

MYRIAD GENETICS INC  
Form 10-K  
August 10, 2016  
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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-K**

(Mark One)

**ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the fiscal year ended June 30, 2016**

**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)

**87-0494517**  
(I.R.S. Employer

of incorporation or organization)

Identification No.)

**320 Wakara Way,**

**Salt Lake City, UT**  
(Address of principal executive offices)

**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

Name of each exchange on which registered

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**Common Stock, \$.01 Par Value Per Share**

**The 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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

Large accelerated filer

Accelerated filer

Non-accelerated filer  (do not check if a smaller reporting company)

Smaller reporting company

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 December 31, 2015, the last business day of the registrant's most recently completed second fiscal quarter, was \$3,028,034,947.

As of August 1, 2016 the registrant had 69,134,651 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 June 30, 2016, for the Annual Meeting of Stockholders to be held on December 1, 2016.

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We, us, 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, BRACAnalysis, BRACAnalysis CDx, BART, COLARIS, COLARIS AP, MELARIS, myPath, myPlan, myChoice, myRisk, Myriad myRisk, PANEXIA, PREZEON, Prolaris, myChoice HRD, Vectra, Vectraview, TruCulture, DiscoveryMAP, RodentMap and EndoPredict are registered trademarks or trademarks of Myriad.

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### **PART I**

#### **Item 1. BUSINESS**

##### **Overview**

We are one of the largest specialty molecular diagnostic laboratories in the world and since our founding in 1992, have tested over 2.0 million patients. We are headquartered in Salt Lake City, Utah and generated worldwide revenues of approximately \$754 million during our fiscal year ended June 30, 2016. We are a leading personalized medicine company dedicated to being a trusted advisor transforming patient lives through pioneering molecular diagnostics. Through our proprietary technologies, we believe we are positioned to identify important disease genes, the proteins they produce, and the biological pathways in which they are involved to better understand the genetic basis of human disease and the role that genes and their related proteins may play in the disease process. We believe that identifying biomarkers (DNA, RNA and proteins) will enable us to develop novel molecular diagnostic tests that can provide important information to solve unmet medical needs.

##### **Our Mission**

Our goal is to provide physicians with critical information to guide the healthcare management of their patients by addressing four major questions a patient may have about their healthcare:

What is the likelihood of my getting a disease?

Do I have a disease?

How aggressively should my disease be treated?

Which therapy will work best to treat my disease?

Over time, we have developed and plan to develop additional products that answer these important questions in six medical specialties: oncology, preventive care, urology, dermatology, autoimmune and neuroscience. We believe that these product channels represent markets where there is a significant opportunity for high-value molecular diagnostic tests to positively impact patient care and drive value for the healthcare system.

##### **Our Business Strategy**

Our strategy is focused on executing the following three strategic imperatives:

1. Transition and expand the hereditary cancer market In fiscal year 2016, approximately 84 percent of our revenue was derived from the sale of products to assess a patient's risk for hereditary cancer. Given that this is our most important market and that we are the worldwide leader in hereditary cancer testing, we are focused on transitioning this market from single-syndrome testing to a more sensitive panel approach. Additionally, we are continuing to expand market penetration as well as grow the number of patients eligible for testing. In the United States, we are currently conducting multiple clinical studies focused on expanding the addressable patient populations who qualify for hereditary cancer testing. Upon completion of these studies, we plan to work with professional guideline organizations to expand access to our hereditary cancer testing products.

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2. Launch new products across a diverse set of disease indications We plan to continue to use our proprietary DNA sequencing, RNA expression and protein analysis technologies, including our supporting bioinformatics and robotic technologies, in an effort to efficiently discover important genes and their proteins and to understand their role in human disease. Based on these biomarkers, we plan to develop highly accurate, informative tests that may help physicians better manage their patients' healthcare. We believe that our technologies provide us with a significant competitive advantage and the potential for numerous product opportunities. Our goal is to commercialize informative molecular diagnostic tests that can save lives and improve the quality of life of patients. In addition to the

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commercially marketed products mentioned below in our molecular diagnostic testing segment we have a pipeline of additional publicly announced tests. We believe the global market for all of our commercial and pipeline products exceeds \$25 billion annually.

3. Expand our molecular diagnostic business internationally We believe that the market for our molecular diagnostic products in Europe, Latin America and Asia represents an attractive commercial opportunity. We have established sales offices in Germany, France, United Kingdom, Spain, Switzerland, Italy, Australia and Canada; laboratory operations in Germany; and international headquarters in Switzerland. We believe that our portfolio of products would benefit patients worldwide by assisting physicians in guiding their health care decisions.

### **Molecular Diagnostic Testing**

Our molecular diagnostic tests are designed to analyze genes, their expression levels and corresponding proteins to assess an individual's risk for developing disease later in life, accurately diagnose disease, determine a patient's likelihood of responding to a particular drug, or assess a patient's risk of disease progression and disease recurrence. Provided with this valuable information, physicians may more effectively manage their patient's healthcare to prevent or delay the onset of disease and help ensure that patients receive the most appropriate treatment for their disease.

Below are the descriptions of our primary molecular diagnostic tests:

**myRisk Hereditary Cancer:** *DNA sequencing test for assessing the risks for hereditary cancers.* Our myRisk Hereditary Cancer test represents the next generation of our existing hereditary cancer testing franchise which we anticipate will eventually replace our current predictive medicine test offerings (BRACAnalysis, BART, Colaris and Colaris AP and Melaris) with a single comprehensive test. myRisk Hereditary Cancer is designed to determine a patient's hereditary cancer risk for breast cancer, ovarian cancer, colon cancer, uterine cancer, melanoma, pancreatic cancer, prostate cancer and gastric cancer. The test analyzes 25 separate genes to look for deleterious mutations that would put a patient at a substantially higher risk than the general population for developing one or more of the above cancers. All 25 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 lower disease risk or risk of cancer recurrence. The myRisk report presents the myRisk Genetic Test Result and myRisk Management Tool that summarizes published management guidelines related to the patient's genetic mutation as well as their personal and family history of cancer. myRisk Hereditary Cancer testing identifies more mutation carriers than BRACAnalysis® and COLARIS® combined. We believe the global market for myRisk Hereditary Cancer and all of our hereditary cancer tests is approximately \$5 billion annually. myRisk Hereditary Cancer was initially released through an early access launch that began in September 2013.

**BRACAnalysis®:** *DNA sequencing test for assessing the risk of developing breast and ovarian cancer.* Our BRACAnalysis test is an analysis of the BRCA1 and BRCA2 genes for assessing a woman's risk of developing hereditary breast and ovarian cancer. A woman who tests positive for a deleterious mutation with the BRACAnalysis test has up to an 87% risk of developing breast cancer and up to a 44% risk of developing ovarian cancer by age 70. As published in the *Journal of the National Cancer Institute*, researchers have shown that pre-symptomatic individuals who have a high risk of developing breast or ovarian cancer can reduce their risk by more than 50% with appropriate preventive therapies. Additionally, BRACAnalysis may be used to assist patients already diagnosed with breast or ovarian cancer and their physicians in determining the most appropriate therapeutic interventions to address their disease.

According to the American Cancer Society, in 2016 there will be approximately 271,000 women in the United States diagnosed with breast cancer or ovarian cancer.

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**BART®:** *DNA sequencing test for hereditary breast and ovarian cancer.* Our BART test is based on proprietary technology for detecting large genomic rearrangements in the genes involved in hereditary breast and ovarian cancer patients. As published in the journal *Cancer*, researchers have shown that up to 10% of hereditary breast and ovarian cancer susceptibility is due to large rearrangement mutations that can't be detected using conventional sequencing technology.

**BRCAAnalysis CDx™:** *DNA sequencing test for use as a companion diagnostic with the PARP inhibitor Lynparza™ (olaparib) currently indicated for use in identifying ovarian cancer patients with deleterious or suspected deleterious germline BRCA variants eligible for treatment with Lynparza™.* Approximately 15% of patients with epithelial ovarian cancer are BRCA positive.

**Tumor BRCAAnalysis CDx™:** *DNA sequencing test designed to be utilized to predict response to DNA damaging agents such as platinum based chemotherapy agents and poly ADP ribose (PARP) inhibitors.* Tumor BRCAAnalysis CDx looks at both germline and somatic mutations in the BRCA1 and BRCA2 genes giving a more complete picture of potential loss of DNA repair ability within the tumor. Approximately 22% of epithelial ovarian cancer patients will test positive for Tumor BRCAAnalysis CDx. Currently the test is only offered through our European laboratory in Munich Germany.

**COLARIS®:** *DNA sequencing test for assessing the risk of colorectal and uterine cancer.* Our COLARIS test is an analysis of the MLH1, MSH2, MSH6, PMS2, EPCAM and MYH genes for assessing a person's risk of developing colorectal and uterine cancer. Individuals who carry a deleterious mutation in one of the colon cancer genes in the COLARIS test have a greater than 80% lifetime risk of developing colon cancer and women have up to a 71% lifetime chance of developing uterine cancer. Colon cancer is a preventable disease if high-risk individuals diligently have colonoscopies and remove any precancerous polyps.

According to the American Cancer Society, approximately 207,000 new cases of colorectal cancer or uterine cancer will be diagnosed in the United States in 2016.

**COLARIS AP®:** *DNA sequencing test for assessing the risk of colorectal cancer.* Our COLARIS AP test detects mutations in the APC and MYH genes, which cause a colon polyp-forming syndrome such as familial adenomatous polyposis (FAP), a more common variation of the syndrome known as attenuated FAP, and the MYH-associated polyposis signature (MAP). Individuals who carry a deleterious mutation in the APC or MYH gene may have a greater than 90% lifetime risk of developing colon cancer. Effective preventive measures include colonoscopy and the removal of pre-cancerous polyps and prophylactic surgery.

**Vectra®DA:** *protein detection test for assessing the disease activity of rheumatoid arthritis.* Our Vectra DA test is a quantitative, objective multi-biomarker blood test validated to measure rheumatoid arthritis (RA) disease activity. Vectra DA assesses multiple mechanisms and pathways associated with RA disease activity and integrates the concentrations of 12 serum proteins into a single score reported on a scale of 1 to 100. The test may be used throughout the course of a patient's disease and provides clinicians with expanded insight on disease severity and the risk of radiographic progression.

According to the Arthritis Foundation, there are over 1.5 million Americans with rheumatoid arthritis. We believe the global market for Vectra DA is approximately \$3 billion annually.

**Prolaris®:** *RNA expression test 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 would 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 to thereby optimize patient treatment.

According to the American Cancer Society, in the United States approximately 181,000 men are expected to be diagnosed with prostate cancer in 2016. We believe the global market for Prolaris is approximately \$1.5 billion annually.





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**EndoPredict®:** *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 would benefit from chemotherapy. EndoPredict predicts the likelihood of metastases to help guide treatment decisions for chemotherapy and extended anti-hormonal therapy. EndoPredict has been shown to accurately predict cancer-specific disease progression and metastases with no confusing intermediate results in 13 published clinical studies with more than 2,200 patients and is CE marked. We believe the global market opportunity for EndoPredict is greater than \$600 million with the majority of that market existing in major European countries, Canada, and the United States.

**myPath Melanoma:** *RNA expression test for diagnosing melanoma.* Our myPath Melanoma test is a gene expression based profile that is performed on biopsy tissue for the purpose of aiding a dermatopathologist in the diagnosis of melanoma. Every year in the United States, there are approximately two million skin biopsies performed specifically for the diagnosis of melanoma. Approximately 14% of these biopsies are classified as indeterminate where a dermatopathologist cannot make a definitive call as to whether the biopsy is benign or malignant. Outcomes for patients are poor if melanoma is not caught in early stages with five year survival rates dropping from 98% for localized to less than 20% for distant stage disease cancer based upon data from the American Cancer Society. We believe myPath Melanoma may provide an accurate tool to assist physicians in correctly diagnosing indeterminate skin lesions.

We believe the global market for myPath Melanoma is approximately \$1 billion annually. myPath Melanoma was released through an early access launch that began in November 2013.

**myChoice® HRD:** *Companion diagnostic to measure three modes of homologous recombination deficiency (HRD) including loss of heterozygosity, telomeric allelic imbalance and large-scale state transitions in cancer cells.* Our myChoice HRD test is the most comprehensive homologous recombination deficiency test to detect when a tumor has lost the ability to repair double-stranded DNA breaks, resulting in increased susceptibility to DNA-damaging drugs such as platinum drugs or PARP inhibitors. The myChoice HRD score is a composite of three proprietary technologies: loss of heterozygosity, telomeric allelic imbalance and large-scale state transitions. Positive myChoice HRD scores, reflective of DNA repair deficiencies, are prevalent in all breast cancer subtypes, ovarian and most other major cancers. In previously published data, Myriad showed that the myChoice HRD test predicted drug response to platinum therapy in certain patients with triple-negative breast and ovarian cancers. It is estimated that 1.4 million people in the United States and Europe who are diagnosed with cancers annually may be candidates for treatment with DNA-damaging agents.

**myPlan Lung Cancer:** *RNA expression test for assessing the aggressiveness of lung cancer.* Our myPlan Lung Cancer test is a gene expression based profile that may aid a physician in making a determination as to the aggressiveness of a patient's lung cancer and based upon this determination more accurately guide patient therapy. Most early stage lung cancer patients do not see added benefit from chemotherapy. We believe the global market for myPlan Lung Cancer is approximately \$200 million annually.

myPlan Lung Cancer was released through an early access launch that began in October 2013.

## **Pharmaceutical and Clinical Services**

Our pharmaceutical and clinical services consist of the following:

Through Myriad RBM, we provide biomarker discovery and pharmaceutical and clinical services to the pharmaceutical, biotechnology, and medical research industries utilizing our multiplexed immunoassay technology. Our technology enables us to efficiently screen large sets of well-characterized clinical samples from both diseased and non-diseased populations against our extensive menu of biomarkers. During the year ended June 30, 2016, Myriad RBM accounted for 3.6% of total revenue. In addition to the fees received from analyzing these samples, we also use this information to create and validate potential companion diagnostic test panels.

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On February 27, 2015, we completed the acquisition of Privatlinik Dr. Robert Schindlbeck GmbH & Co. KG (the Clinic) located approximately 15 miles from the Company's European laboratories in Munich, Germany for total consideration of \$20.1 million. We believe the acquisition of the Clinic should allow us to have better access to payors.

### **The Molecular Diagnostic Industry and Competition**

The markets in which we compete are rapidly evolving, and we face competition from multiple public companies, private companies, and academic/university laboratories for a number of our laboratory testing services.

In the hereditary cancer testing market we have faced increased competition since a landmark U.S. Supreme Court decision in June 2013 invalidated some of the key patent claims covering our hereditary cancer testing products. These patents were originally set to begin expiring in 2015 and beyond. Since this Supreme Court decision, numerous large reference laboratories, small private laboratories, and academic/university laboratories have launched competing hereditary cancer tests. Despite the impact from competition, we continue to have a dominant market position in hereditary cancer testing.

The market for hereditary cancer testing has evolved dramatically over time. Broad reimbursement coverage for hereditary cancer tests began emerging in the early 2000s and coupled with increased public awareness around genetics and Myriad's marketing and promotional efforts, there has been significant growth in testing volumes. One of the largest drivers of growth has been increased testing in asymptomatic patients in the preventive care setting which now comprise nearly half of all tests performed in the United States. We are working to continue to expand awareness around hereditary cancer testing and expand the number of patients that qualify for hereditary cancer testing under medical guidelines and health insurance coverage policies.

Another factor influencing the marketplace has been the advent of next generation sequencing. This has allowed the transition from single syndrome tests to targeted pan-cancer panels in a cost effective manner without sacrificing test accuracy. We launched our first pan-cancer panel, myRisk Hereditary Cancer, in September, 2013, and we believe panel based tests will become standard of care in the marketplace based upon their greater sensitivity at finding cancer causing mutations. We have presented multiple studies showing that myRisk Hereditary Cancer can detect greater than 60 percent more deleterious mutations when compared to our legacy hereditary cancer tests.

Myriad competes in the hereditary cancer testing market based upon several factors including:

- 1) the analytical accuracy of our tests
- 2) our ability to classify genetic variants in hereditary cancer genes
- 3) the quality of our sales and marketing for our products
- 4) the quality of our customer service and support
- 5) turnaround time; and
- 6) value

We believe that we have substantial advantages in terms of our test accuracy and ability to classify variants. Based on our testing experience of over 2.0 million patients, and our substantial investments in our variant classification program, we have compiled a proprietary database of over 40,000 unique genetic variants in the genes tested by myRisk Hereditary Cancer. We believe this database allows us to provide more accurate results to patients and return a variant of unknown significance (VUS) result to patients less frequently. We have demonstrated that this classification advantage leads to lower long-term healthcare costs and lower utilization of unnecessary healthcare services.



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Given our scale relative to other laboratories in the hereditary cancer testing market, we believe we also have substantial competitive advantages in terms of cost efficiencies and laboratory automation, which leads to faster turnaround times for our tests.

In the urology market, we compete against a small number of public and private companies for our prostate cancer prognostic test, Prolaris. We compete in this market primarily based upon the quality of the clinical data supporting the test, its first mover advantage in the marketplace and the strength of its sales support and customer service.

In the autoimmune market, our Vectra DA test competes primarily against traditional methodologies for assessing rheumatoid arthritis disease activity such as a physician's clinical assessment of the patient and single marker laboratory tests such as C-reactive protein (CRP). We believe we have the only clinically validated multi-biomarker product on the market to assess rheumatoid arthritis disease activity.

In the pharmaceutical and clinical services segment, our Myriad RBM division competes against other contract research organizations and academic laboratories for business from pharmaceutical and research customers.

## **Sales and Marketing**

We sell our tests through our own direct sales force and marketing efforts in the United States, Europe, Australia and Canada. Our United States sales force is comprised of approximately 502 individuals across five separate sales channels. In connection with any additional tests that we may launch, we plan to expand our existing oncology, preventive care, urology, dermatology, and autoimmune care sales forces, and build new sales forces to address other physician specialty groups. We have entered into distributor agreements with organizations in selected European, Latin American, Middle Eastern, Asian and African countries.

## **Research and Development**

We plan to continue to use our proprietary DNA sequencing, RNA expression and protein analysis technologies, including our supporting bioinformatics and robotic technologies, in an effort to efficiently discover important genes and their proteins and to understand their role in human disease. Based on these biomarkers we plan to develop highly accurate, informative tests that may help physicians better manage their patients' healthcare. We believe that our technologies provide us with a significant competitive advantage and the potential for numerous product opportunities. For the years ended June 30, 2016, 2015 and 2014, we had research and development expense of \$70.6 million, \$75.5 million, and \$67.5 million, respectively.

## **Acquisitions**

We intend to continue to take advantage of in-licensing or acquisition opportunities to augment our internal research and development programs. We recognize that we cannot meet all of our research discovery goals internally and can benefit from the research performed by other organizations. We hope to leverage our financial strength, product development expertise, and sales and marketing presence to acquire new product opportunities in our molecular diagnostic areas of focus.

In February 2014, we completed the acquisition of privately-held Crescendo Bioscience, Inc. ( Crescendo ) for \$270 million in cash, which was reduced by the repayment of a loan made to Crescendo and other customary adjustments in accordance with the acquisition agreement. We believe that the acquisition of Crescendo facilitates our entry into the high growth autoimmune and inflammatory disease market, diversifies our product revenues and enhances our strength in protein-based diagnostics. The business of Crescendo, including its Vectra®DA blood test for rheumatoid arthritis disease management, is operated as a wholly owned subsidiary.

In February 2015, we completed the acquisition of the Clinic located in Germany approximately 15 miles from our European laboratories in Munich, Germany for total consideration of \$20.1 million. We believe the acquisition of

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the Clinic should facilitate our penetration into the German molecular diagnostic market. The Clinic will allow us to directly negotiate reimbursement with government and private insurance providers in the German market and collaborate with hospitals and physician groups.

In May 2016, we completed the acquisition of Sividon Diagnostics GmbH ( Sividon ), a leading breast cancer prognostic company, for \$39.0 million upfront with the potential for 15.0 million (\$16.7 million converted at the June 30, 2016 period end exchange rate) in additional performance-based milestones. We believe the acquisition brings us the best-in-class breast cancer prognostic test and strengthens our market leading oncology portfolio of high value personalized medicine products.

### **Seasonality**

We experience seasonality in our testing business. The volume of testing is negatively impacted by the summer holiday season which is generally reflected in our fiscal first quarter. Our fiscal second quarter ending December 31 is generally strong as we see an increase in volume from patients who have met their annual insurance deductible. Conversely, fiscal third quarter ending March 31 is typically negatively impacted by the annual reset of patient deductibles. Additionally, we can experience increases in testing volume due to celebrity publicity.

### **Patents and Proprietary Rights**

We own or have license rights to various issued patents as well as patent applications in the United States and foreign countries. These patents and patent applications cover a variety of subject matter including, diagnostic biomarkers, gene expression signatures, antibodies, primers, probes, assays, disease-associated genetic mutations, methods for determining genetic predisposition, methods for disease diagnosis, methods for determining disease progression, methods for disease treatment, 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. We also own additional patent assets and hold other non-exclusive license rights to patents which cover various aspects of our tests or processes. Material patent assets relating to our tests that generate material revenue are described below.

*Vectra DA.* We hold an exclusive license to one issued U.S. patent and pending U.S. patent applications relating to Vectra<sup>®</sup>DA testing. This issued U.S. patent has a term expected to expire in 2031 and these U.S. applications, if issued as patents and depending on term adjustments or terminal disclaimers if applicable, are expected to have similar terms. These patents and applications contain multiple claims including but not limited to claims relating to biomarkers, kits, systems and methods for measuring and monitoring inflammatory disease activity.

*Prolaris.* We own or hold an exclusive license to one allowed U.S. patent application and pending U.S. patent applications relating to Prolaris<sup>®</sup> testing. This allowed U.S. patent application, if and when issued, will have a term expected to expire in 2031 and these U.S. applications, if issued as patents and depending on term adjustments or terminal disclaimers if applicable, are expected to have expiration timeframes ranging from 2030 to 2035. These patents and applications contain multiple claims including but not limited to claims relating to biomarkers, kits, systems and methods for detecting, diagnosing, prognosing and selecting therapy for prostate cancer.

*EndoPredict.* We own or hold an exclusive license to two issued European patents and pending U.S. and European patent applications relating to EndoPredict<sup>®</sup> testing. These issued European patents have a term expected to expire in 2031 and these U.S. and European 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 claims relating to biomarkers, kits, systems and methods for prognosing and selecting therapy for breast cancer.

*myChoice HRD.* We own or hold an exclusive license to two issued U.S. patents and pending U.S. patent applications relating to myChoice<sup>®</sup> HRD testing. These issued U.S. patents have terms expected to expire in 2032

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and these U.S. applications, if issued as patents and depending on term adjustments or terminal disclaimers if applicable, are expected to have expiration timeframes ranging from 2031 to 2035. These patents contain multiple claims including but not limited to claims relating to biomarkers, kits, systems and methods for detecting homologous recombination deficiency and selecting therapy based on such detection.

We intend to seek patent protection in the United States and major foreign jurisdictions for synthetic nucleic acids, antibodies, biomarker signatures, assays, probes, primers, technologies, methods, processes 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 and 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, developing 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 test 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 reliance on trade secrets or 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 genes and proteins 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 all of our hereditary cancer 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 and pharmaceutical and clinical services. We may not be able to continue to license these technologies on commercially reasonable terms, if at all. Additionally, 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.

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In 2010, Crescendo Bioscience, Inc. (now a wholly-owned subsidiary of the Company) entered into a license agreement with the Oklahoma Medical Research Foundation (the OMRF), for the exclusive world-wide right to utilize certain intellectual property rights of OMRF including patent applications relating to what is now Vectra DA testing. Under this license agreement we pay OMRF a royalty based on net sales of our Vectra DA test. This license agreement ends on expiration of the last to expire patent covered by the license agreement, which presently is not anticipated to expire until 2031. OMRF has the right to terminate the license agreement for the uncured breach of any material term of the license agreement.

In 2012, we entered into a license agreement with the University of Texas M.D. Anderson Cancer Center (the UTMDACC), for the exclusive world-wide right to utilize certain rights of UTMDACC in intellectual property relating to what is now myChoice® HRD testing. Under this license agreement we will pay UTMDACC a royalty based on net sales of our myChoice® HRD test, if any. This license agreement ends on expiration of the last to expire patent covered by the license agreement, which presently is not anticipated to expire until 2032. UTMDACC has the right to terminate the license agreement for the uncured breach of any material term of the license agreement.

## **Governmental Regulation**

The services that we provide 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 insurers, for laboratory testing services. Our laboratories in Salt Lake City, Utah, Austin, Texas 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 loses 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 California, Florida, 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.

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If a laboratory is out of compliance with state laws or regulations governing licensed laboratories or with CLIA, 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**

Although the Food and Drug Administration (FDA) has consistently claimed that it has the authority to regulate laboratory-developed tests (LDTs) that are developed, validated and performed only by a CLIA certified laboratory, it has historically exercised enforcement discretion in not otherwise regulating most LDTs and has not required laboratories that furnish LDTs to comply with the agency's requirements for medical devices (e.g., establishment registration, device listing, quality systems regulations, premarket clearance or premarket approval, and post-market controls). In recent years, however, the FDA has stated it intends to end its policy of general enforcement discretion and regulate certain LDTs as medical devices. To this end, on October 3, 2014, the FDA issued two draft guidance documents, entitled *Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)* and *FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs)*, respectively, that set forth a proposed risk-based regulatory framework that would apply varying levels of FDA oversight to LDTs. The FDA has indicated that it does not intend to modify its policy of enforcement discretion until the draft guidance documents are finalized. It is unclear at this time when, or if, the draft guidance documents will be finalized, and even then, the new regulatory requirements are proposed to be phased-in consistent with the schedule set forth in the guidance (in as little as 12 months after the draft guidance is finalized for certain high-priority LDTs). Nevertheless, the FDA may decide to regulate certain LDTs on a case-by-case basis at any time. LDTs with the same intended use as a cleared or approved companion diagnostic are defined in FDA's draft guidance as high-risk LDTs (Class III medical devices) for which premarket review would be first to occur.

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. Companion diagnostic tests are currently subject to regulation by the FDA as medical devices. The FDA issued *Guidance on In-Vitro Companion Diagnostic Devices* in July 2014, which 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. The FDA defined an in vitro companion diagnostic device (IVD Companion Dx) as a device that provides information that is essential for the safe and effective use of a corresponding therapeutic product. The FDA expects that the therapeutic sponsor will address the need for an approved or cleared IVD Companion Dx in its therapeutic product development plan and that, in most cases, the therapeutic product and its corresponding companion diagnostic will be developed contemporaneously. In December 2014, we obtained premarket approval (PMA) for BRACAnalysis CDx, which is used as a companion diagnostic to identify ovarian cancer patients who may benefit from AstraZeneca's PARP inhibitor Lynparza (olaparib). The premarket approval process is a complex, costly and time consuming procedure. PMAs must be supported by valid scientific evidence, 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 pharmaceutical companies, including an expanded collaboration with AstraZeneca for an additional indication for BRACAnalysis CDx, to evaluate the use of several of our tests as companion diagnostics with other drugs.

After a medical device is placed on the market, numerous regulatory requirements apply. These 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;



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labeling regulations, which prohibit the promotion of products for uncleared, unapproved 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.

Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, 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 PMAs of new devices; withdrawal of 510(k) clearance or PMAs; and civil or criminal prosecution. To ensure compliance with regulatory requirements, medical device manufacturers are subject to market surveillance and periodic, pre-scheduled and unannounced inspections by the FDA.

### Other Regulatory Requirements

Our laboratories are subject to federal, state and local regulations relating to the handling and disposal of regulated medical waste, hazardous waste and biohazardous waste, including chemical, biological agents and compounds, blood and bone marrow samples and other human tissue. 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.

### HIPAA and other privacy laws

The Health Insurance Portability and Accountability Act of 1996 ( HIPAA ), established comprehensive federal standards for the privacy and security of health information. The HIPAA standards apply to three types of organizations: health plans, healthcare clearing houses, and healthcare providers that conduct certain healthcare transactions electronically ( Covered Entities ). Title II of HIPAA, the Administrative Simplification Act, contains provisions that address the privacy of health data, the security of health data, the standardization of identifying numbers used in the healthcare system and the standardization of certain healthcare transactions. The privacy regulations protect medical records and other protected health information by limiting their use and release, giving patients the right to access their medical records and limiting most disclosures of 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 Subtitle D of the Health Information Technology for Economic and Clinical Health Act, or HITECH, provisions of the American Recovery and Reinvestment Act of 2009. HITECH expanded and strengthened HIPAA, created new targets for enforcement, imposed new penalties for noncompliance and established new breach notification requirements for Covered Entities. Regulations implementing major provisions of HITECH were finalized on January 25, 2013 through publication of the HIPAA Omnibus Rule (the Omnibus Rule ).

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 and civil litigation, including class action lawsuits.

We are currently subject to the HIPAA regulations and maintain an active compliance program that is designed to identify security incidents and other issues in a timely fashion and enable us to remediate, mitigate harm or

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report if required by law. We are subject to prosecution and/or administrative enforcement and increased civil and criminal penalties for non-compliance, including a new, four-tiered system of monetary penalties adopted under HITECH. We are also subject to enforcement by state attorneys general who were given authority to enforce HIPAA under HITECH. To avoid penalties under the HITECH breach notification provisions, we must ensure that breaches of protected health information are promptly detected and reported within the company, so that we can make all required notifications on a timely basis. However, even if we make required reports on a timely basis, we may still be subject to penalties for the underlying breach.

In May 2016, a complaint was filed with the Office for Civil Rights of the Department of Health and Human Services (OCR) by four patients alleging deficiencies in our policies regarding information that must be disclosed to patients as part of a designated record set under HIPAA. We proactively reached out to OCR on these issues to explain our compliance with all applicable regulations and OCR guidance. To date, this complaint has not resulted in any investigation or other action by OCR.

A similar complaint was filed with the College of American Pathologists (CAP), which is the designated agency administering CLIA for Myriad Genetic Laboratories. We responded to CAP's notice of the complaint and, on July 27, 2016, received a letter notifying us that the matter has been closed.

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 a high 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 constantly change and we may not be able to maintain compliance in all jurisdictions where we do business. Failure to maintain compliance, or changes in state or federal laws regarding privacy or security could result in civil and/or criminal penalties, significant reputational damage and could have a material adverse effect on our business.

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 U.S. 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 and the International Air Transport Association. We generally use third-party vendors to dispose of regulated medical waste, hazardous waste and radioactive materials and contractually require them to comply with applicable laws and regulations.

**Transparency Laws and Regulations**

A federal law known as the Physician Payments Sunshine Act (the Sunshine Act) requires medical device manufacturers 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. Manufacturers must report data for the previous calendar year by the 90<sup>th</sup> day of the then-current calendar year. CMS then publishes the data on a publicly available website no later than June 30<sup>th</sup>. 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, make periodic public disclosures on sales and marketing activities, and such laws may also prohibit or limit certain other sales

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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 we must meet to ensure compliance with applicable laws and regulations, as well as our internal compliance policies and procedures, add further complexity to the billing process. Other factors that complicate billing include:

variability in coverage and information requirements among various payors;

patient financial assistance programs;

missing, incomplete or inaccurate billing information provided by ordering physicians;

billings to payors with whom we do not have contracts;

disputes with payors as to which party is responsible for payment; and

disputes with payors as to the appropriate level of reimbursement.

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

a third party who provides coverage to the patient, such as an insurance company or MCO;

a state or federal healthcare program; or

the patient.

Presently, approximately 85% of our revenue comes from private third party payors.

In February 2011, the American Medical Association Current Procedural Terminology ( CPT ) Editorial Panel approved 101 new molecular pathology codes to describe molecular diagnostic tests that currently require multiple CPT codes for billing purposes. The new reimbursement rates for the new codes went into effect on January 1, 2013.

### **Federal and State Fraud and Abuse Laws**

A variety of 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

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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 universe of claims, and which can result in even higher repayments.

### Anti-Kickback Laws

The Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an

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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 defined 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. The Anti-Kickback Statute is broad and prohibits many arrangements and practices that are lawful in businesses outside of the health care industry.

Recognizing the breadth of the Anti-Kickback Statute and the fact that it may technically prohibit many innocuous or beneficial arrangements within the health care industry, the OIG has issued a series of regulations, or 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 the OIG 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 the 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.

### **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) certain 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 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 the federal health care programs. In addition, various states have enacted similar laws modeled after the False Claims Act that apply to items and services reimbursed under Medicaid and other state health care programs, and, in several states, such laws apply to claims submitted to any payor.

### **Civil Monetary Penalties Law**

The federal Civil Monetary Penalties Law, or 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

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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.

### **International regulations**

We market 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. On September 26, 2012, the European Commission released the first drafts of the new European Union ( EU ) regulations for medical devices and IVDs that if finalized will impose additional regulatory requirements on IVDs used in the EU. 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.

### **Human Resources**

As of June 30, 2016, we have over 2,206 full-time equivalent employees. Most of our employees are engaged directly in research, development, production, sales and marketing activities. We believe that the success of our business will depend, in part, on our ability to attract and retain qualified personnel. Our employees are not covered by a collective bargaining agreement, and we consider our relations with our employees to be good.

### **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 web site address is [www.myriad.com](http://www.myriad.com). We make available free of charge through the Investor Relations section of our web site our Corporate Code of Conduct and Ethics, our Audit Committee and other committee charters and our other corporate governance policies, as well as our Annual 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. We include our web site 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 web site.

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**Item 1A. RISK FACTORS**

**Risks Related to Our Business and Our Strategy**

*We may not be successful in transitioning from our existing product portfolio to our new products, such as our myRisk Hereditary Cancer test, which represents the next generation of our existing hereditary cancer franchise. We may not be able to generate sufficient revenue from our existing tests and our new tests or develop new tests to maintain profitability.*

Although we have developed and marketed several molecular diagnostic tests to date, 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 outside the United States, and to develop and commercialize new molecular diagnostic and companion diagnostic tests. Importantly, in 2014 we launched our myRisk Hereditary Cancer test, which represents the next generation of our existing hereditary cancer testing franchise. We anticipate that the myRisk Hereditary Cancer test will eventually replace our current predictive medicine test offerings (BRACAnalysis, BART, Colaris and Colaris AP and Melaris) with a single comprehensive test. However, we may not be successful in transitioning from our existing product portfolio to our new tests and in launching and commercializing our new tests. The demand for our existing molecular diagnostic tests may decrease or may not continue to increase at historical rates due to sales of the myRisk Hereditary Cancer test and our other new tests that are replacing our existing product portfolio, or for other reasons. 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 pipeline of new molecular diagnostic and companion diagnostic test candidates is in various stages of development and may take several 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 maintain profitability. Even if we succeed in marketing myRisk Hereditary Cancer and 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 able to maintain profitability.

*We may not be able to sustain or increase profitability on a quarterly or annual basis.*

In order to develop and commercialize our molecular diagnostic and companion diagnostic tests, we expect to incur significant expenses over the next several years as we increase our research and development activities, expand clinical validation trials for our molecular diagnostic tests and companion diagnostic tests currently in development, potentially license or acquire additional companies or technologies and engage in commercialization activities in anticipation of the launch of additional molecular diagnostic tests companion diagnostic tests. Because of the numerous risks and uncertainties associated with developing our tests and their potential for commercialization, we are unable to predict the extent of any future profits. If we are unable to sustain or increase profitability, the market value of our common stock will likely decline. Our ability to maintain profitability will depend upon numerous factors, including:

our ability to transition from our existing product portfolio to our new products, such as our myRisk Hereditary Cancer test, and to commercialize these new tests;



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our ability to obtain full or partial reimbursement for new products;

our ability to sell our other existing molecular diagnostic tests to new patients;

our ability to identify biomarkers that may lead to future molecular diagnostic tests and companion diagnostic tests;

our ability to develop test candidates and receive any required regulatory approvals, including FDA approval as may be required for existing tests if LDTs become FDA regulated or for new tests such as myChoice HRD testing or a kit version of EndoPredict;

our ability to successfully commercialize our tests in our existing markets and to extend into new markets outside the United States;

the approval and introduction of competitive tests;

reductions in reimbursement by third-party payors or their willingness to provide full or even partial reimbursement for our tests;

our ability to maintain and enforce our intellectual property rights covering our molecular diagnostic tests and companion diagnostic tests;

our ability to maintain and grow our sales force and marketing team to market our tests;

our ability to successfully integrate, develop and grow products and services and the business of any other companies or technologies that we may license or acquire;

our ability to increase commercial acceptance of our current molecular diagnostic tests; and

our ability to maintain or grow our current revenues.

***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.***

As of June 30, 2016, we had \$238.9 million in cash, cash equivalents and marketable securities. For the fiscal year ended June 30, 2016 our consolidated revenues were \$753.8 million, and net cash from operating activities was \$166.3 million. To develop and bring new molecular diagnostic tests and companion diagnostic tests to market, we must commit substantial resources to costly and time-consuming research, development testing and clinical testing.

While we anticipate that our existing cash, cash equivalents and marketable securities and expected net cash to be generated from sales of our molecular diagnostic tests and pharmaceutical and clinical services 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. If we are unable to secure additional funding, we may be required to reduce research and development projects, limit sales and marketing activities, scale back our expansion efforts outside the United States, reduce headcount or potentially even discontinue operations. Our future capital requirements will depend on many factors that are currently unknown to us, including:

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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;

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;

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the progress, cost and results of our international expansion efforts;

the costs of expanding our sales and marketing functions and commercial operation facilities in the United States and in new markets;

the costs, timing and outcome of any litigation against us; and

the costs to satisfy our current and future obligations.

***We 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.***

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, add experienced management personnel and increase our test offerings. For example, in May 2011, we completed the acquisition of Rules Based Medicine, Inc., which we renamed Myriad RBM, and are now offering pharmaceutical and clinical services and developing additional product candidates using the acquired technology. In February 2014, we completed the acquisition of Crescendo Bioscience, Inc., and are now offering molecular diagnostic tests for patients suffering from rheumatoid arthritis and developing additional product candidates in the inflammatory and autoimmune disease area. Additionally, in February 2015, we acquired the Clinic and believe the acquisition may facilitate our penetration into the German molecular diagnostic market. In May 2016, we acquired Sividon Diagnostics GmbH. Now as a wholly-owned subsidiary, Sividon will continue to offer EndoPredict testing in the European market, which we offered under an exclusive distribution agreement with Sividon prior to the acquisition. 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. 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 market place;

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, including for environmental-related costs, as a result of our acquisitions, some of which we may not discover during our due diligence;

we may incur significant additional operating expenses;

our ongoing business may be disrupted or receive insufficient management attention; and

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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. Future acquisitions could result in the use of our available cash and marketable securities, potentially dilutive issuances of equity securities, the incurrence of 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.

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*We may not be able to successfully integrate the operations of businesses that we acquire with our own or realize the anticipated benefits of the acquisitions, which could adversely affect our financial condition, results of operations and business prospects.*

There can be no assurance that we will be able to successfully integrate our recent acquisitions or develop or commercialize products based on recently acquired technologies, or that we will be able to successfully integrate any other companies, products or technologies that we acquire and may not realize all or any of the expected benefits of any acquisitions as and when planned. Additionally, we may experience increased expenses, distraction of our management, personnel and customer uncertainty.

The difficulties and risks associated with the integration of any other businesses that we may acquire include:

possible inconsistencies in the standards, controls, procedures, policies and compensation structures;

the increased scope and complexity of the acquired company's operations;

the potential loss of key employees and the costs associated to retain key employees;

risks and limitations on our ability to consolidate corporate and administrative infrastructures of the two companies; and

the possibility of unanticipated delays, costs or inefficiencies associated with the integration of our operations with the operations of any other companies that we may acquire.

As a result of these difficulties and risks, we may not accomplish the integration of the business of any companies we may acquire smoothly, successfully or within our budgetary expectations and anticipated timetable. Accordingly, we may fail to realize some or all of the anticipated benefits of the acquisition, such as increase in our scale, diversification, cash flows and operational efficiency and meaningful accretion to our diluted earnings per share.

*If we were successfully sued for product liability, we could face substantial liabilities that exceed our resources.*

Our business exposes us to potential liability risks inherent in the testing, marketing and processing of molecular diagnostic products, including possible misdiagnoses. Although we are insured against such risks in amounts that we believe to be commercially reasonable, our present professional and product liability insurance may be inadequate. A successful product liability claim in excess of our insurance coverage could have a material adverse effect on our business. Any successful product liability claim may prevent us from obtaining adequate product liability insurance in the future on commercially desirable or reasonable terms. An inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the commercialization of our products.

*We are dependent on our information technology and telecommunications systems, and any failure of these systems could harm our business.*

We depend on information technology, or IT, and telecommunications systems for significant aspects of our business. These IT and telecommunications 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. Failures or significant downtime of our IT or telecommunications systems could prevent us from processing samples, providing test results to physicians, billing payors, addressing patient or physician inquiries, conducting research and development activities and conducting general and administrative elements of our business. Any disruption or loss of IT or telecommunications systems on which critical aspects of our operations depend could have an adverse effect on our business, financial condition and results of operations.

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***Security breaches, loss of data and other disruptions 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. We manage and maintain our applications and data utilizing on-site 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, breaches or interruptions due to employee error, malfeasance or other disruptions, or lapses in compliance with privacy and security mandates. Any such virus, breach or interruption could compromise our networks and the information stored there could be accessed by unauthorized parties, publicly disclosed, lost or stolen. We have measures in place that are designed prevent, and if necessary to detect and respond to such security 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 HIPPA, government enforcement actions and regulatory 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, 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.

***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, 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, establishing a credit 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 SEC 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 shareholders 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

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raise additional funds through collaborations, strategic alliances 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.

### ***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, biological specimens, chemicals and wastes. 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.

### ***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, or the ACA became law. This law substantially changed the way health care is financed by both governmental and private insurers, and significantly impacts our industry. [The ACA contains a number of provisions that are expected to impact our business and operations, some of which in ways we cannot currently predict, including those governing enrollment in state and federal health care programs, reimbursement changes and fraud and abuse, which will impact existing state and federal health care programs and will result in the development of new programs.]

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 healthcare 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.

### ***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 British pound, the Australian dollar and the Canadian dollar. 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**

### ***We generate most of our revenues from two products and we may not be able to maintain revenue growth and profitability.***

We may not be able to generate revenue growth or maintain existing revenue levels. Presently, our molecular diagnostic business operates profitably providing a cash contribution to our current funding and operational needs. We may not, however, be able to continue to operate our molecular diagnostic business on a profitable

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basis. We launched our first molecular diagnostic test, BRACAnalysis, our test for hereditary breast and ovarian cancer, in November 1996. BRACAnalysis test sales accounted for approximately 15% of our revenues for the year ended June 30, 2016, and this percentage has been declining in recent years as we transition to our myRisk Hereditary Cancer test. An interruption or cessation of BRACAnalysis sample flow would have a material impact on our revenues and future profitability. In 2014 we launched our myRisk Hereditary Cancer test, which represents the next generation of our existing hereditary cancer franchise. We may not be successful in transitioning from our existing product portfolio to our new products, such as myRisk Hereditary Cancer Test, and in commercializing these tests over time. Other potential events or factors that may have a significant impact on our ability to sustain revenue growth and profitability for our molecular diagnostic business include the following:

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 outside the United States;

the efforts of third party payors to limit or decrease the amounts that they are willing to pay for our tests;

increased licensing or royalty costs, and our ability to maintain and enforce the intellectual property rights underlying our tests and services;

changes in intellectual propriety law applicable to our patents or enforcement in the United States and foreign countries;

potential obsolescence of our tests;

our inability to increase commercial acceptance of our molecular diagnostic tests;

increased competition and loss of market share; and

increased regulatory requirements.

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



## Edgar Filing: MYRIAD GENETICS INC - Form 10-K

As part of our business strategy, we have expanded into international markets. We have established sales offices in Germany, Switzerland, France, Spain, the United Kingdom, Italy, Canada and Australia; laboratory operations in Germany; and international headquarters in Switzerland. 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:

failure by us to obtain regulatory approvals or adequate reimbursement for the use of our tests in various countries;

difficulty in staffing and managing foreign operations;

managing multiple payor reimbursement and self-pay systems;

logistics and regulations associated with shipping patient samples, including infrastructure conditions and transportation delays;

limits in our ability to penetrate international markets if we are not able to process tests locally;

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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;

multiple, conflicting and changing laws and regulations such as tax laws, export and import restrictions, employment laws, data and privacy laws, regulatory requirements and other governmental approvals, permits and licenses; and

regulatory and compliance risks that relate to maintaining accurate information and control over sales and distributors activities that may fall within the purview of the U.S. Foreign Corrupt Practice Act, anti-boycott and other laws.

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, including countries in the European Union, 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.

***We may experience increased price competition and price erosion, including price decreases from CMS and private payors.***

CMS has reduced the reimbursement rate for some of our products in the past and as a result we may experience further pricing pressures from managed care organizations and other private third-party payors in the future. 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.

***Our pharmaceutical testing services customers may reduce the amount of testing they conduct through us.***

If there is a change in the regulatory environment or intellectual property law, or our pharmaceutical testing services customers consolidate, our customers may divert resources from testing, resulting in a reduced demand for our laboratory testing services. Alternatively, customers may decide to perform their own laboratory testing services in-house.

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***We rely on a single laboratory facility to process each of our molecular diagnostic tests in the United States and Europe and a single laboratory facility to perform our pharmaceutical and clinical services. Failure to maintain the operations of these laboratories in compliance with applicable regulations would seriously harm our business.***

We rely on a CLIA-certified laboratory 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 VectraDA test; a single laboratory facility in Munich, Germany to perform our international molecular diagnostic tests; and a CLIA-certified laboratory facility in Austin, Texas to perform our pharmaceutical and clinical testing services. These facilities and certain pieces of laboratory equipment would be difficult to replace and may require significant replacement lead-time. In the event our clinical testing facilities were to lose their CLIA certification or other required certifications or licenses or were affected by a man-made or natural disaster, we would be unable to continue our molecular diagnostic and pharmaceutical and clinical services 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 or pharmaceutical and clinical services business would result in a loss of goodwill, including damage to our reputation. If our molecular diagnostic or pharmaceutical and clinical services 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, 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 these equipment, robots, and reagents. The equipment, robots, or the reagents may not remain available in commercial quantities at acceptable costs. If we are unable to obtain when needed additional or alternative equipment, 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 and pharmaceutical and clinical services would be adversely affected.

***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 and clinical service 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, have the disease, benefit from a particular therapy or has an aggressive form of the disease that the test is intended to predict.

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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.*

The clinical laboratory and genetics testing fields are intense and highly competitive. Tests that are developed are characterized by rapid technological change. Our competitors in the United States and abroad are numerous and include, among others, major diagnostic companies, reference laboratories, molecular diagnostic firms, universities and other research institutions. Some of our potential competitors have 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. We could be adversely affected if we do not discover genes, proteins or biomarkers and characterize their function, develop molecular diagnostic and pharmaceutical and clinical services based on these discoveries, obtain required regulatory and other approvals and launch these tests and their related services before our competitors. 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. We expect competition to intensify in the fields in which we are involved as technical advances in these fields occur and become more widely known and changes in intellectual property laws generate challenges to our intellectual property position.

*If our current research collaborators or scientific advisors terminate their relationships with us or develop relationships with a competitor, our ability to discover genes, proteins, and biomarkers, and to validate and commercialize 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 and the results of studies conducted at our request. 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 could have a material adverse effect on our business.

*If we fail to retain our key personnel and hire, train and retain qualified employees and consultants, we may not be able to successfully continue our business.*

Because of the specialized scientific nature of our business, we are highly dependent upon our ability to attract and retain qualified management, scientific and technical personnel. We are currently recruiting additional qualified management, scientific and technical personnel. Competition for such personnel is intense. Loss of the

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services of or failure to recruit additional key management, scientific and technical personnel would adversely affect our research and development programs and molecular diagnostic and pharmaceutical and clinical services business and may have a material adverse effect on our business as a whole.

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 to which each employee is subject expires for certain key employees on the applicable date of termination of employment.

*As we expand our commercial tests we may be required to incur significant costs and devote significant efforts to expand our existing tests sales and marketing capabilities.*

Our sales and marketing experience and capabilities consist primarily of our sales force that markets our molecular diagnostic tests to oncologists, Ob/Gyns, urologists, dermatopathologists and rheumatologists in the United States. We are currently expanding our sales efforts outside the United States, which will require us to hire additional personnel and engage in additional sales and marketing efforts. We have limited sales and marketing experience outside the United States. As we expand our business operations internationally, we expect to face a number of additional costs and risks, including the need to recruit a large number of additional experienced marketing and sales personnel.

### **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 June 30, 2016, 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 maintain 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;

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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 PTO 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. 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

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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 and pharmaceutical and clinical services, 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 have wrongfully used or disclosed alleged trade secrets of their former employers.*

As is commonplace in our industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. 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;

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 strengthen and expand HIPAA privacy and security compliance requirements, increase penalties for violators, extend enforcement authority to state attorneys general and impose 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;

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the federal anti-kickback law, or the Anti-Kickback Statute, which prohibits knowingly and willfully offering, paying, soliciting, receiving, or providing 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 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 manufacturers 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 applicable laboratories to report private payer data in a timely and accurate manner beginning in 2017 and every three years thereafter (and in some cases annually);

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.

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.

***Failure to comply with government 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 healthcare 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.





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*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 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 has stated it intends to end its policy of general enforcement discretion and regulate certain LDTs as medical devices. To this end, on October 3, 2014, the FDA issued two draft guidance documents, entitled "Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)" and "FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs)", respectively, that set forth a proposed risk-based regulatory framework that would apply varying levels of FDA oversight to LDTs. The FDA has indicated that it does not intend to modify its policy of enforcement discretion until the draft guidance documents are finalized. It is unclear at this time when, or if, the draft guidance documents will be finalized, and even then, the new regulatory requirements are proposed to be phased-in consistent with the schedule set forth in the guidance (in as little as 12 months after the draft guidance is finalized for certain high-priority LDTs such as LDTs with the same intended use as a cleared or approved companion diagnostic). Nevertheless, the FDA may decide 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.

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

Our companion diagnostic 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

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Act (FDC Act), by comparable agencies in foreign countries, and by other regulatory agencies and governing bodies. Under the FDC Act, 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 obtained FDA approval for our BRACAnalysisCDx test, which is used as a companion diagnostic to identify ovarian cancer patients who may benefit from AstraZeneca's PARP inhibitor Lynparza (olaparib), we cannot predict whether or when we will be able to obtain FDA approval for other companion diagnostics that we are developing.

***If the government and third-party payors fail to provide coverage and adequate payment for our tests 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 providers, private health insurers and other organizations. These third-party payors are increasingly attempting to contain healthcare costs by demanding price discounts or rebates and limiting both coverage on which diagnostic tests they will pay for and the amounts that they will pay for new molecular diagnostic tests. We have recently experienced price reductions from CMS for some of our products and may experience future price reductions from 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 or that similar or additional diagnostic tests will be approved in the future. Moreover, there can be no assurance that any new tests we launch, such as myRisk Hereditary Cancer, myPath Melanoma and myPlan Lung Cancer, 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. Adequate 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. Further, beginning in 2018 under PAMA, Medicare reimbursement for any given diagnostic test will be 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.

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.

***Our business could be adversely impacted by the adoption of the ICD-10-CM Code Set.***

CMS has adopted a new coding set for diagnoses, commonly known as ICD-10-CM, which significantly expands the current coding set. ICD-10-CM is currently required to be used on all claims with dates of service on or after



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October 1, 2015. We may be required to incur significant expense in implementing ICD-10-CM, and, if we do not adequately implement it, our business could be adversely impacted. In addition, if as a result of the new coding set, physicians fail to provide appropriate codes for desired tests, we may not be reimbursed for tests we perform.

### **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 two years ended June 30, 2016, our stock price has ranged from \$28.82 per share to \$46.24 per share. In addition, the stock market in general has experienced extreme price and volume fluctuations. Events or factors that may have a significant impact on our business and on the market price of our common stock include the following:

failure 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 the governmental or private insurers 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 and pharmaceutical and clinical services;

delays or other problems with operating our laboratory facilities;

failure of any of our research and development programs;

changes in intellectual property laws of our patents or enforcement 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;

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changes in the governmental regulatory approved 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;

future sales or anticipated sales of our common stock by us or our stockholders;

the timing and amount of repurchases of our common stock;

general market conditions;

seasonal slowness in sales, particularly in the quarters ending September 30 and March 31, the effects of which may be difficult to understand during periods of growth;

celebrity publicity;

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economic, healthcare 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 against companies has been on the rise. If any of our stockholders brought a 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.

*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 shareholder 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 our 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 then current market price, and may limit the ability of our stockholders to approve transactions that they think may be in their best interests.

### **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 307,000 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, dermatology and women s health molecular diagnostic business are performed at this location. The leases on our existing Salt Lake City facilities have terms of fifteen years, expiring from 2022 through 2027, and provide for renewal options for up to ten additional years.

We also lease approximately 36,000 square feet in Austin, Texas under a lease that expires in June 2020. This space is dedicated to administration, research and development and the CLIA-certified laboratory. Activities related to our pharmaceutical and clinical services are performed at this location.





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In addition, we lease approximately 54,000 square feet in South San Francisco, California under a lease that expires in February 2017. This space is dedicated to administration, research and development and the CLIA-certified laboratory for our Crescendo subsidiary. Activities related to our autoimmune molecular diagnostic business are performed at this location.

We also lease approximately 3,600 square feet in Munich, Germany under a lease expiring in March 2018. This space is used as a laboratory for our international molecular diagnostic businesses.

In December 2012, we entered into a lease expiring in November 2017 for approximately 5,000 square feet in Zurich, Switzerland. This space is used for the administration of our international operations. We also maintain lease agreements for our administrative offices in Paris, France; Madrid, Spain; Milan, Italy; London, United Kingdom; Canada and Australia.

As part of our acquisition of Sividon in March 2016 we acquired a lease on an approximately 7,500 square foot facility with laboratory and office space in Cologne, Germany expiring in December 2017.

As part of our acquisition of the Clinic in February 2015, we acquired 20 buildings comprising 127,000 square feet in Herrsching, Germany. Activities related to our pharmaceutical and clinical services are performed at this location.

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 at least the next two years. We continue to make investments in capital equipment as needed to meet the anticipated demand for our molecular diagnostic tests and our pharmaceutical and clinical services.

### **Item 3. LEGAL PROCEEDINGS**

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.

**Table of Contents****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. The following table sets forth the high and low sales prices for our common stock, as reported by The NASDAQ Global Select Market for the last two fiscal years:

	High	Low
<b>Fiscal Year Ended June 30, 2016:</b>		
Fourth Quarter	\$ 39.74	\$ 28.82
Third Quarter	\$ 43.68	\$ 33.87
Second Quarter	\$ 46.24	\$ 36.47
First Quarter	\$ 41.81	\$ 30.30
<b>Fiscal Year Ended June 30, 2015:</b>		
Fourth Quarter	\$ 36.70	\$ 31.34
Third Quarter	\$ 39.95	\$ 31.86
Second Quarter	\$ 39.95	\$ 31.56
First Quarter	\$ 40.50	\$ 34.33

**Stockholders**

As of August 2, 2016, there were approximately 85 stockholders of record of our common stock and, according to our estimates, approximately 23,643 beneficial owners of our common stock.

**Equity Compensation Plan Information**

We incorporate information regarding the securities authorized for issuance under our equity compensation plans into this section by reference from the section entitled "Equity Compensation" Equity Compensation Plan Information" to be included in the proxy statement for our 2016 Annual Meeting of Stockholders.

**Unregistered Sales of Securities**

None.

**Issuer Purchases of Equity Securities**

In June 2016, we announced that our board of directors had authorized us to repurchase an additional \$200 million of our outstanding common stock increasing the cumulative share repurchase authorization since we first authorized the program in May 2010 to \$1.4 billion. In connection with our most recent stock repurchase authorization, we have been 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 market conditions. As of the date of this report, we have not entered into an accelerated share repurchase agreement under our most recent stock repurchase program. The repurchase program may be suspended or discontinued at any time without prior notice. The transactions occurred in open market purchases and pursuant to a trading plan under Rule 10b5-1.

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The details of the activity under our stock repurchase programs during the fiscal quarter ended June 30, 2016, were as follows:

**Issuer Purchases of Equity Securities**

(in millions, except per share data)

Period	(a) Total Number of Shares Purchased	(b) Average Price Paid per Share	(c)	(d)
			Total Number of Shares Purchased Part of Publicly Announced Plans or Programs	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs
April 1, 2016 to April 30, 2016	0.3	\$ 37.94	0.3	36.6
May 1, 2016 to May 31, 2016	0.7	\$ 34.71	0.7	13.1
June 1, 2016 to June 30, 2016	0.7	\$ 31.89	0.7	192.3
Total	1.7		1.7	\$ 192.3

**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 June 30, 2011 and ending on June 30, 2016 (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 Stock Market, Inc. and the NASDAQ Health Care Providers Stock Index 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 June 30, 2011 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.

	6/30/2011	6/29/2012	6/28/2013	6/30/2014	6/30/2015	6/30/2016
Myriad Genetics, Inc.	100.00	104.67	118.32	171.68	149.67	134.74
NASDAQ Stock Index (U.S.)	100.00	105.82	122.71	158.94	179.80	174.60
NASDAQ Health Care Providers Stocks	100.00	112.44	147.95	204.25	277.80	211.05

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**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.

**Table of Contents****Item 6. SELECTED CONSOLIDATED FINANCIAL DATA**

The following table sets forth our selected consolidated financial data and has been derived from our audited consolidated financial statements. Consolidated balance sheets as of June 30, 2016 and 2015, as well as consolidated statements of operations for the years ended June 30, 2016, 2015 and 2014 and the reports thereon are included elsewhere in this Annual Report on Form 10-K. The information below should be read in conjunction with our audited consolidated financial statements (and notes thereon) and Management's Discussion and Analysis of Financial Condition and Results of Operations, included in Item 7.

*In millions, except per share amounts*

	Years Ended June 30,				
	2016	2015	2014	2013	2012
<b>Consolidated Statement of Operations Data:</b>					
Molecular diagnostic testing	\$ 705.7	\$ 695.5	\$ 748.2	\$ 582.4	\$ 472.4
Pharmaceutical and clinical services	48.1	27.6	30.0	30.8	23.6
Total Revenue	753.8	723.1	778.2	613.2	496.0
Costs and expenses:					
Cost of molecular diagnostic testing	132.8	132.8	96.1	64.4	51.5
Cost of pharmaceutical and clinical services	24.5	14.6	13.1	15.3	13.2
Research and development expense	70.6	75.5	67.5	53.7	42.6
Selling, general and administrative expense	359.1	366.0	327.1	251.8	208.4
Total costs and expenses	587.0	588.9	503.8	385.2	315.7
Operating income	166.8	134.2	274.4	228.0	180.3
Other income (expense):					
Interest income	0.9	0.4	5.4	5.5	4.6
Other	1.2	0.3	(2.0)	(0.2)	(0.4)
Total Other Income	2.1	0.7	3.4	5.3	4.2
Income before income taxes	168.9	134.9	277.8	233.3	184.5
Income tax provision	43.6	54.7	101.6	86.1	72.4
Net income	\$ 125.3	\$ 80.2	\$ 176.2	\$ 147.2	\$ 112.1
Earnings per basic share:					
Basic	\$ 1.79	\$ 1.12	\$ 2.33	\$ 1.82	\$ 1.33
Diluted	\$ 1.71	\$ 1.08	\$ 2.25	\$ 1.77	\$ 1.30
Weighted average shares outstanding:					
Basic	70.0	71.3	75.7	80.9	84.6
Diluted	73.4	74.5	78.2	83.3	86.5
			As of June 30,		
	2016	2015	2014	2013	2012
<b>Consolidated Balance Sheet Data:</b>					
Cash, cash equivalents and marketable investment securities	\$ 238.9	\$ 185.4	\$ 270.5	\$ 531.1	\$ 454.2
Working capital	242.2	214.9	241.8	419.5	377.5
Total assets	880.5	766.2	823.8	803.8	690.6
Stockholders' equity	748.1	662.1	719.0	728.6	635.7

**Table of Contents****Quarterly Financial Data (Unaudited)***In millions, except per share amounts*

	Quarters Ended			
	Jun 30, 2016	Mar 31, 2016	Dec 31, 2015	Sep 30, 2015
<b>Consolidated Statement of Operations Data:</b>				
Molecular diagnostic testing	\$ 173.8	\$ 177.4	\$ 182.6	\$ 171.9
Pharmaceutical and clinical services	12.7	13.1	10.7	11.6
<b>Total Revenue</b>	<b>186.5</b>	<b>190.5</b>	<b>193.3</b>	<b>183.5</b>
<b>Costs and expenses:</b>				
Cost of molecular diagnostic testing	34.2	33.6	34.1	30.9
Cost of pharmaceutical and clinical services	5.8	6.6	6.5	5.6
Research and development expense	19.5	17.2	16.7	17.2
Selling, general and administrative expense	91.3	90.5	90.8	86.5
<b>Total costs and expenses</b>	<b>150.8</b>	<b>147.9</b>	<b>148.1</b>	<b>140.2</b>
<b>Operating income</b>	<b>35.7</b>	<b>42.6</b>	<b>45.2</b>	<b>43.3</b>
<b>Other income (expense):</b>				
Interest income	0.4	0.3	0.1	0.1
Other	1.2	0.2	(0.3)	0.1
<b>Total other income (expense)</b>	<b>1.6</b>	<b>0.5</b>	<b>(0.2)</b>	<b>0.2</b>
<b>Income before income taxes</b>	<b>37.3</b>	<b>43.1</b>	<b>45.0</b>	<b>43.5</b>
<b>Income tax provision</b>	<b>13.9</b>	<b>8.6</b>	<b>7.9</b>	<b>13.2</b>
<b>Net income</b>	<b>\$ 23.4</b>	<b>\$ 34.5</b>	<b>\$ 37.1</b>	<b>\$ 30.3</b>
<b>Earnings per share:</b>				
Basic	\$ 0.33	\$ 0.49	\$ 0.53	\$ 0.44
Diluted	\$ 0.32	\$ 0.47	\$ 0.50	\$ 0.42
<b>Weighted average shares outstanding:</b>				
Basic	70.0	70.9	70.5	68.7
Diluted	72.4	73.8	74.6	72.6

The quarterly data has been recast to reflect push back of the tax effect related to the adoption of ASU 2016-09.

**Table of Contents***In millions, except per share amounts*

	Quarters Ended			
	Jun 30, 2015	Mar 31, 2015	Dec 31, 2014	Sep 30, 2014
<b>Consolidated Statement of Operations Data:</b>				
Molecular diagnostic testing	\$ 178.8	\$ 173.0	\$ 179.2	\$ 164.5
Pharmaceutical and clinical services	11.1	7.0	5.2	4.3
Total Revenue	189.9	180.0	184.4	168.8
Costs and expenses:				
Cost of molecular diagnostic testing	32.0	32.9	35.1	32.8
Cost of pharmaceutical and clinical services	5.5	4.2	2.8	2.1
Research and development expense	18.7	16.7	17.5	22.6
Selling, general and administrative expense	97.5	90.4	92.7	85.4
Total costs and expenses	153.7	144.2	148.1	142.9
Operating income	36.2	35.8	36.3	25.9
Other income (expense):				
Interest income	0.1	0.1	0.1	0.1
Other	(0.8)	(0.3)	1.5	(0.1)
Total other income	(0.7)	(0.2)	1.6	0.0
Income before income taxes	35.5	35.6	37.9	25.9
Income tax provision	16.8	14.1	13.9	9.9
Net income	\$ 18.7	\$ 21.5	\$ 24.0	\$ 16.0
Earnings per share:				
Basic	\$ 0.27	\$ 0.30	\$ 0.33	\$ 0.22
Diluted	\$ 0.26	\$ 0.29	\$ 0.32	\$ 0.21
Weighted average shares outstanding:				
Basic	69.4	70.7	72.5	72.8
Diluted	72.4	73.9	75.4	76.0

**Table of Contents****Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS****Overview**

Our consolidated revenues consist primarily of sales of molecular diagnostic tests and pharmaceutical and clinical services through our wholly-owned subsidiaries Myriad Genetic Laboratories, Inc., Myriad Genetics GmbH, Crescendo Bioscience, Inc., Myriad RBM, Privatlinik Dr. Robert Schindlbeck GmbH (the Clinic) & Co. KG and Sividon Diagnostics GmbH. During the year ended June 30, 2016, we reported total revenues of \$753.8 million, net income of \$125.3 million and diluted earnings per share of \$1.71 that included income tax expense of \$43.6 million.

In May 2016, we completed the acquisition of Sividon Diagnostics GmbH (Sividon), a leading breast cancer prognostic company, for \$39.0 million cash up front with the potential for 15.0 (\$16.7 converted at the June 30, 2016 end rate) in additional performance-based milestones. We believe the acquisition brings us the best-in-class breast cancer prognostic test and strengthens our market leading oncology portfolio of high value personalized medicine products.

In February 2015, we completed the acquisition of the Clinic located in Germany approximately 15 miles from the Company's European laboratories for total consideration of \$20.1 million. We believe acquisition of the Clinic should facilitate our penetration into the German molecular diagnostic market. The Clinic will allow us to directly negotiate reimbursement with government and private insurance providers in the German market and collaborate with hospitals and physician groups.

See Note 15 Segment and Related Information in the notes to our consolidated financial statements for information regarding our operating segments.

Our research and development expenses include 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. In general, costs associated with research and development can fluctuate dramatically due to the timing of clinical studies, the staging of products in the pipeline and other factors.

Our selling, general and administrative expenses include costs associated with growing our businesses domestically and internationally. Selling, general and administrative expenses consist primarily of salaries, commissions and related personnel costs for sales, marketing, customer service, billing and collection, legal, finance and accounting, information technology, human resources, and allocated facilities expenses. We expect that our selling, general and administrative expenses will continue to increase and that such increases may be substantial, depending on the number and scope of any new molecular diagnostic test launches, our efforts in support of our existing molecular diagnostic tests and pharmaceutical and clinical services as well as our continued international expansion efforts.

**Results of Operations**

*Years ended June 30, 2016, 2015 and 2014*

*Revenue*

<i>(In millions)</i>	Years Ended June 30,			Change	
	2016	2015	2014	2016	2015
Revenue	\$ 753.8	\$ 723.1	\$ 778.2	\$ 30.7	\$ (55.1)



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In 2016, the increase in revenue was primarily driven by an increase of \$20.5 million in pharmaceutical and clinical services revenue mainly from the inclusion of \$14.3 million in full-year revenue from the Clinic, which we acquired in February 2015 and a \$9.2 million increase in Prolaris revenues from increased volumes and the initiation of Medicare coverage for a portion of the Medicare population.

In 2015, the decrease in revenue was primarily driven by the loss of a one-time bolus of our BRACAnalysis revenue generated by celebrity publicity during the prior year, approximately \$50.0 million. In addition, 2015 revenue was impacted by a \$12.0 million loss of a contract with a payor and a \$3.0 million decrease due to the reduction in Medicare reimbursement rates, offset by \$29.7 million increase from the inclusion of sales of our VectraDA test for the full fiscal year.

The following table presents additional detail regarding the composition of our total revenue:

<i>(In millions)</i>	Years Ended June 30,			Change		% of Total Revenue		
	2016	2015	2014	2016	2015	2016	2015	2014
<b>Molecular diagnostic revenues:</b>								
Hereditary Cancer Testing	\$ 632.3	\$ 638.3	\$ 720.1	\$ (6.0)	\$ (81.8)	84%	88%	93%
VectraDA	47.8	43.7	14.0	4.1	29.7	6%	6%	2%
Prolaris	11.3	2.1	1.1	9.2	1.0	1%	0%	0%
Other	14.3	11.4	13.0	2.9	(1.6)	2%	2%	2%
Total molecular diagnostic revenue	705.7	695.5	748.2	10.2	(52.7)			
Pharmaceutical and clinical service revenue	48.1	27.6	30.0	20.5	(2.4)	6%	4%	4%
Total revenue	\$ 753.8	\$ 723.1	\$ 778.2	\$ 30.7	\$ (55.1)	100%	100%	