basis through open market transactions or privately negotiated transactions as determined by our management. The amount and timing of stock repurchases under the program will depend on business and market conditions, stock price, trading restrictions, acquisition activity and other factors. As of December 31, 2021, we are authorized to repurchase up to \$110.7 million under our current share repurchase authorization. See “Part II, Item 2. Unregistered Sales of Equity Securities and Use of Proceeds – Issuer Purchases of Equity Securities” below.

Critical Accounting Policies

Critical accounting policies 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 policies 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 molecular diagnostic testing. We perform our obligation under a contract with a customer by processing those diagnostic tests and communicating the test results to customers, in exchange for consideration from the customer. Revenue from the sale of molecular diagnostic 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 and 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 it 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. The Company reserves 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 Income (Loss).

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. 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, 2021, we have recorded goodwill of \$239.2 million on our Consolidated Balance Sheet. This goodwill is attributable to the Myriad Mental Health, Myriad International, and Myriad Women's Health reporting units. We qualitatively evaluated the Myriad Mental Health and Myriad International 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, 2021.

For our Myriad Women's Health reporting unit, we elected to perform a quantitative assessment of goodwill. We measured the fair value of the Myriad Women's Health reporting unit utilizing the market approach and the discounted cash flow method under the income approach. As a result of the assessment, no goodwill impairment charges were recorded as the estimated fair value of the reporting unit exceeded the carrying value of the goodwill as of December 31, 2021. We performed a sensitivity analysis of the discount rate and the revenue growth rate, which are significant assumptions in the calculation of fair value. We determined that a 1% increase in the discount rate or a 1% decline in forecasted revenue growth would not have changed our determination that the fair value of the reporting unit was in excess of its carrying value.

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.

Income Taxes. Our income tax provision is based on income before taxes and is computed using the liability method in accordance with Accounting Standards Codification (“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. If we do not maintain taxable income from operations in future periods, we may increase the valuation allowance for our deferred tax assets and record material adjustments to our income tax expense. 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 Report 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 maintain an investment portfolio in accordance with our written investment policy. The primary objectives of our investment policy are to preserve principal, maintain proper liquidity to meet operating needs and maximize yields. 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 five years or less, with an average maturity of two years. These securities are classified as available-for-sale. Available-for-sale securities are recorded on the balance sheet at fair market value with unrealized gains or losses reported as part of Accumulated other comprehensive income (loss). Realized gains and losses on investment security transactions are reported on the specific-identification method. Dividend and interest income are recognized when earned. 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.

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 marketable investment 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, 2021, we had \$0.2 million in unrealized losses in our investment portfolio. We do not utilize derivative financial instruments to manage our interest rate risks.

We may be exposed to fluctuations in foreign currencies with regard to certain agreements with service providers. Depending on the strengthening or weakening of the United States dollar, realized and unrealized currency fluctuations could be significant.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

MYRIAD GENETICS, INC.

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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, 2021 and 2020, the related consolidated statements of operations, comprehensive income (loss), stockholders' equity and cash flows for the year ended December 31, 2021, the six month period ended December 31, 2020 and each of the two years in the period ended June 30, 2020, 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, 2021 and 2020, and the results of its operations and its cash flows for the year ended December 31, 2021, the six month period ended December 31, 2020 and each of the two years in the period ended June 30, 2020, 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, 2021, 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 25, 2022 expressed an adverse 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 audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

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 molecular diagnostic testing revenue

Description of the Matter During the year ended December 31, 2021, the Company's molecular diagnostic testing revenue was \$666.4 million. As discussed in Note 1 of the consolidated financial statements, molecular diagnostic testing revenue is recognized when the performance obligation is complete. Auditing the measurement of the Company's molecular diagnostic testing revenue was complex and judgmental due to the significant estimation required in estimating 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 and evaluated the design and tested the operating effectiveness of controls over the Company's revenue recognition process. As part of our testing, we considered 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 molecular diagnostic 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 25, 2022

**MYRIAD GENETICS, INC.
AND SUBSIDIARIES**
Consolidated Balance Sheets
(in millions)

	December 31,	
	2021	2020
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 258.4	\$ 117.0
Marketable investment securities	81.4	33.7
Trade accounts receivable	91.3	89.5
Inventory	15.3	27.1
Prepaid taxes	18.4	108.4
Prepaid expenses and other current assets	20.0	13.7
Total current assets	484.8	389.4
Operating lease right-of-use assets	81.8	59.7
Long-term marketable investment securities	59.0	21.0
Property, plant and equipment, net	43.5	40.7
Intangibles, net	404.1	576.5
Goodwill	239.2	329.2
Other assets	8.3	2.3
Total assets	\$ 1,320.7	\$ 1,418.8
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 29.6	\$ 20.5
Accrued liabilities	156.5	79.1
Current maturities of operating lease liabilities	13.0	13.6
Deferred revenue	5.2	32.7
Total current liabilities	204.3	145.9
Unrecognized tax benefits	27.9	30.5
Long-term deferred taxes	35.8	71.3
Long-term debt	—	224.8
Noncurrent operating lease liabilities	79.3	50.6
Other long-term liabilities	5.6	14.7
Total liabilities	352.9	537.8
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.01 par value, 80.0 and 75.4 shares outstanding at December 31, 2021 and 2020, respectively	0.8	0.8
Additional paid-in capital	1,226.3	1,109.5
Accumulated other comprehensive loss	(5.1)	(2.3)
Accumulated deficit	(254.2)	(227.0)
Total Myriad Genetics, Inc. stockholders' equity	967.8	881.0
Non-controlling interest	—	—
Total stockholders' equity	967.8	881.0
Total liabilities and stockholders' equity	\$ 1,320.7	\$ 1,418.8

See accompanying notes to consolidated financial statements.

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

	Year Ended December 31,	Six-month Transition Period Ended December 31,	Years Ended June 30,	
	2021	2020	2020	2019
Molecular diagnostic testing	\$ 666.4	\$ 279.6	\$ 586.9	\$ 789.4
Pharmaceutical and clinical services	24.2	20.2	51.7	61.7
Total revenue	690.6	299.8	638.6	851.1
Costs and expenses:				
Cost of molecular diagnostic testing	185.7	82.6	157.5	168.2
Cost of pharmaceutical and clinical services	11.9	8.8	28.6	32.8
Research and development expense	81.9	35.8	77.2	85.9
Selling, general, and administrative expense	537.8	260.4	507.3	556.6
Legal charges pending settlement	62.0	—	—	—
Goodwill and long-lived asset impairment charges	1.8	—	99.7	—
Total costs and expenses	881.1	387.6	870.3	843.5
Operating income (loss)	(190.5)	(87.8)	(231.7)	7.6
Other income (expense):				
Interest income	0.7	0.7	3.0	3.2
Interest expense	(6.6)	(5.8)	(10.8)	(12.0)
Other	139.3	(1.2)	16.2	1.2
Total other income (expense)	133.4	(6.3)	8.4	(7.6)
Income (loss) before income tax	(57.1)	(94.1)	(223.3)	—
Income tax benefit	(29.9)	(41.0)	(23.7)	(4.4)
Net income (loss)	(27.2)	(53.1)	(199.6)	4.4
Net loss attributable to non-controlling interest	—	—	(0.1)	(0.2)
Net income (loss) attributable to Myriad Genetics, Inc. stockholders	\$ (27.2)	\$ (53.1)	\$ (199.5)	\$ 4.6
Earnings (loss) per share:				
Basic	\$ (0.35)	\$ (0.71)	\$ (2.69)	\$ 0.06
Diluted	\$ (0.35)	\$ (0.71)	\$ (2.69)	\$ 0.06
Weighted average shares outstanding:				
Basic	78.0	75.0	74.3	73.5
Diluted	78.0	75.0	74.3	76.0

See accompanying notes to consolidated financial statements.

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

	Year Ended December 31,	Six-month Transition Period Ended December 31,	Years Ended June 30,	
	2021	2020	2020	2019
Net income (loss) attributable to Myriad Genetics, Inc. stockholders	\$ (27.2)	\$ (53.1)	\$ (199.5)	\$ 4.6
Unrealized gain (loss) on available-for-sale securities, net of tax	(1.0)	(0.5)	0.7	1.2
Change in pension liability	—	—	—	0.6
Change in foreign currency translation adjustment, net of tax	(1.8)	3.4	(0.6)	(3.1)
Comprehensive income (loss)	<u>\$ (30.0)</u>	<u>\$ (50.2)</u>	<u>\$ (199.4)</u>	<u>\$ 3.3</u>

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 income (loss)	Retained earnings (accumulated deficit)	Myriad Genetics, Inc. Stockholders' equity
BALANCES AT JUNE 30, 2018	\$ 0.7	\$ 915.4	\$ (4.1)	\$ 54.1	\$ 966.1
Issuance of common stock under stock-based compensation plans, net of shares exchanged for withholding tax	—	136.0	—	—	136.0
Stock-based payment expense	—	33.5	—	—	33.5
Repurchase and retirement of common stock	—	(16.9)	—	(33.1)	(50.0)
Net income	—	—	—	4.6	4.6
Other comprehensive loss, net of tax	—	—	(1.3)	—	(1.3)
BALANCES AT JUNE 30, 2019	0.7	1,068.0	(5.4)	25.6	1,088.9
Issuance of common stock under stock-based compensation plans, net of shares exchanged for withholding tax	—	3.4	—	—	3.4
Stock-based payment expense	—	25.2	—	—	25.2
Net loss	—	—	—	(199.5)	(199.5)
Reclassification out of accumulated other comprehensive loss upon the deconsolidation of a subsidiary	—	—	0.1	—	0.1
Other comprehensive income, net of tax	—	—	0.1	—	0.1
BALANCES AT JUNE 30, 2020	0.7	1,096.6	(5.2)	(173.9)	918.2
Issuance of common stock under stock-based compensation plans, net of shares exchanged for withholding tax	0.1	(2.0)	—	—	(1.9)
Stock-based payment expense	—	14.9	—	—	14.9
Net loss	—	—	—	(53.1)	(53.1)
Other comprehensive income, net of tax	—	—	2.9	—	2.9
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

See accompanying notes to consolidated financial statements.

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

	Year Ended December 31,	Six-month Transition Period Ended December 31,	Years Ended June 30,	
	2021	2020	2020	2019
CASH FLOWS FROM OPERATING ACTIVITIES:				
Net income (loss) attributable to Myriad Genetics, Inc. stockholders	\$ (27.2)	\$ (53.1)	\$ (199.5)	\$ 4.6
Adjustments to reconcile net income (loss) to net cash provided by operating activities:				
Depreciation and amortization	62.8	35.8	72.0	73.0
Non-cash interest expense	1.5	0.4	0.5	0.4
Non-cash lease expense	12.8	6.4	—	—
Stock-based compensation expense	36.3	14.9	25.2	33.5
Deferred income taxes	(32.1)	44.2	(55.8)	18.6
Unrecognized tax benefits	(2.6)	7.1	1.7	(5.5)
Non-cash impact of foreign currency transactions	—	(1.0)	—	—
Loss on inventory	6.5	—	—	—
Impairment of goodwill and long-lived assets	1.8	—	99.7	—
Gain on sale of businesses and assets	(162.0)	—	(1.0)	—
Payment of contingent consideration	—	—	—	(1.5)
Changes in assets and liabilities:				
Prepaid expenses and other current assets	(6.6)	3.1	2.8	(3.9)
Trade accounts receivable	(8.8)	(21.4)	64.0	(18.2)
Inventory	1.6	2.2	1.6	8.0
Prepaid taxes	89.9	(108.4)	25.1	(25.1)
Other assets	(4.0)	(2.3)	—	—
Accounts payable	9.2	(1.2)	(10.7)	1.1
Accrued liabilities	65.7	(0.2)	4.4	(0.8)
Deferred revenue	(26.6)	(0.2)	30.7	(0.5)
Net cash provided by (used in) operating activities	18.2	(73.7)	60.7	83.7
CASH FLOWS FROM INVESTING ACTIVITIES:				
Capital expenditures	(18.0)	(7.9)	(10.2)	(8.6)
Acquisitions, net of cash acquired	—	—	—	(278.5)
Proceeds from sale of business and assets	379.1	—	21.3	—
Purchases of marketable investment securities	(147.8)	—	(60.8)	(78.5)
Proceeds from maturities and sales of marketable investment securities	61.1	35.9	69.0	79.2
Net cash provided by (used in) investing activities	274.4	28.0	19.3	(286.4)
CASH FLOWS FROM FINANCING ACTIVITIES:				
Proceeds from common stock issued under stock-based compensation plans	91.8	1.8	13.3	23.2
Payment of tax withheld for common stock issued under stock-based compensation plans	(11.5)	(3.8)	(9.8)	(14.5)
Payment of contingent consideration recognized at acquisition	(3.3)	(0.1)	(3.9)	—
Proceeds from revolving credit facility	—	—	—	340.0
Fees associated with refinancing of revolving credit facility	(1.2)	—	(1.0)	(1.4)
Repayment of revolving credit facility	(226.4)	—	(8.6)	(115.0)
Repurchase and retirement of common stock	—	—	—	(50.0)
Net cash provided by (used in) financing activities	(150.6)	(2.1)	(10.0)	182.3
Effect of foreign exchange rates on cash and cash equivalents	(0.6)	1.1	0.5	2.7
Net increase (decrease) in cash and cash equivalents	141.4	(46.7)	70.5	(17.7)
Cash and cash equivalents at beginning of the period	117.0	163.7	93.2	110.9
Cash and cash equivalents at end of the period	\$ 258.4	\$ 117.0	\$ 163.7	\$ 93.2

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. and subsidiaries (collectively, 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 discovers and commercializes genetic tests that determine the risk of developing disease, assess the risk of disease progression, or guide treatment decisions across medical specialties. The Company generates revenue by performing molecular diagnostic tests and, prior to the sale of Myriad RBM, Inc. on July 1, 2021 as described in Note 16, by providing pharmaceutical and clinical services to the pharmaceutical and biotechnology industries and medical research institutions utilizing its multiplexed immunoassay technology. The Company's corporate headquarters are located in Salt Lake City, Utah.

The accompanying consolidated financial statements have been prepared by the Company in accordance with 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"). The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. 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 Company management to make estimates and assumptions relating to the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the 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, certain accrued liabilities, stock-based compensation, and impairment analysis of goodwill and long-lived assets. Actual results could differ from those estimates.

The full impact of the COVID-19 outbreak continues to evolve and its future impacts remain uncertain and unpredictable. The Omicron variant, which has become the most common form of the virus circulating throughout the world and appears to be more transmissible than other variants to date, is causing significant uncertainty. The impact of the Omicron variant and other variants that may emerge cannot be predicted at this time and could depend on numerous factors, including, but not limited to, vaccination rates among the population, the effectiveness of COVID-19 vaccinations against emerging variants, and any new measures that may be introduced by governments or other parties in response to an increase in COVID-19 cases. Management is actively monitoring the impact of the global situation on the Company's financial condition, liquidity, operations, suppliers, industry, and workforce. Given the daily evolution of the COVID-19 outbreak and the global responses to curb its spread, the Company is not able to estimate the effects of the COVID-19 outbreak on its results of operations, financial condition, or liquidity for future periods.

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, cash flows from operations, or net loss for the period.

Concentration of Credit Risk

Financial instruments that potentially subject us to concentrations of credit risk consist primarily of cash and cash equivalents and accounts receivable. Substantially all of the Company's account 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 17%, 16%, 15% and 14% of total revenue for the year ended December 31, 2021, the six-month transition period ended December 31, 2020 and the years ended June 30, 2020 and 2019, 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. No customer accounted for more than 10% of accounts receivable at December 31, 2021 or December 31, 2020.

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.

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 year ended December 31, 2021, the transition period ended December 31, 2020 or during the years ended June 30, 2020 and 2019.

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. 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 Company evaluates its inventories for excess quantities and obsolescence. Inventories that are considered excess or obsolete are expensed. 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 amounts billed to customers for revenue recognized related to molecular diagnostic tests and, prior to the sale of Myriad RBM, Inc. on July 1, 2021 as described in Note 16, pharmaceutical and clinical services. 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 seven years. Repairs and maintenance costs are charged to expense as incurred.

Intangible Assets and Other Long-Lived Assets

Intangible and other long-lived assets are comprised of acquired licenses and technology and, prior to the sale of Myriad RBM, Inc. on July 1, 2021, intellectual property and purchased in-process research and development. Acquired intangible assets are recorded at fair value and amortized over the shorter of the contractual life or the estimated useful life. The classification of the Company's acquired in-process research and development as an indefinite lived asset was deemed appropriate as the related research and development was not yet complete nor had it been abandoned.

The Company capitalizes certain costs incurred to develop internal-use technology, including certain implementation costs incurred in cloud computing arrangements and hosting arrangements that include an internal-use software license. 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. After the implementation of the internal-use cloud computing software or other internal-use technology, 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, 2021 and 2020, the Company had unamortized software costs of \$6.7 million and \$2.3 million, respectively. For the year ended December 31, 2021, amortization expense for capitalized software costs was \$0.2 million. There was no capitalized software amortization expense for the remaining periods presented.

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.

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.

Revenue Recognition

Myriad primarily generates revenue by performing molecular diagnostic testing. Molecular diagnostic revenues are derived from the following categories of products: Hereditary Cancer (MyRisk, BRACAnalysis, BRACAnalysis CDx), Tumor Profiling (MyChoice CDx, Prolaris, and EndoPredict), Prenatal (Foresight and Prequel), Pharmacogenomics (GeneSight), Autoimmune (Vectra), and Other. The Company previously provided pharmaceutical services and clinical services prior to the sale of Myriad RBM, Inc. in July 2021 and Privatlinik Dr. Robert Schindlbeck GmbH & Co. KG (the "Clinic") in February 2020, respectively. 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 Molecular diagnostic revenues. See Note 16 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 clinical and pharmaceutical services indicates transfer of control for revenue recognition purposes.

The following table represents the Company's revenue by type for the year ended December 31, 2021, the transition period ended December 31, 2020, and the years ended June 30, 2020 and 2019:

<i>(In millions)</i>	Year Ended December 31,	Six-month Transition Period Ended December 31,	Years Ended June 30,	
	2021	2020	2020	2019
Molecular diagnostic revenues:				
Hereditary Cancer	\$ 316.3	\$ 159.3	\$ 347.4	\$ 479.7
Tumor Profiling	120.9	33.9	48.3	43.0
Prenatal	106.8	37.6	76.7	104.9
Pharmacogenomics	93.7	29.8	74.1	112.6
Autoimmune	28.2	18.0	39.1	48.3
Other	0.5	1.0	1.3	0.9
Total molecular diagnostic revenue	666.4	279.6	586.9	789.4
Pharmaceutical and clinical service revenue	24.2	20.2	51.7	61.7
Total revenue	\$ 690.6	\$ 299.8	\$ 638.6	\$ 851.1

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

<i>(in millions)</i>	Year Ended December 31,			Six-month Transition Period Ended December 31,		
	2021			2020		
	U.S.	RoW	Total	U.S.	RoW	Total
Molecular diagnostic revenues:						
Hereditary Cancer	\$ 271.0	\$ 45.3	\$ 316.3	\$ 140.9	\$ 18.4	\$ 159.3
Tumor Profiling	80.4	40.5	120.9	28.2	5.7	33.9
Prenatal	106.2	0.6	106.8	37.4	0.2	37.6
Pharmacogenomics	93.7	—	93.7	29.8	—	29.8
Autoimmune	28.2	—	28.2	18.0	—	18.0
Other	—	0.5	0.5	1.0	—	1.0
Total molecular diagnostic revenue	579.5	86.9	666.4	255.3	24.3	279.6
Pharmaceutical and clinical services revenue	24.2	—	24.2	20.1	0.1	20.2
Total revenue	\$ 603.7	\$ 86.9	\$ 690.6	\$ 275.4	\$ 24.4	\$ 299.8

<i>(in millions)</i>	Year Ended June 30,					
	2020			2019		
	U.S.	RoW	Total	U.S.	RoW	Total
Molecular diagnostic revenues:						
Hereditary Cancer	\$ 329.8	\$ 17.6	\$ 347.4	\$ 466.7	\$ 13.0	\$ 479.7
Tumor Profiling	39.2	9.1	48.3	34.6	8.4	43.0
Prenatal	76.4	0.3	76.7	104.9	—	104.9
Pharmacogenomics	74.1	—	74.1	112.6	—	112.6
Autoimmune	39.1	—	39.1	48.3	—	48.3
Other	1.2	0.1	1.3	0.5	0.4	0.9
Total molecular diagnostic revenue	559.8	27.1	586.9	767.6	21.8	789.4
Pharmaceutical and clinical services revenue	36.4	15.3	51.7	37.8	23.9	61.7
Total revenue	\$ 596.2	\$ 42.4	\$ 638.6	\$ 805.4	\$ 45.7	\$ 851.1

Under ASC Topic 606, Revenue from Contracts with Customers (“Topic 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 diagnostic 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. During the year ended June 30, 2020, the Company received approximately \$29.7 million in advance Medicare payments to provide relief from the economic impacts of COVID-19 on the Company. The advanced Medicare payments began being applied against services performed in April 2021 and will continue until the funds previously received are fully earned. A reconciliation of the beginning and ending balances of deferred revenue is shown in the table below:

<i>(in millions)</i>	Year Ended	Six-month	Years Ended June 30,	
	December 31,	Transition Period	2020	2019
	2021	Ended December 31,		
Deferred revenue - beginning balance	\$ 32.7	\$ 32.8	\$ 2.2	\$ 2.6
Revenue recognized	(40.5)	(6.1)	(7.2)	(7.9)
Prepayments	14.0	6.0	37.8	7.5
Divestitures	(1.0)	—	—	—
Deferred revenue - ending balance	\$ 5.2	\$ 32.7	\$ 32.8	\$ 2.2

In accordance with Topic 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 Company's performance to date.

In determining the transaction price, Myriad 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 are 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 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 Income (Loss).

Cash collections for certain diagnostic tests delivered may differ from rates originally 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, 2021, the Company recognized \$15.9 million in revenue which resulted in a \$0.15 impact to earnings (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. Additionally, during the year ended December 31, 2021, revenue of \$6.8 million was recognized due to expanded coverage for Prolaris, for which revenue was fully constrained in a prior period. During the year ended June 30, 2020, the Company recognized a \$9.9 million decrease in revenue, which resulted in a \$(0.10) impact to earnings (loss) per share for tests in which the performance obligation of delivering the tests results was met in prior periods. The changes were 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. In addition, during the year ended June 30, 2020, the Company identified an error related to prior periods for Medicare claims and reduced revenue and recorded an accrued liability for a total of \$4.7 million that will be refunded to Medicare. The impact of correcting the error during that period and the impact to all prior periods was concluded to be immaterial. The correction of the error in the year ended June 30, 2020 resulted in an impact to earnings (loss) per share for the year ended June 30, 2020 of \$(0.05). During the transition period ended December 31, 2020, and year ended June 30, 2019, the impact to revenue and earnings (loss) per share for tests in which the performance obligation of delivering the test results was met in the prior period was immaterial.

In accordance with Topic 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, etc.

The Company has elected to apply 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 has also elected to apply 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 payments 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 Accounting Standards Codification (“ASC”) 718, Compensation – Stock Compensation. 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. 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 Simulation model. 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 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 our stock price.

Other Income (Expense)

The Company recognizes the gain or loss on its divestitures as Other income (expense). During the years ended December 31, 2021 and June 30, 2020, the Company recognized a net gain on divestitures of \$162.0 million and \$1.0 million, respectively. See Note 16 for additional information regarding these divestitures. In addition, during the year ended June 30, 2020, the Company received approximately \$14.6 million, respectively, from the Provider Relief Fund under the CARES Act to reimburse the Company for health care related expenses or lost revenues that are attributable to COVID-19, which was recognized as a component of Other income (expense) in the Consolidated Statements of Operations.

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 and state 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 consolidated financial condition, results of operations or cash flows.

Earnings Per Share

Basic earnings per share 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:

<i>(in millions)</i>	<u>Year Ended December 31,</u> <u>2021</u>	<u>Six-month Transition Period Ended December 31,</u> <u>2020</u>	<u>Years Ended June 30,</u>	
			<u>2020</u>	<u>2019</u>
Denominator:				
Weighted-average shares outstanding used to compute basic EPS	78.0	75.0	74.3	73.5
Effect of dilutive stock options	—	—	—	2.5
Weighted-average shares outstanding and dilutive securities used to compute diluted EPS	<u>78.0</u>	<u>75.0</u>	<u>74.3</u>	<u>76.0</u>

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 common shares, which may be dilutive to future diluted earnings per share, are as follows:

<i>(in millions)</i>	Year Ended	Six-month	Years Ended June 30,	
	December 31,	Transition Period	2020	2019
	2021	Ended December 31,		
		2020		
Anti-dilutive options and RSUs excluded from EPS computation	4.5	6.6	5.5	0.8

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 income (loss) as a separate component of Stockholders' equity.

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

Ending balance December 31, 2020	\$	(3.1)
Period translation adjustments		(1.8)
Ending balance December 31, 2021	\$	(4.9)

Recent Accounting Pronouncements

Recently Adopted Standards

In December 2019, the FASB issued ASU 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes ("ASU 2019-12"). ASC 2019-12 is a new accounting standard to simplify accounting for income taxes and remove, modify, and add to the disclosure requirements of income taxes. The standard is effective for public companies with fiscal years beginning after December 15, 2020, with early adoption permitted. The guidance was adopted with no material impact to the Company's consolidated financial statements.

2. MARKETABLE INVESTMENT SECURITIES

The amortized cost, gross unrealized holding gains, gross unrealized holding losses, and fair value debt securities classified as available-for-sale securities by major security type and class of security at December 31, 2021 and December 31, 2020 were as follows:

<i>(in millions)</i>	Amortized cost	Gross unrealized holding gains	Gross unrealized holding losses	Estimated fair value
December 31, 2021:				
Cash and cash equivalents:				
Cash	\$ 195.2	\$ —	\$ —	\$ 195.2
Cash equivalents	63.2	—	—	63.2
Total cash and cash equivalents	258.4	—	—	258.4
Available-for-sale:				
Corporate bonds and notes	105.7	0.1	(0.2)	105.6
Municipal bonds	16.1	—	—	16.1
Federal agency issues	6.8	—	—	6.8
US government securities	11.9	—	—	11.9
Total	\$ 398.9	\$ 0.1	\$ (0.2)	\$ 398.8

<i>(in millions)</i>	Amortized cost	Gross unrealized holding gains	Gross unrealized holding losses	Estimated fair value
December 31, 2020:				
Cash and cash equivalents:				
Cash	\$ 47.9	\$ —	\$ —	\$ 47.9
Cash equivalents	69.1	—	—	69.1
Total cash and cash equivalents	117.0	—	—	117.0
Available-for-sale:				
Corporate bonds and notes	28.8	0.5	—	29.3
Municipal bonds	9.4	0.2	—	9.6
Federal agency issues	4.0	—	—	4.0
US government securities	11.7	0.1	—	11.8
Total	\$ 170.9	\$ 0.8	\$ —	\$ 171.7

Cash, cash equivalents, and maturities of debt securities classified as available-for-sale are as follows at December 31, 2021:

<i>(in millions)</i>	Amortized cost	Estimated fair value
Cash	195.2	195.2
Cash equivalents	63.2	63.2
Available-for-sale:		
Due within one year	80.3	80.4
Due after one year through five years	60.2	60.0
Due after five years	—	—
Total	\$ 398.9	\$ 398.8

There were no debt securities classified as available-for-sale in a gross unrealized loss position as of December 31, 2021 or December 31, 2020.

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 to receive in connection with the sale of an asset or paid 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, the Company reassesses the fair value of 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 contingent consideration period of approximately 13.5 years, utilizing various potential pay-out scenarios. 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 a component of Accrued liabilities and Other long-term liabilities in the Company's Consolidated Balance Sheets. Changes to the contingent consideration liabilities are reflected in Selling, general, and administrative expense in our Consolidated Statements of Operations. Changes to the unobservable inputs could have a material impact on the Company's financial statements.

The following tables set forth the fair value of the Company's financial assets and liabilities that are re-measured on a regular basis:

<i>(in millions)</i>	Level 1	Level 2	Level 3	Total
December 31, 2021				
Money market funds (a)	\$ 63.2	\$ —	\$ —	\$ 63.2
Corporate bonds and notes	—	105.6	—	105.6
Municipal bonds	—	16.1	—	16.1
Federal agency issues	—	6.8	—	6.8
US government securities	—	11.9	—	11.9
Contingent consideration	—	—	(8.6)	(8.6)
Total	<u>\$ 63.2</u>	<u>\$ 140.4</u>	<u>\$ (8.6)</u>	<u>\$ 195.0</u>

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

<i>(in millions)</i>	Level 1	Level 2	Level 3	Total
December 31, 2020				
Money market funds (a)	\$ 69.1	\$ —	\$ —	\$ 69.1
Corporate bonds and notes	—	29.3	—	29.3
Municipal bonds	—	9.6	—	9.6
Federal agency issues	—	4.0	—	4.0
US government securities	—	11.8	—	11.8
Contingent consideration	—	—	(10.9)	(10.9)
Total	<u>\$ 69.1</u>	<u>\$ 54.7</u>	<u>\$ (10.9)</u>	<u>\$ 112.9</u>

(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:

<i>(in millions)</i>	Year Ended December 31, 2021	Transition Period Ended December 31, 2020	Year Ended June 30, 2020	Year Ended June 30, 2019
Carrying amount at beginning of period	\$ 10.9	\$ 6.8	\$ 13.8	\$ 14.5
Payment of contingent consideration	(3.3)	(0.1)	(3.9)	—
Change in fair value recognized in the statement of operations	1.8	3.5	(2.8)	(1.1)
Translation adjustments recognized in other comprehensive income (loss)	(0.8)	0.7	(0.3)	0.4
Carrying amount at end of period	<u>\$ 8.6</u>	<u>\$ 10.9</u>	<u>\$ 6.8</u>	<u>\$ 13.8</u>

4. PROPERTY, PLANT AND EQUIPMENT, NET

<i>(in millions)</i>	December 31,	
	2021	2020
Leasehold improvements	38.0	35.7
Equipment	112.4	117.9
Property, plant and equipment, gross	150.4	153.6
Less accumulated depreciation	(106.9)	(112.9)
Property, plant and equipment, net	<u>\$ 43.5</u>	<u>\$ 40.7</u>

During the year ended December 31, 2021, the Company completed the sales of Myriad RBM, Inc. and the Myriad Autoimmune business, which resulted in the disposition of \$3.1 million of property, plant and equipment. See Note 16 for additional information regarding these divestitures.

<i>(in millions)</i>	Year Ended December 31, 2021	Six-month Transition Period Ended December 31, 2020	Years Ended June 30,	
			2020	2019
Depreciation expense	\$ 12.1	\$ 5.0	\$ 11.0	\$ 13.7

5. GOODWILL AND INTANGIBLE ASSETS

Goodwill

The changes in the carrying amount of goodwill for the year ended December 31, 2021 is as follows:

<i>(in millions)</i>	Year Ended December 31, 2021	
Beginning balance	\$	329.2
Divestitures		(88.5)
Translation adjustments		(1.5)
Carrying amount at end of period	\$	<u>239.2</u>

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 year ended December 31, 2021, the transition period ended December 31, 2020 or for the fiscal year ended June 30, 2019.

During the year ended June 30, 2020, as a result of the effect of COVID-19 on expected future cash flows and a corresponding decline in market capitalization and enterprise value, the Company performed an interim quantitative impairment review of goodwill for the Myriad Mental Health, Myriad Autoimmune and Myriad International reporting units as of March 31, 2020. Based on this analysis, the Company recognized a goodwill impairment charge of \$80.7 million related to the goodwill from the Myriad Autoimmune reporting unit. The goodwill impairment charge is reflected in Goodwill and long-lived asset impairment charges in the Consolidated Statements of Operations. On July 1, 2021, the Company completed the sale of Myriad RBM, Inc., and as a result the goodwill attributable to the Myriad RBM reporting unit is no longer held by the Company. In addition, on September 13, 2021, select operating assets and intellectual property, including the Vectra® test, from the Myriad Autoimmune business unit were sold. As a result of this divestiture, the goodwill attributable to the Myriad Autoimmune reporting unit is no longer held by the Company.

During the year ended June 30, 2020, the Company also recognized a \$1.3 million impairment charge for goodwill allocated to the Clinic asset group that is included in Goodwill and long-lived asset impairment charges in the Consolidated Statements of Operations.

Intangible Assets

Intangible assets have primarily consisted of amortizable assets of purchased licenses and technologies, customer relationships, and trade names as well as a non-amortizable intangible asset of in-process research and development. Due to the completion of the sales of Myriad RBM, Inc. and the Myriad Autoimmune business, the Company's intangible assets as of December 31, 2021 consist of only purchased licenses and technologies. In connection with these sales, the Company sold \$199.1 million in purchased licenses and technologies, \$4.8 million in-process research and development intangible assets, \$4.7 million in customer relationships, and \$3.0 million in trademarks, resulting in an aggregate decrease of intangible assets of \$120.0 million, net of \$91.6 million in accumulated amortization. See Note 16 for additional information on these divestitures.

The Company's purchased licenses and technologies have estimated remaining useful lives between 1 and 14 years. Prior to the sale of Myriad RBM, Inc., the estimated useful life of acquired in-process research and development was also evaluated in conjunction with the annual impairment analysis of intangible assets. The classification of the acquired in-process research and development as an indefinite lived asset was deemed appropriate during prior years as the related research and development was not yet complete nor had it been abandoned. During the year ended June 30, 2020, the Company decided to abandon the development of one of its in-process research and development intangible assets, and as a result the Company recognized a charge of \$17.7 million, which is reflected in Goodwill and long-lived asset impairment charges in the Consolidated Statements of Operations. The Company concluded there was no impairment of long-lived assets for the year ended December 31, 2021, the transition period ended December 31, 2020, or for the year ended June 30, 2019.

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

At December 31, 2021:	Gross Carrying Amount	Accumulated Amortization	Net
Purchased licenses and technologies	\$ 616.6	\$ (212.5)	\$ 404.1
Total intangible assets	<u>\$ 616.6</u>	<u>\$ (212.5)</u>	<u>\$ 404.1</u>

At December 31, 2020:	Gross Carrying Amount	Accumulated Amortization	Net
Purchased licenses and technologies	\$ 818.2	\$ (248.2)	\$ 570.0
Customer relationships	4.7	(4.5)	0.2
Trademarks	3.0	(1.5)	1.5
Total amortizable intangible assets	<u>825.9</u>	<u>(254.2)</u>	<u>571.7</u>
In-process research and development	4.8	—	4.8
Total unamortized intangible assets	<u>4.8</u>	<u>—</u>	<u>4.8</u>
Total intangible assets	<u>\$ 830.7</u>	<u>\$ (254.2)</u>	<u>\$ 576.5</u>

As of December 31, 2021 the weighted average remaining amortization period for purchased licenses and technologies is approximately 10 years.

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

<i>(in millions)</i>	<u>Year Ended December 31,</u>	<u>Six-month Transition Period Ended December 31,</u>	<u>Years Ended June 30,</u>	
	2021	2020	2020	2019
Amortization of intangible assets	\$ 50.7	\$ 30.8	\$ 61.0	\$ 59.3

Future amortization expense of intangible assets as of December 31, 2021 is estimated to be as follows (in millions):

Years Ended December 31,	Amortization Expense
2022	\$ 40.8
2023	40.8
2024	40.8
2025	40.8
2026	40.8
Thereafter	200.1
Total	<u>\$ 404.1</u>

6. ACCRUED LIABILITIES

<i>(in millions)</i>	<u>December 31,</u>	
	2021	2020
Employee compensation and benefits	\$ 52.8	\$ 48.9
Legal charges pending settlement	62.0	—
Accrued taxes payable	4.0	4.3
Refunds payable and reserves	9.8	9.3
Short-term contingent consideration	3.2	3.4
Accrued royalties	5.4	3.8
Other accrued liabilities	19.3	9.4
Total accrued liabilities	<u>\$ 156.5</u>	<u>\$ 79.1</u>

7. LONG-TERM DEBT

On December 23, 2016, the Company entered into a senior secured revolving credit facility (the "Facility") as borrower, with the lenders from time to time party thereto. On July 31, 2018, the Company entered into Amendment No. 1 to the Facility, which effected an "amend and extend" transaction with respect to the Facility by which the maturity date thereof was extended to July 31, 2023 and the maximum aggregate principal commitment was increased from \$300.0 million to \$350.0 million. On May 1, 2020, the Company entered into Amendment No. 2 to the Amended Facility, which waived the Company's compliance with certain covenants and modified the interest rate and other terms during the modification period from March 31, 2020 through June 30, 2021 ("Modification Period"). On February 22, 2021, the Company entered into Amendment No. 3 (the "Amended Facility"), which, among other things, decreased the maximum aggregate principal commitment from \$350.0 million to \$300.0 million, with a further reduction in the maximum aggregate principal commitment from \$300.0 million to \$250.0 million by September 30, 2021 (if not previously reduced to such amount in connection with certain specified asset sales), waived the Company's compliance with certain financial covenants through the quarter ended March 31, 2022, extended the Modification Period for an additional year through June 30, 2022, and revised certain negative covenants in connection with the extension. The amendments were accounted for as modifications pursuant to guidance in ASC 470-50, Debt. The Company's maximum aggregate principal commitment on its Amended Facility is \$250.0 million as of December 31, 2021.

The Amended Facility contains customary loan terms, interest rates, representations and warranties, affirmative and negative covenants, in each case, subject to customary limitations, exceptions and exclusions. The Amended Facility also contains certain customary events of default. Amendment No. 2 modified the Amended Facility to increase the interest rate to be fixed at a spread of LIBOR plus 350 basis points on drawn balances and the undrawn fee was increased to 50 basis points during the Modification Period. At the end of the Modification Period, interest rates return to the previous pricing based on a spread of LIBOR 150-250 basis points on drawn balances and an undrawn fee ranging from 25 to 45 basis points, in each case, based on the Company's leverage ratio. The LIBOR floor was also increased to 1.0% during the Modification Period.

Covenants in the Amended Facility impose operating and financial restrictions on the Company. These restrictions may prohibit or place limitations on, among other things, the Company's ability to incur additional indebtedness, create certain types of liens, and complete mergers, consolidations, or change in control transactions. The Amended Facility may also prohibit or place limitations on the Company's ability to sell assets, pay dividends or provide other distributions to stockholders. Beginning with the quarter ended June 30, 2022, the Company must maintain specified leverage and interest ratios measured as of the end of each quarter as a financial covenant in the Amended Facility. Amendment No. 2 modified the Amended Facility's compliance with the leverage covenant and the interest coverage ratio covenant, which were waived through March 31, 2021. Amendment No. 2 also revised certain negative covenants of the Amended Facility during the Modification Period. Amendment No. 3 waived compliance with the leverage ratio and the interest coverage ratio covenants through the quarter ended March 31, 2022 and also lowered the minimum liquidity covenant, which was added by Amendment No. 2, to \$150.0 million, and made it applicable through such quarter. Amendment No. 3 restricted the Company from borrowing under the Amended Facility if unrestricted cash and cash equivalents exceed \$150.0 million, unless such borrowings are in connection with permitted acquisitions. The Company was in compliance with all applicable financial covenants at December 31, 2021.

During the year ended December 31, 2021, the Company made principal repayments totaling \$226.4 million on the Amended Facility, including a voluntary principal payment on July 30, 2021 of \$106.4 million to pay off the remaining outstanding balances on the Amended Facility. As a result, the Company had no outstanding balances under the Amended Facility as of December 31, 2021. As of December 31, 2020, the Company had a long-term debt balance of \$224.8 million.

8. OTHER LONG-TERM LIABILITIES

<i>(in millions)</i>	December 31,	
	2021	2020
Contingent consideration	\$ 5.4	\$ 7.4
Other	0.2	7.3
Total other long-term liabilities	<u>\$ 5.6</u>	<u>\$ 14.7</u>

The Company's balance of other long-term liabilities as of December 31, 2021 consists primarily of the long-term portion of contingent consideration related to the Sividon acquisition. During the prior periods the Company's portion of social security taxes that had been deferred under the Coronavirus Aid, Relief and Economic Security Act ("CARES Act") that do not have to be deposited until December 2022 were also recorded as other long-term liabilities. As of December 31, 2021 that balance has been reclassified to a current liability as it will be deposited within the next year.

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 preferred shares outstanding at December 31, 2021 and December 31, 2020.

The Company is authorized to issue up to 150.0 million shares of common stock, par value \$0.01 per share. There were 80.0 million and 75.4 million shares issued and outstanding at December 31, 2021 and 2020, respectively.

Common shares issued and outstanding

(in millions)	Year Ended December 31,	Six-month Transition Period Ended December 31,	Years Ended June 30,	
	2021	2020	2020	2019
Beginning common stock issued and outstanding	75.4	74.7	73.5	70.6
Common stock issued upon exercise of options and employee stock plans	4.6	0.7	1.2	4.5
Repurchase and retirement of common stock	—	—	—	(1.6)
Ending common stock issued and outstanding	80.0	75.4	74.7	73.5

Stock Repurchase Program

In June 2016, the Company's Board of Directors authorized a share repurchase program of \$200.0 million of the Company's outstanding common stock. The Company may repurchase its common stock from time to time or on an accelerated basis through open market transactions or privately negotiated transactions as determined by the Company's management. The amount and timing of stock repurchases under the program will depend on business and market conditions, stock price, trading restrictions, acquisition activity and other factors. As of December 31, 2021, the Company has \$110.7 million remaining on its current share repurchase authorization.

The Company uses the par value method of accounting for its stock repurchases. As a result of the stock repurchases, the Company reduced common stock and additional paid-in capital and recorded charges to Retained earnings (accumulated deficit). During the year ended June 30, 2019, the Company used \$50.0 million to repurchase shares of the Company's common stock as part of an accelerated share repurchase. The shares retired, aggregate common stock and additional paid-in capital reductions, and related charges to Retained earnings (accumulated deficit) for the repurchases for periods ended December 31, 2021, December 31, 2020, June 30, 2020, and June 30, 2019 were as follows:

(in millions)	Year Ended December 31,	Six-month Transition Period Ended December 31,	Years Ended June 30,	
	2021	2020	2020	2019
Shares purchased and retired	—	—	—	1.6
Common stock and additional paid-in-capital reductions	\$ —	\$ —	\$ —	\$ 16.9
Charges to retained earnings	\$ —	\$ —	\$ —	\$ 33.1

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, to make grants of restricted and unrestricted stock and stock unit awards to employees, consultants and directors. Stockholders have approved amendments to the 2017 Plan increasing the shares available to grant under the 2017 Plan. The 2017 Plan allows for issuance of up to 4.6 million shares of common stock, with 3.6 million shares available for grant as of December 31, 2021. 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. To the extent that awards outstanding under the Company's prior equity plans expire or are cancelled without delivery of shares of common stock, they will also be available for issuance pursuant to the 2017 Plan.

The number of shares, terms, and vesting periods are determined by the Company's Board of Directors or a committee thereof on an award-by-award basis. RSUs granted to employees generally vest ratably over four years either on the anniversary of the date on which the RSUs were granted or during the month in which the anniversary occurs. The number of RSUs awarded to certain employees may be increased or reduced based on certain additional performance metrics. Options and RSUs granted to our 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 generally vest ratably over service periods of four years. Options granted generally expire ten years from the date of grant. Options granted to the Company's President and Chief Executive Officer as an inducement to his employment expire seven years from the grant date.

The number of RSUs awarded to certain executive officers and other senior positions that ultimately vest may be increased or reduced based on certain additional performance and market conditions. The performance and market conditions associated with awards granted during the year ended December 31, 2021 include vesting that is based 50% on achieving certain levels of earnings per share targets, and 50% based on achieving certain performance targets compared to the performance of the Nasdaq Health Care Index. The Company estimates the likelihood of achievement of performance conditions at the end of each period. During the transition period ended December 31, 2020, the Company granted stock-based awards to the Company's President and Chief Executive Officer as an inducement material to his commencement of employment and entry into an employment agreement with the Company. The inducement awards are included in the tables presented below.

Stock Options

A summary of option activity under the Company's equity plans, including the Company's inducement awards, is as follows for the year ended December 31, 2021:

<i>(number of shares in millions)</i>	Number of shares	Weighted average exercise price	Weighted average remaining contractual life (years)
Options outstanding at beginning of period	5.2	\$ 23.24	
Options granted	—	—	
Less:			
Options exercised	(3.7)	24.26	
Options canceled or expired	(0.1)	25.18	
Options outstanding at end of period	<u>1.4</u>	20.36	3.08
Options exercisable at end of period	<u>1.0</u>	23.07	2.09
Options vested and expected to vest	1.4	20.36	3.08

There were no options granted during the years ended December 31, 2021, June 30, 2020, and June 30, 2019. During the transition period ended December 31, 2020, 0.7 million options were granted to the Company's President and Chief Executive Officer, with a weighted average grant fair value of \$13.38.

The following table summarizes information about stock options outstanding at December 31, 2021 (number of shares in millions):

Range of exercise prices	Options outstanding		
	Number outstanding at December 31, 2021	Weighted average remaining contractual life (years)	Weighted average exercise price
\$13.38	0.7	5.62	\$ 13.38
\$23.98	0.1	0.18	23.98
\$27.07 - 36.55	0.6	0.74	27.25
	<u>1.4</u>	3.08	\$ 20.38

Restricted Stock Units

A summary of the RSU activity under the Company's equity plans, including the Company's inducement awards and RSU awards with performance metrics, is as follows for the year ended December 31, 2021:

	2021	
	Number of shares	Weighted average grant date fair value
<i>(number of shares in millions)</i>		
RSUs unvested and outstanding at beginning of period	3.2	\$ 20.56
RSUs granted	1.8	29.83
Less:		
RSUs vested	(1.1)	21.32
RSUs canceled	(0.8)	24.48
RSUs unvested and outstanding at end of period	3.1	\$ 24.96

The weighted average grant-date fair value of restricted stock units granted during the year ended December 31, 2021, the transition period ended December 31, 2020, and the years ended June 30, 2020, and June 30, 2019 was \$29.83, \$13.69, \$27.96 and \$46.62, respectively.

The fair value of restricted stock units that vested during the year ended December 31, 2021, the transition period ended December 31, 2020, and the years ended June 30, 2020, and June 30, 2019 was \$22.6 million, \$29.1 million, \$32.4 million and \$27.6 million, respectively.

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

	Year Ended	Six-month	Years Ended June 30,	
	December 31,	Transition Period	2020	2019
<i>(in millions)</i>	2021	Ended December 31,	2020	2019
		2020		
Cost of molecular diagnostic testing	\$ 1.5	\$ 0.6	\$ 1.2	\$ 0.8
Cost of pharmaceutical and clinical services	0.1	0.1	0.3	0.2
Research and development expense	4.2	2.4	5.0	5.4
Selling, general, and administrative expense	30.5	11.8	18.7	27.1
Total stock-based compensation expense	\$ 36.3	\$ 14.9	\$ 25.2	\$ 33.5

As of December 31, 2021, there was \$61.7 million of total unrecognized stock-based compensation expense that will be recognized over a weighted-average period of 2.3 years. We expect all unvested awards to vest, and we recognize 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:

	As of
	December 31, 2021
<i>(in millions)</i>	
Aggregate intrinsic value of options outstanding	\$ 10.2
Aggregate intrinsic value of options fully vested	4.6
Aggregate intrinsic value of RSUs outstanding	86.3

The total intrinsic value of options exercised was as follows:

<i>(in millions)</i>	Year Ended December 31,	Six-month Transition Period Ended December 31,	Years Ended June 30,	
	2021	2020	2020	2019
Total intrinsic value of options exercised	\$ 29.2	\$ 0.5	\$ 8.8	\$ 0.4

Employee Stock Purchase Plan

The Company also has an Employee Stock Purchase Plan that was approved by stockholders in 2012 (the "2012 Purchase Plan"), under which 2.0 million shares of common stock have been authorized. On September 23, 2021, the Board of Directors of the Company approved an amended and restated 2012 Employee Stock Purchase Plan, which authorizes an additional 2.0 million shares of common stock and extends the term of the 2012 Purchase Plan to November 30, 2032, subject in each case to obtaining stockholder approval. The amended and restated 2012 Employee Stock Purchase Plan also amended certain provisions of the 2012 Purchase Plan effective upon approval by the Board of Directors, including expanding the definition of "offering period" to provide that the Board of Directors may determine the period in accordance with the terms of the plan, and capping the number of shares that may be purchased by any participant during an offering period at 5,000 shares. Shares are issued under the 2012 Purchase Plan twice yearly at the end of each offering period. At December 31, 2021, a total of approximately 2.0 million shares of common stock had been purchased under the 2012 Purchase Plan. Shares purchased under and compensation expense associated with the 2012 Purchase Plan for the years reported are as follows:

<i>(in millions)</i>	Year Ended December 31,	Six-month Transition Period Ended December 31,	Years Ended June 30,	
	2021	2020	2020	2019
Shares purchased under the plans	0.2	0.1	0.3	0.2
Plan compensation expense	\$ 1.5	\$ 0.6	\$ 1.7	\$ 1.0

The fair value of shares issued under the Plan that was in effect for each period reported was calculated using the Black-Scholes option-pricing model using the following weighted-average assumptions:

	Year Ended December 31,	Six-month Transition Period Ended December 31,	Years Ended June 30,	
	2021	2020	2020	2019
Risk-free interest rate	0.1%	0.2%	1.8%	2.1%
Expected dividend yield	—%	—%	—%	—%
Expected life (in years)	0.5	0.5	0.5	0.5
Expected volatility	60%	94%	99%	55%

11. INCOME TAXES

Income tax benefit consists of the following:

<i>(in millions)</i>	Year Ended December 31,	Six-month Transition Period Ended December 31,	Years Ended June 30,	
	2021	2020	2020	2019
Current:				
Federal	\$ (1.9)	\$ (75.8)	\$ 26.6	\$ (24.2)
State	3.6	(0.6)	4.9	(0.1)
Foreign	0.1	0.2	0.5	0.2
Total current	<u>1.8</u>	<u>(76.2)</u>	<u>32.0</u>	<u>(24.1)</u>
Deferred:				
Federal	(33.7)	39.1	(51.5)	17.8
State	5.1	(3.4)	(4.1)	1.7
Foreign	0.1	(0.5)	(3.6)	0.4
Change in valuation allowance	(3.2)	—	3.5	(0.2)
Total deferred	<u>(31.7)</u>	<u>35.2</u>	<u>(55.7)</u>	<u>19.7</u>
Total income tax benefit	<u>\$ (29.9)</u>	<u>\$ (41.0)</u>	<u>\$ (23.7)</u>	<u>\$ (4.4)</u>

Income (loss) before income taxes consists of the following:

<i>(in millions)</i>	Year Ended December 31,	Six-month Transition Period Ended December 31,	Years Ended June 30,	
	2021	2020	2020	2019
United States	\$ (53.8)	\$ (101.8)	\$ (240.9)	\$ (0.6)
Foreign	(3.3)	7.7	17.6	0.6
Total	<u>\$ (57.1)</u>	<u>\$ (94.1)</u>	<u>\$ (223.3)</u>	<u>\$ —</u>

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:

(in millions)	Year Ended December 31,		Six-month Transition Period Ended December 31,		Years Ended June 30,			
	2021		2020		2020		2019	
Federal income tax expense at the statutory rate	\$ (12.0)	21.0 %	\$ (19.8)	21.0 %	\$ (46.9)	21.0 %	\$ —	21.0 %
State income taxes, net of federal benefit	(1.8)	3.2 %	(1.2)	1.3 %	4.0	(1.8)%	2.0	6,422.1 %
Research and development credits	2.5	(4.4)%	(1.3)	1.4 %	(2.8)	1.3 %	(3.7)	(11,880.9)%
Uncertain tax positions	(3.0)	5.3 %	0.6	(0.7)%	1.5	(0.7)%	(4.2)	(13,486.4)%
Incentive stock option and employee stock purchase plan expense	0.7	(1.2)%	2.5	(2.7)%	(0.2)	0.1 %	(3.1)	(9,954.3)%
Foreign rate differential	0.5	(0.9)%	(2.1)	2.2 %	0.7	(0.3)%	0.8	2,568.8 %
Change in valuation allowance	(3.2)	5.6 %	(0.3)	0.3 %	3.5	(1.7)%	(0.2)	(642.2)%
CARES Act	2.7	(4.7)%	(20.7)	22.0 %	—	— %	—	— %
Non-deductible meals and entertainment	0.1	(0.2)%	0.5	(0.5)%	1.8	(0.8)%	1.3	4,174.4 %
Non-deductible officer compensation	3.3	(5.8)%	0.1	(0.1)%	1.6	(0.7)%	0.6	1,926.6 %
Asset impairment	—	— %	—	— %	12.6	(5.6)%	—	— %
Non-deductible legal settlement	2.5	(4.5)%	—	— %	—	— %	1.9	6,101.0 %
Acquisitions, Dispositions, and Contingent Consideration	(23.0)	40.3 %	0.7	(0.7)%	(0.3)	0.1 %	0.8	2,568.8 %
Method changes or tax elections	—	— %	—	— %	—	— %	(0.9)	(2,890.0)%
Other, net	0.8	(1.4)%	—	— %	0.8	(0.3)%	0.3	963.4 %
Total income tax benefit	<u>\$ (29.9)</u>	52.3 %	<u>\$ (41.0)</u>	43.5 %	<u>\$ (23.7)</u>	10.6 %	<u>\$ (4.4)</u>	-14,107.7 %

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

(in millions)	December 31,	
	2021	2020
Deferred tax assets:		
Net operating loss carryforwards	\$ 67.2	\$ 72.2
Deferred revenue	1.2	7.2
Stock compensation expense	4.5	11.5
Research and development credits	17.3	24.9
Lease right-of-use asset	22.4	15.2
Accrued expenses and liabilities	14.2	7.6
Other, net	4.5	6.4
Total gross deferred tax assets	131.3	145.0
Less valuation allowance	(38.5)	(42.0)
Total deferred tax assets	92.8	103.0
Deferred tax liabilities:		
Intangible assets	104.9	144.0
Lease liability	20.2	14.6
Property, plant and equipment	3.5	15.7
Total deferred tax liabilities	128.6	174.3
Net deferred tax liability	\$ (35.8)	\$ (71.3)

The CARES Act in 2020 made various tax law changes, including among other things (i) increased the limitation under IRC Section 163(j) for 2019 and 2020 to permit additional expensing of interest, (ii) enacted technical corrections so that qualified improvement property can be immediately expensed under IRC Section 168(k) and net operating losses arising in fiscal tax years beginning before January 1, 2018 and ending after December 31, 2017 can be carried back two years and carried forward twenty years without a taxable income limitation as opposed to carried forward indefinitely, and (iii) made modifications to the federal net operating loss rules including permitting federal net operating losses incurred in 2018, 2019, and 2020 to be carried back to the five preceding taxable years. As a result of the provision provided under the CARES Act, the Company was able to carry-back federal net operating losses to previous periods, resulting in a \$20.7 million tax benefit in the year ended December 31, 2020 and \$2.7 million tax expense in the year ended December 31, 2021.

The Company recognized the sale of Myriad RBM, Inc., Myriad myPath, LLC, and select assets of Crescendo Biosciences, LLC (formerly known as Crescendo Biosciences, Inc. ("CBI")) in the year ended December 31, 2021, which resulted in differences between book and tax treatments. This resulted in the recognition of a \$187.0 million capital loss for the tax basis in the stock of Crescendo, which the Company utilized in the current year due to the \$282.3 million overall capital gain from the three divestitures. Other consequences due to the dispositions were the removal of deferred tax assets and corresponding valuation allowances. The overall net tax benefit of the divestitures during the year ended December 31, 2021 was \$23.4 million.

As a result of the economic impact of COVID-19, the Company has incurred a cumulative three-year loss. Pursuant to ASC Topic 740, the negative evidence of a cumulative loss may be difficult to overcome. However, the Company will have significant future taxable income resulting from the reversal of taxable temporary differences. Primarily due to the availability of such expected future taxable income, the Company concluded that it is more likely than not that the benefits of the majority of its deferred income tax assets will be realized. However, for certain deferred tax assets a valuation allowance has been established, primarily due to limitations imposed by I.R.C. Section 382 and certain jurisdictional limitations. For the year ended December 31, 2021, the Company's valuation allowance decreased by \$3.5 million, primarily due to the expiration of Utah research credits upon which a valuation allowance had been established. The Company will continue to evaluate the impact that the COVID-19 pandemic may have on its results of operations and its ability to realize its deferred tax assets.

At December 31, 2021, 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	\$ 31.2	Yes	2036	2037
Federal capital loss	13.5	No	2026	2026
Utah net operating loss	2.4	No	2022	Indefinite
California net operating loss	3.9	Yes	2027	2042
Other state net operating loss	7.4	Yes	2027	2041
Foreign net operating losses (various jurisdictions)	8.8	No	Various	Various
Federal research credit	6.4	Yes	2027	2042
Utah research credit	6.9	No	2022	2036
California research credit	4.0	No	Indefinite	Indefinite

Consistent with the indefinite reversal criteria of ASC 740, the Company intends to continue to invest undistributed earnings of its foreign subsidiaries indefinitely. However, due to the cumulative losses that have been incurred to date in such foreign operations, the changes of the Tax Cuts and Jobs Act and the aforementioned 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, 2021, the Company had net unrecognized tax benefits of \$32.1 million. The Company's gross unrecognized tax benefits as of the year ended December 31, 2021, the transition period ended December 31, 2020 and the years ended June 30, 2020 and 2019, and the changes in those balances are as follows:

(in millions)	Year Ended December 31,	Six-month Transition Period Ended December 31,	Years Ended June 30,	
	2021	2020	2020	2019
Unrecognized tax benefits at the beginning of period	\$ 37.6	\$ 23.5	\$ 21.7	\$ 24.9
Gross increases - current year tax positions	1.4	13.9	1.6	2.2
Gross increases - prior year tax positions	1.1	1.0	0.7	0.5
Gross increases - acquisitions	—	—	—	2.3
Gross decreases - prior year tax positions	(2.8)	(0.1)	—	(0.1)
Gross decreases - settlements	(5.1)	—	—	(2.7)
Gross decreases - statute lapse	(0.1)	(0.7)	(0.5)	(5.4)
Unrecognized tax benefits at end of year	\$ 32.1	\$ 37.6	\$ 23.5	\$ 21.7
Interest and penalties in year-end balance	\$ 3.3	\$ 2.2	\$ 1.4	\$ 0.8

Interest and penalties related to uncertain tax positions are included as a component of income tax expense and all other interest and penalties are included as a component of other income (expense).

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 the state of California for years ended June 30, 2017-2018; the State of New Jersey for the years ended June 30, 2013-2017; and Switzerland for the years ended June 30, 2015-2016. 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 subject to various claims and legal proceedings covering matters that arise in the ordinary course of its business activities, including the matters described below. Estimates for resolution of legal and other contingencies are accrued when losses are probable and reasonable estimable in accordance with ASC 450, *Contingencies*.

Qui Tam Lawsuit

In June 2016, our wholly-owned subsidiary, 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. The Office of Inspector General subsequently requested additional documentation in December 2017. CBI provided to the Office of Inspector General the documents requested. On January 30, 2020, the United States District Court for the Northern District of California unsealed a qui tam complaint, filed on April 16, 2016 against CBI and the Company, alleging violations of the Federal and California False Claims Acts and the California Insurance Fraud Prevention Act. 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. The Company was not aware of the complaint until after it was unsealed. On May 23, 2020, the court denied CBI and the Company's motion to dismiss. We have accrued \$48.0 million for a potential settlement of this qui tam lawsuit against CBI and the Company, which is included in Accrued liabilities in the Company's Consolidated Balance Sheet. If no settlement is reached, we intend to continue to vigorously defend against this case, but we cannot predict with any degree of certainty the ultimate resolution of this matter or determine whether, or to what extent, any loss with respect to this matter may exceed the amount that we have accrued.

Securities Class Action

On September 27, 2019, a class action complaint was filed in the United States District Court for the District of Utah, against the Company, our former President and Chief Executive Officer, Mark C. Capone, and our Chief Financial Officer, R. Bryan Riggsbee ("Defendants"). On February 21, 2020, the plaintiff filed an amended class action complaint, which added our 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 our business, operations, and acquisitions. The lead plaintiff seeks the payment of damages allegedly sustained by it and the purported 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 United States District Court for the District of Utah denied the Company's motion to dismiss. On December 1, 2021, the United States District Court for the District of Utah granted plaintiff's motion for class certification. We intend to vigorously defend against this action. Due to the nature of this matter and inherent uncertainties, it is not possible to provide an evaluation of the likelihood of an unfavorable outcome or an estimate of the amount or range of potential loss, if any.

Stockholder Derivative Actions

On August 9, 2021, a stockholder derivative complaint was filed in the Delaware Court of Chancery against our former President and Chief Executive Officer, Mark C. Capone, our Chief Financial Officer, R. Bryan Riggsbee, our former Executive Vice President of Clinical Development, Bryan M. Dechairo, and certain of our 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 our 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. We intend to vigorously defend against this action. Due to the nature of this matter and inherent uncertainties, it is not possible to provide an evaluation of the likelihood of an unfavorable outcome or an estimate of the amount or range of potential loss, if any.

On September 17, 2021, a second stockholder derivative complaint was filed in the United States 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 United States District Court for the District of Delaware pending the resolution of the securities class action lawsuit. We intend to vigorously defend against this action. Due to the nature of this matter and inherent uncertainties, it is not possible to provide an evaluation of the likelihood of an unfavorable outcome or an estimate of the amount or range of potential loss, if any.

On January 18, 2022, a third 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 and Marcey stockholder derivative actions. 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. We intend to vigorously defend against this action. Due to the nature of this matter and inherent uncertainties, it is not possible to provide an evaluation of the likelihood of an unfavorable outcome or an estimate of the amount or range of potential loss, if any.

Other Legal Proceedings

On July 27, 2020, a lawsuit was filed against the Company in the Superior Court of Suffolk County, Massachusetts, by Heide Abelli and Victor Pricolo. The plaintiffs claimed negligence, breach of contract and associated torts in connection with an alleged error in testing performed by the Company in 2004. The plaintiffs sought damages allegedly sustained by them by reason of the allegations set forth in their complaint, together with interest and costs. As of December 31, 2021, we accrued \$14.0 million for a potential settlement of this lawsuit, which is included in Accrued liabilities in the Company's Consolidated Balance Sheet as of December 31, 2021. On January 24, 2022, the Company entered into an agreement with the plaintiffs to settle the lawsuit. Pursuant to the terms of the settlement agreement, the Company agreed to pay \$14.0 million to the plaintiffs. The settlement agreement also provides for a full release by the plaintiffs of all claims against the Company and contains no admission of liability, wrongdoing or responsibility on the part of the Company.

On February 3, 2022, a purported class action lawsuit was filed against the Company in the United States District Court in the Northern District of California by Ashley Carroll. Plaintiff alleges, among other things, that the Company made false statements about the accuracy of its Prequel prenatal screening test. The complaint seeks unspecified monetary damages and injunctive relief. We intend to vigorously defend against this action. Due to the nature of this matter and inherent uncertainties, it is not possible to provide an evaluation of the likelihood of an unfavorable outcome or an estimate of the amount or range of potential loss, if any.

As of December 31, 2021, the management of the Company believes any reasonably possible liability that may result from the resolution of any other matters will not have a material adverse effect on the Company's consolidated financial position, operating results, or cash flows. However, it is possible that the ultimate resolution of other matters, if unfavorable, may be material to the results of operations or financial condition for a particular period.

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 one to fourteen 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 or indefinite period of time. These optional periods have not been considered in the determination of the right-of-use-assets or lease liabilities associated with these leases as the Company did not consider it reasonably certain it would exercise the options.

On July 1, 2019, the Company adopted ASU 2016-02 under the modified retrospective approach by initially applying ASU 2016-02 at the adoption date, rather than at the beginning of the earliest comparative period presented. Results for the year ended December 31, 2021, the six-month transition period ended December 31, 2020 and the year ended June 30, 2020 are presented under ASU 2016-02. Prior period amounts were not adjusted and continue to be reported under previous lease accounting guidance. As part of the adoption, the Company elected the package of practical expedients to avoid reassessing prior conclusions about lease identification, lease classification and initial direct costs. The Company also elected the practical expedient allowing the use of hindsight in determining the lease term and assessing impairment of right-of-use assets based on all facts and circumstances through the effective date of the new standard. The Company has elected the recognition exemption for short-term leases for all leases that qualify. Under this exemption, the Company will not recognize right-of-use assets or lease liabilities for those leases that qualify as a short-term lease (leases with lease terms of 12 months or less), which includes not recognizing right-of-use assets or lease liabilities for existing short-term leases in transition. The Company also has elected the practical expedient to avoid separating lease and non-lease components for any of its leases within its existing classes of assets. We recognize each new lease within right-of-use assets and lease liabilities once the lease commences.

The Company performed evaluations of its contracts and determined each of its identified leases are operating leases. For the year ended December 31, 2021, the Company incurred \$20.7 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 right-of-use 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 transition period ended December 31, 2020, the Company incurred \$9.9 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, \$1.8 million was variable lease expense and \$0.1 million was short-term lease expense, neither of which were included in the measurement of the Company's operating right-of-use assets and lease liabilities. For the year ended June 30, 2020, the Company incurred \$18.4 million in lease costs, of which \$2.6 million was variable lease expense and \$0.2 million was short-term lease expense. Prior to the adoption of the lease guidance in ASU 2016-02, the Company's total rent expense for the year ended June 30, 2019 was \$19.7 million.

In December 2021, the Company entered into a non-cancelable operating lease for approximately 63,000 square feet in South San Francisco, California, which will expire in 2033. The lease will commence in April 2023.

As of December 31, 2021, the maturities of the Company's operating lease liabilities were as follows (in millions):

Year Ended:	
2022	\$ 17.4
2023	19.8
2024	22.4
2025	16.6
2026	14.7
Thereafter	88.1
Total future lease payments	179.0
Less: amounts representing interest	(27.9)
Present value of future lease payments	151.1
Less: leases not yet commenced	(58.8)
Less: current maturities of operating lease liabilities	(13.0)
Noncurrent operating lease liabilities	\$ 79.3

As of December 31, 2021, the weighted average remaining lease term is 8.7 years and the weighted average discount rate used to determine the operating lease liability was 5.10%.

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:

<i>(in millions)</i>	Year Ended December 31,	Six-month Transition Period Ended December 31,	Years Ended June 30,	
	2021	2020	2020	2019
Deferred savings plan contributions	\$ 8.4	\$ 4.0	\$ 7.1	\$ 8.3

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. On July 1, 2021, the Company completed the divestiture of Myriad RBM, Inc., and, as a result, now operates a single reporting segment. Prior to the sale, the Myriad RBM, Inc. operating segment was included in the Company's previously reported other segment. The Company's remaining operating segments have been aggregated into a single reporting segment, which primarily provides testing and collaborative development of testing that is designed to assess an individual's risk for developing disease later in life, identify a patient's likelihood of responding to drug therapy and guide a patient's dosing to ensure optimal treatment, or assess a patient's risk of disease progression, and includes corporate services such as finance, human resources, legal and information technology. Segment information is consistent with how management reviews the business, makes investing and resource allocation decisions and assesses operating performance. The CODM evaluates segment performance based on operating income (loss).

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

<i>(in millions)</i>	December 31,	
	2021	2020
<i>Net equipment, leasehold improvements and property:</i>		
United States	\$ 41.7	\$ 38.4
Rest of world	1.9	2.3
Total	\$ 43.6	\$ 40.7
<i>Total assets:</i>		
United States	\$ 870.8	\$ 1,190.3
Rest of world	51.1	56.8
Total	\$ 921.9	\$ 1,247.1
Cash, cash equivalents, and marketable investment securities	398.8	171.7
Total	\$ 1,320.7	\$ 1,418.8

16. 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) on the Company's 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) on the Company's 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) on the Company's 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 Company's Consolidated Statements of Operations for the year ended December, 2021.

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

<i>(in millions)</i>	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	<u>\$ 139.3</u>

17. BUSINESS ACQUISITIONS

Counsyl

On July 31, 2018, the Company completed the acquisition of Counsyl, Inc. ("Counsyl"), a leading provider of genetic testing and DNA analysis services, pursuant to the Agreement and Plan of Merger (the "Merger Agreement"), dated May 25, 2018 for total consideration of \$405.9 million. Pursuant to the terms of the Merger Agreement, Myriad Merger Sub, Inc., a newly created wholly-owned subsidiary of the Company, was merged with and into Counsyl, with Counsyl continuing as the surviving corporation and a wholly-owned subsidiary of Myriad.

To complete the purchase transaction, the Company incurred approximately \$6.8 million of acquisition costs, which are recorded as selling, general and administrative expenses in the period incurred. For the year ended June 30, 2019, Counsyl contributed revenue of approximately \$104.9 million. For the year ended June 30, 2019, operating expenses related to Counsyl were approximately \$67.6 million.

18. SUBSEQUENT EVENT

In the first quarter of 2022, the Company entered into a non-cancelable operating lease for approximately 230,000 square feet in Salt Lake City, Utah, which will commence in 2022, with a lease term of 15 years and total future lease payments of approximately \$77.8 million.

19. SUPPLEMENTAL CASH FLOW INFORMATION

<i>(in millions)</i>	Year Ended December 31,		Six-month Transition Period Ended December 31,		Years Ended June 30,			
	2021		2020		2020	2019		
Cash paid for income taxes	\$	4.6	\$	1.8	\$	1.0	\$	6.5
Cash paid for interest		4.4		5.2		9.5		11.6
Cash received for income tax receivables		90.0		—		—		—
Non-cash investing and financing activities:								
Establishment of operating lease right-of-use assets and lease liabilities								
Operating lease right-of-use assets	\$	41.8	\$	—	\$	74.5	\$	—
Operating lease liabilities		(48.1)		—		(78.8)		—
Accrued liabilities and other long-term liabilities		—		—		4.3		—

20. TRANSITION PERIOD COMPARATIVE DATA (UNAUDITED)

<i>(in millions)</i>	Year Ended		Six-month	
Consolidated Statement of Operations Data:	December 31, 2020		Period Ended December 31, 2019	
Molecular diagnostic testing	\$	513.5	\$	353.1
Pharmaceutical and clinical services		43.6		28.3
Total revenue		557.1		381.4
Costs and expenses:				
Cost of molecular diagnostic testing		157.9		82.2
Cost of pharmaceutical and clinical services		20.3		17.1
Research and development expense		73.3		40.1
Selling, general and administrative expense		496.9		270.4
Goodwill and long-lived asset impairment charges		98.4		1.3
Total costs and expenses		846.8		411.1
Operating loss		(289.7)		(29.7)
Other income (expense):				
Interest income		2.0		1.7
Interest expense		(11.2)		(5.4)
Other		15.3		(0.3)
Total other income (expense)		6.1		(4.0)
Loss before income taxes		(283.6)		(33.7)
Income tax benefit		(59.9)		(4.8)
Net loss		(223.7)		(28.9)
Net loss attributable to non-controlling interest		(0.1)		—
Net loss attributable to Myriad Genetics Inc. stockholders	\$	(223.6)	\$	(28.9)
Loss per share:				
Basic	\$	(2.99)	\$	(0.39)
Diluted	\$	(2.99)	\$	(0.39)
Weighted average shares outstanding:				
Basic		74.8		74.1
Diluted		74.8		74.1

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, 2021, our Disclosure Controls were not effective due to material weaknesses in the Company's internal control over financial reporting as disclosed below.

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.

During the preparation of the condensed consolidated quarterly financial statements as of September 30, 2021, management concluded that a material weakness in internal control over financial reporting existed related to our income tax provision process. Specifically, we did not provide adequate review and control with respect to the completeness and accuracy of inputs used in the income tax provision and related accrual. While the control deficiency did not result in a misstatement of previously issued consolidated financial statements, the control deficiency could have resulted in a misstatement of the income tax related accounts or disclosures that would have resulted in a material misstatement of our consolidated financial statements that would not have been prevented or detected on a timely basis. This material weakness has not been remediated as of December 31, 2021.

Management also concluded that a material weakness in internal control over financial reporting exists related to general information technology controls for information systems that are relevant to the preparation of the financial statements. Specifically, the material weakness resulted from the aggregation of control deficiencies related to systems supporting the Company's internal control processes. Our IT-dependent business process controls were also deemed ineffective because they could have been adversely impacted. While the aggregation of these deficiencies did not result in any misstatement of the consolidated financial statements, the material weakness could have resulted in a misstatement impacting account balances or disclosures that would have resulted in a material misstatement to the consolidated financial statements that would not have been prevented or detected on a timely basis.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. 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 may deteriorate.

Management conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2021 using the criteria issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework (2013). Based on that evaluation, management believes that our internal control over financial reporting was not effective as of December 31, 2021.

The effectiveness of our internal control over financial reporting as of December 31, 2021, has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their report included elsewhere herein.

3. Plan to Remediate Material Weaknesses

Management is committed to the remediation of the material weaknesses described above, as well as the continued improvement of our internal control over financial reporting.

We have begun the process of, and we are focused on, designing and implementing effective internal control measures to improve our internal control over financial reporting and remediate the material weaknesses identified above. Our efforts include the following actions:

Discrete Tax Transactions

- We are continuing to take steps to design and implement enhanced controls over the review of information underlying discrete transactions in the income tax provision.

Information Technology General Controls ("ITGCs")

- We are implementing additional training to ensure a clear understanding of risk assessment, controls and monitoring activities related to automated processes and systems and ITGCs related to financial reporting.
- We are implementing improved IT policies, procedures and control activities for key systems which impact our financial reporting.
- We are increasing resources dedicated to monitoring ITGCs related to financial reporting, including additional personnel with the appropriate level of knowledge, experience and training, to ensure compliance with policies and procedures.

While these actions and planned actions are subject to ongoing management evaluation and will require validation and testing of the design and operating effectiveness of internal controls over a sustained period of financial reporting cycles, we are committed to the continuous improvement of our internal control over financial reporting and will continue to diligently review our internal control over financial reporting for that purpose.

4. Remediation of Previously Reported Material Weakness

The material weakness identified in our internal control over financial reporting in connection with the preparation of our Consolidated Financial Statements as of and for the transition period ended December 31, 2020 (the "prior material weakness") has been remediated. The prior material weakness identified related to the accounting for intercompany transactions, foreign currency exchanges and foreign currency translation related to our international subsidiaries. Specifically, as part of our financial statement close process, certain of our control activities were not sufficiently designed or operating effectively to ensure all of our policies were in compliance with generally accepted accounting principles, consistent in their application, retained in appropriate documentation and communicated to relevant parties. As a result of the prior material weakness, we recorded certain immaterial corrections to intercompany accounts, as well as foreign currency exchange and translation gains and losses, in our Consolidated Financial Statements for the transition period ended December 31, 2020.

We implemented control measures to improve our internal control over financial reporting and remediated the prior material weakness. We took the following actions to remediate the prior material weakness:

- We designed additional control and review procedures needed to provide more robust and comprehensive internal controls over financial reporting that address the risks of material misstatement related to the accounting for intercompany transactions, foreign currency exchanges and foreign currency translation within our business processes.
- We implemented additional application controls in our financial systems, implemented formal review procedures, and formally documented our newly designed processes for the identified areas.
- We subjected the additional controls implemented to testing and concluded that the controls are operating effectively.

5. Change in Internal Control over Financial Reporting

The Company has completed a multi-year transformation project to achieve better analytics and process efficiencies and other systematic and control improvements through the use of Oracle Fusion Cloud Services System. As of October 1, 2021, Oracle Cloud is now our primary accounting system.

Other than as described above, there were no changes in our internal control over financial reporting that occurred during the year ended December 31, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

6. 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, 2021, 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, because of the effect of the material weaknesses described below on the achievement of the objectives of the control criteria, Myriad Genetics, Inc. and subsidiaries (the Company) has not maintained effective internal control over financial reporting as of December 31, 2021, based on the COSO criteria.

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. The following material weaknesses have been identified and included in management's assessment. Management identified material weaknesses in controls over income taxes and information technology general controls.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of Myriad Genetics, Inc. and subsidiaries as of December 31, 2021 and 2020, and the related consolidated statements of operations, comprehensive income (loss), stockholders' equity and cash flows for the year ended December 31, 2021, the six month period ended December 31, 2020, and each of the two years in the period ended June 30, 2020, and the related notes. These material weaknesses were considered in determining the nature, timing and extent of audit tests applied in our audit of the 2021 consolidated financial statements, and this report does not affect our report dated February 25, 2022, which 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 25, 2022

Item 9B. OTHER INFORMATION

None.

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,” “Delinquent Section 16(a) Reports” and “Corporate Code of Conduct” in our Proxy Statement for the 2022 Annual Meeting of Stockholders to be held on June 2, 2022.

Item 11. EXECUTIVE COMPENSATION

The response to this item is incorporated by reference from the discussion responsive thereto under the captions “Executive Compensation,” “Management and Corporate Governance – Committees of the Board of Directors and Meetings – Compensation and Human Capital Committee Interlocks and Insider Participation,” “Compensation Committee Report” and “Management and Corporate Governance – Board’s Role in the Oversight of Risk Management” in our Proxy Statement for the 2022 Annual Meeting of Stockholders to be held on June 2, 2022.

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 “Executive Compensation - Equity Compensation Plan Information” in our Proxy Statement for the 2022 Annual Meeting of Stockholders to be held on June 2, 2022.

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 2022 Annual Meeting of Stockholders to be held on June 2, 2022.

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 2022 Annual Meeting of the Stockholders to be held on June 2, 2022.

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” at 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-K (Exhibit 3.1)	8/15/2011	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
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
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
10.4	.1 Lease Agreement, dated March 11, 2008, between the Registrant and Boyer Research Park Associates IX, by its general partner, The Boyer Company, L.C.		10-K (Exhibit 10.32)	8/28/2008	000-26642
	.2 Amendment to Lease Agreement, dated February 12, 2010 between the Registrant and Boyer Research Park Associates IX, L.C.		10-Q (Exhibit 10.4)	5/5/2010	000-26642

Exhibit Number	Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/Registration Number
10.5	Lease Agreement, dated January 31, 2019 between the Registrant and Boyer Research Park Associates X, L.C., by its Manager, The Boyer Company, L.C.		10-K (Exhibit 10.6)	8/13/2019	000-26642
Agreements with Executive Officers and Directors					
10.6	Non-Employee Director Compensation Policy+		10-KT (Exhibit 10.8)	3/16/2021	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	Separation and Consulting Agreement, dated February 7, 2022, by and between Myriad Genetics, Inc. and Jerry Lanchbury+		8-K (Exhibit 10.1)	2/9/2022	000-26642
Equity Compensation Plans					
10.16	2010 Employee, Director and Consultant Equity Incentive Plan, as amended+		8-K (Exhibit 10.1)	12/2/2016	000-26642
10.17	Form of Stock Option Agreement under the 2010 Equity Incentive Plan+		10-Q (Exhibit 10.3)	2/1/2011	000-26642
10.18	Form of Director Stock Option Agreement under the 2010 Equity Incentive Plan+		10-Q (Exhibit 10.4)	2/1/2011	000-26642

Exhibit Number	Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/Registration Number
10.19	2017 Employee, Director and Consultant Equity Incentive Plan, as amended+		8-K (Exhibit 10.1)	12/7/2020	000-26642
10.20	Form of Restricted Stock Unit Agreement under the 2017 Equity Incentive Plan+		10-K (Exhibit 10.11)	8/13/2020	000-26642
10.21	Amended and Restated 2012 Employee Stock Purchase Plan+		10-Q (Exhibit 10.1)	11/4/2021	000-26642
10.22	2013 Executive Incentive Plan, as amended+		8-K (Exhibit 10.2)	12/1/2017	000-26642
Credit Agreement					
10.23	Amendment No. 3, dated February 22, 2021, to the Credit Agreement, dated December 23, 2016, among the Company, the lenders from time to time party thereto, and JPMorgan Chase Bank, N.A., as administrative agent, as amended July 31, 2018 and May 1, 2020.		8-K (Exhibit 10.1)	2/23/2021	000-26642
Merger Agreements					
10.24	Agreement and Plan of Merger among the Registrant, Myriad Merger Sub, Inc., Assurex Health, Inc. and Fortis Advisors LLC, dated as of August 3, 2016.		10-Q (Exhibit 10.1)	11/2/2016	000-26642
10.25	Agreement and Plan of Merger among the Registrant, Cinnamon Merger Sub, Inc., a wholly owned subsidiary of Myriad, Inc., Counsyl, Inc. and Fortis Advisors, dated as of May 25, 2018.		10-K (Exhibit 10.18)	8/24/2018	000-26642
Other					
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			
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			

<u>Exhibit Number</u>	<u>Exhibit Description</u>	<u>Filed with this Report</u>	<u>Incorporated by Reference herein from Form or Schedule</u>	<u>Filing Date</u>	<u>SEC File/Registration Number</u>
101	The following materials from Myriad Genetics, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2021, formatted in XBRL (eXtensible Business Reporting Language): (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Comprehensive Income, (iii) Consolidated Statements of Stockholders' Equity, (iv) Consolidated Statements of Cash Flows, and (v) 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 25, 2022.

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 R. Bryan Riggsbee 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: <u>/s/ Paul J. Diaz</u> Paul J. Diaz	President, Chief Executive Officer and Director (Principal Executive Officer)	February 25, 2022
By: <u>/s/ R. Bryan Riggsbee</u> R. Bryan Riggsbee	Chief Financial Officer (Principal Financial and Accounting Officer)	February 25, 2022
By: <u>/s/ S. Louise Phanstiel</u> S. Louise Phanstiel	Chair of the Board	February 25, 2022
By: <u>/s/ Heiner Dreismann</u> Heiner Dreismann, Ph.D.	Director	February 25, 2022
By: <u>/s/ Rashmi Kumar</u> Rashmi Kumar	Director	February 25, 2022
By: <u>/s/ Dennis Langer</u> Dennis Langer, M.D., J.D.	Director	February 25, 2022
By: <u>/s/ Lee N. Newcomer</u> Lee N. Newcomer, M.D.	Director	February 25, 2022
By: <u>/s/ Colleen F. Reitan</u> Colleen F. Reitan	Director	February 25, 2022
By: <u>/s/ Daniel M. Skovronsky</u> Daniel M. Skovronsky, M.D., Ph.D.	Director	February 25, 2022
By: <u>/s/ Daniel K. Spiegelman</u> Daniel K. Spiegelman	Director	February 25, 2022

LIST OF SUBSIDIARIES OF MYRIAD GENETICS, INC.

Company Name

Jurisdiction of Incorporation

Company Name	Jurisdiction of Incorporation
Myriad Genetic Laboratories, Inc. ¹	Delaware
Assurex Health, Inc. ¹	Delaware
Crescendo Bioscience, LLC ²	Delaware
Myriad Women's Health, Inc. ¹	Delaware
Myriad GmbH ⁴	Germany
Myriad Services GmbH ³	Germany
Myriad Genetics Espana SL ¹	Spain
Myriad Genetics SAS ³	France
Myriad Genetics S.r.l. ¹	Italy
Myriad Genetics GmbH ³	Switzerland
Myriad Genetics LTD ³	United Kingdom
Myriad Genetics Canada Corp ³	Canada
Myriad Genetics B.V. ¹	Netherlands
Myriad Genetics Australia PTY LTD ³	Australia
Myriad International GmbH ⁴	Germany
Assurex Health, Ltd ⁵	Canada
Myriad Genetics GK ¹	Japan

1 – A wholly-owned subsidiary of Myriad Genetics, Inc., a Delaware corporation.

2 – Crescendo Bioscience, LLC is owned by Myriad Genetics, Inc. and Myriad Genetics GK.

3 – A wholly-owned subsidiary of Myriad Genetics B.V.

4 – A wholly-owned subsidiary of Myriad Services GmbH

5 – A majority owned subsidiary of Assurex Health, Inc.

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements of Myriad Genetics, Inc.:

1. Registration Statement on Form S-8 (File No. 333-245718) pertaining to the Myriad Genetics, Inc. Non-Qualified Stock Option Agreement, Performance-Based Non-Qualified Stock Option Agreement, Restricted Stock Unit Agreement, and Performance-Based Restricted Stock Unit Agreement
2. Registration Statement on Form S-8 (File No. 333-222913, File No. 333-229574, File No. 333-236324, File No. 333-254337) pertaining to the Myriad Genetics, Inc. 2017 Employee, Director and Consultant Equity Incentive Plan, as amended,
3. Registration Statement on Form S-8 (File No. 333-185325) pertaining to the Myriad Genetics, Inc. 2012 Employee Stock Purchase Plan,
4. Registration Statements on Form S-8 (File No.'s 333-171994, 333-179281, 333-185325, 333-193767, 333-209354 and 333-215959) pertaining to the Myriad Genetics, Inc. 2010 Employee, Director and Consultant Equity Incentive Plan, as amended, and
5. Registration Statements on Form S-8 (File No.'s 333-115409, 333-120398, 333-131653, 333-140830, 333-150792, 333-157130 and 333-164670) pertaining to the Myriad Genetics, Inc. 2003 Employee, Director and Consultant Stock Option Plan, as amended;

of our reports dated February 25, 2022 with respect to the consolidated financial statements of Myriad Genetics, Inc. and the effectiveness of internal control over financial reporting of Myriad Genetics, Inc. included in this Annual Report (Form 10-K) of Myriad Genetics, Inc. for the year ended December 31, 2021.

/s/ Ernst & Young LLP

Salt Lake City, UT

February 25, 2022

SARBANES-OXLEY SECTION 302 CERTIFICATION

I, Paul J. Diaz, certify that:

1. I have reviewed this annual report on Form 10-K of Myriad Genetics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
 - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 25, 2022

/s/ Paul J. Diaz

Paul J. Diaz

President and Chief Executive Officer

SARBANES-OXLEY SECTION 302 CERTIFICATION

I, R. Bryan Riggsbee, certify that:

1. I have reviewed this annual report on Form 10-K of Myriad Genetics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
 - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 25, 2022

/s/ R. Bryan Riggsbee

R. Bryan Riggsbee
Chief Financial Officer

Certification
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), each of the undersigned officers of Myriad Genetics, Inc., a Delaware corporation (the “Company”), does hereby certify, to such officer’s knowledge, that:

The Annual Report on Form 10-K for the year ended December 31, 2021 (the “Form 10-K”) of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 25, 2022

Date: February 25, 2022

/s/ Paul J. Diaz

/s/ R. Bryan Riggsbee

Paul J. Diaz
President and Chief Executive Officer

R. Bryan Riggsbee
Chief Financial Officer