MYRIAD GENETICS INC
Form 10-K
August 15, 2012
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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, 2012

¨ **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
Preferred Share Purchase Rights	

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 accelerated filer , large 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, 2011, the last business day of the registrant s most recently completed second fiscal quarter, was $1,756,740,004.

As of August 6, 2012 the registrant had 81,693,318 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, 2012.

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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, OnDose, 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 perform all of our molecular diagnostic testing and analysis in our own reference laboratories and employ a number of proprietary technologies that help us 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. These technologies include the cornerstone technologies of biomarker discovery, high-throughput DNA sequencing, RNA expression and multiplex protein analysis. 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).

We believe in improving the healthcare management of patients by providing physicians with critical information that addresses unmet clinical 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 by potentially delaying or even preventing the onset of disease. In addition, by understanding an individual s genetics and likelihood of responding to particular therapies, we believe that physicians may be able to tailor a patient s therapy to improve patient outcomes. By analyzing the expression levels of appropriate genes, we believe that we can provide information to the physician on disease progression, to potentially enable the physician to determine how aggressively to treat the patient s disease. Further, we have tests in development which analyze protein biomarkers. We think this protein information will help diagnose and determine treatment for many diseases.

To date, we have launched nine commercial molecular diagnostic tests. We market these tests through our own approximate 385-person sales force in the United States. We also market our BRACAnalysis®, COLARIS®, and COLARIS AP® tests through our own European sales force and have entered into marketing collaborations with other organizations in selected Latin American, European and Asian 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 $496.0 million for the year ended June 30, 2012, an increase of 23% over the prior fiscal year.

During the fiscal year ended June 30, 2012, we devoted our resources to supporting our predictive medicine, personalized medicine and prognostic medicine tests, and our companion diagnostic business, as well as to the research and development of future molecular diagnostic candidate tests. For the year ended June 30, 2012, we had net income of $112.2 million, and at June 30, 2012, we had an accumulated deficit of $12.7 million. For the years ended June 30, 2012, 2011 and 2010, we had research and development expense of $42.6 million, $27.8 million and $21.9 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, 2012 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 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.

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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, 2012 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 Munich, Germany; Paris, France; Madrid, Spain; and Milan, Italy; laboratory operations in Munich, Germany; and international headquarters in Zurich, Switzerland. We believe that our predictive medicine, personalized medicine and 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 finally 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, assess a patient s risk of disease progression and disease recurrence, and measure a patient s exposure to drug therapy to ensure optimal dosing and reduced drug toxicity. Armed with this valuable information, physicians may be able to 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.

To date, we have launched nine 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 a comprehensive 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.

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According to the American Cancer Society, in 2012 there will be approximately 251,000 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 81.7% of our total revenue during the year ended June 30, 2012.

COLARIS ®: predictive medicine test for hereditary colorectal cancer and uterine cancer. Our COLARIS test is a comprehensive analysis of the MLH1, MSH2, MSH6 and PMS2 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 191,000 new cases of colorectal or uterine cancer will be diagnosed in 2012. 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.

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 8.7% or our total revenue during the year ended June 30, 2012.

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 76,000 new cases of melanoma will be diagnosed in the United States in 2012. 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.

OnDose®: personalized medicine test for chemotherapy toxicity to 5-FU. Our OnDose test is a nanoparticle immunoassay that is designed to assist oncologists in optimizing 5-FU (fluorouracil) anti-cancer drug therapy in colon cancer patients on an individualized basis. The OnDose test provides pharmacokinetic data to the oncologist to help guide dose adjustments of 5-FU to ensure that the potential cancer is being treated

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appropriately in order to reduce side effects and toxicity. As published in the *Journal of Clinical Oncology*, a prospective clinical study in 208 colon cancer patients demonstrated an increase in median overall survival of 6 months and a reduction in grade 3 or 4 toxic events of 40% in those patients who were dosed using the OnDose technology compared to patients dosed using current standard of care.

According to IMS prescription data, there were approximately 300,000 prescriptions written for patients diagnosed with colorectal cancer that receive 5-FU chemotherapy last year. The OnDose test is currently priced at $300 per test, and we estimate that a minimum eight tests per patient are required to determine and maintain the optimum 5-FU dose for each patient. The OnDose test is covered by some MCOs and health insurance providers in the United States. We own or have exclusive patent rights to two U.S. patents and two U.S. patent applications covering OnDose 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 44,000 men and women in the United States in 2012. 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 10 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 can help oncologists in identifying patients who may not respond to these classes of cancer drugs.

According to the American Cancer Society, approximately 840,000 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. patent 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 the 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 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 242,000 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.

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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 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 and up to 20% of patients will experience medically significant toxicity issues (grade 3 or 4 toxicity).

According to IMS prescription data, there are approximately 430,000 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 application covering TheraGuide 5-FU 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, 2012, 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, 2012, Myriad RBM generated $23.6 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.

Importantly, the data generated through our companion diagnostic services can business provide new insights into biological systems and enable us to generate potential new molecular diagnostic tests. Under the terms of the agreements with a 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.

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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 193 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 525 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 isolated *BRCA1* and *BRCA2* nucleic acids, compositions of matter on 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 applicable to BRAC*Analysis* testing. We are a defendant in a lawsuit brought by the Association for Molecular Pathology, *et al* . (the Plaintiffs) on May 12, 2009 in the United States District Court for the Southern District of New York (the District Court). The Plaintiffs sought a declaratory ruling that 15 claims of seven patents relating to the *BRCA1* and *BRCA2* genes, which patents are exclusively licensed to us, are invalid and unenforceable, and enjoining us (and the other defendants) from taking any actions to enforce these claims of these patents. On April 19, 2010, the District Court ruled that these 15 claims at issue were invalid. On June 16, 2010, we filed a Notice to Appeal with the United States Court of Appeals for the Federal Circuit (the Court of Appeals) appealing the District Court decision. On July 29, 2011 the Court of Appeals reversed the District Court s decision, in part, holding that the nine composition claims relating to isolated DNA molecules and one method claim relating to screening potential cancer therapeutics are patent-eligible under 35 U.S.C. Section 101. However, the Court of Appeals affirmed the District Court s decision that the remaining five method claims are patent ineligible.

On December 7, 2011, Plaintiffs filed a Petition for a Writ of Certiorari with the Supreme Court of the United States (the Supreme Court), seeking the Supreme Court s review of the decision of the Court of Appeals. On January 13, 2012, we filed our Brief in Opposition to the Plaintiffs Petition for a Writ of Certiorari. On March 26, 2012 the

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Supreme Court granted the Plaintiffs Petition for a Writ of Certiorari and remanded the case back to the Court of Appeals for reconsideration in light of the Supreme Court s recent decision in Mayo v. Prometheus Laboratories. Accordingly, the Court of Appeals will now reconsider its decision. Briefs of the parties and *amici curiae* were submitted June 15, 2012 and the Court of Appeals heard the case on July 20, 2012. A decision from the Court of Appeals is expected before the end of 2012.

Apart from the 15 claims being challenged in this lawsuit, there are over 500 separate claims under 24 patents which also cover the intellectual property utilized in, or related to, our BRAC*Analysis* predictive medicine test for breast and ovarian cancer which are not subject to this lawsuit. Accordingly, we do not believe that this lawsuit will have a material adverse impact on the Company even if we do not ultimately prevail.

COLARIS. We own or have non-exclusive license rights to eight 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 *MLH*1, *MSH2* and *PMS2* compositions of matter on isolated *MLH*1, *MSH2* and *PMS2* nucleic acids, methods of detecting mutations in the *MLH1* and *MSH2* genes, methods for determining *MLH1*-, *MSH2*- and *PMS2*-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 10 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 *MYH* compositions of matter on isolated *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.

OnDose. We have exclusive license rights to two issued U.S. patents and two U.S. patent applications relating to OnDose testing. The U.S. patents have terms that are expected to expire commencing in 2025, with the last patent expected to expire in 2026, and contain multiple claims, including but not limited to claims relating to composition of matter on antibodies, methods, and kits for performing immunoassays to measure 5-fluorouracil levels in a sample.

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 isolated *PTEN* nucleic acids and 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 four 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 the aggressiveness of cancer, methods of determining risk of cancer recurrence based on gene expression signatures, and methods for disease progression.

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TheraGuide 5-FU. We own one U.S. patent and two patent applications 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 applications disclose varied subject matter, including but not limited to subject matter relating to compositions of matter on *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.

We intend to seek patent protection in the United States and major foreign jurisdictions for genes, 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. 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 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.

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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 2018. 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 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 AP 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 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.

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 issued patents that relate to the PALB2 gene, on a world-wide basis. Under this license agreement we made a one-time payment to Johns Hopkinsopkins for a fully paid up, exclusive, irrevocable license for 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.

In December 2011, we entered into a license agreement with the University of Cologne and the University of Dusseldorf (collectively referred to as RAD51C Licensors) for the exclusive right to utilize certain intellectual property rights of the RAD51C Licensors, including a patent application that relates to the RAD51C gene, on a world-wide basis with non-exclusive rights in Germany. Under this license agreement we made a one-time payment to the RAD51C Licensors and pay royalties based on net sales of tests that include RAD51C. This license

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agreement ends of the expiration date of the last to expire patent covered by the license agreement, which is not anticipated to expire until April 2031. The RAD51C Licensors have the right to terminate the license agreements 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. Many 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.

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 heavily 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.

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 is accredited, 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.

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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 laboratory, it has generally exercised enforcement discretion in not otherwise regulating most tests developed and performed by high complexity CLIA-certified laboratories. However, for the past few years, the FDA indicated that it was reviewing the regulatory requirements that will apply to LDTs, and held a two-day public meeting on July 19 and July 20, 2010 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. 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, for the next five years, to give at least sixty days prior notice to Congress in accordance with the recently enacted Food and Drug Administration Safety and Innovation Act, or FDASIA. The notice must include anticipated details of the action.

The FDA issued a Draft Guidance 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 a companion diagnostic 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 also refers to tests that may be useful, but are not necessarily a determining factor in the safe and effective use of the therapeutic product. In addition, most LDTs, for which the FDA does not currently require premarket clearance or approval, will not fall within the scope of the Draft Guidance. If the FDA requires premarket review of our LDTs in the future and one or more of those tests are necessary for the safe and effective use of a drug, we and the pharmaceutical or biotechnology company which developed the drug may be subject to the FDA s guidance if it becomes final.

HIPAA and other privacy laws

The Health Insurance Portability and Accountability Act of 1996, or HIPAA, established for the first time comprehensive United States 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).

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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.

Under HITECH s new breach notification requirements, Covered Entities must, within 60 days of discovery of a breach of protected health information that has not been encrypted or otherwise secured, notify each individual whose information has been, or is reasonably believed to have been, accessed, acquired, or disclosed as a result of a breach. Covered Entities must also report breaches to the Department of Health and Human Services, or HHS, and in some cases, publish information about the breach in local or prominent media outlets.

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 the breach reporting requirements, and the penalties for violation vary widely and new privacy and security laws in this area are evolving. 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. 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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Billing

Billing for diagnostic services is generally highly complex. Laboratories must bill various payors, such as private third-party payors, including MCOs; governmental health care program, 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.

Billing for diagnostic services in connection with governmental payor programs is subject to numerous federal and state regulations and other requirements, resulting in additional costs to us. These additional costs include those related to:

- variability in coverage and information requirements among various payors;
- increased complexity in our billing due to the additional procedures and processes required by governmental payor programs;
- training and education of our employees and customers;
- compliance and legal costs; and
- costs related to, among other factors, medical necessity denials and the absence of advance beneficiary notices.

Reimbursement

Depending on the billing 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 governmental payor program; and

the patient.

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

In February 2011, the American Medical Association CPT Editorial Panel approved 101 new analyte-specific codes to describe several molecular genetic tests that currently require multiple CPT codes for billing purposes. The new codes became effective on January 1, 2012 and replaced the old codes used to bill third-party private payors. Third-party private payors that cover Myriad s tests have converted to the new codes and have continued to reimburse at historical rates. Medicare has yet to determine the reimbursement level for the new codes, however, we expect Medicare to announce the new reimbursement rates in November 2012. The new reimbursement levels are expected to go into effect on January 1, 2013. If Medicare reimbursement levels for the new codes do not recognize the value of the molecular genetic tests, our earnings and cash flows could be adversely impacted.

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, or DOJ, the Office of Inspector General for the Department of

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Health and Human Services, or 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. These contractors include RACs, Medicaid Integrity Contractors, or MICs, and Zone Program Integrity Contractors, or ZPICs. In addition, CMS conducts CERT audits, the purpose of which is to detect improper Medicare payments. Any overpayments identified must be repaid to the Medicare program 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 Law 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 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 value, such as, for example, cash payments, gifts or gift certificates, discounts, or the furnishing of services, supplies or equipment. The Anti-Kickback Law 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 Law 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. Compliance with all requirements of a safe harbor immunizes the parties to the business arrangement from prosecution under the Anti-Kickback Law. 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 Law may occur even if only one purpose of an arrangement is to induce referrals. The penalties for violating the Anti-Kickback Law 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 Law, 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. A financial relationship is created by an investment interest or a compensation arrangement. A laboratory cannot bill Medicare or any other party for services furnished pursuant to a prohibited self-referral. Several Stark Law exceptions are relevant to arrangements involving clinical laboratories, including: (1) fair market value compensation for the provision of items or services; (2) payments by physicians to a laboratory for clinical laboratory services; and (3) certain space and equipment rental arrangements that satisfy certain requirements. Penalties for violating the Stark Law include the return of funds received for all prohibited referrals, fines, civil monetary penalties and possible exclusion from the 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. The number of filings of qui tam actions has increased significantly in recent years. When an entity is determined to have violated the False Claims Act, it may be required to pay 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. Conduct that violates the False Claims Act

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may also lead to exclusion from the federal health care programs. Given the number of claims likely to be at issue, potential damages under the False Claims Act for even a single inappropriate billing arrangement could be significant. 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 all payors.

Federal Prohibitions on Health Care Fraud and False Statements Related to Health Care Matters

In addition to the administrative simplification regulations discussed above, HIPAA created two new federal crimes: health care fraud and false statements relating to health care matters. The health care fraud statute prohibits knowingly and willfully executing a scheme to defraud any health care benefit program, including a private insurer. The false statements statute prohibits knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false, fictitious, or fraudulent statement in connection with the delivery of or payment for health care benefits, items, or services. A violation of this statute is a felony and may result in fines, imprisonment, or exclusion from the federal health care programs.

Program Integrity Requirements

The ACA also included a number of provisions intended to strengthen the integrity of the Medicare and Medicaid programs as well as the Children s Health Insurance Program, or CHIP. These provisions are expected to bolster the ability of state and federal agencies to prevent and detect fraud and abuse. Such measures include enhanced background screening procedures for providers and suppliers participating or enrolling in Medicare, Medicaid, or CHIP; expansion of state and federal authority to suspend Medicare and Medicaid payments pending an investigation of a credible allegation of fraud ; a grant of broad discretion to CMS to impose temporary moratoria on the enrollment of providers and suppliers by category; and a mandate that all Medicare, Medicaid and CHIP providers and suppliers implement an ethics and compliance program that contains the core elements to be established by CMS.

Human Resources

As of July 25, 2012, we had 1,169 full-time equivalent employees, including 45 persons holding doctoral or medical doctor degrees. 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. 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 able to generate sufficient revenue from our existing 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 tests and companion diagnostic services. The demand for our existing molecular diagnostic tests may decrease or may not continue to increase at historical rates for a number of reasons. For example, because BRAC*Analysis* testing and 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. We recently opened a reference laboratory in Germany and expanded sales efforts into selected countries in Europe but may not be able to generate sufficient profits from European sales to recover the costs of our investment. Our pipeline of new molecular diagnostic and companion diagnostic 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 tests and companion diagnostic services through the utilization of our technologies or technologies we license or acquire from others. Even if we develop tests for commercial use, we may not be able to develop tests that:

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

We must generate significant revenue to maintain profitability. Even if we succeed in marketing our existing molecular diagnostic tests and companion diagnostic services to physicians for use in new patients and in developing and commercializing any additional molecular diagnostic tests and companion diagnostic services, 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 test and companion diagnostic services candidates, 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 test and companion diagnostic services 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 and companion diagnostic services. 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 sell our existing molecular diagnostic tests and companion diagnostic services to new patients;

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

our ability to develop test candidates and receive required regulatory approvals;

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;

the willingness of third-party payors to provide full or even partial reimbursement for our 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 companion diagnostic services; and

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our ability to maintain or grow our current revenues.

Our Term Loan and Option Agreement with Crescendo Bioscience may result in a substantial loss.

On September 8, 2011, we issued a six-year term loan for $25.0 million to Crescendo Bioscience, Inc., or Crescendo, of South San Francisco, California, which is developing molecular diagnostic tests for patients suffering from autoimmune disorders, including rheumatoid arthritis. We made this loan under a Loan and Security Agreement, or Loan Agreement, and also secured an exclusive three-year option to acquire the company pursuant to a definitive merger agreement, which we refer to as the Option Agreement. As of June 30, 2012, we had recorded on our balance sheet a $19.0 million note receivable related to the Loan Agreement and an $8.0 million other asset related to the Option Agreement. Although we do not anticipate that Crescendo will default under the Loan Agreement or that the value of the Option Agreement will deteriorate over time, there can be no assurance that Crescendo will repay the loan or ultimately succeed in its business plan. In the event that Crescendo does not make the principal and accrued interest payments in accordance with the Loan Agreement and we do not exercise our option to purchase Crescendo, we would be required to record a loss up to $25.0 million and any unpaid interest.

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. For example, if we exercise our option to acquire Crescendo, the purchase price will be paid in cash and will be based on a predetermined multiple of revenue based on Crescendo s growth rate at the time the option is exercised, or else a fixed purchase price, in accordance with the agreement. If we exercise the Crescendo option or another acquisition target is identified, we would require funds in addition to our current operating plan to acquire and integrate the target company. 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 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 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.

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, 2012, we had $454.2 million in cash, cash equivalents and marketable securities. For the fiscal year ended June 30, 2012 our consolidated revenues were approximately $496.0 million, and net cash from operating activities was approximately $141.8 million. To develop and bring new molecular diagnostic tests and companion diagnostics to market, we must commit substantial resources to costly and time-consuming research, development testing and clinical testing.

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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 companion diagnostic 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:

- our ability to maintain the existing licenses to our molecular diagnostic tests and enter into collaborations, licensing or other arrangements favorable to us;
- 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 by us or our licensors of preparing, filing and prosecuting patent applications, maintaining and enforcing our current issued patents, and defending intellectual property-related claims;
- the costs of acquiring technologies or businesses, and our ability to successfully integrate and achieve the expected benefits of our business development activities and acquisitions;
- the progress, cost and results of our international 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 companion diagnostic services and developing additional product candidates using the acquired technology. Additionally, in September 2011, we acquired a three-year exclusive option to acquire Crescendo, a company that is developing molecular diagnostic tests for patients suffering from autoimmune disorders, including rheumatoid arthritis. However, 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 services, 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

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

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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.

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.

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.

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Changes in healthcare 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 Healthcare Reform Act became law. This law substantially changes the way health care is financed by both governmental and private insurers, and significantly impacts our industry. The Healthcare Reform Act 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 federal healthcare programs, reimbursement changes and fraud and abuse, which will impact existing government healthcare programs and will result in the development of new programs.

In addition to the Healthcare Reform Act, there will continue to be proposals by legislators at both the federal and state levels, regulators and 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 third-party payors. While in general it is too early to predict specifically what effect the Health Reform Act and its implementation or any future healthcare reform legislation or policies will have on our business, current and future healthcare reform legislation and policies could have a material adverse effect on our business and financial condition.

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 and the Swiss franc. 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, operating expenses and net income. 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 a single product and we may not be able to maintain or increase revenue growth and profitability.

Even though we have experienced double-digit revenue growth in our molecular diagnostic business every year since the initial launch of our first test in 1996; we may not be able to continue this 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 basis. We launched our first molecular diagnostic test, BRAC*Analysis*, our test for hereditary breast and ovarian cancer, in November 1996. BRAC*Analysis* test sales accounted for 82% of our revenues for the year ended June 30, 2012. An interruption or cessation of BRAC*Analysis* sample flow would have a material impact on our revenues and future profitability. 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 licensing or royalty costs;
- 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;

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- the efforts of third party payors to limit or decrease the amounts that they are willing to pay for our tests;
- changes in intellectual propriety laws of 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; and
- increased regulatory requirements.

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

As part of our business strategy, we are expanding into international markets. We have established offices in Paris, France; Madrid, Spain; Milan, Italy; laboratory operations and a sales and administrative office in Munich, Germany; and international headquarters in Zurich, Switzerland. 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;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes or 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;
- 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, 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 future international expansion and 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 expanding 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 expanding 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.

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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.

We rely on a single laboratory facility to process our molecular diagnostic tests in the United States, a single laboratory facility to process our molecular diagnostic tests in Europe and a single laboratory facility to perform our companion diagnostic services.

We rely on a single CLIA-certified laboratory facility in Salt Lake City, Utah to perform our Unites States molecular diagnostic tests, a single laboratory facility in Munich, Germany to perform our European molecular diagnostic tests, and a single CLIA-certified laboratory facility in Austin, Texas to perform our companion diagnostic 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 man-made or natural disasters, we would be unable to continue our molecular diagnostic and companion diagnostic business at current levels to meet customer demands for a significant period of time. Although we maintain insurance on these facilities, including business interruption insurance, it may not be adequate to protect us from all potential losses if these facilities were damaged or destroyed. In addition, any interruption in our molecular diagnostic or companion diagnostic business would result in a loss of goodwill, including damage to our reputation. If our molecular diagnostic or companion diagnostic business were interrupted, it would seriously harm our business.

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 test and service offerings that we have launched in recent years or that we 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 safety and clinical efficacy of our tests and their potential advantages over existing tests;
- our ability to sell our molecular diagnostic tests to patients who have not previously used our 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 and patients to utilize our tests, which can be difficult to interpret. This difficulty is caused by a combination of factors, including the large number, sometimes thousands, of different mutations in the genes which our tests analyze, the need to characterize each specific mutation, and the ability of our tests to predict only as to a statistical probability, not certainty, that a tested individual will develop the disease that the test is intended to predict.

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

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include, among others, major diagnostic companies, reference laboratories, molecular diagnostic firms, universities and other research institutions. Many 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 companion diagnostic tests 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 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 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.

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 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 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 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 companion diagnostic 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 cancer-related molecular diagnostic tests to oncologists, Ob/Gyns and urologists 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 Unites States.

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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.

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 at all or on a timely basis.

We currently rely on a small number of suppliers to provide our gene sequencing equipment, multiplex protein analysis equipment, robots, and specialty reagents required in connection with our research. We believe that currently there are limited alternative suppliers of gene sequencing and multiplex protein analysis 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 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 companion diagnostic services would be adversely affected.

Risks Related to Our Intellectual Property

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

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, 2012, our patent portfolio included 193 issued patents owned or licensed by us and numerous patent applications in the United States and other countries with claims covering 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 predisposing genes we identify and related technologies, processes, methods and other inventions that we believe are patentable. Our ability to preserve our trade secrets and other intellectual property is also critical to our long-term success. If we do not adequately protect our intellectual property, 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. Specifically, as disclosed in Part I Item 3, of this Annual Report on Form 10-K, we are a defendant in a lawsuit brought by the Association for Medical Pathology and others. While we do not believe that an adverse decision from this case will enable others to commercialize genetic tests that are competitive with our BRAC*Analysis* test, our business could be materially adversely impacted in the future from an adverse opinion.

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

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

If a third party files a patent application with claims to a gene, protein, or biomarker we have discovered, 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 gene, protein, or biomarker 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. 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, 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 gene and protein 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 genes or proteins 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 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

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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.

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:

the Clinical Laboratory Improvement Amendments of 1988, or CLIA, which require that laboratories obtain certification from the federal government;

FDA laws and regulations;

the Health Insurance Portability and Accountability Act, or HIPAA, which established 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 the Health Information Technology for Economic and Clinical Health Act, or 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;

the federal anti-kickback law, or the Anti-Kickback Law, 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 prohibition on reassignment of Medicare claims, which, subject to certain exceptions, precludes the reassignment of Medicare claims to any other party;

the rules regarding billing for diagnostic tests reimbursable by the Medicare program, which prohibit a physician or other supplier from marking up the price of the technical component or professional component of a diagnostic test ordered by the physician or other supplier and performed by a physician who does not share a practice with the billing physician or supplier; state laws that prohibit other

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specified practices, such as billing physicians for testing that they order; waiving coinsurance, copayments, deductibles, and other amounts owed by patients; billing a state Medicaid program at a price that is higher than what is charged to one or more other payors; 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 government health care programs, or prohibitions or restrictions on our laboratories ability to provide 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. Such occurrences, regardless of their outcome, could damage our reputation and adversely affect important business relationships with third parties, including managed care organizations, or MCOs, and other private third-party payors.

Failure to comply with complex 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 extensive laws and regulations governing the submission of claims for payment for our services, including 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 and with the policies and procedures of third-party payors could result in our inability to receive payment for our services or in attempts by third-party payors, 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 government health care programs, and can subject us to liability under the federal False Claims Act and similar laws. Further, a government agency could attempt to hold us liable for causing the improper submission of claims by another entity for services that we performed if we were found to have knowingly participated in the arrangement at issue.

Our 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 the Centers for Medicare and Medicaid Services, or CMS; a CMS agent (typically a state agency); or, if the laboratory is accredited, a CMS-approved accreditation organization. Sanction for failure to comply with CLIA requirements, including proficiency testing violations, may be 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.

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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.

While the FDA does not currently regulate the activities or tests performed by laboratories like our clinical laboratories, the FDA has stated that it has the right to do so, and the FDA may seek to regulate or require clearance or approval of our molecular diagnostic or personalized medicine tests in the future. In July, 2010, the FDA s office of In-Vitro Diagnostics held a public meeting to discuss oversight of laboratory developed tests. The FDA highlighted the lack of standardized clinical validation at the assay level under current CLIA regulatory guidelines and noted that CLIA does not require post-market surveillance or monitoring of laboratory developed tests. The comment period for providing the FDA with written comments expired on August 15, 2010, but the FDA has not yet published additional guidance on the oversight of laboratory developed tests. We cannot provide any assurance that FDA regulation, including pre-market review, will not be required in the future for our molecular diagnostic tests. If pre-market review is required, our business could be negatively impacted if we are required to stop selling molecular diagnostic tests pending their clearance or approval or the launch of any new tests that we develop could be delayed by new requirements.

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 part, upon the availability of reimbursement from third-party payors. Such third-party payors include government healthcare 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. 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. 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.

U.S. and foreign governments continue to propose and pass legislation designed to reduce the cost of healthcare. For example, in some foreign markets, the government controls the pricing of many healthcare products. We expect that there will continue to be federal and state proposals to implement governmental controls or impose healthcare 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 and a new set of CPT codes for molecular genetic tests.

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 October 1, 2013. 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.

In March 2011, the American Medical Association CPT Editorial Panel approved 101 new analyte-specific codes to describe several molecular genetic tests that currently require multiple CPT codes for billing purposes. The new codes are scheduled to replace the current codes used to bill Medicare on January 1, 2013. Medicare reimbursement levels for the new codes have yet to be determined. If reimbursement levels for the new codes do not recognize the value of the molecular diagnostic tests, our revenues and earnings could be adversely impacted.

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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 and other life science 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, 2012, our stock price has ranged from $14.11 per share to $27.00 per share. In addition, the stock market 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:

termination of the licenses underlying our molecular diagnostic and companion diagnostic tests;

delays or other problems with operating our laboratory facilities;

failure of any of our research and development programs;

changes in intellectual property laws 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;

introduction of technological innovations or new commercial tests by us or our competitors;

missing or changing the financial guidance we provide;

changes in estimates or recommendations by securities analysts relating to our common stock or the securities of our competitors;

changes in the 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;

general market conditions;

changes in the structure of healthcare payment systems and changes in the governmental or private insurers reimbursement levels for our molecular diagnostic tests;

failure to sustain revenue growth or margins in our molecular diagnostic business;

failure of any of our test candidates to achieve commercial success;

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;

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, in the past, when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. 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;

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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 also 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

Not applicable.

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 laboratory space that has received federal certification under CLIA. Activity related to our molecular diagnostic business is performed at this location. We have entered into an agreement to sublease 87,000 square feet of our office and laboratory space through January 2013. The leases on our existing Salt Lake City facilities have terms of fifteen years, expiring from 2017 through 2025, and provide for renewal options for up to ten additional years.

In May 2011, we entered into a lease agreement for approximately 3,600 square feet in Munich, Germany. This space is used as a laboratory for our molecular diagnostic business in Europe. The lease on our Munich Germany facility has a term of approximately 5 years expiring in October of 2016. We lease office space at our headquarters in Zurich, Switzerland. We also maintain lease agreements for our administrative offices in Paris, France; Madrid, Spain; and Milan, Italy. We also lease approximately 6,000 square feet of laboratory and office space in Reutlingen, Germany under a lease that expires in March of 2014 with the option to extend for one year periods. Cell co-culture systems and TruCulture products are manufactured at this location. This facility is designed to comply with ISO standards, the European Union equivalent of Good Manufacturing, or GMP, in the United States.

In addition, Myriad RBM leases approximately 36,000 square feet in Austin, Texas under a lease that expires in June 2015. This space is dedicated to administration, research and development and laboratory space that has received federal certification under CLIA. Beginning in July 2012, we leased approximately 8,300 square feet of laboratory and office space in Saranac Lake, New York under a lease that expires in August 2017 with the right to renew for two additional five-year periods. Our immunoassay development and manufacturing of immunoassay kits are performed at the Saranac Lake facility.

We believe that our existing facilities and equipment are well maintained and in good working condition. We believe our current facilities and those planned or under construction 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.

Item 3. LEGAL PROCEEDINGS

We are a defendant in a lawsuit brought by the Association for Molecular Pathology, *et al* . (the Plaintiffs) on May 12, 2009 in the United States District Court for the Southern District of New York (the District Court). The Plaintiffs sought a declaratory ruling that 15 claims of seven patents relating to the *BRCA1* and *BRCA2* genes, which patents are exclusively licensed to us, are invalid and unenforceable, and enjoining us (and the other defendants) from taking any actions to enforce these claims of these patents. The 15 claims at issue in the lawsuit are part of the intellectual property relating to our BRAC*Analysis* predictive medicine test for breast and ovarian cancer. On April 19, 2010, the District Court ruled that these 15 claims at issue were invalid. On June 16, 2010, we filed a Notice to Appeal with the United States Court of Appeals for the Federal Circuit (the Court of Appeals) appealing the District Court decision. On July 29, 2011 the Court of Appeals reversed the District Court s

decision, in part, holding that the nine composition claims relating to isolated DNA molecules and one method claim relating to

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screening potential cancer therapeutics via changes in cell growth rates are patent-eligible under 35 U.S.C. Section 101. However, the Court of Appeals affirmed the District Court s decision that the remaining five method claims directed to comparing or analyzing DNA sequences are patent ineligible.

On December 7, 2011, Plaintiffs filed a Petition for a Writ of Certiorari with the Supreme Court of the United States (the Supreme Court), seeking the Supreme Court s review of the decision of the Court of Appeals as it pertains to the composition claims relating to isolated DNA molecules, and the Court of Appeals decision that 19 of the Plaintiffs lacked standing. On January 13, 2012, we filed our Brief in Opposition to the Plaintiffs Petition for a Writ of Certiorari. On March 26, 2012 the Supreme Court granted the Plaintiffs Petition for a Writ of Certiorari, vacated the Court of Appeals decision, and remanded the case back to the Court of Appeals for reconsideration in light of the Supreme Court s decision in Mayo v. Prometheus Laboratories on March 20, 2012. Accordingly, the Court of Appeals will now reconsider its decision dated July 29, 2011. Briefs of the parties and *amici curiae* were submitted June 15, 2012 and the Court of Appeals heard the case on July 20, 2012. A decision from the Court of Appeals is expected before the end of 2012.

Apart from the 15 claims being challenged in this lawsuit, there are over 500 separate claims under 24 patents which also cover the intellectual property utilized in, or related to, our BRAC*Analysis* predictive medicine test for breast and ovarian cancer which are not subject to this lawsuit. Accordingly, we do not believe that this lawsuit will have a material adverse impact on the Company even if we do not ultimately prevail.

We are not a party to any other 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.

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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
Fiscal Year Ended June 30, 2012:		
Fourth Quarter	$ 27.00	$ 22.02
Third Quarter	$ 25.75	$ 19.95
Second Quarter	$ 23.96	$ 17.90
First Quarter	$ 24.21	$ 17.51
Fiscal Year Ended June 30, 2011:		
Fourth Quarter	$ 25.89	$ 19.85
Third Quarter	$ 23.15	$ 17.72
Second Quarter	$ 24.15	$ 16.07
First Quarter	$ 16.81	$ 14.11

Stockholders

As of August 6, 2012, there were approximately 104 stockholders of record of our common stock and, according to our estimates, approximately 44,616 beneficial owners of our common stock.

Dividends

We have not paid cash dividends to our stockholders since our inception. While we periodically evaluate methods for returning cash to our shareholders, such as the payment of cash dividends, we currently intend to continue to reinvest the majority of our earnings in the business.

Unregistered Sales of Securities

None.

Issuer Purchases of Equity Securities

We have previously announced the following stock repurchase programs for repurchases of our common stock:

Date Authorized	Amount Authorized	Date Completed
May 2010	$ 100 million	August 2011
August 2010	$ 100 million	February 2011
March 2011	$ 100 million	September 2011
August 2011	$ 200 million	ongoing
Total:	$ 500 million	

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.

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The details of the activity under our stock repurchase programs during the fiscal quarter ended June 30, 2012, were as follows:

Issuer Purchases of Equity Securities

Period	(a) Total Number of Shares Purchased	(b) Average Price Paid per Share	(c) Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	(d) Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs
April 1, 2012 to April 30, 2012	18,931	$ 23.00	18,931	$ 160,210,235
May 1, 2012 to May 31, 2012	699,389	$ 25.31	699,389	142,509,199
June 1, 2012 to June 30, 2012	1,855,685	$ 23.10	1,855,685	99,649,684
Total	2,574,005		2,574,005	$ 99,649,684

Stock Performance Graph

The graph set forth below compares the annual percentage change in our cumulative total stockholder return on our common stock, as adjusted for a two-for-one stock split effected on March 25, 2009, during a period commencing on June 30, 2007 and ending on June 30, 2012 (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 Services 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, 2007 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.

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	6/29/2007	6/30/2008	6/30/2009	6/30/2010	6/30/2011	6/29/2012
Myriad Genetics, Inc.	100.00	122.40	191.72	80.40	122.13	127.83
NASDAQ Stock Index (U.S.)	100.00	87.47	71.60	83.11	110.80	120.72
NASDAQ Health Services Stocks	100.00	91.76	86.97	113.48	141.24	150.58

Note: Information used on the graph was obtained from the CRSP Total Return Indexes, a source believed to be a 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.

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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, 2012 and 2011, as well as consolidated statements of income for the years ended June 30, 2012, 2011 and 2010 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 thousands, except per share amounts	Years Ended June 30,				
	2012	**2011**	**2010**	**2009**	**2008**
Consolidated Statement of Income Data:					
Molecular diagnostic testing	$ 472,390	$ 400,046	$ 362,648	$ 326,527	$ 222,855
Companion diagnostic services	23,615	2,038			
Total Revenue	496,005	402,084	362,648	326,527	222,855
Costs and expenses:					
Cost of molecular diagnostic testing	51,452	45,637	44,286	43,267	32,340
Cost of companion diagnostic services	13,207	1,077			
Research and development expense	42,645	27,751	21,873	17,914	18,482
Selling, general and administrative expense	208,383	169,841	161,414	138,884	110,428
Total costs and expenses	315,687	244,306	227,573	200,065	161,250
Operating income	180,318	157,778	135,075	126,462	61,605
Other income (expense):					
Interest income	4,629	2,226	5,660	12,478	13,709
Other	(407)	(353)	99	(2,493)	(320)
Income from continuing operations before income taxes	184,540	159,651	140,834	136,447	74,994
Income tax provision (benefit)	72,389	58,941	(11,469)	193	608
Income from continuing operations	112,151	100,710	152,303	136,254	74,386
Loss from discontinued operations				(51,639)	(26,541)
Net income	$ 112,151	$ 100,710	$ 152,303	$ 84,615	$ 47,845
Earnings (loss) per basic share:					
Continuing operations	$ 1.33	$ 1.12	$ 1.58	$ 1.46	$ 0.84
Discontinued operations				(0.60)	(0.30)
Earnings (loss) per basic share	$ 1.33	$ 1.12	$ 1.58	$ 0.91	$ 0.54
Earnings (loss) per diluted share:					
Continuing operations	$ 1.30	$ 1.10	$ 1.54	$ 1.38	$ 0.80
Discontinued operations				(0.50)	(0.30)
Earnings (loss) per diluted share	$ 1.30	$ 1.10	$ 1.54	$ 0.86	