MYRIAD GENETICS INC
Form 10-K
August 14, 2013
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended June 30, 2013

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

Commission file number: 0-26642

MYRIAD GENETICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**87-0494517**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
320 Wakara Way, Salt Lake City, UT	**84108**
(Address of principal executive offices)	**(Zip Code)**

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

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

Title of each class	**Name of each exchange on which registered**
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 x 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 x

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 x 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 x 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 x	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 x

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, 2012, the last business day of the registrant s most recently completed second fiscal quarter, was $2,209,171,779.

As of August 1, 2013 the registrant had 80,446,692 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 for the Annual Meeting of Stockholders to be held on December 5, 2013.

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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, BRAC*Analysis*, COLARIS, COLARIS AP, MELARIS, PANEXIA, PREZEON, TheraGuide, Prolaris, TruCulture, DiscoveryMAP and RodentMap are registered trademarks or trademarks of Myriad.

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PART I

Item 1. BUSINESS

Overview

We are a leading molecular diagnostic company dedicated to making a difference in patients lives through the discovery and commercialization of transformative tests which assess a person s risk of developing disease, guide treatment decisions and assess risk of disease progression and recurrence. We believe in improving healthcare for patients by providing physicians with critical information to solve unmet medical needs. By understanding the underlying genetic basis of disease, we believe that individuals who have a greater risk of developing disease can be identified and physicians may be able to use this information to improve patient outcomes and better manage patient healthcare. In addition, by understanding the RNA expression levels of certain genes, we believe that we can improve patient healthcare by providing information on the aggressiveness of their disease. Further, we believe that the analysis of the expression of groups of proteins may provide a physician with life-saving information to guide treatment decisions for their patients with cancer and other major diseases.

Our goal is to provide physicians with this critical information that may guide the healthcare management of their patients to prevent disease, diagnose the disease at an earlier stage, determine the most appropriate therapy, or assess the aggressiveness of their disease. We employ a number of proprietary technologies, including DNA, RNA and protein analysis, that help us to understand the genetic basis of human disease and the role that genes and their related proteins may play in the onset and progression of disease. We use this information to guide the development of new molecular diagnostic tests that are designed to assess an individual s risk for developing disease later in life (predictive medicine), identify a patient s likelihood of responding to drug therapy and guide a patient s dosing to ensure optimal treatment (personalized medicine), or assess a patient s risk of disease progression and disease recurrence (prognostic medicine).

Our business strategy for future growth is focused on three key initiatives. First, we are working to grow and expand our existing products and markets. Second, we are developing our business internationally and have recently established operations in Europe. Finally, we intend to launch new transformative products across a diverse set of disease indications, complementing our current businesses in oncology, women s health and urology.

We offer nine commercial molecular diagnostic tests, including six predictive medicine tests, two personalized medicine tests, and one prognostic medicine test. We market these tests through our own sales force of approximately 400 people in the United States. We also market our BRACAnalysis, COLARIS, COLARIS AP, and Prolaris tests through our own European sales force and have entered into marketing collaborations and distributor agreements with other organizations in selected Latin American, European, Asian and African countries. We also generate revenue by providing companion diagnostic services to the pharmaceutical and biotechnology industries and medical research institutions utilizing our multiplexed immunoassay technology. Total revenue was $613.2 million for the year ended June 30, 2013, an increase of 24% over the prior fiscal year.

During the fiscal year ended June 30, 2013, we devoted our resources to supporting (i) our predictive medicine, personalized medicine and prognostic medicine tests, (ii) our companion diagnostic business, and (iii) our research and development efforts on future molecular diagnostic candidate tests. For the year ended June 30, 2013, we had net income of $147.1 million. For the years ended June 30, 2013, 2012 and 2011, we had research and development expense of $53.7 million, $42.6 million and $27.8 million, respectively. Additional financial information about our three reportable segments is included in Note 10 to our audited financial statements for the fiscal year ended June 30, 2013 included with this Annual Report.

Our Business Strategy

Our business strategy is to understand the relationship between genes and their protein products and human diseases in order to develop the next generation of molecular diagnostic tests. Through our proprietary

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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 underlying molecular basis for the cause of human disease. We believe that identifying these genes, proteins, and pathways will enable us to develop novel molecular diagnostic tests. Our business strategy includes the following key elements:

Discover important DNA, RNA and protein biomarkers, understand their function and determine their role in human disease. 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. We believe that our technologies provide us with a significant competitive advantage and the potential for numerous product opportunities.

Acquire promising biomarkers from other organizations. We intend to continue to take advantage of in-licensing or acquisition opportunities to augment our in-house tests development programs. For example, in September 2011, we obtained a three-year exclusive option to acquire Crescendo Bioscience, Inc., a company that is developing and marketing molecular diagnostic tests for patients suffering from autoimmune disorders, including rheumatoid arthritis, as described further in Note 13 to our financial statements for the fiscal year ended June 30, 2013 included in this Annual Report. 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 molecular diagnostic areas of focus.

Independently develop and commercialize new transformative molecular diagnostic tests. Our goal is to internally develop informative molecular diagnostic tests that can save lives and improve the quality of life of patients. Additionally, we plan to sell these tests through our own internal sales force and marketing efforts. In connection with any additional tests that we may launch, we plan to expand our existing oncology, urology, and women s health sales forces and build new sales forces to address other physician specialty groups.

Grow our molecular diagnostic business in the United States across multiple disease indications. We plan to continue to seek to expand our markets and increase the market penetration of our existing molecular diagnostic tests. Additionally, we plan to pursue new test opportunities in oncology, women s health, urology, dermatology, autoimmune and neuroscience diseases to capitalize on our leadership position in the molecular diagnostic industry.

Expand our molecular diagnostic business internationally. We believe that the market for our molecular diagnostic products in the major market countries in Europe, Latin America and Asia represents an attractive commercial opportunity. We have established sales offices in Canada, France, Spain, United Kingdom, Germany, Switzerland and Italy; laboratory operations in Germany; and international headquarters in Switzerland. We believe that our predictive medicine, personalized medicine, prognostic medicine and companion diagnostic products would benefit patients world-wide by assisting physicians in guiding their health care decisions. Our strategy is to continue to focus primarily on Europe and then expand to Latin America and Asia.

Molecular Diagnostic Tests

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

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We offer nine primary commercial molecular diagnostic tests. Our current commercial molecular diagnostic tests are:

BRACAnalysis ®: predictive medicine test for hereditary breast and ovarian cancer. Our BRAC*Analysis* 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 BRAC*Analysis* 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 cancer can reduce their risk by approximately 50% with appropriate preventive therapies. Additionally, as published in the *New England Journal of Medicine*, researchers have shown that pre-symptomatic individuals who carry gene mutations can lower their risk of developing ovarian cancer by approximately 60% with appropriate preventive therapies. Additionally, BRAC*Analysis* 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 2013 there will be approximately 255,000 women in the United States diagnosed with breast cancer or ovarian cancer. The test is currently priced at $3,340 and is covered by all major managed care organizations, or MCOs, and health insurance providers in the United States. We own or have exclusive rights to 24 U.S. patents covering BRAC*Analysis* testing. BRAC*Analysis* accounted for 75.1% of our total revenue during the year ended June 30, 2013.

BART ® (BRAC*Analysis* Large Rearrangement Test): *predictive medicine test for hereditary breast and ovarian cancer.* Our *BART* test is a predictive medicine test 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. BART may be used to identify these mutation carriers. The test is currently priced at $700 and is covered by all major MCOs and health insurance providers in the United States. We own seven U.S. patents covering BART testing. BART accounted for 9.6% of our total revenue during the year ended June 30, 2013.

COLARIS ®: predictive medicine test for hereditary colorectal cancer 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 cancer or 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. Highly effective preventive measures for colon cancer include colonoscopy and the removal of precancerous polyps and for uterine cancer includes hysterectomy. Through proper application of screening and polyp removal, colon cancer is a preventable disease.

According to the American Cancer Society, approximately 192,000 new cases of colorectal or uterine cancer will be diagnosed in 2013. According to the American Society of Clinical Oncologists, familial forms of colorectal cancer are estimated to account for 10% to 30% of all cases. The test is currently priced at $4,480 and is covered by all major MCOs and health insurance providers in the United States. We own or have non-exclusive licensed rights to eight U.S. patents covering COLARIS testing.

COLARIS AP®: predictive medicine test for hereditary colorectal cancer. Our COLARIS AP test detects mutations in the APC and MYH genes, which cause a colon polyp-forming syndrome known 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.

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Our COLARIS AP test is currently priced at $2,050 and is covered by all major MCOs and health insurance providers in the United States. We own or have exclusive rights to ten U.S. patents covering COLARIS AP testing.

COLARIS and COLARIS AP accounted for 8.5% or our total revenue during the year ended June 30, 2013.

MELARIS ®: predictive medicine test for hereditary melanoma. Our MELARIS test analyzes mutations in the p16 gene to determine genetic susceptibility to malignant melanoma. Individuals who test positive for a deleterious mutation in the p16 gene with the MELARIS test have a 75-fold increased risk of developing melanoma during their lifetimes as compared to the general population. Melanoma may be prevented through appropriate screening and a specific threshold of action for mutation carriers, in which pre-cancerous lesions are removed before cancer can develop.

According to the American Cancer Society, approximately 77,000 new cases of melanoma will be diagnosed in the United States in 2013. Melanoma is lethal within five years in 86% of cases where it has spread to another site in the body. However, when melanoma is diagnosed at an early stage, fewer than 10% of patients die within five years. The MELARIS test is currently priced at $900 and is covered by most major MCOs and health insurance providers in the United States. We own or have license rights to five U.S. patents covering MELARIS testing.

PANEXIA : predictive medicine test for pancreatic cancer. Our PANEXIA test is a comprehensive analysis of the *PALB2* and *BRCA2* genes for assessing a person s risk of developing pancreatic cancer later in life. Individuals with a mutation detected by the PANEXIA test have up to an 8.6-fold higher risk than the general population of developing pancreatic cancer. If an individual with a family history of pancreatic cancer receives the PANEXIA test and is identified as having a deleterious mutation, increased surveillance and other predictive steps can be taken in an effort to detect the cancer at an early stage where it may be more treatable.

According to the American Cancer Society, pancreatic cancer is estimated to affect approximately 45,000 men and women in the United States in 2013. Pancreatic cancer generally has a very poor prognosis for most patients because it is usually detected at a late stage after the cancer has already metastasized to other parts of the body. The PANEXIA test is currently priced at $3,025. We own or have exclusive patent rights to ten U.S. patent applications covering PANEXIA testing.

PREZEON®: personalized and prognostic medicine test for cancer. Our PREZEON test is an immunohistochemistry test that analyzes the PTEN gene and assesses loss of PTEN function in many cancer types. The PTEN gene is one of the most important tumor suppressor genes and its loss of function is associated with more aggressive disease progression and poorer survival. The PTEN gene plays a role in the disease progression of all four of the major cancers breast, prostate, colon, and lung cancer. The PTEN gene also plays a critical role in cell signaling pathways that are the target of a number of cancer drugs such as EGFR, mTOR and PIK3CA inhibitors. Analysis of PTEN function may help oncologists in identifying patients who may not respond to these classes of cancer drugs.

According to the American Cancer Society, approximately 844,000 new cases of these cancers will be diagnosed this year. The PREZEON test is currently priced at $500. We own or have exclusive patent rights to six U.S. patents covering PREZEON testing.

Prolaris®: prognostic medicine test for prostate cancer. Our Prolaris test is a 46-gene molecular diagnostic 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 meet this significant need to improve physicians ability to predict disease outcome and to thereby optimize treatment. The Prolaris test is based on the understanding of cell division and tumor growth and provides rigorous, quantitative measures of the expression levels of multiple genes related to progression of the cell cycle. As published in the *British Journal of Cancer*, researchers analyzed the Prolaris test scores of 352 men with prostate cancer who

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were managed through active surveillance and the Prolaris test was the strongest predictor of prostate cancer death and was highly statistically significant ($p = 1.4 \times 10^{-10}$). The Prolaris test outperformed both the Gleason and PSA score in this study.

According to the American Cancer Society, in the United States approximately 239,000 men are expected to be diagnosed with prostate cancer this year. The Prolaris test is currently priced at $3,400. We own or have exclusive patent rights to four U.S. patent applications covering Prolaris testing.

TheraGuide® 5-FU: personalized medicine test for drug toxicity. Our TheraGuide 5-FU test analyzes mutations in the DPYD gene and variations in the TYMS gene to assess patient risk of toxicity to 5-FU (fluorouracil) anti-cancer drug therapy. Cancer patients who test positive for a deleterious mutation in the DPYD gene and variations in the TYMS gene have an increased risk of suffering toxicity from 5-FU chemotherapy and up to 20% of patients will experience medically significant toxicity issues (grade 3 or 4 toxicity). These patients should be considered for either a reduced dose of 5-FU or other chemotherapy regimens. 5-FU is widely prescribed for the treatment of colorectal cancer, metastatic breast cancer, skin cancer, and head and neck cancers.

According to IMS prescription data, there are approximately 425,000 prescriptions written for patients who receive 5-FU therapy each year in the United States. The TheraGuide 5-FU test is currently priced at $1,175 and is covered by many MCOs and health insurance providers in the United States. We own or have exclusive rights to two U.S. patent applications covering TheraGuide 5-FU testing.

We plan to launch three new molecular diagnostic tests in fiscal year 2014. These planned new diagnostic tests include:

myRisk Hereditary Cancer : predictive medicine test for hereditary cancer. Our myRisk Hereditary Cancer test represents the next generation of our existing hereditary cancer franchise and will eventually replace our current predictive medicine test offerings (BRAC*Analysis*, Colaris, Colaris AP, Melaris, and Panexia) 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, endometrial cancer, melanoma, and pancreatic cancer. The test analyzes 25 separate genes to look for deleterious mutations which would put a patient at a substantially higher risk than the general population for developing one or more of the above six cancers. All 25 genes in the panel are well documented in clinical literature for the role they play in hereditary cancer and have actionable clinical interventions for the patient to lower disease risk or risk of cancer recurrence.

Based on current American Cancer Society data, in the United States there are over 600,000 new cancer diagnoses in the six cancers covered by myRisk Hereditary Cancer every year. myRisk Hereditary Cancer will have a list price between $4,000 and $4,500. We own or have exclusive license rights to 54 issued U.S. patents and 4 pending U.S. patent applications relating to myRisk Hereditary Cancer testing.

myPath Melanoma : diagnostic test for the identification of 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 fourteen percent of these biopsies are indeterminate where a dermatopathologist cannot make a definitive call of 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 95% for stage 1 cancer to less than 20% for stage 4 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.

There are approximately 280,000 indeterminate diagnosis of melanoma every year. The pricing for myPath Melanoma has not yet been determined. We own or have exclusive license rights to one U.S. patent applications relating to myPath Melanoma testing.

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myPlan Lung Cancer : prognostic medicine test for 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. In a clinical study presented at the American Society of Clinical Oncology Meeting in 2012, 27% of patients with a myPlan Lung Cancer low-risk score died of lung cancer within five years of diagnosis compared to 89% of the patients with a high-risk score. We believe this test may be clinically applicable in the approximately 30,000 new lung cancer diagnoses every year that are early stage lung cancer.

The pricing for myPlan Lung Cancer has not yet been determined. We own or have exclusive license rights to two U.S. patent applications relating to myPlan Lung Cancer testing.

Companion Diagnostic Services and Other Revenue

On May 31, 2011, we completed the acquisition of the privately-held molecular diagnostic company, Rules-Based Medicine, Inc. of Austin, Texas, for a cash purchase price of approximately $80.0 million. As of June 30, 2013, Rules-Based Medicine is operating as a wholly-owned subsidiary of Myriad under the name of Myriad RBM, Inc. or Myriad RBM . The acquisition expanded our test pipeline into new disease states, including neuroscience disorders, infectious diseases and inflammatory diseases. We believe that the tests being developed by Myriad RBM will complement the tests that we are developing using our strong research capabilities in nucleic acid (DNA and RNA) analysis with proprietary multiplex immunoassay (protein) technology. Myriad RBM has strategic collaborations with over 20 major pharmaceutical and biotechnology companies, which coupled with our industry-leading position in PARP inhibitor and PI3K inhibitor companion diagnostics, creates a leading franchise in companion diagnostics. In addition, our acquisition of Myriad RBM provides us with access to samples from additional patient cohorts for new molecular diagnostic test development and clinical validation activities.

Through Myriad RBM, we provide biomarker discovery and companion diagnostic 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. By analyzing the data generated from these tests, we attempt to discover biomarker patterns that indicate a particular disease or disorder with a high degree of accuracy. During the year ended June 30, 2013, Myriad RBM generated $30.8 million in revenue from providing its companion diagnostic services. In addition to the fees received from analyzing these samples, we also use this information to create and validate potential diagnostic test panels that can aid us in the development of potential new molecular diagnostic tests that could aid a physician in making diagnostic and treatment decisions.

Our companion diagnostic services consist of the following:

Multi-Analyte Profile (MAP): We have compiled a library of over 550 individual human and rodent immunoassays for use in our multi-analyte profile (MAP) testing services and we are continuously adding new assays to this library. We have assembled what we believe are the most clinically relevant human immunoassays from this library into our DiscoveryMAP® assay panel, which we typically employ with pharmaceutical collaborators in human clinical trials. We have also developed RodentMAP®, a proprietary panel for use in pre-clinical animal studies and OncologyMAP®, which measures cancer-related proteins to assist researchers accelerate the pace of discovery, validation and translation of cancer biomarkers for early detection, patient stratification and therapeutic monitoring. Our MAP services are designed to provide a comprehensive and cost-effective evaluation of the biomarker patterns critical to applications such as drug safety and efficacy, disease diagnosis, diseases modeling, patient stratification as well as personal health assessments.

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Importantly, the data generated through our companion diagnostic services business can provide new insights into biological systems and enable us to generate potential new molecular diagnostic tests. Under the terms of the agreements with many of our collaborators, we retain the rights to the companion diagnostic products. We have licensed rights to the Luminex platform used in our MAP testing services.

Multiplexed Immunoassay Kits: Customers in all segments of the life sciences market often require both outsourced and in-house testing. Many of our pharmaceutical and biotechnology customers need bioassay kits for complimentary in-house testing. Therefore, we have developed multiplexed immunoassay kits that enable our customers to leverage our technology services with their in-house capabilities. Our internally developed multiplexed immunoassay kits include all of the components necessary for a customer to perform a test on their own Luminex instrument. We have licensed rights to the Luminex platform used in our multiplexed immunoassay kits.

TruCulture®: TruCulture is a simple, self-contained whole blood culture that can be deployed to clinical sites around the world for acquiring cell culture data without specialized facilities or training. The TruCulture system may allow pharmaceutical and biotechnology companies to identify drug toxicity prior to human trials, potentially enabling a decision as to whether to continue a drug s development earlier in the development process and thereby save significant research and development costs. We have exclusive patent rights to one U.S. patent covering our TruCulture and other co-culture services.

Patents and Proprietary Rights

We own or have license rights to 234 issued patents as well as numerous patent applications in the United States and foreign countries. These patents and patent applications cover a variety of subject matter including, diagnostic biomarkers, genes, proteins, gene expression signatures, antibodies, primers, probes, assays, disease-associated genetic mutations and single-nucleotide polymorphisms, methods for determining genetic predisposition, methods for disease diagnosis, methods for determining disease progression, methods for correlation claims, and methods for disease treatment, and general molecular diagnostic techniques.

The following is a summary of key U.S. patents covering our current molecular diagnostic tests and companion diagnostic services. Many of the issued U.S. patents relating to BRAC*Analysis*, COLARIS, COLARIS AP, MELARIS, PREZEON, PANEXIA and TruCulture also have related foreign issued patents in various countries, including in Europe, Canada, Japan, Australia and New Zealand, claiming similar subject matter and having similar expiration dates. For many of the patents, we hold rights through exclusive or non-exclusive license agreements, which are summarized in the following section under the caption License Agreements. We also own additional patent applications and hold other non-exclusive license rights to patents which cover various aspects of our tests or processes.

BRACAnalysis. We own or have exclusive license rights to over 500 claims in 24 issued U.S. patents relating to BRAC*Analysis* testing. These U.S. patents have terms that are expected to expire commencing in 2014, with the last patent expected to expire in 2029. These patents contain multiple claims, including claims relating to compositions of matter on synthetic *BRCA1* and *BRCA2* nucleic acids, probes and primers, methods of detecting genetic mutations in the *BRCA1* and *BRCA2* genes and the use thereof for diagnosing predisposition to breast or ovarian cancer, and general molecular diagnostic technology relating to BRAC*Analysis* testing.

BART. We own or have exclusive license rights to seven issued U.S. patents relating to BART testing. These U.S. patents have terms that are expected to expire commencing in 2015, with the last patent expected to expire in 2025. These patents contain multiple claims, including but not limited to claims relating to composition of matter on synthetic *BRAC1* and *BRCA2* nucleic acids, composition of matter on probes and primers, methods of detecting genomic rearrangements and methods of determining *BRCA1* and *BRCA2* related predisposition to cancer.

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COLARIS. We own or have exclusive or non-exclusive license rights to 19 issued U.S. patents relating to COLARIS testing. These U.S. patents have terms that are expected to expire commencing in 2013, with the last patent expected to expire in 2023. These patents contain multiple claims, including but not limited to claims relating to *MLH1*, *MSH2, PMS2* and *MYH* compositions of matter on synthetic *MLH1*, *MSH2, PMS2* and *MYH* nucleic acids, methods of detecting mutations in the *MLH1, MSH2* and *MYH* genes, methods for determining *MLH1-*, *MSH2-, PMS2-,* and *MYH-* related predisposition to cancer, such as Lynch Syndrome cancers, and general molecular diagnostic technology applicable to COLARIS testing.

COLARIS AP. We own or have exclusive license rights to 11 issued U.S. patents relating to COLARIS AP testing. These U.S. patents have terms that are expected to expire commencing in 2017, with the last patent expected to expire in 2026. These patents contain multiple claims, including claims relating to compositions of matter on synthetic *MYH* nucleic acids, methods of detecting *MYH* mutations and methods of detecting a predisposition to colorectal cancer using *MYH*, and general molecular diagnostic technology applicable to COLARIS AP testing.

MELARIS. We own or have exclusive license rights to five issued U.S. patents relating to MELARIS testing. These U.S. patents have terms that are expected to expire commencing in 2014, with the last patent expected to expire in 2023. These patents contain multiple claims, including claims relating to methods of detecting mutations in the *p16* gene and their use for diagnosing predisposition to melanoma, and general molecular diagnostic technology applicable to MELARIS testing.

PANEXIA. We own or have exclusive license rights to eight U.S. patents and two U.S. patent applications relating to PANEXIA testing. These U.S. patents have terms that are expected to expire commencing in 2015 with the last patent expected to expire in 2029. Subject to applicable extensions, we anticipate that the expiration dates of these patent applications, if issued, will commence in 2029. These patent applications disclose varied subject matter, including but not limited to composition of matter claims on *PALB2* and *BRCA2* gene mutations and methods of diagnosing a predisposition to pancreatic cancer based on *PALB2* and *BRCA2* gene mutations.

PREZEON. We have exclusive license rights to six issued U.S. patents relating to PREZEON testing. These U.S. patents have terms that are expected to expire commencing in 2017, with the last patent expected to expire in 2018. These patents contain multiple claims, including but not limited to claims relating to *PTEN* compositions of matter on antibodies, methods of detecting *PTEN* expression and *PTEN* mutations, and methods of detecting cancer or a predisposition to cancer using *PTEN*, and methods of guiding therapeutic treatment decisions based on PTEN status.

Prolaris. We own or have exclusive license rights to six U.S. patent applications relating to Prolaris testing. Subject to applicable extensions, we anticipate that the expiration dates of these patent applications, if issued, will commence in 2030. These patent applications disclose varied subject matter, including but not limited to compositions of matter claims on gene expression signatures and methods of determining aggressiveness of prostate cancer and the likelihood of progression risk of recurrence of prostate cancer based on gene expression signatures.

TheraGuide 5-FU. We own one U.S. patent and one U.S. patent application relating to TheraGuide 5-FU testing. The patent will expire in 2023. Subject to applicable extensions, we anticipate that the expiration date of the U.S. patent applications, if issued, will commence in 2027. The patent and application disclose varied subject matter, including but not limited to subject matter relating to compositions of matter on synthetic *DPYD* nucleic acids containing specific mutations, diagnostic methods relating to *DPYD* mutations, and general molecular diagnostic technology applicable to TheraGuide 5-FU.

TruCulture. We have exclusive license rights to commercialize technology covered by one issued U.S. patent for our TruCulture product. This U.S. patent is expected to expire in 2019. This patent contains multiple claims, including but not limited to claims relating to methods and kits for determining the immune defense activity of blood.

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myRisk Hereditary Cancer. We own or have exclusive license rights to 54 issued U.S. patents and 4 pending U.S. patent applications relating to myRisk Hereditary Cancer™ testing. Subject to applicable extensions, we anticipate that the expiration dates of these patents will commence in 2014, with the last patent, if issued from the currently pending applications, expected to expire in 2029. These patents and patent applications disclose and claim varied subject matter, including claims relating to compositions of matter on synthetic nucleic acids, probes and primers, methods of detecting genetic mutations in the 25 genes that comprise the test (individually and in numerous combinations) and the use thereof for diagnosing predisposition to various cancers, and general molecular diagnostic technology relating to myRisk Hereditary.

myPath Melanoma. We own or have exclusive license rights to one U.S. patent applications relating to myPath Melanoma testing. Subject to applicable extensions, we anticipate that the expiration date of this patent application, if issued, will commence in 2027. This patent application discloses varied subject matter, including but not limited to compositions of matter claims on gene expression signatures and methods of detecting melanoma, methods of determining aggressiveness, likelihood of progression, risk of recurrence and optimal therapy based on gene expression signatures.

myPlan Lung Cancer. We own or have exclusive license rights to two U.S. patent applications relating to myPlan Lung Cancer testing. Subject to applicable extensions, we anticipate that the expiration dates of these patent applications, if issued, will commence in 2032. These patent applications disclose varied subject matter, including but not limited to compositions of matter claims on gene expression signatures and methods of determining cancer aggressiveness, likelihood of progression, risk of recurrence and optimal therapy for lung cancer based on gene expression signatures.

We intend to seek patent protection in the United States and major foreign jurisdictions for synthetic nucleic acids, proteins, 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 such as was the case in our recent Supreme Court case discussed in Item 3, Legal Proceedings. 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.

Our tests and processes may also conflict with patents which have been or may be granted to competitors, academic institutions or others. As the molecular diagnostic industries expand and more patents are issued, the risk increases that our products and processes may give rise to interferences filed by others in the U.S. Patent and Trademark Office or foreign patent offices, or to claims of patent infringement by other companies, institutions or individuals. 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, IHC, robotic and

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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 predictive medicine 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 multiple 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 companion diagnostic 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.

In October 1991, we entered into a license agreement with the University of Utah Research Foundation (the University), for the exclusive rights to utilize certain intellectual property rights of the University, including issued patents that relate to the *BRCA1* gene, on a world-wide basis. Under this license agreement we pay the University a royalty based on net sales of our BRAC*Analysis* test. This license agreement ends on the last to expire patent covered by the license agreement which presently is not anticipated to expire until April 2015. The University has the right to terminate the license agreement for the uncured breach of any material term of the license agreement.

We entered into separate license agreements with the University, Endorecherche, Inc., The Hospital for Sick Children and The Trustees of the University of Pennsylvania (collectively referred to as the BRCA2 Licensors) in November 1994, January 1995, March 1995 and March 1996, respectively, for exclusive rights to utilize certain intellectual property rights of the respective BRCA2 Licensors, including issued patents that relate to the *BRCA2* gene, on a world-wide basis. Under these license agreements we pay each of the BRCA2 Licensors a royalty based on net sales of our BRAC*Analysis* test. Each of these license agreements ends on the expiration date of the last to expire patent covered by the respective license agreements which presently is not anticipated to expire until December 2015. The BRCA2 Licensors have the right to terminate the license agreements for the uncured breach of any material term of the license agreements.

In April 2000, we entered into a license agreement with Dana-Farber Cancer Institute, Inc., Oregon Health Sciences University, University of Vermont and State Agricultural College and Yale University (collectively the COLARIS Licensors) for the non-exclusive rights to utilize certain intellectual property rights of the COLARIS Licensors, including issued patents that relate to the MLH1, MLH2 and PMS2 genes, on a world-wide basis. Under this license agreement we pay the COLARIS Licensors a royalty based on net sales of our COLARIS test. This license agreement ends on the expiration date of the last to expire patent covered by the license agreement, which presently is not anticipated to expire until October 2023. The COLARIS Licensors have the right to terminate the license agreement for the uncured breach of any material term of the license agreement.

In April 2000, we entered into a license agreement with Genzyme Corporation (Genzyme) for the non-exclusive rights to utilize certain intellectual property rights of Genzyme, including issued patents that relate to the MSH2 gene, on a world-wide basis. Under this license agreement we pay Genzyme a royalty based on net sales of our COLARIS test. This license agreement ends, on a country by country basis, on the expiration date of the last to expire patent covered by the license agreement, which presently is not anticipated to expire until

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October 2023. Either party has the right to terminate the license agreement for the uncured breach of any material term of the license agreement.

In March 2004 and June 2007, we entered into separate license agreements with the University of Wales and Human Genome Sciences, Inc. (HGSI) respectively (collectively referred to as the COLARIS AP Licensors) for the exclusive rights to certain intellectual property rights of the respective licensors, including issued patents that relate to the *MYH* gene, on a world-wide basis. Under these license agreements we pay each of the COLARIS AP Licensors a royalty based on net sales of our COLARIS and COLARIS AP tests. Each of these license agreements ends on the expiration date of the last to expire patent covered by the respective license agreements which presently is not anticipated to expire until February of 2018 for the HGSI license and April 2023 for the University of Wales license. The COLARIS AP Licensors have the right to terminate the license agreements for the uncured breach of any material term of the license agreements. On July 1, 2013 and July 19, 2013 respectively, all rights of University of Wales and HGSI related to the MYH gene were assigned to Myriad.

In October 2009, we entered into a license agreement with Johns Hopkins University for the exclusive right to utilize certain intellectual property rights of Johns Hopkins, including patent applications that relate to the PALB2 gene, on a world-wide basis. Under this license agreement we pay John Hopkins University a royalty based on net sales of our PANEXIA test. This license agreement ends on the expiration date of the last to expire patent covered by the license agreement, which presently is not anticipated to expire until March 2030. Johns Hopkins University has the right to terminate the license agreement for the uncured breach of any material term of the license agreements.

Competition

Competition is intense in our existing and potential markets. Our competitors in the United States and abroad are numerous and include, other molecular diagnostic companies, diagnostic reference laboratories, large multi-national healthcare companies, and universities and other research institutions. For instance, some laboratories provide a test intended to predict the cancer s aggressiveness among patients with prostate cancer and other laboratories provide hereditary cancer testing for melanoma, colorectal and uterine cancer. Some of our potential competitors have considerably greater financial, technical, marketing and other resources than we do. We expect competition to intensify in our current fields as technical advances occur and become more widely known. For example, following our Supreme Court case discussed in Item 3, Legal Proceedings, Ambry Genetics Corporation and Gene By Gene commenced offering certain clinical diagnostic testing for hereditary breast and ovarian cancer that compete with our BRACAnalysis testing and future molecular diagnostic testing we plan to launch. We anticipate that others may also launch their own molecular diagnostic tests which may compete with our testing products and services.

The technologies for discovering the underlying cause of major diseases, patients response to therapies, and disease progression, as well as the approaches for commercializing those discoveries are rapidly evolving. Rapid technological developments could result in our potential tests or processes becoming obsolete before we recover a significant portion of our related research and development costs and associated capital expenditures. If we do not discover biomarkers, develop molecular diagnostic tests and related information services based on such discoveries, obtain regulatory and other approvals, and launch such services before our competitors, we could be adversely affected. Moreover, any molecular diagnostic tests that we may develop could be made obsolete by less expensive or more effective tests or methods that may be developed in the future.

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 government health care programs. The significant areas of regulation are summarized below.

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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 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, or 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.

Standards for testing under CLIA vary based on the level of test complexity. Laboratories performing high complexity testing must comply with more stringent requirements than laboratories performing waived or moderate complexity testing. Our laboratories in Salt Lake City, Utah and Austin, Texas are CLIA certified to perform high complexity tests.

In addition, CLIA requires each certified laboratory to enroll in an approved proficiency testing program if it performs testing in any category for which proficiency testing is required. Such laboratories must periodically test specimens received from an outside proficiency testing organization and then must submit the results back to that organization for evaluation. A laboratory that fails to achieve a passing score on a proficiency test may lose its right to perform testing in the category at issue. 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 referring 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, or CMS, a CMS agent (typically a state agency), or, if the laboratory holds a CLIA Certificate of Accreditation, a CMS-approved accreditation organization. Our laboratories are accredited by the College of American Pathologists, or CAP, which is a CMS-approved accreditation organization. Those laboratories must comply with all CLIA requirements as well as with any additional requirements imposed by CAP.

CLIA provides that a state may adopt laboratory regulations that are more stringent than those under federal law. In some cases, state licensure programs actually substitute for the federal CLIA program. In other instances, the state s regulations may be in addition to the CLIA program. 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 from California, Florida, and New York, to the extent that they accept specimens from one or more of these states, each of which require out-of-state laboratories to obtain licensure. If a laboratory is out of compliance with state laws or regulations governing licensed laboratories, penalties for violation vary from state to state but may include suspension, limitation, revocation or annulment of the license, assessment of financial penalties or fines, or imprisonment. We believe that we are in material compliance with all applicable licensing laws and regulations.

We may become aware from time to time of other states that require out-of-state laboratories to obtain licensure to accept specimens from the state, and other states may impose such requirements in the future. If we identify any other state with such requirements, or if we are contacted by any other state advising us of such requirements, we intend to follow all instructions from the state regulators regarding compliance with such requirements.

Food and Drug Administration

Although the Food and Drug Administration (FDA) has consistently claimed that it has the authority to regulate laboratory-developed tests, or LDTs, that are validated by the developing laboratory and performed only by that

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laboratory, it has generally exercised enforcement discretion in not otherwise regulating most tests developed and performed by high complexity CLIA-certified laboratories. Nevertheless, the FDA indicated that it is reviewing the regulatory requirements that apply to LDTs. In July 2010, the FDA held a two-day public meeting to obtain input from stakeholders on how it should apply its authority to implement a reasonable, risk-based, and effective regulatory framework for LDTs, including genetic tests. However, the FDA has not yet issued the promised additional guidance but may do so in the future. Before any draft or final guidance is issued, however, the FDA will be required to provide Congress at least sixty days prior notice in accordance with the requirements of the Food and Drug Administration Safety and Innovation Act, or FDASIA. The notice must include anticipated details of the action. FDASIA was signed into law on July 9, 2012, and the notice requirement will sunset five years thereafter.

The FDA issued a Draft Guidance for Industry and Food and Drug Administrative Staff on In-Vitro Companion Diagnostic Devices on July 14, 2011, which, if finalized, is intended to assist companies developing in vitro companion diagnostics 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, or IVD Companion Diagnostic Device, as a device that provides information that is essential for the safe and effective use of a corresponding therapeutic product. This definition is much narrower than the commonly used term companion diagnostic, which refers generally to tests that may be useful, but are not necessarily a determining factor in the safe and effective use of the therapeutic product. The FDA expects that the therapeutic sponsor will address the need for an approved or cleared IVD Companion Diagnostic Device in its therapeutic product development plan. The sponsor of the therapeutic product can decide to develop its own IVD Companion Diagnostic Device, partner with a diagnostic device sponsor to develop the appropriate IVD Companion Diagnostic Device, or explore modification of an existing IVD diagnostic device (its own or another sponsor s) to accommodate the appropriate intended use. The FDA has approved a number of drug/diagnostic device companions in accordance with the Draft Guidance. However, this guidance may not apply to the LDTs that are used as companion diagnostics that merely provide useful information.

HIPAA and other privacy laws

The Health Insurance Portability and Accountability Act of 1996, or HIPAA, established for the first time comprehensive federal protection for the privacy and security of health information. The HIPAA standards apply to three types of organizations, or Covered Entities : health plans, healthcare clearing houses, and healthcare providers which conduct certain healthcare transactions electronically. 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. HIPAA requires Covered Entities to obtain a written assurance of compliance from individuals or organizations who provide services to Covered Entities involving the use or disclosure of protected health information (Business Associates).

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 amends HIPAA and, among other things, expands and strengthens HIPAA, creates new targets for enforcement, imposes new penalties for noncompliance and establishes new breach notification requirements for Covered Entities and Business Associates. Regulations implementing major provisions of HITECH were finalized on January 25, 2013 through publication of the HIPAA Omnibus Rule (the Omnibus Rule). The Omnibus Rule contained significant changes for Covered Entities and Business Associates with respect to permitted uses and disclosures of Protected Health Information.

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Under HITECH s new 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, they must be reported through local and national media, depending on the size of the breach.

We are currently subject to the HIPAA regulations and maintain an active compliance program. We are subject to audit under HHS s HITECH-mandated audit program. We may also be audited in connection with a privacy complaint. 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 addition to the federal privacy regulations, there are a number of state laws regarding the privacy and security of health information and personal data that are applicable to clinical laboratories. The compliance requirements of these laws, including additional breach reporting requirements, and the penalties for violation vary widely and new privacy and security laws in this area are evolving. Many states have also implemented genetic testing and privacy laws imposing specific patient consent requirements and protecting test results. In some cases, we are prohibited from conducting certain tests without a certification of patient consent by the physician ordering the test. Requirements of these laws and penalties for violations vary widely. We believe that we have taken the steps required of us to comply with health information privacy and security statutes and regulations in all jurisdictions, both state and federal. However, 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 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, or 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, such as HIV and hepatitis B and C, 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.

Foreign regulations

We market 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 (EC) released the first drafts of the new 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 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.

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Reimbursement and Billing

Reimbursement and billing for diagnostic services is generally highly complex. Laboratories must bill various payors, such as private third-party payors, including MCOs 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;
- 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;