

MYRIAD GENETICS INC  
Form 10-K  
August 28, 2008  
Table of Contents

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-K**

(Mark One)

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

For the fiscal year ended June 30, 2008

**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)*

Edgar Filing: MYRIAD GENETICS INC - Form 10-K

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

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

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

<b>Title of each class</b>	<b>Name of each exchange on which registered</b>
Common Stock, \$.01 Par Value Per Share	The NASDAQ Stock Market LLC

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  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes  No

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

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

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, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer

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

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant (without admitting that any person whose shares are not included in such calculation is an affiliate), computed by reference to the price at which the common stock was last sold on December 31, 2007, the last business day of the registrant's most recently completed second fiscal quarter, was \$2,023,702,135.

As of August 25, 2008 the registrant had 45,651,701 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 November 13, 2008.

---

## **Table of Contents**

### **PART I**

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

##### **Overview**

We are a leading healthcare company focused on the development and marketing of novel molecular diagnostic and therapeutic products. We employ a number of proprietary technologies that permit us to understand the genetic basis of human disease and the role that genes and their related proteins play in the onset, progression and treatment of disease. We use this information to guide the development of new healthcare products that are designed to treat disease and assess a person's risk of disease later in life.

Our molecular diagnostic business focuses on the analysis of genes and their alterations to assess an individual's risk for developing disease later in life (predictive medicine) and to assess a patient's risk of disease progression, disease recurrence, drug toxicity, and drug response (personalized medicine). To date we have launched five commercial molecular diagnostic products, including both predictive medicine and personalized medicine products. We market these products through our own 200-person sales force in the United States and we have entered into marketing collaborations with other organizations in selected foreign countries. Molecular diagnostic revenue was \$222.9 million for the year ended June 30, 2008, an increase of 53% over the prior fiscal year.

We believe that the future of medicine lies in the creation of new classes of drugs that treat the underlying cause, not just the symptoms, of disease and that may be useful in disease prevention. By understanding the genetic basis of disease, we believe we will be able to develop drugs that are more effective and have fewer side effects. In addition, we believe that advances in the emerging field of molecular diagnostics will improve our ability to determine which patients are subject to a greater risk of developing disease and who therefore would benefit from preventive therapies. Molecular diagnostic products may also guide a patient's healthcare to ensure the patient receives the most appropriate drug at the optimal dose.

To treat complex diseases effectively it is important to understand the function of genes and their proteins, how the disruption of important biological pathways can lead to disease, and the optimal point of therapeutic intervention in the pathway so that drugs may be developed to prevent, modify, or halt disease progression. Myriad researchers have made important discoveries in the fields of cancer and infectious diseases such as AIDS. These discoveries point to novel disease pathways that we believe may pave the way for the development of new classes of drugs. As we learn more about the genetic basis of disease, we believe that we may be able to develop drugs that are more effective and have fewer side effects. Our major drug development programs include Azixa for the treatment of primary and metastatic brain tumors, Vivecon for the treatment of AIDS, MPC-2130 for the treatment of hematologic cancers, MPC-3100 for the treatment of solid tumors, and MPC-0920 for the treatment of thrombosis. Flurizan, our drug candidate for the treatment of Alzheimer's disease was discontinued in as much as our U.S. Phase III trial did not achieve statistical significance.

We have devoted substantially all of our resources to undertaking our drug discovery and development programs, operating our molecular diagnostic business, and continuing our research and development efforts. Our revenues for the fiscal year ended June 30, 2008 consisted primarily of sales of molecular diagnostic products (67%), pharmaceutical license revenue (30%), and research payments (3%). For the year ended June 30, 2008, we had a net profit of \$47.8 million. As of June 30, 2008 we had an accumulated deficit of \$204.6 million.

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

Our business strategy is to understand the relationship between genes, proteins and human diseases in order to develop the next generation of therapeutic and molecular diagnostic products. 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 therapeutic and molecular diagnostic products. Our business strategy includes the following key elements:

*Discover important disease genes, understand their function and determine their role in human disease.* We will continue to use our proprietary technologies, including our bioinformatics and robotic technologies, in an effort to efficiently discover important genes and proteins and to understand their role in human disease. These technologies enable us to go beyond a single gene, protein or drug target and explore a large number of potential drug targets involved in a disease



---

## **Table of Contents**

pathway. We also use proprietary RNA expression, immunohistochemistry ( IHC ), and DNA analysis technologies to identify genetic abnormalities that contribute to the disease process. We believe these technologies provide us with a significant competitive advantage and numerous product opportunities.

*Grow and expand our molecular diagnostic business.* We will continue to seek to increase the domestic and foreign market penetration of our existing molecular diagnostic products. Additionally, we will pursue new product opportunities in both the areas of predictive medicine and personalized medicine to capitalize on our leadership position. We believe that molecular diagnostics will play an increasingly important role in the management of a patient's healthcare. By understanding each patient's different genetic make-up, predictive medicine may assist physicians in prescribing appropriate prophylactic therapies to those patients at greatest risk for disease. Personalized medicine may assist physicians in selecting the most appropriate therapy for a particular patient following diagnosis.

*Develop and commercialize therapeutic products.* We will continue to employ our assay development and high-throughput screening technologies in an effort to rapidly identify lead compounds for potential drug development. We intend to take selected drug candidates, particularly in the areas of cancer, and viral diseases, through the clinical development process independently. We are focusing on these indications due to the large unmet medical need for effective and less toxic drugs. If any of our drug candidates receives regulatory approval, we intend to build a commercial operation focused on promoting that drug to specialist physicians.

*Acquire promising drug candidates and biomarkers/genes from other organizations.* We intend to continue to take advantage of in-licensing opportunities to augment our in-house product development programs. We recognize that we cannot meet all of our research discovery needs internally and can benefit from the research performed by other organizations. We hope to leverage our financial strength and product development expertise to acquire new product opportunities in our therapeutic and molecular diagnostic areas of focus.

Historically, we have utilized a strategy of combining a profitable, rapidly growing molecular diagnostic business with significant pharmaceutical opportunities. We believe that this strategy has reduced the risk typically associated with a more traditional biotechnology company, while affording us the upside opportunity for pharmaceutical product development. As we consider our future strategic direction, management will do a comprehensive review and consider our strategic alternatives, including but not limited to: continuing the Company's current strategy of operating a diagnostics business in tandem with a pharmaceutical business; a possible corporate restructuring which would separate the molecular diagnostic business from the pharmaceutical business as independent operating entities; or other strategies that management may consider. Management will report its analysis to our Board of Directors who will be responsible for determining the most appropriate strategy to move the Company forward.

### **Molecular Diagnostic Products**

Molecular diagnostic products analyze genes and their mutations to assess an individual's risk for developing disease later in life, as well as a patient's risk of disease progression, disease recurrence, drug toxicity, and drug response. Armed with this risk assessment information, individuals can take action to prevent or delay the onset of disease and physicians can ensure that patients receive the most appropriate healthcare for the treatment of their disease.

To date, we have launched five commercial molecular diagnostic products. We market these products through our own 200-person sales force in the United States and we have entered into marketing collaborations with other organizations in selected foreign countries. Molecular diagnostic revenues were \$222.9 million for the year ended June 30, 2008, an increase of 53% over the prior fiscal year. Our current commercial molecular diagnostic products are described below:

*BRACAnalysis®: molecular diagnostic product for breast and ovarian cancer.* BRACAnalysis is a comprehensive analysis of the BRCA1 and BRCA2 genes for assessing a woman's risk for breast and ovarian cancer. A woman who tests positive with the BRACAnalysis test has an 82% risk of developing breast cancer during her lifetime and up to a 54% risk of developing ovarian cancer. BRACAnalysis provides important information that we believe will help the patient and her physician make better informed lifestyle, surveillance, preventive medication and treatment decisions. As published in the



---

**Table of Contents**

*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.

According to the American Cancer Society, in 2008 there will be approximately 263,000 women in the United States diagnosed with invasive breast cancer, Ductal Carcinoma In Situ (DCIS), or ovarian cancer. This year in the United States an estimated 56,000 women will die from these cancers. The test is currently priced at \$3,120 and is covered by all major health maintenance organizations and health insurance providers in the United States. We own or have licensed rights to 23 U.S. patents covering BRACAnalysis.

*COLARIS®: molecular diagnostic product for colorectal cancer and uterine cancer.* COLARIS is a comprehensive analysis of the MLH1, MSH2, and MSH6 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 a 60% lifetime chance of developing uterine cancer. Highly effective preventive measures for colon cancer include colonoscopy and the removal of precancerous polyps. Through proper application of screening and polyp removal, colon cancer is a preventable disease.

Colorectal cancer is the second leading cause of cancer deaths in the United States. According to the American Cancer Society, approximately 189,000 new cases of colorectal or uterine cancer will be diagnosed this year. Familial forms of colorectal cancer are estimated to account for 10% to 30% of all cases according to the American Society of Clinical Oncologists. The test is currently priced at \$2,950 and is covered by all major health maintenance organizations and health insurance providers in the United States. We own or have licensed rights to eight U.S. patents covering COLARIS.

*COLARIS AP®: molecular diagnostic product for colon cancer.* COLARIS AP 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. The test is currently priced at \$1,795 and is covered by all major health maintenance organizations and health insurance providers in the United States. We own or have licensed rights to 11 U.S. patents covering COLARIS AP.

*MELARIS®: molecular diagnostic product for melanoma.* MELARIS analyzes mutations in the p16 gene to determine genetic susceptibility to malignant melanoma, a deadly form of skin cancer. Individuals who test positive for MELARIS have a 75-fold increased risk of developing melanoma during their lifetimes as compared to the general population. MELARIS, which assesses a person's risk of developing melanoma, provides important information that we believe will be useful in the surveillance and prevention of melanoma. Melanoma can 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 62,000 new cases of melanoma will be diagnosed in the United States in 2008. 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. MELARIS is currently priced at \$745 and is covered by most major health maintenance organizations and health insurance providers in the United States. We own or have licensed rights to 11 U.S. patents covering MELARIS.

*THERAGUIDE 5-FU: molecular diagnostic product for chemotherapy toxicity.* THERAGUIDE 5-FU analyzes mutations in the DPYD gene and variations in the TYMS gene to assess patient risk of 5-FU toxicity and to help guide physician dosing decisions. Cancer patients who test positive for THERAGUIDE 5-FU have an increased risk of suffering toxicity from 5-FU chemotherapy and should be considered for a reduced dose of 5-FU or for other chemotherapy regimens. There are approximately 500,000 5-FU prescriptions written each year in the United States and approximately 16-20% of patients given 5-FU will experience medically significant toxicity issues (grade 3 or 4 toxicity). 5-FU is widely prescribed for the treatment of colon, breast, skin, and head and neck cancers.





---

## **Table of Contents**

According to IMS Prescription data there are approximately 250,000 new patients put on 5-FU each year. THERAGUIDE 5-FU is currently priced at \$1,100 and is covered by certain health maintenance organizations and health insurance providers in the United States. We own or have licensed rights to five U.S. patent application covering THERAGUIDE 5-FU.

### **Therapeutic Products in Development**

We have developed and integrated a powerful set of technologies that enable us to identify novel drug targets. Each drug target is tested in high-throughput screening against our chemically diverse library, comprised of approximately 400,000 different small molecule compounds. Our staff of medicinal and analytical chemists develops analogs based on the original lead structure using molecular modeling and other techniques to increase the efficacy, improve the safety, increase the solubility, and increase the oral bioavailability of the lead compounds. Once a candidate drug has been selected, we assess its safety and efficacy in vivo and perform the necessary toxicology and pharmacokinetic analysis in preparation for submission of an Investigational New Drug, or IND, application.

We currently have five drug candidates in clinical trials or late-stage preclinical development. Our most advanced drug development programs are described below:

*Azixa: drug candidate for solid primary and metastatic brain tumors.* Azixa is a novel, small-molecule drug candidate that has a dual mode of action. It is both a vascular disruption agent and a tubulin inhibitor that is currently in Phase 2 clinical trials. The first phase of the Phase 2 studies is designed to confirm the safety profile of Azixa in combination with other chemotherapeutic agents. We are investigating both carboplatin and temozolomide in the Phase 2 trials. The second phase of the Phase 2 trials will assess its ability to improve the overall survival of patients with brain tumors. The Phase 2 studies will explore Azixa's efficacy in both primary brain tumors and metastatic brain tumors. The trial will compare the survival of patients treated with a chemotherapeutic agent alone to those treated with Azixa plus the chemotherapy drug.

Azixa has demonstrated the ability to effectively cross the blood-brain barrier and is not subject to multiple drug resistance. Azixa has shown activity in Phase 1 studies against brain metastases from lung, breast, colon, and skin (melanoma). According to the National Cancer Institute approximately 170,000 new cases of brain metastases will be diagnosed in the United States in 2008. We own or have exclusive licensed rights to 19 U.S. patent applications covering Azixa.

*Vivecon: preclinical drug candidate for AIDS.* Vivecon, an orally available viral maturation inhibitor, is in Phase 1 clinical testing. The study is designed to evaluate the safety and pharmacokinetic profile of Vivecon in healthy volunteers. Vivecon represents a new class of drug candidates for the treatment of AIDS. Vivecon, a novel maturation inhibitor, has demonstrated strong anti-HIV activity in the low nanomolar range. More importantly, Vivecon has been shown to be active against drug resistant strains of HIV.

According to the National Institute of Allergy and Infectious Diseases, or NIAID, it is estimated that approximately 40,000 new cases of AIDS will be diagnosed in the United States in 2008 and more than 900,000 Americans are living with HIV infection. We own or have exclusive licensed rights to four U.S. patent applications covering Vivecon.

*MPC-2130: drug candidate for hematologic cancers.* Our drug candidate MPC-2130, a novel apoptosis inducing small molecule, is in Phase 1 clinical testing. The testing is designed to evaluate the safety and pharmacokinetic profile of MPC-2130 in patients with hematologic (blood) cancers as well as refractory cancers that have progressed despite previous chemotherapy. In preclinical studies, MPC-2130 demonstrated cancer cell killing activity in ovarian cancer and prostate cancer as well as two lymphoma cell lines, Burkitt's lymphoma and T-cell lymphoma. In addition, it has been shown that MPC-2130 is not subject to multiple drug resistance.

---

## **Table of Contents**

According to the American Cancer Society, approximately 119,000 Americans will be diagnosed with hematologic cancers in 2008. We own six U.S. patent applications covering MPC-2130.

*MPC-3100: preclinical drug candidate for the treatment of cancer.* Our drug candidate MPC-3100, an Hsp 90 inhibitor, is in late stage preclinical development and is scheduled to enter human clinical testing in the next fiscal year. HSP 90 is an important molecular chaperone that stabilizes oncogenic proteins and enables tumors to develop drug resistance. MPC-3100 is a small molecular drug with good oral bioavailability and will be studied in patients with solid tumors to evaluate its safety and pharmacokinetic profile. In preclinical studies, MPC-3100 caused tumor regression at doses that were well tolerated in animals.

According to the American Cancer Society, approximately 1.2 million new cases of solid tumor cancers will be diagnosed in the United States in 2008. We own or have exclusive licensed rights to two U.S. patent applications covering MPC-3100.

*MPC-0920: drug candidate for thrombosis.* Our drug candidate MPC-0920, an orally available direct thrombin inhibitor, has completed a Phase 1 clinical study. The trial used an escalating dose regimen designed to evaluate the safety, pharmacokinetic, and pharmacodynamic profile of MPC-0920 in healthy volunteers. MPC-0920 has demonstrated characteristics that may offer improvements over traditional anticoagulants, which have limitations such as non-selectivity, inability to effect thrombin-bound fibrin, and drug and food interactions. We believe that deep-vein thrombosis and atrial fibrillation represent two potentially large markets, and our intentions are to partner MPC-0920 with a major pharmaceutical company. We own or have exclusive licensed rights to two U.S. patents and one U.S. patent application covering MPC-0920.

*Flurizan (tarenflurbil): drug candidate for Alzheimer's disease.* On June 30, 2008, we announced the results of our U.S. 18-month Phase 3 study of Flurizan in patients with mild Alzheimer's disease. The study did not achieve statistical significance on either of its primary endpoints—cognition and activities of daily living. As a result the Company is discontinuing all ongoing Flurizan clinical studies, including its global Phase 3 trial.

### **Patents and Proprietary Rights**

We intend to seek patent protection in the United States and major foreign jurisdictions for genes, proteins, antibodies, drug targets, drug compounds, diagnostic markers, 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. We also rely upon trade secret rights to protect certain other technologies which may be used in discovering and characterizing new genes and proteins and which may be used in the development of novel therapeutic and molecular diagnostic products. However, any such patents may not issue, and the breadth or the degree of protection of any claims of such patents may not afford us with significant protection. 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 own or have licensed rights to 312 issued patents as well as numerous patent applications in the United States and foreign countries. However, 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, any patents issued to us or our licensors may not afford meaningful protection for our technology or products or may be subsequently circumvented, invalidated or narrowed, or found unenforceable.

Our processes and potential products may also conflict with patents which have been or may be granted to competitors, academic institutions or others. As the biotechnology industry expands and more patents are issued, the risk increases that our processes and potential products may give rise to interferences filed by others in the U.S. Patent and Trademark Office, or to claims of patent infringement by other companies, institutions or individuals. These entities or persons could bring legal actions against us claiming damages and seeking to enjoin clinical testing, manufacturing and marketing of the related product or process. If any of these actions are successful, in addition to any potential liability for damages, we could be required to cease the infringing activity or obtain a license in order to continue to manufacture or market the relevant product 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 obtain a license to any technology that we may require to commercialize our technologies or potential products could have a material adverse effect on our business.



## **Table of Contents**

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, DNA analysis, IHC, robotic and bioinformatic technologies. 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 products after obtaining regulatory clearance, competitors may be able to market competing processes and products.

Others may obtain patents having claims which cover aspects of our products or processes which are necessary for or useful to the development, use or manufacture of our services or products. Should any other group obtain patent protection with respect to our discoveries, our commercialization of potential therapeutic and molecular diagnostic products could be limited or prohibited.

## **License Agreements**

We are a party to multiple license agreements which give us the rights to use certain technologies in our research, development, testing processes, and commercialization of products. 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 products or may be subsequently circumvented, invalidated or narrowed, or found unenforceable. Our failure to maintain rights to this technology could have a material adverse effect on our business.

We entered into a license agreement with the University of Utah Research Foundation, or 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 BRACAnalysis molecular diagnostic products. This license agreement ends on the later of October 8, 2011 or the last to expire patent covered by the license agreement which presently is not anticipated to expire until April 2018.

We also entered into separate license agreements with the University, The Trustees of the University of Pennsylvania, The Hospital for Sick Children and Endorecherche, Inc. (collectively referred to as the Licensors) for the exclusive rights to utilize certain intellectual property rights of the respective Licensors, including issued patents that relate to the BRCA2 gene, on a world-wide basis. Under these license agreements we pay each of the Licensors a royalty based on net sales of our BRACAnalysis molecular diagnostic products. Each of these license agreements ends on the last to expire patent covered by the respective license agreements which presently is not anticipated to expire until December 2015.

We entered into a license agreement with Maxim Pharmaceuticals, Inc. and Cytovia, Inc. (subsequently acquired by EpiCept Corporation and hereafter referred collectively to as EpiCept) for the exclusive rights to utilize certain intellectual property rights of EpiCept, including patents that relate to Azixa, on a world-wide basis. Under this license agreement we will pay EpiCept a royalty based on future net sales of Azixa or any other product which utilizes EpiCept's intellectual property rights licensed to us. The license agreement also provides for milestone payments based on the occurrence of certain events. This license agreement ends on the later of ten years after the date of the first commercial sale of a licensed product or the last to expire patent covered by the license agreement which presently is not anticipated to expire until July 2024.

## **Competition**

Competition is intense in our existing and potential markets. Our competitors in the United States and abroad are numerous and include, among others, major pharmaceutical companies, diagnostic reference laboratories, biotechnology firms, 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.

We expect to encounter significant competition with respect to any drugs that may be developed using our technologies. Companies that complete clinical trials, obtain required regulatory approvals and commence commercial sales of therapeutic products prior to us

## **Table of Contents**

may achieve a significant competitive advantage. We may not be able to develop such products successfully and we may not obtain patents covering such products that provide protection against competitors. Moreover, competitors may succeed in developing therapeutic products that circumvent our products, and our competitors may succeed in developing technologies or products that are more effective than those we develop or that would render our technologies or products less competitive or obsolete.

The technologies for discovering genes that cause major diseases and approaches for commercializing those discoveries are rapidly evolving. Rapid technological developments could result in our potential services, products, 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 additional disease-causing genes, characterize their functions, develop molecular diagnostic products and related information services based on such discoveries, obtain regulatory and other approvals, and launch such services or products before our competitors, we could be adversely affected. Moreover, any molecular diagnostic products 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**

Regulation by governmental authorities in the United States and foreign countries is a significant factor in the development, manufacture and marketing of our products and services and in our ongoing research and development activities. The therapeutic products, and some of the molecular diagnostic products to be developed by us, will require regulatory approval by governmental agencies prior to commercialization. Various federal statutes and regulations also govern or influence the testing, manufacturing, safety, labeling, storage, record keeping, and marketing of therapeutic products. The process of obtaining these approvals and the subsequent compliance with applicable statutes and regulations require the expenditure of substantial time and financial resources. Any failure by us or our collaborators, licensors or licensees to obtain, or any delay in obtaining regulatory approval could have a material adverse effect on our business.

*Therapeutics.* We intend to develop therapeutic products which will be subject to regulation by the Food and Drug Administration, or FDA, and foreign regulatory authorities and require approval before they may be clinically tested and commercially marketed for human therapeutic use in the United States and other countries. The precise regulatory requirements with which we will have to comply are undergoing periodic revisions and refinement.

The steps required before a therapeutic product may be marketed in the United States are numerous and include, but are not limited to:

completion of preclinical laboratory tests, animal studies, chemical process development, and formulation studies;

the submission to the FDA of an IND, which must become effective before clinical trials may commence;

performance of adequate and well-controlled clinical trials to establish the safety and efficacy of the drug for its intended use;

the submission of a New Drug Application, or NDA, to the FDA; and

FDA approval of the NDA, including approval of all product labeling and initial advertising.

The testing and approval process requires substantial time, effort, and financial resources and we cannot be certain that any approvals for any of our products will be granted on a timely basis, if at all.

Clinical trials are typically conducted in three sequential Phases which may overlap:

PHASE 1: Initial safety study in healthy human subjects or patients where the candidate therapy is tested for safety, dosage tolerance, absorption, distribution, metabolism, and excretion.

PHASE 2: Studies in a limited patient population designed to identify possible adverse effects and safety risks, to determine the efficacy of the product for specific targeted diseases and to determine tolerance and optimal dosage.

---

**Table of Contents**

PHASE 3: Studies in an expanded patient population to further evaluate clinical efficacy and to further test for safety.

We cannot be certain that we will successfully complete Phase 1, Phase 2 or Phase 3 testing of any compound within any specific time period, if at all. Furthermore, the FDA or the sponsor may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

The results of product development, preclinical studies and clinical studies are submitted to the FDA as part of an NDA. The FDA may refuse to accept an NDA for filing if it finds that the NDA is not sufficiently complete to permit a substantive review. Even if the FDA files the NDA, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Once the NDA is approved, the FDA may withdraw product approval or limit product use if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. In addition, the FDA may require testing and surveillance programs to monitor the effect of approved products which have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs.

Satisfaction of the above FDA requirements or similar requirements of state, local and foreign regulatory agencies typically takes several years and the actual time required may vary substantially, based upon the type, complexity and novelty of the product or indication. The FDA may grant fast track approval for therapies intended to treat severe or life-threatening diseases such as cancer or AIDS. This route to approval is intended to shorten the total time for clinical studies and marketing approvals for a drug to treat life-threatening illnesses; however, there can be no assurance that these fast track procedures will shorten the time of approval for any of our product candidates. Government regulation may delay or prevent marketing of potential products for a considerable period of time and impose costly procedures upon our or our partners activities. The FDA or any other regulatory agency may not grant any approvals on a timely basis, if at all. Success in early stage clinical trials does not assure success in later stage clinical trials. Data obtained from clinical activities is not always conclusive and may be susceptible to varying interpretations which could delay, limit or prevent regulatory approval. Even if a product receives regulatory approval, the approval may be significantly limited to specific indications and dosages. Delays in obtaining, or failures to obtain regulatory approvals may have a material adverse effect on our business. In addition, we cannot predict what adverse governmental regulations may arise from future U.S. or foreign governmental action.

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including record-keeping requirements and reporting of adverse experiences with the drug. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA to assess compliance with current Good Manufacturing Practices, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. We cannot be certain that we or our present or future suppliers will be able to comply with current Good Manufacturing Practices regulations and other FDA regulatory requirements.

*Molecular diagnostics.* We are subject to governmental regulation at the federal, state, and local levels as a clinical laboratory. The Clinical Laboratory Improvement Amendments, or CLIA, provide for the regulation of clinical laboratories by the Department of Health and Human Services, or HHS, and we are subject to HHS regulations, which mandate that all clinical laboratories be certified to perform testing on human specimens and provide specific conditions for certification. These regulations also contain guidelines for the qualification, responsibilities, training, working conditions and oversight of clinical laboratory employees. In addition, specific standards are imposed for each type of test which is performed in a laboratory. CLIA and the regulations promulgated thereunder are enforced through quality inspections of test methods, equipment, instrumentation, materials and supplies on a periodic basis. We are CLIA certified and any change in CLIA or these regulations or in the interpretation thereof could have a material adverse effect on our business.

The FDA has regulatory responsibility over instruments, test kits, reagents and other medical devices used to perform diagnostic testing by clinical laboratories. In the past, the FDA has claimed regulatory authority over laboratory-developed tests, but has exercised enforcement discretion in not regulating most laboratory-developed tests performed by high complexity CLIA-certified laboratories. The FDA has indicated in the past that it intends to revisit its regulations on specific reagents, which are used in laboratory-developed tests, including laboratory developed genetic testing. Increased FDA regulation of these reagents could lead to increased costs and delays in introducing new tests and could result in our having to obtain clearance or approval for our tests as FDA-regulated medical devices.



---

## **Table of Contents**

In July 2007, the FDA issued draft guidance for a class of in vitro diagnostic devices known as In Vitro Diagnostic Multivariate Index Assays, or IVDMIAs. The guidance document details the FDA's intention to regulate these types of devices. In this draft guidance, the FDA provides examples of devices that the FDA does not consider to meet the definition of IVDMIAs and that are outside the scope of its guidance document. One such category is genotype determination, which is the type of analysis performed for all our currently marketed products. Such genotype determination devices are not considered by the FDA to meet the definition of IVDMIAs and fall outside the scope of its guidance document.

Some states have implemented regulations concerning molecular diagnostic testing that require licensing or registration of general clinical laboratory activities. We believe that we have taken all steps required of us in such jurisdictions in order for us to conduct business in those jurisdictions. However, we may not be able to maintain state-level regulatory compliance in all states where we do and intend to do business. Failure to maintain state regulatory compliance, or changes in state regulatory schemes, could result in a substantial curtailment or even prohibition of our clinical activities and could have a material adverse effect on our business.

In 1996, Congress passed the Health Insurance Portability and Accountability Act, or HIPAA. HIPAA, among other things, required HHS to issue regulations that are designed to improve the efficiency and effectiveness of the healthcare system by facilitating the transfer of health information along with protecting the confidentiality and security of health information. Specifically, Title II of HIPAA, the Administrative Simplification Act, contains four 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 data content, codes and formats used in healthcare transactions. We are currently subject to the HIPAA regulations and maintain an active program designed to address regulatory compliance issues. Penalties for non-compliance with HIPAA include both civil and criminal penalties. Violations could result in civil penalties of up to \$25,000 per type of violation in each calendar year and criminal penalties of up to \$250,000 per violation.

The privacy regulations protect medical records and other personal 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. In addition to the federal privacy regulations, there are a number of state laws regarding the confidentiality of health information that are applicable to clinical laboratories. The penalties for violation of state privacy laws may vary widely and new privacy laws in this area are pending. We believe that we have taken the steps required of us to comply with health information privacy and confidentiality 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, could result in civil and/or criminal penalties and could have a material adverse effect on our business.

HHS has transactions and code sets regulations which establish standards for electronic transactions and for code sets to be used in those transactions. They also contain requirements concerning the use of these standards by health plans, healthcare clearinghouses, and certain healthcare providers. In addition, HHS has security regulations which establish standards for the security of electronic protected health information to be implemented by health plans, healthcare clearinghouse, and certain healthcare providers. We believe we have taken the steps required of us to comply with both the transaction and code sets as well as the security regulations. However, failure to maintain compliance with these regulations could result in civil and/or criminal penalties and could have a material adverse effect on our business.

Our business is also subject to regulation under state and federal laws regarding environmental protection and hazardous substances control, such as the Occupational Safety and Health Act, the Environmental Protection Act, and the Toxic Substance Control Act. We believe that we are in material compliance with these and other applicable laws and that the costs of our ongoing compliance will not have a material adverse effect on our business. However, statutes or regulations applicable to our business may be adopted which impose substantial additional costs to assure compliance or otherwise materially adversely affect our operations.

## **Reimbursement**

Sales of therapeutic and molecular diagnostic products depend significantly on the availability of third-party reimbursement. To date, third-party payors have agreed to provide reimbursement for our molecular diagnostic products currently on the market and we anticipate that third-party payors will provide reimbursement for our therapeutic products. It is time consuming and expensive for us to seek reimbursement from third-party payors. Reimbursement may not be available or sufficient to allow us to sell our products on a competitive and profitable basis.

## **Table of Contents**

The passage of the Medicare Prescription Drug and Modernization Act of 2003, or MMA, imposes new requirements for the distribution and pricing of prescription drugs for Medicare beneficiaries which may affect the marketing of our products. Although the MMA has increased access to pharmaceuticals through implementation of Part D in 2006, this may lead to increased pressure on prices coming from the concentrated buying power of the Managed Care Organizations, or MCOs, that administer the Part D plans on behalf of Medicare beneficiaries. These MCOs, along with Pharmacy Benefit Managers, negotiate pricing discounts to secure formulary placement for the plan or for their employer clients. Failure to achieve favorable status or failure to be included in these formularies could have a materially adverse effect on our business. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payors which could have a materially adverse effect on our business.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. We expect that there will continue to be a number of federal and state proposals to implement governmental pricing controls. While we cannot predict whether such legislative or regulatory proposals will be adopted, the adoption of such proposals could have a material adverse effect on our business, financial condition and profitability.

## **Available Information**

We are a Delaware corporation with our principal executive offices located at 320 Wakara Way, Salt Lake City, Utah 84108. Our telephone number is (801) 584-3600 and our web site address is [www.myriad.com](http://www.myriad.com). We make available free of charge through the Investor Relations section of our web site our Corporate Code of Conduct and Ethics, 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.

## **Human Resources**

As of August 1, 2008, we had 994 full-time equivalent employees, including 108 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.

---

**Table of Contents**

**Item 1A. RISK FACTORS**

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

*We are a company in the early stages of development and commercialization and may never achieve the goals of our business plan.*

Although we have developed and marketed several molecular diagnostic products to date, we believe our future success is dependent upon our ability to successfully develop and commercialize additional molecular diagnostic products and our potential therapeutic products. All of our therapeutic products are still in development and many are still in the early stages of development. Our drug candidate Azixa is currently the subject of Phase 2 clinical trials for metastatic brain cancer and primary brain cancer. We are conducting a Phase 1 clinical trial for the evaluation of Vivecon for the treatment of AIDS. Our drug candidate MPC-2130 is currently the subject of a Phase 1 clinical trial for advanced metastatic tumors or blood cancers as well as refractory cancer that has progressed despite previous chemotherapy. Our drug candidate MPC-0920 has completed a Phase 1 clinical trial for the treatment of thrombosis. Other potential therapeutic products are in various stages of pre-clinical development. Any therapeutic products under development by us may take several more years to develop and must undergo extensive preclinical and clinical testing. Additionally, therapeutic products are subject to substantial regulatory review. We may be unable to discover or develop any therapeutic or additional predictive medicine products through the utilization of our technologies. Even if we develop products for commercial use, we may not be able to develop products that:

meet applicable regulatory standards, in a timely manner or at all;

successfully compete with other technologies and products;

avoid infringing the proprietary rights of others;

can be manufactured in sufficient quantities or at reasonable cost; or

can be successfully marketed.

We must generate significant revenue to maintain profitability. Even if we succeed in developing and commercializing one or more of our therapeutic drug candidates or any additional molecular diagnostic products, we may not be able to generate sufficient revenue and we may never be able to maintain profitability.

*We have a history of operating losses.*

We have a limited operating history and until our fiscal year ended June 30, 2008, have experienced operating losses since our inception. We had an accumulated deficit of \$204.6 million as of June 30, 2008. In order to develop and commercialize our products, we expect to incur significant expenses over the next several years as we expand clinical trials for our product candidates currently in clinical development, including Azixa and Vivecon, advance our other product candidates into clinical trials, expand our research and development activities, and seek regulatory approvals and engage in commercialization activities in anticipation of potential FDA and other foreign regulatory approvals of our product candidates. Because of the numerous risks and uncertainties associated with developing our product candidates and their potential for commercialization, we are unable to predict the extent of any future profits. Additionally, we may not be able to sustain or increase profitability on a quarterly or annual basis. 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 identify drug targets and lead compounds that may lead to future therapeutic products;

our ability to develop candidate drugs and receive required regulatory approvals;

our ability to obtain regulatory approval for and successfully commercialize our therapeutic products;

the approval and introduction of competitive products;

the willingness of third-party payors to provide full or even partial reimbursement coverage for our products;

our ability to develop a sales force and marketing team to market our therapeutic products; and

our ability to increase commercial acceptance of our current molecular diagnostic products and to develop and successfully commercialize additional molecular diagnostic products.

our ability to maintain or grow current product revenues.

---

**Table of Contents**

*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 will enable us to maintain currently planned operations for at least the next two years. 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 therapeutic and molecular diagnostic products. Our ongoing drug discovery programs and our efforts to develop therapeutic and molecular diagnostic products will require substantial cash resources. If, for example, we discover a new drug target with promising therapeutic properties, we would require funding in addition to our current operating plan to move the drug candidate into preclinical studies and clinical trials. Additionally, if a new disease gene is discovered through these efforts, we would require funds in addition to our current operating plan to demonstrate clinical utility and develop and launch a new molecular diagnostic product. 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.

Because of our potential long-term capital requirements, we may access the public or private equity markets whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time. We have an effective shelf registration on file with the SEC pursuant to which up to \$43.4 million of our securities remain available for sale at our discretion, subject to certain limitations under federal securities laws and the rules of the NASDAQ Global Select Market. In addition, under SEC rules, we currently qualify as a well-known seasoned issuer, or WKSII. Accordingly, while we are a WKSII, we can at any time file a registration statement registering additional securities which would become automatically effective upon filing. If additional funds are raised by issuing equity securities, existing shareholders may suffer significant dilution.

*We have limited sources of revenue and if we are unable to secure additional funding, we may have to reduce or discontinue operations.*

As of June 30, 2008, we had approximately \$420.1 million in cash, cash equivalents and marketable securities. For the fiscal year ended June 30, 2008 our revenues were approximately \$333.6 million, and cash from operating activities was approximately \$103.7 million. Our revenues resulted from sales of our molecular diagnostic products of \$222.9 million, \$100.0 million in pharmaceutical revenue, consisting of a non-refundable upfront fee received from H. Lundbeck A/S (Lundbeck) in connection with an agreement we entered into with Lundbeck for European commercialization of our former Alzheimer's disease therapeutic candidate, Flurizan, and \$10.8 million from our research collaborations and other projects. To develop and bring new molecular diagnostic products to market and to develop and bring our therapeutic product candidates to market, we must commit substantial resources to costly and time-consuming research, preclinical testing and clinical trials. While we anticipate that our existing cash, cash equivalents and marketable securities will be sufficient to fund our current operations for at least the next two years, we may need or want to raise additional financing within this period of time. Our future capital requirements will depend on many factors that are currently unknown to us, including:

our ability to enter into strategic collaborations, licensing or other arrangements favorable to us;

the progress and results of our Phase 2 clinical trials for Azixa and any future trials we may initiate as a result of these trials;

the progress and results of our Phase 1 clinical trial for Vivecon and any future trials we may initiate based on the results of this trial;

the progress and results of our Phase 1 clinical trial for MPC-2130, and any future trials we may initiate based on the results of this trial;

our ability to partner MPC-0920 or results of future clinical trials for MPC-0920;

the results of our preclinical studies and testing for our preclinical programs, and any decisions to initiate clinical trials if supported by the preclinical results;

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

the costs, timing and outcome of regulatory review of Azixa, Vivecon, MPC-2130, and MPC-3100 and any other preclinical drug candidates that progress to clinical trials;

the scope, progress, results and cost of preclinical development, clinical trials and regulatory review of any new drug candidates we may discover or acquire;

the progress, results, and costs of developing additional molecular diagnostic products;

the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our issued patents, and defending intellectual property-related claims;

## **Table of Contents**

the costs of establishing sales and marketing functions and commercial manufacturing capacities if any of our drug candidates is approved;

the costs to satisfy our obligations under potential future collaborations; and

the timing, receipt and amount of sales or royalties, if any, from Azixa, Vivecon, MPC-2130, MPC-0920, and any other drug candidates.

Additional funds may not be available when we need them on terms that are acceptable to us, if at all. If adequate funds are not available on a timely basis, we may be required to:

terminate or delay preclinical studies, clinical trials, regulatory approvals, or other development for one or more of our drug candidates or molecular diagnostic products;

delay our establishment of sales and marketing capabilities, commercial manufacturing capabilities, or other activities that may be necessary to commercialize our drug candidates or molecular diagnostic products;

curtail significant discovery and development programs that are designed to identify new drug candidates or new molecular diagnostic products; or

enter into strategic collaborations that we would otherwise not enter into on terms less favorable than we may otherwise obtain.

*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. In addition, clinical trials or marketing of any potential therapeutic products may expose us to liability claims from the use of these therapeutic products. Although we are insured against such risks in amounts that we believe to be commercially reasonable, our present 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.

### **Risks Related to Regulatory Approval of Our Drug Candidates and Other Government Regulations**

*If we do not obtain required regulatory approval, we will be unable to market and sell our therapeutic candidates.*

Our therapeutic candidates are subject to extensive regulation by the FDA and similar regulatory agencies in other countries relating to development, clinical trials, manufacturing and commercialization. In the U.S. and in many foreign jurisdictions, rigorous preclinical testing and

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

clinical trials and an extensive regulatory review process must be successfully completed before a new therapeutic can be sold. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. The time required to obtain approval by the FDA is unpredictable and depends on many factors, including the complexity of the therapeutic candidate. To date, our clinical-stage therapeutic candidates, Azixa, Vivecon, MPC-0920, and MPC-2130 have been studied in a relatively small number of patients. Early-stage clinical trials in small numbers of patients are often not predictive of results in later-stage clinical trials with a larger and more diverse patient population. Even therapeutic candidates with favorable results in late-stage pivotal clinical trials may fail to get approved for commercialization for many reasons, including:

failure to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a therapeutic candidate is safe and effective for a particular indication;



**Table of Contents**

inability to demonstrate that a therapeutic candidate's benefits outweigh its risks;

inability to demonstrate that the therapeutic candidate presents a significant advantage over existing therapies;

the FDA's or comparable foreign regulatory authorities' disagreement with the manner in which we and our collaborators interpret the data from preclinical studies or clinical trials;

the FDA's or comparable foreign regulatory authorities' failure to approve our manufacturing processes or facilities or the processes or facilities of our collaborators; or

a change in the approval policies or regulations of the FDA or comparable foreign regulatory authorities.

It is possible that none of our current therapeutic candidates or any other therapeutic candidates we may seek to develop in the future will ever obtain the appropriate regulatory approvals necessary for us to begin selling them.

***Our clinical trials may not yield results that will enable us to obtain regulatory approval for our therapeutic candidates.***

We will only receive regulatory approval to commercialize a therapeutic candidate if we can demonstrate to the satisfaction of the FDA or an applicable foreign regulatory agency, in well-designed and conducted clinical trials, that the therapeutic candidate is safe and effective and otherwise meets the appropriate standards required for approval for a particular indication. Clinical trials are lengthy, complex and extremely expensive processes with uncertain results. We have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA. In connection with the clinical trials of our current therapeutic candidates and any other therapeutic candidates that we may seek to develop in the future, we face risks including:

the therapeutic candidate may not prove to be safe and efficacious;

patients may die or suffer other adverse effects for reasons that may or may not be related to the therapeutic candidate being tested;

the results of later-stage clinical studies may not confirm the positive results of earlier trials;

the results may not meet the level of statistical significance required by the FDA or other regulatory agencies for approval; and

the FDA or other regulatory agencies may require additional or expanded trials.

Of the large number of drugs in development, only a small percentage result in the submission of an NDA to the FDA and even fewer are approved for commercialization. If we fail to demonstrate the safety and efficacy of our therapeutic candidates, we will not be able to obtain the required regulatory approvals to commercialize these therapeutic candidates. Furthermore, even if we do receive regulatory approval to market a commercial product, any such approval may be subject to limitations on the indicated uses for which we may market the product.

***Because our therapeutic candidates are in an early stage of development, there is a high risk of failure, and we may never succeed in developing marketable products or generating product revenue.***

We have no therapeutic candidates that have received regulatory approval for commercial sale. Our most advanced therapeutic candidate is Azixa for the treatment of primary and metastatic brain tumors. Our next most advanced therapeutic candidate is Vivecon for the treatment of AIDS. We do not expect to have any commercial therapeutic products on the market for a number of years, if at all. Trial and error is inherent in

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

drug discovery and development, and we may fail at numerous stages along the way. Success in preclinical studies of a drug candidate may not be predictive of similar results in humans during clinical trials, and successful results from early clinical trials of a drug candidate may not be replicated in later clinical trials. We may face additional challenges with some of our drug candidates that are members of new classes of drugs which attempt to modify the course of a disease rather than simply addressing the symptoms of the disease. Measurement of success, protocols and regulatory standards for such disease-modifying drugs have not been defined and are still evolving. A number of companies in the pharmaceutical and biotechnology industries, including us, have suffered significant setbacks in late-stage clinical trials even after achieving promising results in early-stage development. Accordingly, the results from the completed and ongoing studies and trials for our therapeutic candidates may not be predictive of the results we may obtain in later-stage trials.

## **Table of Contents**

*If clinical trials for our therapeutic candidates are prolonged or delayed, we may be unable to commercialize our therapeutic candidates on a timely basis, which would require us to incur additional costs and delay our receipt of any revenue from potential product sales.*

We may encounter problems with our completed, ongoing or planned clinical trials that will cause us or any regulatory authority to delay or suspend those clinical trials or delay the analysis of data derived from them. A number of events, including any of the following, could delay the completion of our ongoing and planned clinical trials and negatively impact our ability to obtain regulatory approval for, and to market and sell, a particular therapeutic candidate, including our clinical-stage drug candidates:

modifications or conditions imposed on us by the FDA or any foreign regulatory authority regarding the scope or design of our clinical trials, including modifications to or conditions imposed on ongoing trials based on the results and data from completed trials;

delays in obtaining, or our inability to obtain, required approvals from institutional review boards or other reviewing entities at clinical sites selected for participation in our clinical trials;

insufficient supply or deficient quality of our drug candidates or other materials necessary to conduct our clinical trials;

negative or inconclusive results from clinical trials, or results that are inconsistent with earlier results, that necessitate additional clinical study;

clinical trial holds imposed by the data safety monitoring committees for our trials due to serious and/or unexpected drug-related side effects experienced by subjects in clinical trials; or

failure of our third-party contractors or our investigators to comply with regulatory requirements or otherwise meet their contractual obligations to us in a timely manner.

Our clinical trials may not begin as planned, may need to be restructured, and may not be completed on schedule, if at all. We meet with the FDA and other governmental and self-regulatory bodies from time-to-time regarding our research and clinical trials. Any such meeting could provide us with new information or requirements that would cause us to modify ongoing or future clinical trials or research efforts, which could delay or make commercially untenable such clinical trials or research efforts. Delays in our clinical trials may result in increased development costs for our drug candidates. In addition, if our clinical trials are delayed, our competitors may be able to bring products to market before we do and the commercial viability of our drug candidates, including our clinical-stage therapeutic candidates, could be significantly reduced.

*If we encounter difficulties enrolling subjects in our clinical trials, or subjects drop out of trials in progress, our trials could be delayed or otherwise adversely affected.*

Clinical trials for our therapeutic candidates require sufficient patient enrollment. We may not be able to enroll a sufficient number of qualified patients in a timely or cost-effective manner. Any delays in patient enrollment could result in increased costs and longer development times. Enrollment of patients is affected by many factors, including:

the limited size of the patient population for certain target indications;

the nature and design of the trial protocol;

the proximity of patients to clinical sites;

the availability of other effective treatments for the relevant disease (whether approved or experimental);

the eligibility criteria for enrollment in our clinical trials;

perceived risks and benefits of the drug candidate under study; and

competing studies or trials.

Our failure to enroll patients in our clinical trials could delay the completion of the clinical trial beyond our current expectations. Furthermore, enrolled patients may drop out of our clinical trials, which could impair the validity or statistical significance of the clinical trials. In addition, the FDA could require us to conduct clinical trials with a larger number of subjects than we may have projected for any of our therapeutic candidates. If we have difficulty enrolling or retaining a sufficient number of patients to participate and complete our clinical trials as planned, we may need to delay or terminate ongoing or planned clinical trials. Delays in enrolling patients in our clinical trials or the withdrawal of subjects enrolled in our clinical trials would adversely affect our ability to develop and seek approval for our drug candidates, could delay or eliminate our ability to generate products and revenue and could impose significant additional costs on us.

## **Table of Contents**

***Failure to comply with foreign regulatory requirements governing clinical trials and marketing approval for drugs could prevent us from selling our drug candidates in foreign markets, which may adversely affect our operating results and financial condition.***

The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement for marketing our therapeutic candidates outside the United States vary greatly from country to country and may require additional testing. We have no experience in obtaining foreign regulatory approvals for our therapeutic drug candidates. The time required to obtain approvals outside the United States may differ from that required to obtain FDA approval. We may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other countries or by the FDA. Failure to comply with these regulatory requirements or obtain required approvals could impair our ability to develop foreign markets for our therapeutic candidates.

***Our therapeutic candidates will remain subject to ongoing regulatory requirements even if they receive marketing approval, and if we fail to comply with requirements, we could lose these approvals and the sale of any approved commercial products could be suspended.***

Even if we receive regulatory approval to market a particular therapeutic candidate, the product will remain subject to extensive regulatory requirements, including requirements relating to manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion and record keeping. In addition, as clinical experience with a drug expands after approval because it is typically used by a greater number of patients after approval than during clinical trials, side effects and other problems may be observed after approval that were not seen or anticipated during pre-approval clinical trials. Such post-approval problems are sometimes not well understood until after a new drug has been on the market for some time. If we fail to comply with the regulatory requirements of the FDA and other applicable U.S. and foreign regulatory authorities or previously unknown problems with any approved commercial products, manufacturers or manufacturing processes are discovered, we could be subject to administrative or judicially imposed sanctions or other setbacks, including:

restrictions on the products, manufacturers or manufacturing processes;

civil or criminal penalties;

fines;

injunctions;

product seizures or detentions;

import bans;

product recalls and related publicity requirements;

suspension or withdrawal of regulatory approvals;

total or partial suspension of production; and

refusal to approve pending applications for marketing approval of new products or supplements to approved applications.

*If we are unable to comply with applicable governmental regulations, we may not be able to continue our molecular diagnostic operations.*

The establishment and operation of our molecular diagnostic laboratory and the production and marketing of services and products developed through our technologies, as well as our ongoing research and development activities, are subject to regulation by numerous federal, state and local governmental authorities in the United States. We have been accredited under the Clinical Laboratory Evaluation Program by the Department of Health of the State of New York. Failure to maintain state regulatory compliance, or changes in state regulatory schemes, could result in a substantial curtailment or even prohibition of our molecular diagnostic operations and could have a material adverse effect on our business. We have also received federal accreditation from the Department of Health and Human Services under the Clinical Laboratory Improvement Amendments, or CLIA to operate our clinical laboratory. CLIA is a federal law that regulates clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. To renew CLIA certification, laboratories are subject to survey and inspection every two years. Moreover, CLIA inspectors may make random inspections of these laboratories. If we were to lose our CLIA certification, whether as a result of a revocation, suspension or limitation, we would no longer be able to continue our molecular diagnostic operations which would have a material adverse effect on our business.

---

## **Table of Contents**

Furthermore, while the FDA has elected not to substantially regulate the activities or tests performed by laboratories like our clinical laboratory, 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 products in the future. In September 2006, the FDA issued draft guidance on a new class of tests called In Vitro Diagnostic Multivariate Index Assays, or IVDMIAs. Under this draft guidance, some laboratory-developed tests may be determined to be IVDMIAs and could be classified as Class II or Class III medical devices, which may require varying levels of FDA pre-market review depending upon intended use and on the level of control necessary to assure the safety and effectiveness of the test. In July 2007, the FDA posted revised draft guidance on IVDMIAs. In this draft guidance, the FDA provides examples of devices that the FDA does not consider to meet the definition of IVDMIAs and that are outside the scope of its guidance document. One such category is genotype determination, which is the type of analysis performed for all our currently marketed products. The comment period for this revised guidance expired in October 2007, and it is not clear whether or when the FDA may finalize this draft guidance. We cannot provide any assurance, however, that FDA regulation, including pre-market review, will not be required in the future for our molecular diagnostic products. Extension of FDA regulation to our molecular diagnostic products may occur through new enforcement policies adopted by the FDA of new legislation enacted by Congress. If pre-market review is required, our business could be negatively impacted if we are required to stop selling molecular diagnostic products pending their pre-market clearance or approval.

### **Risks Related to Commercialization of Our Products and Product Candidates**

*Our current molecular diagnostic products and therapeutic products in development may never achieve significant commercial market acceptance.*

We may not succeed in achieving significant commercial market acceptance of any of our products and services. While we have marketed several of our molecular diagnostic products for several years and have gained some market acceptance we need to convince physicians and consumers of the benefits of our current molecular diagnostic products in order to increase our sales of those products. Our ability to successfully commercialize our current molecular diagnostic products, as well as any future molecular diagnostic or therapeutic products 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 products and their potential advantages over existing therapeutic products and molecular diagnostic products.

The agreement by third-party payors to provide full or even partial reimbursement coverage for our products, the scope and extent of which will affect patients willingness or ability to pay for our products and will likely heavily influence physicians' decisions to recommend our products.

The willingness of physicians and patients to utilize molecular diagnostic products which are difficult to perform and interpret. This difficulty is caused by a combination of factors, including the large number, sometimes many hundreds, of different mutations in the genes which our tests analyze, the need to characterize each specific mutation, and the ability of our products to predict only as to a statistical probability, not certainty, that a tested individual will develop the disease for which the test has been completed.

These factors present obstacles to commercial acceptance of our products, 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.

*We may not be able to maintain or increase revenue growth and profitability for our molecular diagnostic products.*

BRACAnalysis, our product for breast and ovarian cancer, was the first molecular diagnostic product that we launched in November 1996. Sales of BRACAnalysis account for a majority of our molecular diagnostic revenues. An interruption or cessation of BRACAnalysis sample flow would have a material impact on our revenues and future profitability.

We have experienced revenue growth in our molecular diagnostic business over past years; however, we may not be able to continue this revenue growth or maintain existing revenue levels. Presently, our molecular diagnostic business subsidiary operates profitably providing a cash contribution to our other funding and operational needs. We may not, however, be able to continue to operate our molecular diagnostic business on a profitable basis. 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;



**Table of Contents**

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;

potential obsolescence of our products; and

our inability to increase commercial acceptance of our molecular diagnostic products.

***We rely on a single laboratory facility to process our molecular diagnostic tests.***

We rely on a single CLIA-approved laboratory facility in Salt Lake City, Utah to process our molecular diagnostic tests. This facility and certain pieces of laboratory equipment would be difficult to replace and may require significant replacement lead-time. This facility may be affected by natural disasters such as earthquakes, floods and fires. In the event our clinical testing facility or equipment is affected by man-made or natural disasters, we would be unable to continue our molecular diagnostic business and meet customer demands for a significant period of time. Although we maintain insurance on this facility, including business interruption insurance, it may not be adequate to protect us from all potential losses if this facility were damaged or destroyed. In addition, any interruption in our molecular diagnostic business would result in a loss of goodwill, including damage to our reputation. If our molecular diagnostic business were interrupted, it would seriously harm our business.

***We depend on the success of our lead product candidates, Azixa and Vivecon, which are still under development.***

We have invested significant resources in the development of Azixa and Vivecon. We anticipate that our future success will depend on the successful development and commercialization of Azixa for primary and metastatic brain tumors and Vivecon for HIV infected individuals. The commercial success of these product candidates will depend on several factors, including the following:

successful completion of our current Phase 2 clinical trials of Azixa for the treatment of primary and metastatic brain tumors, and any future trials we may conduct based on the results of the Phase 2 trials;

successful completion of our current Phase 1 clinical trial in Vivecon for the treatment of HIV infected individuals, and any future trials we may conduct based on the results of the Phase 1 trial;

receipt of marketing approvals from the FDA and similar foreign regulatory authorities;

if approved, the successful commercial launch of Azixa or Vivecon;

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

producing batches of the active pharmaceutical ingredient used in Azixa or Vivecon in commercial quantities through a validated process;

manufacturing and supplying Azixa or Vivecon in sufficient quantities to meet commercial demand; and

acceptance of Azixa or Vivecon or competitive products in the medical community and with third-party payors.

If we are not successful in developing or commercializing Azixa or Vivecon, or if we are significantly delayed in doing so, our business will be materially harmed and we may need to curtail or cease drug development operations.

***If we do not compete effectively with scientific and commercial competitors, we may not be able to successfully commercialize our products.***

The biotechnology research field is intense and highly competitive. This research is characterized by rapid technological change. Our competitors in the United States and abroad are numerous and include, among others, major pharmaceutical companies, reference laboratories, biotechnology 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 protein pathways and characterize their function, develop therapeutic and molecular diagnostic products based on these discoveries, obtain regulatory and other approvals and launch these products and their related services before our competitors. We also expect to encounter significant competition with respect to any therapeutic or molecular diagnostic products that we may develop or

## **Table of Contents**

commercialize. Those companies that complete clinical trials, obtain required regulatory approvals and commence commercial sales of therapeutic products before we do may achieve a significant competitive advantage in marketing and commercializing their products. We may not be able to develop therapeutic or molecular diagnostic products successfully and may not obtain patents covering these products that provide protection against our competitors. Moreover, our competitors may succeed in developing therapeutic or molecular diagnostic products that circumvent our technologies or products. Furthermore, our competitors may succeed in developing technologies or products that are more effective than those developed by us or that would render our technologies or products 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, biomarkers, and drug targets, and to commercialize therapeutic and molecular diagnostic products 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, biomarkers, and protein pathways involved in human disease and commercialize therapeutic and molecular diagnostic products 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 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.

***We have no experience manufacturing therapeutic products, and we currently intend to rely on third-party manufacturers to manufacture such products for us.***

We have no manufacturing experience and no commercial scale manufacturing capabilities for therapeutic products. We currently rely upon third parties to produce material for preclinical and clinical testing purposes and expect to continue to do so in the future. We also expect to rely upon third parties, including our collaborators, for the commercial production of approved therapeutic products. There are a limited number of manufacturers that operate under the FDA's current Good Manufacturing Practices, or cGMP, regulations. If we are unable to arrange for third-party manufacturing of our products, or to do so on commercially reasonable terms, our clinical trials may be delayed, or we may not be able to complete development of our therapeutic products or market them.

Reliance on third-party manufacturers also entails risks to which we would not be subject if we manufactured products ourselves, including reliance on the third party for regulatory compliance and quality assurance, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control, the possibility of termination or non-renewal of the agreement by the third party, based on its own business priorities, at a time that is costly or inconvenient for us, and potential import/export issues with foreign manufacturers that we may use. Although we have no current intention to do so, if in the future we elected to



---

**Table of Contents**

manufacture certain of our therapeutic products in our own manufacturing facilities, we would need to invest substantial additional funds and recruit qualified personnel in order to build or lease and operate any manufacturing facilities.

***We have limited sales, marketing and distribution capabilities, and with respect to our potential therapeutic products, we may be dependent on third parties to successfully perform these functions on our behalf, or we may be required to incur significant costs and devote significant efforts to augment our existing capabilities.***

We have limited sales, marketing and distribution experience and capabilities. These capabilities consist primarily of our sales force that markets our cancer-related molecular diagnostic products to oncologists and Ob/Gyns in the United States. We believe that if we develop therapeutic products in the area of cancer, given the concentrated nature of the oncology market, we would be able to leverage the efforts of our existing oncology sales force to market these products. However, depending on the nature of the therapeutic products and services for which we obtain marketing approval, we may need to rely significantly on sales, marketing and distribution arrangements with our collaborators and other third parties. For example, some types of pharmaceutical products require a large sales force and extensive marketing capabilities for effective commercialization. To date, we have not entered into an arrangement for marketing any current drug candidate, and we may not be able to do so on commercially reasonable terms when required. For therapeutic products for diseases with small medical specialty groups, we may elect to develop our own sales and marketing force. If in the future we elect to perform sales, marketing and distribution functions for such types of products ourselves, we would face a number of additional 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 machines, robots, and specialty reagents required in connection with our research. We believe that currently there are limited alternative suppliers of gene sequencing machines, robots, and reagents. The gene sequencing machines, robots, or the reagents may not remain available in commercial quantities at acceptable costs. If we are unable to obtain when needed additional gene sequencing machines, robots, or an adequate supply of reagents or other ingredients at commercially reasonable rates, our ability to continue to identify genes and perform molecular diagnostic testing would be adversely affected.

***If the government and third-party payors fail to provide coverage and adequate reimbursement rates for our products and future products, if any, our revenue and prospects for profitability will be harmed.***

In both domestic and foreign markets, sales of our molecular diagnostic products or any future drug or diagnostic products will depend in part, upon the availability of reimbursement from third-party payors. Such third-party payors include government health 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 drugs or tests they will pay for and the amounts that they will pay for new drugs or molecular diagnostic products. The fact that a drug or diagnostic product has been approved for reimbursement in the past, for any particular indication or in any particular jurisdiction, does not guarantee that such a drug or diagnostic product will remain approved for reimbursement or that similar or additional drugs or diagnostic products 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 products or, if approved, our drugs. We might need to conduct post-marketing studies in order to demonstrate the cost-effectiveness of any future products to such payors satisfaction. Such studies might require us to commit a significant amount of management time and financial and other resources. Our future products might not ultimately be considered cost-effective. 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 prescription pharmaceuticals. In the United States, we expect that there will continue to be federal and state proposals to implement similar governmental controls. In addition, recent changes in the Medicare program and increasing emphasis on managed care in the United States will continue to put pressure on pharmaceutical product pricing. Cost control initiatives could decrease the price that we would receive for any products in the future, which would limit our revenue and profitability. Accordingly, legislation and regulations affecting the pricing of pharmaceuticals might change before our drug candidates are approved for marketing. Adoption of such legislation could further limit reimbursement for pharmaceuticals.

---

**Table of Contents**

**Risks Related to Our Intellectual Property**

*If we are not able to protect our proprietary technology, others could compete against us more directly, which would harm our business.*

As of June 30, 2008, our patent portfolio included 312 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 drug targets we discover, for therapeutic compounds we develop, 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 one or more of our drug candidates or molecular diagnostic products 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 biotechnology and pharmaceutical 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, drug candidates, and any future products are covered by valid and enforceable patents or are effectively maintained as trade secrets. To date there has not emerged from the U.S. Patent and Trademark Office, or PTO, the U.S. courts, or from patent offices or courts in foreign countries, a consistent policy regarding the breadth of claims allowed in biotechnology patents. Our patent applications may never issue as patents, and the claims of any issued patents may not afford meaningful protection for our technology or products. In addition, any patents issued to us or our licensors may be challenged, and subsequently narrowed, invalidated or circumvented. 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 products, will provide us with any competitive advantages or will not be challenged by third parties;

we will develop additional proprietary technologies or drug candidates that are patentable; or

the patents of others will not have an adverse effect on our business.

If a third party files a patent application with claims to a drug target, gene or protein we have discovered, the PTO may declare an 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 products based on the drug target, gene or protein, or may be required to seek a license. A license may not be available to us on commercially acceptable terms, if at all.

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

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.

---

**Table of Contents**

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

Our products may also conflict with patents that have been or may be granted to others. Our industry includes many organizations seeking to rapidly identify drug targets, small-molecule compounds, proteins, and genes through the use of genomic, proteomic and other technologies. To the extent any patents are issued to those organizations on drug targets, proteins, genes or uses for such genes and proteins, the risk increases that the sale of our molecular diagnostic products currently being marketed or under development, and any sales of therapeutic drugs developed by us, 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 drug targets that are similar or identical to our products. 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, manufacturing or marketing our products. 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 products 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 and other proprietary information.***

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

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

We license intellectual property that is important to our business, 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, the ability to distribute our current products, or inhibit our ability to commercialize future product candidates. Our business may suffer if any current or future licenses terminate, if the licensors fail to abide by the terms of the license, if the licensors fail to prevent infringement by third parties, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms.

***We may be subject to claims that we or our employees have wrongfully used or disclosed alleged trade secrets of their former employers.***

As is commonplace in our industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.



## **Table of Contents**

### **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 biotechnology 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, 2008, our stock price has ranged from \$21.72 per share to \$59.18 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:

results of our Phase 2 clinical trials for Azixa and any future clinical trials we may conduct based on the results of the Phase 2 trials;

results of our current Phase 1 clinical trials of Vivecon for the treatment of AIDS and any future trials that we may initiate based on the results of the Phase 1 trial;

results of our Phase 1 clinical trial for MPC-2130, and any future trials we may initiate based on the results of our current trial;

our ability to partner MPC-0920 or results of future clinical trials for MPC-0920;

results of clinical trials conducted by others on drugs that would compete with our drug candidates;

failure or delays in advancing drug candidates from our preclinical programs, or other drug candidates we may discover or acquire in the future, into clinical trials;

failure or discontinuation of any of our research programs;

our entry into or the loss of a significant collaboration;

delays or other problems with manufacturing our drug candidates or approved products;

regulatory developments 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 products by us or our competitors;

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

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

failure to meet estimates or recommendations by securities analysts that cover our common stock;

public concern over our drug candidates or any approved products;

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;

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

failure of any of our drug candidates, if approved, 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 biotechnology 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 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;

**Table of Contents**

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.

We also have 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. These provisions, 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 headquarters and facilities are located in Salt Lake City, Utah. We currently lease a total of 220,000 square feet of building space dedicated to research and development, administration and laboratory space that has received federal certification under CLIA. Activity related to our research, drug development and molecular diagnostic segments is performed at this location. We have also entered into an agreement to lease an additional 87,000 square feet currently under construction adjacent to our existing facilities. The leases on our existing facilities have terms of fifteen years, expiring from 2017 through 2024, and provide for renewal options for up to ten additional years.

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 our drug development requirements and the anticipated demand for our molecular diagnostic products.

**Item 3. LEGAL PROCEEDINGS**

We are not a party to any material legal proceedings.

**Item 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

No matters were submitted to a vote of our security holders during the fourth quarter of the year ended June 30, 2008.

**Table of Contents****PART II****Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES****Market Information**

Our Common Stock began trading on the NASDAQ National Market on October 6, 1995 under the symbol MYGN. Effective July 1, 2006, the NASDAQ National Market changed its name and split into two different tiers, the NASDAQ Global Market and the NASDAQ Global Select Market, and we were automatically transferred to the NASDAQ Global Select Market. The following table sets forth the high and low sales prices for our Common Stock, as reported by the NASDAQ Global Select market for the last two fiscal years:

	High	Low
<b>Fiscal Year Ended June 30, 2008:</b>		
Fourth Quarter	\$ 50.58	\$ 39.93
Third Quarter	\$ 49.74	\$ 34.35
Second Quarter	\$ 59.18	\$ 44.25
First Quarter	\$ 52.92	\$ 36.24
<b>Fiscal Year Ended June 30, 2007:</b>		
Fourth Quarter	\$ 40.30	\$ 33.94
Third Quarter	\$ 37.43	\$ 30.00
Second Quarter	\$ 31.87	\$ 23.98
First Quarter	\$ 26.66	\$ 21.72

**Stockholders**

As of August 20, 2008, there were approximately 143 stockholders of record of our Common Stock and, according to our estimates, approximately 23,580 beneficial owners of our Common Stock.

**Dividends**

We have not paid dividends to our stockholders since our inception and we do not plan to pay cash dividends in the foreseeable future. We currently intend to retain earnings, if any, to finance our growth.

**Unregistered Sales of Securities**

None.

**Issuer Purchases of Equity Securities**

None.



**Table of Contents****Quarterly Financial Data (Unaudited)**

<i>In thousands, except per share amounts</i>	Quarters Ended			
	June 30, 2008	March 31, 2008	December 31, 2007	September 30, 2007
<b>Consolidated Statement of Operations Data:</b>				
Molecular diagnostic revenue	\$ 64,679	\$ 59,023	\$ 53,097	\$ 46,056
Pharmaceutical revenue	100,000			
Research and other revenue	2,177	2,742	3,645	2,210
<b>Total revenue</b>	<b>166,856</b>	<b>61,765</b>	<b>56,742</b>	<b>48,266</b>
Costs and expenses:				
Molecular diagnostic cost of revenue	9,051	8,263	7,690	7,335
Research and development expense	55,224	31,161	27,306	26,025
Selling, general and administrative expense	36,366	30,157	30,482	26,488
<b>Total costs and expenses</b>	<b>100,641</b>	<b>69,581</b>	<b>65,478</b>	<b>59,848</b>
<b>Operating income (loss)</b>	<b>66,215</b>	<b>(7,816)</b>	<b>(8,736)</b>	<b>(11,582)</b>
Other income (expense):				
Interest income	2,935	3,250	3,667	3,857
Other	(3,000)	(65)	2	(274)
<b>Income (loss) before income taxes</b>	<b>66,150</b>	<b>(4,631)</b>	<b>(5,067)</b>	<b>(7,999)</b>
Income tax provision	608			
<b>Net income (loss)</b>	<b>\$ 65,542</b>	<b>\$ (4,631)</b>	<b>\$ (5,067)</b>	<b>\$ (7,999)</b>
Basic earnings (loss) per share	\$ 1.47	\$ (0.10)	\$ (0.11)	\$ (0.18)
Diluted net earnings (loss) per share	\$ 1.40	\$ (0.10)	\$ (0.11)	\$ (0.18)
Basic weighted average shares outstanding	44,655	44,448	44,094	43,568
Diluted weighted average shares outstanding	46,969	44,448	44,094	43,568

<i>In thousands, except per share amounts</i>	Quarters Ended			
	June 30, 2007	March 31, 2007	December 31, 2006	September 30, 2006
<b>Consolidated Statement of Operations Data:</b>				
Molecular diagnostic revenue	\$ 42,268	\$ 37,991	\$ 34,175	\$ 30,851
Research revenue	3,210	2,979	2,960	2,692
<b>Total revenue</b>	<b>45,478</b>	<b>40,970</b>	<b>37,135</b>	<b>33,543</b>
Costs and expenses:				
Molecular diagnostic cost of revenue	7,602	7,577	7,529	8,105
Research and development expense	24,771	22,890	24,764	26,245

Edgar Filing: MYRIAD GENETICS INC - Form 10-K

Selling, general and administrative expense	25,371	19,595	16,211	14,193
Total costs and expenses	57,744	50,062	48,504	48,543
Operating loss	(12,266)	(9,092)	(11,369)	(15,000)
Other income (expense):				
Interest income	3,814	3,123	2,573	2,602
Other	648	32		(27)
	4,462	3,155	2,573	2,575
Net loss	\$ (7,804)	\$ (5,937)	\$ (8,796)	\$ (12,425)
Basic and diluted net loss per share	\$ (0.18)	\$ (0.14)	\$ (0.22)	\$ (0.31)
Basic and diluted weighted average shares outstanding	43,242	41,503	39,808	39,700

---

**Table of Contents**

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

**Overview**

We are a leading healthcare company focused on the development and marketing of novel molecular diagnostic and therapeutic products. We employ a number of proprietary technologies that permit us to understand the genetic basis of human disease and the role that genes and their related proteins play in the onset and progression of disease. We use this information to guide the development of new healthcare products that are designed to treat major diseases and assess a person's risk of disease later in life.

We have devoted substantially all of our resources to our three reportable operating segments: (1) research, which focuses on the discovery of genes related to major common diseases, (2) molecular diagnostics, which focuses on the analysis of genes and their alterations to assess the risk for developing disease later in life (predictive medicine) and to assess the risk of disease progression, disease recurrence, drug toxicity, and drug response (personalized medicine), and (3) drug development, which focuses on the development of therapeutic products for the treatment and prevention of major diseases. See Note 8 Segment and Related Information in the notes to our consolidated financial statements for information regarding these operating segments. Until the fiscal year ended June 30, 2008, our revenues have consisted primarily of sales of molecular diagnostic products and research payments. During the year ended June 30, 2008, we reported a net income of \$47.8 million. In fiscal 2008, our revenue included \$100.0 million in pharmaceutical revenue, consisting of a non-refundable upfront fee received from H. Lundbeck A/S (Lundbeck), in connection with an agreement we entered into with Lundbeck for European commercialization of our former Alzheimer's disease therapeutic candidate, Flurizan. As of June 30, 2008 we had an accumulated deficit of \$204.6 million.

We incurred research and development expenses of \$139.7 million, \$98.7 million, and \$83.0 million for the years ended June 30, 2008, 2007, and 2006 respectively. Our research and development expenses include costs incurred for our drug candidates currently in human clinical trials, including Azixa, Vivecon, MPC-2130, and MPC-0920. Currently, the only costs we track by each drug candidate are external costs such as services provided to us by clinical research organizations, manufacturing of drug supply, and other outsourced research. We do not assign to each drug candidate our internal costs such as salaries and benefits, facilities costs, lab supplies and the costs of preclinical research and studies. All research and development costs for our drug candidates are expensed as incurred.

The timing and amount of any future expenses, completion dates, and revenues for our drug candidates is not readily determinable due to the early stage of development of those candidates.

We do not know if we will be successful in developing any of our drug candidates. While expenses associated with the completion of our current clinical programs are expected to be substantial and increase, we believe that accurately projecting total program-specific expenses through commercialization is not possible at this time. The timing and amount of these expenses will depend upon the costs associated with potential future clinical trials of our drug candidates, and the related expansion of our research and development organization, regulatory requirements, advancement of our preclinical programs and product manufacturing costs, many of which cannot be determined with accuracy at this time. We are also unable to predict when, if ever, material net cash inflows will commence from our drug candidates. This is due to the numerous risks and uncertainties associated with the duration and cost of clinical trials, which vary significantly over the life of a project as a result of unanticipated events arising during clinical development, including:

the scope, rate of progress, and expense of our clinical trials and other research and development activities;

the length of time required to enroll suitable subjects; the number of subjects that ultimately participate in the trials;

the efficacy and safety results of our clinical trials and the number of additional required clinical trials;

the terms and timing of regulatory approvals;

our ability to market, commercialize, manufacture and supply, and achieve market acceptance for our product candidates that we are developing or may develop in the future; and



Edgar Filing: MYRIAD GENETICS INC - Form 10-K

the filing, prosecuting, defending or enforcing any patent claims or other intellectual property rights.

---

## **Table of Contents**

A change in the outcome of any of the foregoing variables in the development of a drug candidate could mean a significant change in the costs and timing associated with the development of that drug candidate. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those which we currently anticipate to complete clinical development of a drug candidate, or if we experience significant delays in enrollment in any of our clinical trials, we would be required to expend significant additional financial resources and time on the completion of clinical development.

Additionally, we expect to incur substantial sales, marketing and other expenses in connection with building our therapeutic and molecular diagnostic businesses. We expect that earnings will fluctuate from quarter to quarter and that such fluctuations may be substantial.

### **Critical Accounting Policies**

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

revenue recognition;

allowance for doubtful accounts; and

share-based payment expense.

*Revenue Recognition.* Molecular diagnostic revenue includes revenue from the sale of molecular diagnostic products and related marketing agreements, and is recorded at the invoiced amount net of any discounts or allowances. Molecular diagnostic revenue is recognized upon completion of the test, communication of results, and when collectability is reasonably assured.

Revenue from non-refundable upfront license fees where the Company has continuing involvement is recognized ratably over the development or agreement period or upon termination of a development or license agreement when the Company has no ongoing obligation

Research revenue includes revenue from research agreements, milestone payments, and technology licensing agreements. In applying the principles of SAB 104 and EITF 00-21 to research and technology license agreements we consider the terms and conditions of each agreement separately to arrive at a proportional performance methodology of recognizing revenue. Such methodologies involve recognizing revenue on a straight-line basis over the term of the agreement, as underlying research costs are incurred, or on the basis of contractually defined output measures such as units delivered. We make adjustments, if necessary, to the estimates used in our calculations as work progresses and we gain experience. The principal costs under these agreements are for personnel expenses to conduct research and development but also include costs for materials and other direct and indirect items necessary to complete the research under these agreements. Actual results may vary from our estimates. Payments received on uncompleted long-term contracts may be greater than or less than incurred costs and estimated earnings and have been recorded as other receivables or deferred revenues in the accompanying consolidated balance sheets. Revenue from milestone payments for which we have no continuing performance obligations is recognized upon achievement of the related milestone. When we have continuing performance obligations, the milestone payments are deferred and recognized as revenue over the term of the arrangement as we complete our performance obligations. We recognize revenue from up-front nonrefundable license fees on a straight-line basis over the period of our continued involvement in the research and development project.

*Allowance for Doubtful Accounts.* The preparation of our financial statements in accordance with U.S. GAAP requires us to make estimates and assumptions that affect the reported amount of assets at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Trade accounts receivable are comprised of amounts due from sales of our molecular diagnostic products, which are recorded net of any discounts or contractual allowances. We analyze trade accounts receivable and consider historic experience, customer creditworthiness, facts and circumstances specific to outstanding balances, and payment terms when evaluating the adequacy of the allowance for doubtful accounts.

We periodically evaluate and adjust the allowance for doubtful accounts when trends or significant events indicate that a change in estimate is appropriate. Such changes in estimate could materially affect our results of operations or financial position; however, to date these changes have not been material. It is possible that we may need to adjust our estimates in future periods.



**Table of Contents**

After a review of our allowance for doubtful accounts as of June 30, 2008 and 2007, we have determined that a hypothetical ten percent increase in our allowance for doubtful accounts would result in additional bad debt expense and an increase to our allowance for doubtful accounts of \$410,000 and \$260,000, respectively.

*Share-Based Payment Expense.* Financial Accounting Standards Board Statement No. 123R, Share-Based Payment, or SFAS 123R, sets accounting requirements for share-based compensation to employees, including employee stock purchase plans, and requires us to recognize in our consolidated statements of operations the grant-date fair value of our stock options and other equity-based compensation. The determination of grant-date fair value is estimated using an option-pricing model, which includes variables such as the expected volatility of our share price, the exercise behavior of our employees, interest rates, and dividend yields. These variables are projected based on our historical data, experience, and other factors. Changes in any of these variables could result in material adjustments to the expense recognized for share-based payments.

**Recent Accounting Pronouncements**

In February 2007, the Financial Accounting Standards Board, or FASB, issued SFAS No. 159, or SFAS 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115 or SFAS 159*. SFAS 159 permits entities to choose to measure many financial instruments and certain other items at fair value. The objective is to improve financial reporting by providing entities with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. SFAS 159 is effective for fiscal years beginning after November 15, 2007. Our adoption of SFAS 159 on July 1, 2008 is not expected to have a material effect on our consolidated financial position or results of operations.

In September 2006, FASB issued SFAS No. 157, *Fair Value Measurements* (SFAS 157). SFAS No. 157 establishes a framework for measuring fair value and expands disclosures about fair value measurements. The changes to current practice resulting from the application of this statement relate to the definition of fair value, the methods used to measure fair value and the expanded disclosures about fair value measurements. SFAS No. 157 is effective for fiscal years beginning after November 15, 2007. The adoption of this standard by us on July 1, 2008 is not expected to have a material effect on our consolidated financial position or results of operations.

In December 2007, the FASB issued SFAS No. 141(R), *Business Combinations*, or SFAS 141(R). SFAS 141(R) replaced SFAS No. 141, *Business Combinations*, originally issued in June 2001. SFAS 141(R) retains the purchase method of accounting for acquisitions, but requires a number of changes, including changes in the way assets and liabilities are recognized in purchase accounting. It also changes the recognition of assets acquired and liabilities assumed arising from contingencies, requires the capitalization of in-process research and development at fair value, and requires the expensing of acquisition-related costs as incurred. Generally, SFAS 141(R) is effective on a prospective basis for all business combinations completed on or after January 1, 2009. We are currently in the process of evaluating the extent of those potential impacts.

In December 2007, the Emerging Issues Task Force, or EITF, issued EITF Issue No. 07-1, *Accounting for Collaborative Arrangements*, or EITF 07-1. EITF 07-1 provides guidance concerning: determining whether an arrangement constitutes a collaborative arrangement within the scope of the Issue; how costs incurred and revenue generated on sales to third parties should be reported in the income statement; how an entity should characterize payments on the income statement; and what participants should disclose in the notes to the financial statements about a collaborative arrangement. The provisions of EITF 07-1 will be adopted in 2009. We are in the process of evaluating the impact of adopting EITF 07-1 on our financial statements.

**Results of Operations***Years ended June 30, 2008 and 2007*

Molecular diagnostic revenue is comprised primarily of sales of our molecular diagnostic products. Molecular diagnostic revenue for the fiscal year ended June 30, 2008 was \$222.9 million compared to \$145.3 million for the prior fiscal year, an increase of 53%. This 53% increase in molecular diagnostic revenue is primarily attributable to increased testing volume. Increased sales, marketing, and education efforts resulted in wider acceptance of our products by the medical community and increased testing volumes for the fiscal year ended June 30, 2008. We are currently in the process of expanding our sales force, executing a public awareness marketing campaign, and increasing our market penetration in the Ob/Gyn market. Through these efforts we are attempting to broaden

---

**Table of Contents**

utilization of our products with current physician customers and increase the number of new physician customers prescribing our products. We believe these efforts will allow us to continue to grow molecular diagnostic revenue in future periods; however, there can be no assurance that molecular diagnostic revenue will continue to increase at historical rates.

Pharmaceutical revenue is comprised of co-marketing agreement payments received relating to a therapeutic product. On May 21, 2008, we entered into an agreement with Lundbeck for European commercialization of our former Alzheimer's disease therapeutic candidate, Flurizan. As consideration for entering into the agreement we received a \$100 million non-refundable upfront fee which we expected to recognize over 15 years. On June 30, 2008, we announced the results of our U.S. 18-month Phase 3 study of Flurizan in patients with mild Alzheimer's disease. The study did not achieve statistical significance on either of its primary endpoints—cognition and activities of daily living. As a result we discontinued all ongoing Flurizan clinical studies, including our global Phase 3 trial, and have no further performance obligations under the agreement. The discontinuance of the Flurizan development program and any ongoing development activity related to Flurizan resulted in the recognition of the full \$100.0 million upfront fee as pharmaceutical revenue in fiscal 2008.

Research and other revenue is comprised of research payments received pursuant to collaborative agreements. Research revenue for the fiscal year ended June 30, 2008 was \$10.8 million compared to \$11.8 million for the prior fiscal year. This 9% decrease in research revenue is primarily attributable to the successful completion of research collaborations during 2008. Research revenue from our research collaboration agreements is recognized using a proportional performance methodology. Consequently, as these programs progress and outputs increase or decrease, revenue may increase or decrease proportionately. In the future we expect to continue to de-emphasize external collaborations.

Molecular diagnostic cost of revenue is comprised primarily of salaries and related personnel costs, laboratory supplies, royalty payments, equipment costs and facilities expense. Molecular diagnostic cost of revenue for the fiscal year ended June 30, 2008 was \$32.3 million compared to \$30.8 million for the prior fiscal year. This increase of 5% in molecular diagnostic cost of revenue is primarily due to the 53% increase in molecular diagnostic revenues for the fiscal year ended June 30, 2008 compared to the prior fiscal year. Our gross profit margin was 85% for the fiscal year ended June 30, 2008 compared to 79% for the prior fiscal year. This increase in gross profit margins is primarily attributable to technology improvements and efficiency gains in the operation of our molecular diagnostic laboratory. There can be no assurance that molecular diagnostic gross profit margins will continue to increase and we expect that our gross profit margins will fluctuate from quarter to quarter based on the introduction of new products as well as new technologies and operating systems in our molecular diagnostic laboratory.

Research and development expenses are comprised primarily of salaries and related personnel costs, laboratory supplies, equipments cost, facilities expense, and costs associated with our clinical trials. Research and development expenses for the fiscal year ended June 30, 2008 were \$139.7 million compared to \$98.7 million for the prior fiscal year. This increase of 42% was primarily due to:

one-time sub-license costs of approximately \$20 million being claimed under our license agreement with Encore Pharmaceuticals, Inc. based on license revenue under our Lundbeck co-marketing agreement with Lundbeck;

increased costs of approximately \$10.1 million associated with our pharmaceutical development programs;

increased costs of approximately \$6.0 million associated with our molecular diagnostic research programs; and

increased SFAS 123R share-based payment expense of approximately \$4.9 million.

We expect our research and development expenses will fluctuate over the next several years as we develop additional molecular diagnostic products, conduct additional clinical trials to support the potential commercialization of our product candidates currently in clinical development, including Azixa, Vivecon, and MPC-2130, advance our other product candidates into clinical trials, and expand our research and development activities. In the near term, we expect these expenses to be lower than recent historical levels due to the termination of our Flurizan development program. We also expect to incur some ancillary expenses in connection with the termination of our Flurizan development program which may be significant in amount.

Selling, general and administrative expenses consist primarily of salaries, commissions and related personnel costs for sales, marketing, customer service, billing and collection, executive, legal, finance and accounting, information technology, human



**Table of Contents**

resources, and allocated facilities expenses. Selling, general and administrative expenses for the fiscal year ended June 30, 2008 were \$123.5 million compared to \$75.4 million for the prior fiscal year. This increase of 64% was primarily attributable to:

increased sales and marketing expense of approximately \$18.6 million to support the 53% growth in our molecular diagnostic revenues, which included the expansion of our oncology and Ob/Gyn sales force, as well as commissions, travel, and initiative programs;

expansion of our commercialization efforts to support the anticipated product launch of Flurizan which resulted in an increase of approximately \$8.2 million;

an increase of \$5.7 million in bad debt expense with resulted from growth in our molecular diagnostic sales;

increased marketing costs of approximately \$5.0 million associated with the launch of our public awareness campaign for our *BRACAnalysis* predictive medicine product;

general increases in expenses of approximately \$4.8 million to support growth in administrative support and facility costs;

general increases in costs of approximately \$3.3 million to support growth in our molecular diagnostic business and therapeutic development efforts; and

increased SFAS 123R share-based payment expense of approximately \$2.5 million.

We expect our selling, general and administrative expenses will continue to fluctuate depending on the number and scope of any new product launches, our efforts in support of our existing molecular diagnostic products, and our drug discovery and drug development efforts.

Interest income for the fiscal year ended June 30, 2008 was \$13.7 million, compared to \$12.1 million for the prior fiscal year. The increase was due primarily to increases in cash, cash equivalents, and marketable investment securities.

Other income and expense for the fiscal year ended June 30, 2008 decreased \$3.9 million from income of \$0.6 million for the fiscal year ended June 30, 2007 to \$3.3 million expense for the fiscal year ended June 30, 2008. The decrease is primarily attributable to the write-off of \$3 million in our preferred stock investment in Encore Pharmaceuticals as a result of our discontinuation of the Flurizan development program.

*Years ended June 30, 2007 and 2006*

Molecular diagnostic revenue is comprised primarily of sales of our molecular diagnostic products. Molecular diagnostic revenue for the fiscal year ended June 30, 2007 was \$145.3 million compared to \$100.6 million for the prior fiscal year, an increase of 44%. Increased sales, marketing, and education efforts resulted in wider acceptance of our products by the medical community and increased testing volumes for the fiscal year ended June 30, 2007.

Research revenue for the fiscal year ended June 30, 2007 was \$11.8 million compared to \$13.7 million for the prior fiscal year. This 13% decrease in research revenue is primarily attributable to the successful completion of a research collaboration in the prior year. Research revenue from our research collaboration agreements is recognized using a proportional performance methodology. Consequently, as these programs progress and outputs increase or decrease, revenue may increase or decrease proportionately.

Molecular diagnostic cost of revenue for the fiscal year ended June 30, 2007 was \$30.8 million compared to \$27.6 million for the prior fiscal year. This increase of 11% in molecular diagnostic cost of revenue is primarily due to the 44% increase in molecular diagnostic revenues for the fiscal year ended June 30, 2007 compared to the prior fiscal year. Our gross profit margin was 79% for the fiscal year ended June 30, 2007

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

compared to 73% for the prior fiscal year. This increase in gross profit margins is primarily attributable to technology improvements and efficiency gains in the operation of our molecular diagnostic laboratory.

Research and development expenses for the fiscal year ended June 30, 2007 were \$98.7 million compared to \$83.0 million for the prior fiscal year. This increase of 19% was primarily due to increased costs associated with our ongoing clinical trials of Flurizan and Azixa.

Selling, general and administrative expenses for the fiscal year ended June 30, 2007 were \$75.4 million compared to \$49.2 million for the prior fiscal year. This increase of 53% was primarily attributable to:

increased sales and marketing commissions, headcount, and related costs to support the 44% growth in our molecular diagnostic business, which resulted in an increase of \$9.3 million compared to the prior fiscal year;



---

**Table of Contents**

marketing costs associated with the preparation of a direct-to-consumer advertising campaign, which resulted in an increase of \$4.3 million compared to the prior fiscal year;

increased bad debt expense, which resulted in an increase of \$3.6 million compared to the prior fiscal year;

increased share-based payment expense of approximately \$2.9 million compared to the prior fiscal year; and

general increases in costs to support growth in our molecular diagnostic business and therapeutic development efforts, which resulted in an increase of approximately \$6.1 million compared to the prior fiscal year.

**Liquidity and Capital Resources**

Cash, cash equivalents, and marketable investment securities increased \$111.7 million, or 36%, from \$308.3 million at June 30, 2007 to \$420.1 million at June 30, 2008. This increase is primarily attributable to receipt of a \$100 million cash payment received from Lundbeck under the co-marketing agreement for Flurizan, cash generated from our molecular diagnostic revenue and, to a lesser extent, research collaboration payments and proceeds from the exercise of stock options, warrants, and sales of our common stock under our Employee Stock Purchase Plan. This increase was partially offset by expenditures for our ongoing clinical trials, internal research and drug development programs, acquisition of capital assets, and other expenditures incurred in the ordinary course of business.

Net cash provided by operating activities was \$103.7 million during the fiscal year ended June 30, 2008 compared to \$25.9 million used in operating activities during the prior fiscal year. Trade receivables increased \$21.1 million between June 30, 2008 and June 30, 2007, primarily due to the 53% increase in molecular diagnostic sales during the same period. Accounts payable increased by \$9.1 million and accrued liabilities increased \$27.7 million between June 30, 2007 and June 30, 2008, primarily due to amounts owed related to our ongoing clinical trials and a maximum license fee of \$20 million that may be payable in connection with our co-marketing agreement with Lundbeck.

Our investing activities used cash of \$31.3 million during the fiscal year ended June 30, 2008 compared to \$46.7 million used in investing activities during the prior fiscal year. For the fiscal year ended June 30, 2008, purchases of marketable investment securities used cash of \$191.7 million, maturities of marketable investment securities provided cash of \$174.4 million, and capital expenditures for research equipment used cash of \$13.7 million.

Financing activities provided cash of \$21.9 million during the fiscal year ended June 30, 2008 and provided cash of \$117.4 million in the prior fiscal year. The decrease in cash provided by financing activities is attributed primarily to net proceeds of \$105.3 million received in the prior year from an underwritten offering of 3.0 million shares of our common stock pursuant to our outstanding shelf registration statement on Form S-3 (Registration No. 333-123914). As of June 30, 2008, we have approximately \$43.4 million of securities available for sale under this shelf registration statement. During the fiscal year ended June 30, 2008, we received \$20.7 million from the exercise of stock options and the purchase of our common stock from our Employee Stock Purchase Plan and \$1.2 million from the exercise of warrants.

We believe that with our existing capital resources, we will have adequate funds to maintain our current and planned operations for at least the next two years, although no assurance can be given that changes will not occur that would consume available capital resources before such time and we may need or want to raise additional financing within this period of time. Our future capital requirements, cash flows, and results of operations could be affected by and will depend on many factors that are currently unknown to us, including:

the progress and results of our current Phase 2 clinical trials of Azixa for the treatment of cancer and any additional trials that we may initiate based on the Phase 2 results;

the progress and results of our Phase 1 clinical trials for Vivecon and MPC-2130 and any future trials that we may initiate based on the Phase 1 results;

**Table of Contents**

the results of our preclinical studies and testing for our preclinical programs and any decisions to initiate clinical trials if supported by the preclinical results;

the costs, timing and outcome of regulatory review of Azixa, Vivecon, MPC-2130, MPC-0920, and any preclinical drug candidates that may progress to clinical trials;

the costs of establishing sales and marketing functions and of establishing or contracting for commercial manufacturing capacities if any of our drug candidates is approved;

the scope, progress, results and cost of preclinical development, clinical trials and regulatory review of any new drug candidates we may discover or acquire;

the costs and expenses incurred in supporting our existing molecular diagnostic products;

the progress, results and cost of developing additional molecular diagnostic products for our molecular diagnostic business;

the costs, timing and results of launching new molecular diagnostic products;

the costs, timing and outcome of any regulatory review of our existing or future molecular diagnostic products;

the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our issued patents and defending intellectual property-related claims;

the costs, timing and outcome of any litigation against us associated with any of our current or future products;

our ability to enter into strategic collaborations, licensing or other arrangements favorable to us; and

the costs to satisfy our obligations under potential future collaborations.

**Off-Balance Sheet Arrangements**

None.

**Contractual Obligations**

The following table represents our consolidated contractual obligations as of June 30, 2008 (in thousands):

	Total	Less than one year	1-3 Years	4-5 Years	More than 5 years
Operating leases	\$ 102,360	\$ 5,655	\$ 15,941	\$ 16,343	\$ 64,421

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

Purchase obligations	310	310			
Contractual services	7,173	6,429	744		
 Total	 \$ 109,843	 \$ 12,394	 \$ 16,685	 \$ 16,343	 \$ 64,421

Contractual services represent financial commitments for drug development and clinical trial activities that can be terminated at our request. The expected timing of payment for the obligations listed above is estimated based on current information. Actual payment timing and amounts may differ depending on the timing of goods or services received or other changes. The table above only includes payment obligations that are fixed or determinable. The table excludes potential milestone payments we may be required to pay under license agreements in the aggregate of up to \$23 million based on the progress of our drug candidates currently in development, as the likelihood and timing of these payments are not yet determinable. The table also excludes royalties to third parties based on future sales of any of our product candidates that are approved for sale, as the amounts, timing, and likelihood of any such payments are unknown.

### **Effects of Inflation**

We do not believe that inflation has had a material impact on our business, revenues, or operating results during the periods presented.

### **Certain Factors That May Affect Future Results of Operations**

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

---

**Table of Contents**

Words such as may, anticipate, estimate, expects, projects, intends, plans, believes and words and terms of similar substance used in any discussion of future operating or financial performance, identify forward-looking statements. All forward-looking statements are management's present expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those described in the forward-looking statements. These risks include, but are not limited to: the risk that we may be unable to further identify, develop or achieve commercial success for new products and technologies; the risk that we may be unable to discover drugs that are safer and more efficacious than our competitors; the risk we may be unable to develop manufacturing capability for approved products; the risk that sales of our existing molecular diagnostic products may decline or will not continue to increase at historical rates; the risk that we may be unable to develop additional molecular diagnostic products that help assess which patients are subject to greater risk of developing diseases and who would therefore benefit from new preventive therapies; the possibility of delays in the research and development necessary to select drug development candidates and delays in clinical trials; the risk that clinical trials may not result in marketable products; the risk that we may be unable to successfully finance and secure regulatory approval of and market our drug candidates; the risk that clinical trials will not be completed on the timelines we have estimated; uncertainties about our ability to obtain new corporate collaborations and acquire new technologies on satisfactory terms, if at all; the development of competing products and services; the risk that we may be unable to protect our proprietary technologies; the risk of patent-infringement claims; risks of new, changing and competitive technologies and regulations in the United States and internationally; and other factors discussed under the heading "Risk Factors" contained in Item 1A of this Annual Report.

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

**Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

We maintain an investment portfolio in accordance with our written investment policy. The primary objectives of our investment policy are to preserve principal, maintain proper liquidity to meet operating needs and maximize yields. Our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure to any single issue, issuer or type of investment.

Our investments consist of securities of various types and maturities of three years or less, with a maximum average maturity of 12 months. These securities are classified as available-for-sale. Available-for-sale securities are recorded on the balance sheet at fair market value with unrealized gains or losses reported as part of accumulated other comprehensive income/loss. Realized gains and losses on investment security transactions are reported on the specific-identification method. Dividend and interest income are recognized when earned. A decline in the market value of any available-for-sale security below cost that is deemed other than temporary results in a charge to earnings and establishes a new cost basis for the security.

We currently hold \$4 million in securities, classified as marketable investment securities, with an auction reset feature ( "auction rate securities" ). In February 2008, auctions began to fail for these securities and each auction since then has failed. We have determined that any change in fair value to these auction rate securities would not have a material impact upon our financial statements, taken as a whole.

The securities held in our investment portfolio are subject to interest rate risk. Changes in interest rates affect the fair market value of the marketable investment securities. After a review of our marketable securities as of June 30, 2008, we have determined that in the event of a hypothetical ten percent increase in interest rates, the resulting decrease in fair market value of our marketable investment securities would be insignificant to the consolidated financial statements as a whole.

**Table of Contents****Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA****MYRIAD GENETICS, INC.**

<b>Index to Financial Statements</b>	<b>Number</b>
<u>Reports of Independent Registered Public Accounting Firms</u>	F-1
<u>Consolidated Balance Sheets as of June 30, 2008 and 2007</u>	F-3
<u>Consolidated Statements of Operations for the Years Ended June 30, 2008, 2007 and 2006</u>	F-4
<u>Consolidated Statements of Stockholders' Equity and Comprehensive Income (Loss) for the Years Ended June 30, 2008, 2007 and 2006</u>	F-5
<u>Consolidated Statements of Cash Flows for the Years Ended June 30, 2008, 2007 and 2006</u>	F-6
<u>Notes to Consolidated Financial Statements</u>	F-7

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

Not applicable.

**Item 9A. CONTROLS AND PROCEDURES****1. Disclosure Controls and Procedures**

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

As of the end of the period covered by this Annual Report on Form 10-K, we evaluated the effectiveness of the design and operation of the Company's Disclosure Controls, which was done under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer. Based on the evaluation of our Disclosure Controls, our Chief Executive Officer and Chief Financial Officer have concluded that, as of June 30, 2008, our Disclosure Controls were effective to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is made known to management, including our Chief Executive Officer and Chief Financial Officer, and that such information is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

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

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) and 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, a company's principal executive and principal financial officers and effected by the company's board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that:

pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company;



---

**Table of Contents**

provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and

provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

Our management assessed the effectiveness of our internal control over financial reporting as of June 30, 2008. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control - Integrated Framework*. Based on our assessment, management believes that, as of June 30, 2008, our internal control over financial reporting is effective based on those criteria.

**b. Attestation Report of the Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders

Myriad Genetics, Inc.:

We have audited Myriad Genetics, Inc.'s internal control over financial reporting as of June 30, 2008, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Myriad Genetics Inc.'s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

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

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

**Table of Contents**

In our opinion, Myriad Genetics, Inc. maintained, in all material respects, effective internal control over financial reporting as of June 30, 2008, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheet of Myriad Genetics, Inc. as of June 30, 2008 and 2007, and the related consolidated statements of operations, stockholders' equity and comprehensive income (loss), and cash flows for the years then ended of Myriad Genetics, Inc. and our report dated August 25, 2008 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Salt Lake City, Utah

August 25, 2008

**c. Change in Internal Control over Financial Reporting**

No change in our internal control over financial reporting occurred during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**Item 9B. OTHER INFORMATION**

None.



**Table of Contents**

**PART III**

**Item 10. DIRECTORS AND EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

The response to this item is incorporated by reference from the discussion responsive thereto under the captions Management, Section 16(a) Beneficial Ownership Reporting Compliance and Code of Conduct and Ethics in our Proxy Statement for the 2008 Annual Meeting of Stockholders to be held on November 13, 2008.

**Item 11. EXECUTIVE COMPENSATION**

The response to this item is incorporated by reference from the discussion responsive thereto under the captions Compensation Discussion and Analysis, Executive Compensation, Management-Committees of the Board of Directors and Meetings-Compensation Committee Interlocks and Insider Participation, Director Compensation and Compensation Committee Report in our Proxy Statement for the 2008 Annual Meeting of Stockholders to be held on November 13, 2008.

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

The response to this item is incorporated by reference from the discussion responsive thereto under the captions Security Ownership of Certain Beneficial Owners and Management and Executive Compensation-Equity Compensation Plan Information in our Proxy Statement for the 2008 Annual Meeting of Stockholders to be held on November 13, 2008.

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

The response to this item is incorporated by reference from the discussion responsive thereto under the caption Certain Relationships and Related Transactions and Management The Board of Directors in our Proxy Statement for the 2008 Annual Meeting of Stockholders to be held on November 13, 2008.

**Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES**

The response to this item is incorporated by reference from the discussion responsive thereto in the proposal entitled Independent Public Accountants (Notice Item 3) in our Proxy Statement for the 2008 Annual Meeting of the Stockholders to be held on November 13, 2008.

**Table of Contents**

**PART IV**

**Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES**

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

**1. Financial Statements**

See Index to Consolidated Financial Statements at Item 8 to this Annual Report on Form 10-K.

**2. Financial Statement Schedule**

The following schedule is filed as part of this Form 10-K:

Schedule II Schedule of Valuation and Qualifying Accounts for the Years Ended June 30, 2008, 2007, and 2006

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

**3. Exhibits**

The following is a list of exhibits filed as part of this Annual Report on Form 10-K.

**Exhibit**

<b>Number</b>	<b>Description</b>
(3.1 (a))g	Restated Certificate of Incorporation of the Registrant (Filed as Exhibit 3.1 (a))
(3.1 (b))g	Certificate of Amendment of Restated Certificate of Incorporation (Filed as Exhibit 3.1 (b))
(3.1 (c))g	Certificate of Designations of Series A Junior Participating Preferred Stock (Filed as Exhibit 3.1 (c))
(3.2)p	Restated By-Laws of the Registrant (Filed as Exhibit 3.2)
(4.1)	See Exhibits 3.1(a), 3.1(b), 3.1(c) and 3.2
(4.2)f	Form of Common Stock Certificate (Filed as Exhibit 4.2)
(4.3)j	Rights Agreement dated as of July 17, 2001, between the Registrant and Mellon Investor Services, LLC (filed as Exhibit 4.1)
(4.4)f	Agreement of Substitution and Amendment of Common Shares Rights Agreement by and between the Registrant and American Stock Transfer and Trust Company dated August 16, 2002 (Filed as Exhibit 4.4)
(10.1 (a))\$f	2002 Amended and Restated Employee, Director and Consultant Stock Option Plan (Filed as Exhibit 10.1)
(10.1 (b))\$n	Form of Incentive Stock Option Agreement under the 2002 Amended and Restated Employee, Director and Consultant Stock Option Plan (Filed as Exhibit 10.9)
(10.1 (c))\$n	Form of Non-Qualified Stock Option Agreement under the 2002 Amended and Restated Employee, Director and Consultant Stock Option Plan (Filed as Exhibit 10.10)

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

(10.2 (a))\$p	2003 Employee, Director and Consultant Stock Option Plan, as amended (Filed as Exhibit 99.1)
(10.2 (b))\$n	Form of Incentive Stock Option Agreement under the 2003 Employee, Director and Consultant Stock Option Plan (Filed as Exhibit 10.7)
(10.1 (c))\$n	Form of Non-Qualified Stock Option Agreement under the 2003 Employee, Director and Consultant Stock Option Plan (Filed as Exhibit 10.8)
(10.3)\$k	Employee Stock Purchase Plan, as amended (Filed as Exhibit 99.2)
(10.4)\$a	Employment Agreement between Myriad Genetics, Inc., Myriad Genetic Laboratories, Inc. and Peter D. Meldrum, dated May 15, 1993 (Filed as Exhibit 10.3)
(10.5)\$a	Employment Agreement between Myriad Genetics, Inc., Myriad Genetic Laboratories, Inc. and Mark H. Skolnick, Ph.D., dated January 1, 1994 (Filed as Exhibit 10.4)
(10.6)\$a	Employment Agreement between Myriad Genetics, Inc., Myriad Genetic Laboratories, Inc. and Jay M. Moyes, dated July 12, 1993 (Filed as Exhibit 10.5) [NOTE: Because Jay is an NEO in the proxy, his contracts need to stay in for now.]
(10.7)\$m	Employment Agreement between Myriad Genetics, Inc., Myriad Genetic Laboratories, Inc. and Gregory C. Critchfield, M.D., dated September 14, 1998 (Filed as Exhibit 10.7)

**Table of Contents**

(10.8)\$m	Employment Agreement between Myriad Genetics, Inc., Myriad Pharmaceuticals, Inc. and Adrian N. Hobden, Ph.D., dated September 30, 1998 (Filed as Exhibit 10.8)
(10.9)@a	Exclusive License Agreement between the Registrant and the University of Utah Research Foundation, dated October 8, 1991, as amended (Breast Cancer BRCA1) (Filed as Exhibit 10.13)
(10.10)@a	Exclusive License Agreement between the Registrant and the University of Utah Research Foundation, dated November 23, 1994 (Breast Cancer BRCA2) (Filed as Exhibit 10.17)
(10.11)b	Lease Agreement, dated October 12, 1995, between the Boyer Research Park Associates V, by its general partner, the Boyer Company and the Registrant (Filed as Exhibit 10.2)
(10.12)b	Amendment to Lease Agreement, dated March 29, 1996 between the Boyer Research Park Associates V, by its general partner, the Boyer Company and the Registrant (Filed as Exhibit 10.3)
(10.13)c	Lease Agreement-Research Park Building Phase II, dated March 6, 1998, between the Research Park Associated VI, by its general partner, the Boyer Company, L.C. and the Registrant (Filed as Exhibit 10.44)
(10.14)d	Memorandum of Lease between the Company and Boyer Foothill Associates, Ltd. dated August 24, 1998 (Filed as Exhibit 10.1)
(10.15)d	Memorandum of Lease between the Company and Boyer Research Park Associates VI, L.C. dated August 24, 1998 (Filed as Exhibit 10.2)
(10.16)d	Subordination Agreement and Estoppel, Attornment and Non-Disturbance Agreement (Lease to Deed of Trust) between the Company and Wells Fargo Bank, National Association dated June 24, 1998 (Filed as Exhibit 10.3)
(10.17)e	Lease Agreement, dated March 31, 2001 between the Registrant and Boyer Research Park Associates VI, by its general partner, The Boyer Company, L.C. (Filed as Exhibit 10.1)
(10.18)e	Agreement, dated March 31, 2001, between the Registrant and Boyer Research Park Associates VI, by its general partner, The Boyer Company, L.C. (Filed as Exhibit 10.2)
(10.19)\$i	Form of Executive Retention Agreement (Filed as Exhibit 10.1)
(10.20 (a))\$l	Executive Retention Agreement, dated November 17, 2006, between Myriad Genetics, Inc. and Mark. C. Capone (Filed as Exhibit 10.1)
(10.20 (b))\$q	Form of Amendment to Form of Executive Retention Agreement (Filed as Exhibit 10.1)
(10.21)h	Lease Agreement, dated June 29, 2005 between the Registrant and Boyer Research Park Associates VIII, by its general partner, The Boyer Company, L.C. (Filed as Exhibit 99.1)
(10.22)h	Letter of Understanding regarding Lease Agreement, dated June 29, 2005 between the Registrant and Boyer Research Park Associates VIII, by its general partner, The Boyer Company, L.C. (Filed as Exhibit 99.2)
(10.23)@n	Exclusive License Agreement, dated March 15, 1995, between the Registrant and the Hospital for Sick Children (Filed as Exhibit 10.1)
(10.24)@n	Exclusive License Agreement, dated January 6, 1995, between the Registrant and Endorecherche (Filed as Exhibit 10.2)
(10.25)@n	Exclusive License Agreement, dated March 13, 1996, between the Registrant and The Trustees of the University of Pennsylvania (Filed as Exhibit 10.3)
(10.26)@n	License and Collaboration Agreement, dated November 19, 2003, among the Registrant, Maxim Pharmaceuticals, Inc., and Cytovia, Inc. (now known as Epicept Corporation) (Filed as Exhibit 10.4)
(10.27)n	Myriad Genetics, Inc. Management Performance Program (Filed as Exhibit 10.5)
(10.28)n	Myriad Genetics, Inc. Non-Employee Director Compensation Policy (Filed as Exhibit 10.6)
(10.29)\$o	Employment Agreement between Myriad Genetics, Inc., Myriad Genetic Laboratories, Inc. and James S. Evans dated March 3, 1995 (Filed as Exhibit 10.1)
(10.30)\$o	Resignation Agreement between Myriad Genetics, Inc. and Jay M. Moyes dated November 1, 2007 (Filed as Exhibit 10.2)
(10.31)\$	Summary of compensation arrangements applicable to the Registrant's Named Executive Officers (FY 2008 Bonus and FY 2009 Salary)

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

- (10.32) Lease Agreement, dated March 11, 2008 between the Registrant and Boyer Research Park Associates IX, by it general partner, The Boyer Company, L.C.
- (10.33)# Co-marketing Agreement, dated May 21, 2008 between the Registrant and H. Lundbeck A/S
- (21.1) List of Subsidiaries of the Registrant
- (23.1) Consent of Independent Registered Public Accounting Firm (KPMG LLP)
- (23.2) Consent of Independent Registered Public Accounting Firm (Ernst & Young LLP)
- (31.1) Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- (31.2) Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- (32) Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

**Table of Contents**

- @ Confidential treatment has been granted by the Commission as to certain portions.
- # Confidential treatment has been requested from the Commission as to certain portions.
- \$ Management contract or compensatory plan or arrangement.
- a Previously filed with the Commission as Exhibits to, and incorporated herein by reference from, the Company's Registration Statement filed on Form S-1, File No. 33-95970.
- b Previously filed and incorporated herein by reference from the Form 10-Q for the period ending September 30, 1996, File No. 0-26642.
- c Previously filed and incorporated herein by reference from the Form 10-K for the period ending June 30, 1998, File No. 0-26642.
- d Previously filed and incorporated herein by reference from the Form 10-Q for the period ending September 30, 1998, File No. 0-26642.
- e Previously filed and incorporated herein by reference from the Form 10-Q for the period ending March 31, 2001, File No. 0-26642.
- f Previously filed and incorporated herein by reference from the Form 10-K for the period ending June 30, 2002, File No. 0-26642.
- g Previously filed and incorporated herein by reference from the Form 10-K for the period ending June 30, 2001, File No. 0-26642.
- h Previously filed and incorporated herein by reference from the Form 8-K filed on July 5, 2005, File No. 0-26642.
- i Previously filed and incorporated herein by reference from the Form 10-Q for the period ending March 31, 2005, File No. 0-26642.
- j Previously filed and incorporated herein by reference from the Form 8-K filed on July 18, 2001, File No. 0-26642.
- k Previously filed and incorporated herein by reference from the Form 8-K filed on November 20, 2006, File No. 0-26642.
- l Previously filed and incorporated herein by reference from the Form 10-Q for the period ending December 31, 2006, File No. 0-26642.
- m Previously filed and incorporated herein by reference from the Form 10-K for the period ending June 30, 2004, File No. 0-26642.
- n Previously filed and incorporated herein by reference from the Form 10-Q for the period ending September 30, 2007, File No. 0-26642.
- o Previously filed and incorporated herein by reference from the Form 8-K on November 6, 2007, File No. 0-26642.
- p Previously filed and incorporated herein by reference from the Form 8-K filed on November 16, 2007, File No. 0-26642.
- q Previously filed and incorporated herein by reference from the Form 10-Q for the period ending December 31, 2007, File No. 0-26642.

**Table of Contents**

Where a document is incorporated by reference from a previous filing, the Exhibit number of the document in that previous filing is indicated in parentheses after the description of such document.

**Table of Contents****SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on August 28, 2008.

**MYRIAD GENETICS, INC.**

By: /s/ Peter D. Meldrum  
**Peter D. Meldrum**  
**President and Chief Executive Officer**

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

<b>Signatures</b>	<b>Title</b>	<b>Date</b>
By: /s/ Peter D. Meldrum <b>Peter D. Meldrum</b>	President, Chief Executive Officer and Director (principal executive officer)	August 28, 2008
By: /s/ James S. Evans <b>James S. Evans</b>	Chief Financial Officer (principal financial and accounting officer)	August 28, 2008
By: /s/ John T. Henderson <b>John T. Henderson, M.D.</b>	Chairman of the Board	August 28, 2008
By: /s/ Walter Gilbert <b>Walter Gilbert, Ph.D.</b>	Vice Chairman of the Board	August 28, 2008
By: /s/ Mark H. Skolnick <b>Mark H. Skolnick, Ph.D.</b>	Chief Scientific Officer and Director	August 28, 2008
By: /s/ Gerald P. Belle <b>Gerald P. Belle</b>	Director	August 28, 2008
By: /s/ Linda S. Wilson <b>Linda S. Wilson, Ph.D.</b>	Director	August 28, 2008
By: /s/ Robert S. Attiyeh <b>Robert S. Attiyeh</b>	Director	August 28, 2008
By: /s/ Dennis Langer <b>Dennis Langer, M.D., J.D.</b>	Director	August 28, 2008



Table of Contents

## Schedule II

## MYRIAD GENETICS, INC.

## Schedule of Valuation and Qualifying Accounts

Years Ended June 30, 2008, 2007, and 2006

*(In thousands)*

	Balance at Beginning of Period	Addition Charged to Cost and Expenses	Deductions (1)	Balance at End of Period
<b>Allowance for doubtful accounts:</b>				
Year ended June 30, 2008	\$ 2,600	\$ 11,500	\$ (10,000)	\$ 4,100
Year ended June 30, 2007	\$ 1,795	\$ 5,650	\$ (4,845)	\$ 2,600
Year ended June 30, 2006	\$ 1,395	\$ 2,114	\$ (1,714)	\$ 1,795

(1) Represents amounts written off against the allowance.  
See reports of independent registered public accounting firms.

**Table of Contents**

**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Description of Exhibits</b>
(10.31)\$	Summary of compensation arrangements applicable to the Registrant's Named Executive Officers (FY 2008 Bonus and FY 2009 Salary)
(10.32)	Lease Agreement, dated March 11, 2008 between the Registrant and Boyer Research Park Associates IX, by its general partner, The Boyer Company, L.C.
(10.33)#	Co-marketing Agreement, dated May 21, 2008 between the Registrant and H. Lundbeck A/S
(21.1)	List of Subsidiaries of the Registrant
(23.1)	Consent of Independent Registered Public Accounting Firm (KPMG LLP)
(23.2)	Consent of Independent Registered Public Accounting Firm (Ernst & Young LLP)
(31.1)	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
(31.2)	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
(32)	Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

# Confidential treatment has been requested from the Commission as to certain portions.

\$ Management contract or compensatory plan or arrangement.

**Table of Contents**

**Report of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders

Myriad Genetics, Inc.

We have audited the accompanying consolidated balance sheets of Myriad Genetics, Inc. and subsidiaries as of June 30, 2008 and 2007, and the related consolidated statements of operations, stockholders' equity and comprehensive income (loss), and cash flows for each of the two years then ended. Our audits also included the financial statement schedule listed in the Index at Item 15(a). These consolidated financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements and schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Myriad Genetics, Inc. and subsidiaries at June 30, 2008 and 2007, and the consolidated results of their operations and their cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Myriad Genetics, Inc.'s internal control over financial reporting as of June 30, 2008, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated August 25, 2008 expressed an unqualified opinion thereon.

Ernst & Young LLP

Salt Lake City, Utah

August 25, 2008

F-1

**Table of Contents**

**Report of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders

Myriad Genetics, Inc.:

We have audited the accompanying consolidated statements of operations, stockholders' equity and comprehensive income (loss), and cash flows of Myriad Genetics, Inc. and subsidiaries for the year ended June 30, 2006. In connection with our audit of the consolidated financial statements, we have also audited the accompanying consolidated financial statement schedule. These consolidated financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements and financial statement schedule based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the results of operations and cash flows of Myriad Genetics, Inc. and subsidiaries for the year ended June 30, 2006, in conformity with U.S. generally accepted accounting principles. Also in our opinion, the related financial statement schedule, when considered in relation to the consolidated financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

KPMG LLP

Salt Lake City, Utah

September 6, 2006, except for Note 1(o),

as to which the date is August 26, 2008

**Table of Contents****MYRIAD GENETICS, INC.****AND SUBSIDIARIES**

Consolidated Balance Sheets

June 30, 2008 and 2007

(In thousands, except per share amounts)

	2008	2007
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 237,734	\$ 143,432
Marketable investment securities	90,994	70,679
Prepaid expenses	3,143	5,972
Trade accounts receivable, less allowance for doubtful accounts of \$4,100 in 2008 and \$2,600 in 2007	40,663	31,103
Other receivables	4,769	1,348
Total current assets	377,303	252,534
Equipment and leasehold improvements:		
Equipment	63,095	54,868
Leasehold improvements	11,701	9,826
	74,796	64,694
Less accumulated depreciation	44,770	39,806
Net equipment and leasehold improvements	30,026	24,888
Long-term marketable investment securities	91,328	94,201
Other assets	685	3,917
	\$ 499,342	\$ 375,540
<b>Liabilities and Stockholders Equity</b>		
Current liabilities:		
Accounts payable	\$ 24,884	\$ 15,763
Accrued liabilities	46,770	19,031
Deferred revenue	2,033	383
Total current liabilities	73,687	35,177
Commitments and contingencies		
Stockholders equity:		
Preferred stock, \$0.01 par value. Authorized 5,000 shares; issued and outstanding no shares		
Common stock, \$0.01 par value. Authorized 60,000 shares; issued and outstanding 44,744 shares in 2008 and 43,440 shares in 2007	447	434
Additional paid-in capital	630,000	592,727
Accumulated other comprehensive loss	(237)	(398)

Edgar Filing: MYRIAD GENETICS INC - Form 10-K

Accumulated deficit	(204,555)	(252,400)
Total stockholders' equity	425,655	340,363
	\$ 499,342	\$ 375,540

See accompanying notes to consolidated financial statements.

F-3

**Table of Contents****MYRIAD GENETICS, INC.****AND SUBSIDIARIES**

Consolidated Statements of Operations

Years ended June 30, 2008, 2007, and 2006

(In thousands, except per share amounts)

	2008	2007	2006
Molecular diagnostic revenue	\$ 222,855	\$ 145,285	\$ 100,621
Pharmaceutical revenue	100,000		
Research and other revenue	10,774	11,841	13,658
Total revenue	333,629	157,126	114,279
Costs and expenses:			
Molecular diagnostic cost of revenue	32,340	30,813	27,644
Research and development expense	139,715	98,670	82,976
Selling, general, and administrative expense	123,493	75,370	49,248
Total costs and expenses	295,548	204,853	159,868
Operating income (loss)	38,081	(47,727)	(45,589)
Other income (expense):			
Interest income	13,709	12,112	7,412
Other	(3,337)	653	(12)
Total other income	10,372	12,765	7,400
Income (loss) before taxes	48,453	(34,962)	(38,189)
Income tax provision	608		
Net income (loss)	\$ 47,845	\$ (34,962)	\$ (38,189)
Earnings per share			
Basic	\$ 1.08	\$ (0.85)	\$ (1.05)
Diluted	\$ 1.02	\$ (0.85)	\$ (1.05)
Weighted average shares outstanding			
Basic	44,189	41,055	36,278
Diluted	46,704	41,055	36,278

See accompanying notes to consolidated financial statements.

**Table of Contents****MYRIAD GENETICS, INC.****AND SUBSIDIARIES**

Consolidated Statements of Stockholders Equity and Comprehensive Income (Loss)

Years ended June 30, 2008, 2007, and 2006

(In thousands)

	Common stock		Additional	Accumulated	Accumulated	Comprehensive	Stockholders
	Shares	Amount	paid-in	income	deficit	income (loss)	equity
			capital	(loss)			
Balances at June 30, 2005	30,862	\$ 309	\$ 315,147	\$ (534)	\$ (179,249)		\$ 135,673
Issuance of common stock for cash upon exercise of options and employee stock purchase plan	771	8	10,174				10,182
Issuance of common stock for cash, net of offering costs of \$251	8,050	80	139,658				139,738
Share-based payment expense			2,589				2,589
Net loss					(38,189)	(38,189)	(38,189)
Unrealized losses on marketable investment securities:							
Unrealized holding losses arising during period						(212)	(212)
Other comprehensive (loss)				(212)		(212)	(212)
Comprehensive loss						\$ (38,401)	
Balances at June 30, 2006	39,683	397	467,568	(746)	(217,438)		249,781
Issuance of common stock for cash upon exercise of options and employee stock purchase plan	757	7	12,164				12,171
Issuance of common stock for cash, net of offering costs of \$170	3,000	30	105,250				105,280
Share-based payment expense			7,745				7,745
Net loss					(34,962)	(34,962)	(34,962)
Unrealized gains on marketable investment securities:							
Unrealized holding gains arising during period						348	348
Other comprehensive income				348		348	348
Comprehensive loss						\$ (34,614)	
Balances at June 30, 2007	43,440	434	592,727	(398)	(252,400)		340,363
Issuance of common stock for cash upon exercise of options and employee stock purchase plan	1,274	13	20,658				20,671



Edgar Filing: MYRIAD GENETICS INC - Form 10-K

Issuance of common stock for cash upon exercise of warrants	30	1,200	1,200
Share-based payment expense		15,415	15,415
Net income		47,845	47,845
Unrealized gains on marketable investment securities:			
Unrealized holding gains arising during period			161
Other comprehensive income		161	161
Comprehensive income			\$ 48,006
Balances at June 30, 2008	44,744	\$ 447	\$ 630,000
		\$ (237)	\$ (204,555)
			\$ 425,655

See accompanying notes to consolidated financial statements.

**Table of Contents****MYRIAD GENETICS, INC.****AND SUBSIDIARIES**

## Consolidated Statements of Cash Flows

Years ended June 30, 2008, 2007, and 2006

(In thousands)

	2008	2007	2006
<b>Cash flows from operating activities:</b>			
Net income (loss)	\$ 47,845	\$ (34,962)	\$ (38,189)
<b>Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:</b>			
Depreciation and amortization	8,781	7,544	6,855
Loss (gain) on disposition of assets	337	(653)	12
Share-based compensation expense	15,415	7,745	2,589
Bad debt expense	11,500	5,650	2,114
Loss on cost-basis investment	3,000		
<b>Changes in operating assets and liabilities:</b>			
Prepaid expenses	2,829	(3,646)	1,005
Trade accounts receivable	(21,060)	(15,933)	(5,698)
Other receivables	(3,421)	49	(252)
Accounts payable	9,121	3,959	(93)
Accrued liabilities	27,739	4,130	3,856
Deferred revenue	1,650	266	(226)
<b>Net cash provided by (used in) operating activities</b>	<b>103,736</b>	<b>(25,851)</b>	<b>(28,027)</b>
<b>Cash flows from investing activities:</b>			
Capital expenditures for equipment and leasehold improvements	(13,675)	(11,400)	(7,680)
Increase (decrease) in other assets	(349)	20	(100)
Purchases of marketable investment securities	(191,701)	(197,841)	(165,519)
Proceeds from maturities of marketable investment securities	174,420	162,480	100,470
<b>Net cash used in investing activities</b>	<b>(31,305)</b>	<b>(46,741)</b>	<b>(72,829)</b>
<b>Cash flows from financing activities:</b>			
Net proceeds from public offering of common stock		105,280	139,738
Net proceeds from common stock issued under share-based compensation plans	20,671	12,171	10,182
Net proceeds from warrants	1,200		
<b>Net cash provided by financing activities</b>	<b>21,871</b>	<b>117,451</b>	<b>149,920</b>
<b>Net increase in cash and cash equivalents</b>	<b>94,302</b>	<b>44,859</b>	<b>49,064</b>
<b>Cash and cash equivalents at beginning of year</b>	<b>143,432</b>	<b>98,573</b>	<b>49,509</b>
<b>Cash and cash equivalents at end of year</b>	<b>\$ 237,734</b>	<b>\$ 143,432</b>	<b>\$ 98,573</b>
<b>Supplemental disclosures of noncash investing and financing activities:</b>			
Fair value adjustment on marketable investment securities charged to stockholders' equity	\$ 161	\$ 348	\$ (212)
See accompanying notes to consolidated financial statements.			



---

**Table of Contents**

**MYRIAD GENETICS, INC.**

**AND SUBSIDIARIES**

Notes to Consolidated Financial Statements

**(1) Organization and Summary of Significant Accounting Policies**

**(a) Organization and Business Description**

Myriad Genetics, Inc. and subsidiaries (collectively, the Company) is a leading biotechnology company focused on the development and marketing of novel therapeutic and molecular diagnostic products. The Company employs a number of proprietary technologies that permit it to understand the genetic basis of human disease and the role that genes and their related proteins play in the onset and progression of disease. The Company uses this information to guide the development of new healthcare products that will treat major diseases and assess a person's risk of disease later in life. The Company's operations are located in Salt Lake City, Utah.

**(b) Principles of Consolidation**

The consolidated financial statements presented herein include the accounts of Myriad Genetics, Inc. and its wholly owned subsidiaries, Myriad Genetic Laboratories, Inc., and Myriad Pharmaceuticals, Inc. All intercompany amounts have been eliminated in consolidation.

**(c) Recent Accounting Pronouncements**

In February 2007, the FASB issued SFAS No. 159, or SFAS 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115*. SFAS 159 permits entities to choose to measure many financial instruments and certain other items at fair value. The objective is to improve financial reporting by providing entities with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. SFAS 159 is effective for fiscal years beginning after November 15, 2007. The Company's adoption of SFAS 159 on July 1, 2008 is not expected to have a material effect on its consolidated financial position or results of operations.

In September 2006, the Financial Accounting Standards Board (FASB) issued SFAS No. 157, *Fair Value Measurements* (SFAS 157). SFAS No. 157 establishes a framework for measuring fair value and expands disclosures about fair value measurements. The changes to current practice resulting from the application of this statement relate to the definition of fair value, the methods used to measure fair value and the expanded disclosures about fair value measurements. SFAS No. 157 is effective for fiscal years beginning after November 15, 2007. The adoption of this standard by us on July 1, 2008 is not expected to have a material effect on the Company's consolidated financial position or results of operations.

In December 2007, the FASB issued SFAS No. 141(R), *Business Combinations*. (SFAS 141(R) replaced SFAS No. 141, *Business Combinations*, originally issued in June 2001.) SFAS 141(R) retains the purchase method of accounting for acquisitions, but requires a number of changes, including changes in the way assets and liabilities are recognized in purchase accounting. It also changes the recognition of assets acquired and liabilities assumed arising from contingencies, requires the capitalization of in-process research and development at fair value, and requires the expensing of acquisition-related costs as incurred. Generally, SFAS 141(R) is effective on a prospective basis for all business combinations completed on or after January 1, 2009. We are currently in the process of evaluating the extent of those potential impacts.

In December 2007, the Emerging Issues Task Force (EITF) issued EITF Issue No. 07-1, *Accounting for Collaborative Arrangements*. EITF 07-1 provides guidance concerning: determining whether an arrangement constitutes a collaborative arrangement within the scope of the Issue; how costs incurred and revenue generated on sales to third parties should be reported in the income statement; how an entity should characterize payments on the income statement; and what participants should disclose in the notes to the financial statements about a collaborative arrangement. The provisions of

Edgar Filing: MYRIAD GENETICS INC - Form 10-K

EITF 07-1 will be adopted in 2009. We are in the process of evaluating the impact of adopting EITF 07-1 on our financial statements.

F-7

**Table of Contents**

**MYRIAD GENETICS, INC.**

**AND SUBSIDIARIES**

Notes to Consolidated Financial Statements - Continued

**(d) Cash Equivalents**

Cash equivalents of \$205.7 million and \$124.8 million at June 30, 2008 and 2007, respectively, consist of highly liquid debt instruments with maturities at date of purchase of 90 days or less. As of June 30, 2008 and 2007, the carrying value of cash equivalents approximates fair value.

**(e) Marketable Investment Securities**

The Company has classified its marketable investment securities as available-for-sale. These securities are carried at estimated fair value with unrealized holding gains and losses, net of the related tax effect, included in accumulated other comprehensive income (loss) in stockholders equity until realized. Gains and losses on investment security transactions are reported on the specific-identification method. Dividend and interest income are recognized when earned.

A decline in the market value of any available-for-sale security below cost that is deemed other than temporary results in a charge to earnings and establishes a new cost basis for the security. Losses are charged against Other income when a decline in fair value is determined to be other-than-temporary. In accordance with EITF 03-1, and FAS 155-1, *The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments*, we review several factors to determine whether a loss is other-than-temporary. These factors include but are not limited to: (i) the extent to which the fair value is less than cost and the cause for the fair value decline, (ii) the financial condition and near term prospects of the issuer, (iii) the length of time a security is in an unrealized loss position and (iv) our ability to hold the security for a period of time sufficient to allow for any anticipated recovery in fair value. The Company recognized no other than temporary impairments for the years ended June 30, 2008, 2007, and 2006. Available-for-sale investment securities with remaining maturities of greater than one year are classified as long-term.

**(f) Trade Accounts Receivable and Allowance for Doubtful Accounts**

Trade accounts receivable are comprised of amounts due from sales of the Company's molecular diagnostic products and are recorded at the invoiced amount, net of discounts and allowances. The allowance for doubtful accounts is based on the Company's best estimate of the amount of probable losses in the Company's existing accounts receivable, which is based on historical write-off experience, customer creditworthiness, facts and circumstances specific to outstanding balances, and payment terms. Account balances are charged against the allowance after all means of collection have been exhausted and the potential for recovery is considered remote. The Company does not have any off-balance-sheet credit exposure related to its customers.

**(g) Other Receivables**

Other receivables are comprised of amounts due from stock option exercises, licences receivables and amounts due from the Company's European partner, H. Lundbeck A/S (Lundbeck), for certain shared development costs of Flurizan. As of June 30, 2008, the Company has recorded approximately \$3.7 million in other receivables from Lundbeck.

**(h) Equipment and Leasehold Improvements**

Equipment and leasehold improvements are stated at cost. Depreciation and amortization are computed using the straight-line method based on the lesser of estimated useful lives of the related assets or lease terms. Equipment items have depreciable lives of five years. Leasehold

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

improvements are depreciated over the shorter of the estimated useful lives or the associated lease terms, which range from three to fifteen years. For the years ended June 30, 2008, 2007, and 2006, the Company incurred depreciation expense of \$8.2 million, \$7.0 million, and \$6.3 million, respectively.

F-8

**Table of Contents**

**MYRIAD GENETICS, INC.**

**AND SUBSIDIARIES**

Notes to Consolidated Financial Statements - Continued

**(i) Impairment of Long-Lived Assets**

The Company accounts for long-lived assets in accordance with the provisions of Statement of Financial Accounting Standards (SFAS) No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*. This statement requires that long-lived assets be reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future net cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated future cash flows, an impairment charge is recognized in the amount by which the carrying amount of the asset exceeds the fair value of the asset. Assets to be disposed of are reported at the lower of the carrying amount or fair value less costs to sell. No impairments of long-lived assets were recorded for the years ended June 30, 2008, 2007, and 2006.

**(j) Other Assets**

Other assets are comprised of purchased intellectual property, an investment in a privately held pharmaceutical company, and a purchased library of chemical compounds. The private pharmaceutical company investment is accounted for under the cost method. Management reviews the valuation of these investments for possible impairment as changes in facts and circumstances indicate that impairment should be assessed.

The amount recognized by the Company upon the ultimate liquidation of investments may vary significantly from the estimated fair value at June 30, 2008. The library of chemical compounds and related purchased intellectual property are being amortized ratably over the expected useful life of two to five years.

At June 30, 2008, the Company wrote-off its cost basis investment in the privately held pharmaceutical company, which resulted in a \$3.0 million expense recorded in other expense in the accompanying consolidated statements of operations.

**(k) Revenue Recognition**

The Company applies the provisions of SEC Staff Accounting Bulletin No. 104, *Revenue Recognition*, or SAB 104, as well as EITF 00-21, *Revenue Arrangements with Multiple Deliverables*, or EITF 00-21, to all of its revenue transactions.

Molecular diagnostic revenues include revenues from the sale of molecular diagnostic products and related marketing agreements, and are recorded at the invoiced amount net of any discounts or contractual allowances. Molecular diagnostic revenue is recognized upon completion of the test, communication of results to the patient, and when collectability is reasonably assured.

Revenue from non-refundable upfront license fees where the Company has continuing involvement is recognized ratably over the development or agreement period or upon termination of a development or license agreement when the Company has no ongoing obligation

Research revenue includes revenue from research agreements, milestone payments, and technology licensing agreements. In applying the principles of SAB 104 and EITF 00-21 to research and technology license agreements we consider the terms and conditions of each agreement separately to arrive at a proportional performance methodology of recognizing revenue. Such methodologies involve recognizing revenue on a straight-line basis over the term of the agreement, as



---

**Table of Contents**

**MYRIAD GENETICS, INC.**

**AND SUBSIDIARIES**

Notes to Consolidated Financial Statements - Continued

underlying research costs are incurred, or on the basis of contractually defined output measures such as units delivered. We make adjustments, if necessary, to the estimates used in our calculations as work progresses and we gain experience. The principal costs under these agreements are for personnel expenses to conduct research and development but also include costs for materials and other direct and indirect items necessary to complete the research under these agreements. Actual results may vary from our estimates. Payments received on uncompleted long-term contracts may be greater than or less than incurred costs and estimated earnings and have been recorded as other receivables or deferred revenues in the accompanying consolidated balance sheets. Revenue from milestone payments for which we have no continuing performance obligations is recognized upon achievement of the related milestone. When we have continuing performance obligations, the milestone payments are deferred and recognized as revenue over the term of the arrangement as we complete our performance obligations. We recognize revenue from up-front nonrefundable license fees on a straight-line basis over the period of our continued involvement in the research and development project.

***(l) Income Taxes***

The Company recognizes income taxes under the asset and liability method in accordance with SFAS No. 109, *Accounting for Income Taxes* ( SFAS 109 ). This approach requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the carrying amounts and the tax bases of assets and liabilities.

The provision for income taxes, including the effective tax rate and analysis of potential tax exposure items, if any, requires significant judgment and expertise in federal and state income tax laws, regulations and strategies, including the determination of deferred tax assets and liabilities and any estimated valuation allowances deemed necessary to value deferred tax assets. The Company's judgment and tax strategies are subject to audit by various taxing authorities. While the Company believes it has provided adequately for its income tax liabilities in the consolidated financial statements, adverse determinations by these taxing authorities could have a material adverse effect on the consolidated financial condition, results of operations or cash flows.

***(m) Earnings (Loss) Per Share***

Basic earnings (loss) per share (EPS) is computed based on the weighted-average number of shares of our Common Stock outstanding. Diluted EPS is computed based on the weighted-average number of shares of our Common Stock including common stock equivalents. Potentially dilutive common shares consisting of stock options and warrants were not included in the diluted loss per share attributable to common stockholders for the years ended June 30, 2007, and 2006 because the inclusion of such shares would have had an antidilutive effect.

The following is a reconciliation of the numerators and denominators of the basic and diluted EPS computations (*in thousands*):

**Table of Contents****MYRIAD GENETICS, INC.****AND SUBSIDIARIES**

## Notes to Consolidated Financial Statements - Continued

	2008	2007	2006
<b>Numerator:</b>			
Net income (loss)	\$ 47,845	\$ (34,962)	\$ (38,189)
<b>Denominator:</b>			
Weighted-average shares outstanding used to compute basic EPS	44,189	41,055	36,278
Effect of dilutive stock options	2,515		
Weighted-average shares outstanding and dilutive securities used to compute diluted EPS	46,704	41,055	36,278

For the years ended June 30, 2008, 2007, and 2006, there were outstanding potential common shares of 2,603,051, 8,491,862, and 8,044,582, respectively, that were excluded from the computation of diluted EPS because the effect would have been anti-dilutive. These potential dilutive common shares may be dilutive to future diluted earnings per share.

**(n) Use of Estimates**

The preparation of the consolidated financial statements in accordance with U.S. generally accepted accounting principles requires Company management to make estimates and assumptions relating to the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the period. Significant items subject to such estimates and assumptions include the carrying amount of fixed assets, valuation allowances for receivables and deferred income tax assets, certain accrued liabilities, share-based compensation, and the valuation of investments in privately held companies. Actual results could differ from those estimates.

**(o) Reclassifications**

Certain prior period amounts have been reclassified to conform to current period presentation. Approximately \$2,038,000 and \$781,000 of research and development expense was reclassified to sales, general, and administrative expense for the years ended June 30, 2007 and 2006, respectively, to more accurately reflect the nature of the underlying expenses.

**(p) Fair Value Disclosure**

At June 30, 2008 and 2007, the consolidated financial statements carrying amount of the Company's financial instruments approximates fair value.

**Table of Contents****MYRIAD GENETICS, INC.****AND SUBSIDIARIES**

## Notes to Consolidated Financial Statements - Continued

**(2) Marketable Investment Securities**

The amortized cost, gross unrealized holding gains, gross unrealized holding losses, and fair value for available-for-sale securities by major security type and class of security at June 30, 2008 and 2007 were as follows (in thousands):

	Amortized cost	Gross unrealized holding gains	Gross unrealized holding losses	Estimated fair value
At June 30, 2008:				
Available-for-sale:				
Corporate bonds and notes	\$ 134,186	\$ 606	\$ (867)	\$ 133,925
Federal agency issues	21,186	116	(6)	21,296
Tax auction securities	4,000		(210)	3,790
Euro dollar bonds	23,189	134	(12)	23,311
	\$ 182,561	\$ 856	\$ (1,095)	\$ 182,322

	Amortized cost	Gross unrealized holding gains	Gross unrealized holding losses	Estimated fair value
At June 30, 2007:				
Available-for-sale:				
Corporate bonds and notes	\$ 80,302	\$ 13	\$ (298)	\$ 80,017
Certificate of deposit	7,002		(3)	6,999
Federal agency issues	24,198		(66)	24,132
Tax auction securities	35,550			35,550
Euro dollar bonds	18,226		(44)	18,182
	\$ 165,278	\$ 13	\$ (411)	\$ 164,880

Maturities of debt securities classified as available-for-sale are as follows at June 30, 2008 (in thousands):

	Amortized cost	Estimated fair value
Available-for-sale:		
Due within one year	\$ 91,324	\$ 90,994
Due after one year through three years	91,237	91,328



**Table of Contents****MYRIAD GENETICS, INC.****AND SUBSIDIARIES**

## Notes to Consolidated Financial Statements - Continued

All securities in an unrealized loss position as of June 30, 2008 are debt securities. Debt securities in an unrealized loss position as of June 30, 2008 were not impaired at acquisition and the declines in fair value are primarily due to interest rate fluctuations and unrealized temporary losses related to certain marketable investment securities, with an auction reset feature (auction rate securities). Management believes that the declines in fair value are not other-than-temporary and that the Company has the ability and intent to hold these investments until a recovery of fair value. Debt securities available for sale in an unrealized loss position as of June 30, 2008 and 2007 are summarized as follows (in thousands):

	Less than 12 months		More than 12 months		Total	
	Fair value	Unrealized losses	Fair value	Unrealized losses	Fair value	Unrealized losses
<b>At June 30, 2008:</b>						
Debt securities:						
Corporate bonds and notes	\$ 27,264	\$ (549)	\$ 34,147	\$ (318)	\$ 61,411	\$ (867)
Federal agency issues			4,980	(6)	4,980	(6)
Euro dollar bonds	2,007	(12)			2,007	(12)
Auction Rate Securities			1,890	(210)	1,890	(210)
	\$ 29,271	\$ (561)	\$ 41,017	\$ (534)	\$ 70,288	\$ (1,095)

	Less than 12 months		More than 12 months		Total	
	Fair value	Unrealized losses	Fair value	Unrealized losses	Fair value	Unrealized losses
<b>At June 30, 2007:</b>						
Debt securities:						
Corporate bonds and notes	\$ 36,177	\$ (62)	\$ 43,840	\$ (236)	\$ 80,017	\$ (298)
Certificates of deposit	6,999	(3)			6,999	(3)
Federal agency issues	17,940	(59)	3,192	(7)	21,132	(66)
Euro dollar bonds	3,468	(7)	14,714	(37)	18,182	(44)
	\$ 64,584	\$ (131)	\$ 61,746	\$ (280)	\$ 126,330	\$ (411)

**(3) Leases**

The Company leases office and laboratory space under four non-cancelable operating leases, with terms that expire between 2017 and 2025. The Company also leases information technology equipment under two non-cancelable operating leases, with terms that expire between 2008 and 2009. Future minimum lease payments under these leases as of June 30, 2008 are as follows (in thousands):

<b>Fiscal year ending:</b>	
2009	\$ 5,655
2010	7,532

Edgar Filing: MYRIAD GENETICS INC - Form 10-K

2011	8,409
2012	8,150
2013	8,192
Thereafter	64,421
	\$ 102,359

Rental expense was \$5.2 million in 2008, \$4.2 million in 2007, and \$3.2 million in 2006.

**(4) Share-Based Compensation**

The Company accounts for share-based compensation under the provisions of FAS No. 123(R), *Share-Based Payment* (FAS 123R),. Statement 123R sets accounting requirements for share-based compensation to employees, including employee stock purchase plans, and requires companies to recognize in the statement of operations the grant-date fair value of stock options and other equity-based compensation.

**Table of Contents****MYRIAD GENETICS, INC.****AND SUBSIDIARIES**

## Notes to Consolidated Financial Statements - Continued

In 2003 the Company adopted the 2003 Employee, Director and Consultant Stock Option Plan (the 2003 Plan) under which 6.9 million shares of common stock have been reserved for issuance upon the exercise of options that the Company grants from time to time. Additional shares represented by options previously granted under the Company's 2002 Amended and Restated Employee, Director and Consultant Stock Option Plan (the 2002 Plan) which are canceled or expire after the date of stockholder approval of the 2003 Plan without delivery of shares of stock by the Company and any shares which have been reserved but not granted under the 2002 Plan as of the date of stockholder approval of the 2003 Plan were available for grant under the 2003 Plan.

The exercise price of options granted in 2008, 2007, and 2006 was equivalent to the fair market value of the stock at the date of grant. The number of shares, terms, and vesting period are determined by the board of directors on an option-by-option basis. Options generally vest ratably over service periods of four years and expire ten years from the date of grant. As of June 30, 2008, 921,074 shares are available for future grant under the 2003 Plan.

The Company's share-based payment plans are accounted for under Statement 123R. The fair value of each option grant is estimated on the date of the grant using the Black-Scholes option-pricing model with the following weighted-average assumptions used for grants for the fiscal year ended June 30:

	2008	2007	2006
Risk-free interest rate	3.4%	4.6%	4.3%
Expected dividend yield	0%	0%	0%
Expected lives (in years)	4.9 - 5.7	4.8 - 6.0	4.4 - 5.0
Expected volatility	45%	56%	63%

Expected option lives and volatilities are based on historical data of the Company and other factors.

A summary of activity is as follows:

	2008		2007		2006	
	Number of shares	Weighted average exercise price	Number of shares	Weighted average exercise price	Number of shares	Weighted average exercise price
Options outstanding at beginning of year	8,461,862	\$ 27.19	8,014,582	\$ 25.92	7,364,358	\$ 25.70
Options granted	1,903,275	43.90	1,337,910	30.02	1,421,905	22.23
Less:						
Options exercised	(1,215,457)	15.29	(670,559)	15.01	(648,438)	12.83
Options canceled or expired	(296,645)	37.22	(220,071)	35.34	(123,243)	38.69
Options outstanding at end of year	8,853,035	32.08	8,461,862	27.19	8,014,582	25.92
Options exercisable at end of year	5,628,335	29.61	6,227,634	27.34	6,625,482	26.70
Options vested and expected to vest	8,241,575	31.84	8,053,533	27.56	7,836,244	26.00
Weighted average fair value of options granted during the year		19.82		16.23		12.27





**Table of Contents****MYRIAD GENETICS, INC.****AND SUBSIDIARIES**

## Notes to Consolidated Financial Statements - Continued

The following table summarizes information about stock options outstanding at June 30, 2008:

Range of exercise prices	Options outstanding			Options exercisable	
	Number outstanding at June 30, 2008	Weighted average remaining contractual life (years)	Weighted average exercise price	Number exercisable at June 30, 2008	Weighted average exercise price
\$ 4.69 - 20.56	2,427,670	5.35	\$ 15.34	2,147,267	\$ 14.67
20.64 - 25.57	2,482,443	5.93	24.13	1,821,696	23.84
25.88 - 46.55	2,220,248	7.90	37.03	678,148	36.67
46.62 - 93.81	1,722,674	5.51	60.74	981,224	68.16
	8,853,035	6.18	32.08	5,628,335	29.61

Share-based compensation expense recognized under FAS 123R included in the consolidated statement of operations for the fiscal years ended June 30, 2008, 2007 and 2006 was as follows (*in thousands, except per share data*):

	2008	2007	2006
Cost of Revenue	\$ 560	\$ 297	\$ 118
Research and Development	8,064	3,161	1,091
Selling, general, and administrative	6,791	4,287	1,380
Total employee stock-based compensation expense	\$ 15,415	\$ 7,745	\$ 2,589
Effect on earnings (loss) per share:			
Basic	\$ 0.35	\$ 0.19	\$ 0.07
Diluted	\$ 0.33	\$ 0.19	\$ 0.07

As of June 30, 2008, there was approximately \$40.4 million of total unrecognized share-based compensation cost related to share-based compensation granted under our plans that will be recognized over a weighted-average period of 2.7 years. The total intrinsic value of options exercised during the fiscal years ended June 30, 2008, 2007 and 2006 was approximately \$37.5 million, \$13.4 million and \$5.3 million, respectively. The aggregate intrinsic value of fully vested options and options expected to vest as of June 30, 2008 was approximately \$138.4 million.

The Company also has an Employee Stock Purchase Plan (the Plan) which was adopted and approved by the board of directors and stockholders in December 1994, under which a maximum of 1,000,000 shares of common stock may be purchased by eligible employees. At June 30, 2008, 671,613 shares of common stock had been purchased under the Plan. For the years ended June 30, 2008, 2007, and 2006, shares purchased under the Plan were 58,517, 87,168, and 122,109, respectively. Expenses associated with the Plan were approximately \$605,000, \$711,000, and \$628,000, for the years ended June 30, 2008, 2007, and 2006, respectively. The fair value of shares issued under the Plan was calculated using the Black-Scholes option-pricing model with the following weighted-average assumptions for the fiscal years ended June 30:

Edgar Filing: MYRIAD GENETICS INC - Form 10-K

	2008	2007	2006
Risk-free interest rate	3.3%	4.7%	4.7%
Expected dividend yield	0%	0%	0%
Expected lives (in years)	0.5	0.5	0.5
Expected volatility	34%	42%	42%

F-15

**Table of Contents****MYRIAD GENETICS, INC.****AND SUBSIDIARIES**

## Notes to Consolidated Financial Statements - Continued

During 2008, 30,000 warrants previously granted to placement agents were exercised at a price of \$40.00 per share for total consideration of \$1,200,000.

**(5) Income Taxes**

The Company recorded income tax expense of \$608,000 in 2008 and recorded no income tax expense in 2007. The difference between the expected tax expense or benefit for the periods presented and the actual tax expense is primarily attributable to a corresponding decrease in 2008 and increase in 2007, respectively, of the amount of Company's valuation allowance.

The tax effects of temporary differences that give rise to significant portions of the deferred tax assets and liabilities at June 30, 2008 and 2007 are presented below (in thousands):

	2008	2007
Deferred tax assets:		
Net operating loss carryforwards	\$ 114,959	\$ 125,991
Property, plant and equipment	2,300	404
Accrued vacation	1,306	1,052
Allowance for doubtful accounts	1,529	970
Stock compensation expense	2,392	1,520
Write-down of investment	2,014	895
Research and development credits	27,187	24,376
Alternative minimum tax credit	608	
Other	1,127	323
<b>Total gross deferred tax assets</b>	<b>153,422</b>	<b>155,531</b>
Less valuation allowance	(153,422)	(155,531)
<b>Net deferred tax assets</b>	<b>\$</b>	<b>\$</b>

The net change in the total valuation allowance was a decrease of \$2.1 million for the year ended June 30, 2008 and an increase of \$22.4 million for the year ended June 30, 2007. Approximately \$53.6 million of gross deferred tax assets at June 30, 2008, if recognizable in future years, will be recognized as additional paid-in capital, and the remainder will be allocated as an income tax benefit to be reported in the consolidated statement of operations.

At June 30, 2008, the Company had total federal, alternative minimum tax and state tax net operating loss carryforwards of approximately \$308.2 million. If not utilized, these operating loss carryforwards expire beginning in 2012 through 2028. The Company had approximately \$27.2 million of research and development tax credits, which can be carried forward to reduce federal and state income taxes. If not utilized, the research and development tax credit carryforwards expire beginning in 2009 through 2028.

Under the rules of the Tax Reform Act of 1986, the Company has undergone changes of ownership, and consequently, the availability of the Company's net operating loss and research and development credit carryforwards in any one year are limited. The maximum amount of carryforwards available in a given year is limited to the product of the Company's value on the date of ownership change and the federal

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

long-term tax-exempt rate, plus any limited carryforward not utilized in prior years. Utilization of the Company's net operating loss and credit carryforwards may be subject to substantial annual limitation due to the ownership change limitations provided by the Internal Revenue Code and similar state provisions. Such annual limitation could result in the expiration of the net operating loss and credits before utilization. Utilization of the Company's net operating loss carryforward against net income for the year ended June 30, 2008 is not limited.

F-16

**Table of Contents**

**MYRIAD GENETICS, INC.**

**AND SUBSIDIARIES**

Notes to Consolidated Financial Statements - Continued

In July 2006, the Financial Accounting Standards Board ( FASB ) issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes - an interpretation of FASB Statement No. 109* ( FIN 48 ), which clarifies the accounting for uncertainty in tax positions. FIN 48 requires that the impact of a tax position be recognized in the financial statements if that position is more likely than not of being sustained on audit, based on the technical merits of the position. The Company adopted the provisions of FIN 48 on July 1, 2007. As a result, the Company recorded no unrecognized tax benefits.

The Company recorded no additional unrecognized tax benefits in the year ended June 30, 2008. The Company does not anticipate a material change to the total amount of unrecognized tax benefits within the next twelve months.

Interest and penalties related to income tax liabilities are included in Other Expense. As a result of the implementation of FIN 48, the Company recorded no cumulative effect adjustment to retained earnings for accrued interest and penalties on unrecognized tax benefits. During the year ended June 30, 2008, the Company recorded no additional interest and penalties on unrecognized tax benefits.

The Company files U.S. and state income tax returns in jurisdictions with various statutes of limitations. The 2004 through 2007 tax years remain subject to examination at June 30, 2008. The Company's consolidated Federal tax return and any significant state tax returns are not currently under examination.

**(6) Employee Deferred Savings Plan**

The Company has a deferred savings plan which qualifies under Section 401(k) of the Internal Revenue Code. Substantially all of the Company's employees are covered by the plan. The Company makes matching contributions of 50% of each employee's contribution with the employer's contribution not to exceed 4% of the employee's compensation. The Company's contributions to the plan were \$2,149,000, \$1,598,000, and \$1,431,000 for the years ended June 30, 2008, 2007, and 2006, respectively.

**(7) Collaborative Research Agreements**

In June 2006, the Company entered into a \$10.1 million research collaboration to apply its high-speed genomic sequencing capability and bioinformatics expertise to deliver molecular genetic information to the collaborator. Revenue related to this collaboration is recognized when completed information is delivered to the collaborator. Under this agreement the Company recognized research revenue of \$0 and \$7.0 million for the fiscal year ended June 30, 2008, and 2007, respectively.

In June 2005, the Company entered into a \$10.1 million research collaboration to apply its high-speed genomic sequencing capability and bioinformatics expertise to deliver molecular genetic information to the collaborator. Revenue related to this collaboration is recognized when completed information is delivered to the collaborator. Under this agreement the Company recognized research revenue of \$1.9 million and \$7.1 million for the fiscal years ended June 30, 2007 and 2006, respectively.

In June 2004, the Company entered into a five-year, \$14.2 million research agreement to utilize its expertise to characterize pathogen-host protein interactions. Revenue related to this collaboration is being recognized on a cost-to-cost basis. Under this agreement the Company recognized research revenue of \$3.3 million, \$2.4 million and \$2.4 million for the fiscal years ended June 30, 2008, 2007, and 2006, respectively.

**(8) Segment and Related Information**

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

The Company's business units have been aggregated into three reportable segments: (i) research, (ii) molecular diagnostics, and (iii) drug development. The research segment is focused on the discovery of genes related to major common diseases. The molecular diagnostics segment provides testing to determine predisposition to common diseases. The drug development segment is focused on the development of therapeutic products for the treatment and prevention of major diseases.

F-17

**Table of Contents****MYRIAD GENETICS, INC.****AND SUBSIDIARIES**

## Notes to Consolidated Financial Statements - Continued

The accounting policies of the segments are the same as those described in the summary of significant accounting policies (note 1). The Company evaluates segment performance based on loss from operations before interest income and expense and other income and expense.

	<b>Research</b>	<b>Molecular diagnostics</b>	<b>Pharmaceutical development</b>	<b>Total</b>
<b>Year ended June 30, 2008:</b>				
Revenues	\$ 6,774	\$ 222,855	\$ 104,000	\$ 333,629
Depreciation and amortization	2,388	3,495	2,898	8,781
Segment operating income (loss)	(31,115)	95,238	(26,042)	38,081
<b>Year ended June 30, 2007:</b>				
Revenues	11,841	145,285		157,126
Depreciation and amortization	2,540	2,511	2,493	7,544
Segment operating income (loss)	(20,849)	59,978	(86,856)	(47,727)
<b>Year ended June 30, 2006:</b>				
Revenues	13,658	100,621		114,279
Depreciation and amortization	2,654	2,123	2,078	6,855
Segment operating income (loss)	(15,496)	34,969	(65,062)	(45,589)
		<b>2008</b>	<b>2007</b>	<b>2006</b>
Total operating income (loss) for reportable segments		\$ 38,081	\$ (47,727)	\$ (45,589)
Unallocated amounts:				
Interest income		13,709	12,112	7,412
Other		(3,337)	653	(12)
Income tax provision		(608)		
Net income (loss)		\$ 47,845	\$ (34,962)	\$ (38,189)

The following table sets forth a comparison of balance sheet items by operating segment:

**Table of Contents****MYRIAD GENETICS, INC.****AND SUBSIDIARIES**

## Notes to Consolidated Financial Statements - Continued

<i>(In thousands)</i>	<b>June 30, 2008</b>	<b>June 30, 2007</b>
<i>Net equipment and leasehold improvements:</i>		
Research	\$ 6,959	\$ 8,200
Molecular diagnostics	12,717	9,576
Drug development	10,350	7,112
<b>Total</b>	<b>30,026</b>	<b>24,888</b>
<i>Total Assets:</i>		
Research	10,435	14,150
Molecular diagnostics	54,604	42,142
Drug development	14,247	10,936
<b>Total</b>	<b>\$ 79,286</b>	<b>\$ 67,228</b>

The following table reconciles assets by operating segment to total assets:

<i>(In thousands)</i>	<b>June 30, 2008</b>	<b>June 30, 2007</b>
Total assets by segment	\$ 79,286	\$ 67,228
Cash, cash equivalents, and marketable investment securities (1)	420,056	308,312
<b>Total</b>	<b>\$ 499,342</b>	<b>\$ 375,540</b>

(1) The Company manages cash, cash equivalents, and marketable investment securities at the consolidated level for all segments

The Company's revenues were derived from the sale of molecular diagnostic products and research all performed in the United States and, in 2008, an upfront license fee payment of \$100 million from one licensee. Additionally, all of the Company's long-lived assets are located in the United States. All of the Company's research segment revenue was generated from two, five, and eight collaborators in fiscal 2008, 2007, and 2006, respectively. No revenue from any collaborator was in excess of 10% of the Company's consolidated revenues for fiscal years 2008, 2007, and 2006, respectively.

**(9) Stockholder Rights Plan**

The Company has in place a Stockholder Rights Plan (the Plan). The Plan provides registered holders of the Company's common stock one preferred share purchase right for each outstanding share of the Company's common stock. Each right entitles the holder to purchase one one-hundredth of a share of a new series of junior participating preferred stock. The rights have certain anti-takeover effects and allow the Company's stockholders (other than the acquiror) to purchase common stock in the Company or in the acquiror at a substantial discount. Prior to the ten days following the acquisition by a person or group of beneficial ownership of 15% or more of the Company's common stock, the Board



of Directors may redeem the rights in whole, but not in part, at a price of \$0.01 per right.

F-19

**Table of Contents****MYRIAD GENETICS, INC.****AND SUBSIDIARIES**

## Notes to Consolidated Financial Statements - Continued

**(10) Investment in Prolexys Pharmaceuticals, Inc.**

In April 2001, the Company contributed technology to Prolexys Pharmaceuticals, Inc. (Prolexys), in exchange for a 49% ownership interest and investors contributed a combined \$82 million in cash in exchange for the remaining 51% ownership in Prolexys. As of June 30, 2008, the Company's ownership percentage in Prolexys is 23.39%.

The Company accounts for its investment in Prolexys using the equity method. Because the Company's initial investment in Prolexys consisted of technology with a carrying value of \$0 on the Company's consolidated financial statements, and given the uncertainty of the realizability of the difference between the \$82 million carrying amount and the Company's proportionate share of the net assets of Prolexys, the Company's initial investment in Prolexys was recorded as \$0. The Company allocated \$41 million of this difference to technology which is being reduced as the related technology amortization expenses, including in-process research and development charges, are recorded at Prolexys. At June 30, 2008, the remaining technology basis difference is estimated to be \$5.4 million. The original \$41 million of unallocated basis difference is being accreted to income, offset by the Company's share of Prolexys' losses, over the period of expected benefit of 10 years. For the period from the original investment in Prolexys through June 30, 2008, the Company's portion of the Prolexys' net losses exceeded the accretion of the unallocated basis. Accordingly, the Company's investment in Prolexys is carried at \$0.

Summarized balance sheet information as of June 30, 2008 and 2007 for Prolexys is as follows (in thousands):

	2008	2007
	(Unaudited)	
Current assets	\$ 2,785	\$ 4,834
Noncurrent assets	1,232	2,254
Current liabilities	761	1,150
Noncurrent liabilities	171	
Stockholders' equity	3,085	5,938

Summarized statement of operations information for Prolexys for the years ended June 30, 2008, 2007, and 2006 is as follows (in thousands):

	2008	2007	2006
		(Unaudited)	
Total revenues	\$ 138	\$ 47	\$ 1,253
Other operating costs and expenses	8,025	11,046	33,310
Net loss	(7,717)	(10,572)	(23,802)

**(11) Public Offering of Common Stock**

In February 2007, the Company received \$105.3 million in net proceeds from an underwritten public offering of 3,000,000 shares of common stock pursuant to the Company's outstanding shelf registration on Form S-3 (Registration No. 333-123914). The Company has approximately \$43.4 million of securities available for future sale under this shelf registration statement.

**Table of Contents****MYRIAD GENETICS, INC.****AND SUBSIDIARIES**

## Notes to Consolidated Financial Statements - Continued

**(12) Acquisition**

On April 10, 2008, the Company acquired NaturNorth Technologies, LLC. The Company purchased NaturNorth to acquire key technology. The Company has accounted for the acquisition as a purchase of assets under the guidance of EITF 98-3 *Determining Whether a Nonmonetary Transaction Involves Receipt of Productive Assets or of a Business*.

The preliminary aggregate purchase price was approximately \$1,350,000, which represented cash consideration. The following table summarizes the allocation of the preliminary aggregate purchase price for NaturNorth Technologies, LLC and the estimated useful life for the acquired intangible asset (in thousands):

	<b>2008</b>
R&D Supplies	\$ 452
Acquired Intangible:	
Existing Technology (two year estimated useful life)	250
Plant, property and equipment	648
<b>Net Assets Acquired</b>	<b>\$ 1,350</b>

The NatureNorth tangible assets acquired by the Company were valued at their respective current fair value. The R&D supplies, consisting primarily of raw material inventory, was immediately expensed to research and development as it represented material to be used for in-process research and development projects and have no alternative uses. The acquired fixed assets had an estimated useful life of five years and the acquired intangible asset had an estimated useful life of two years.

**(13) Commitments and Contingencies**

The Company has entered into license agreements for exclusive rights to utilize certain intellectual property rights related to our drug candidates Azixa and Vivecon. Under these agreements we will pay milestone payments totaling up to \$23 million. Payment of milestones is based on the occurrence of potential future events, including the initiation of certain human clinical trials, filing of a New Drug Application with the Food and Drug Administration, receipt of regulatory approval, and specific revenue targets.

Various legal claims have been filed against the Company that relate to the ordinary course of business and are currently pending resolution. In the opinion of management upon consultation with legal counsel, the ultimate resolution of these matters is not expected to have a material adverse effect on the financial position or future results of operations of the Company.

**(14) Co-Marketing and Development Agreements**

In May 2008, the Company entered into a collaboration agreement with Lundbeck granting certain marketing rights for the Company's therapeutic candidate Flurizan. Under the terms of the agreement Lundbeck paid the Company a \$100 million, non-refundable fee, and agreed to pay future royalties, sales-based milestones, and share certain development costs.

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

Upon receipt of the up-front payment from Lundbeck in June, 2008 the Company also recorded a one-time sublicense fee of \$20 million which represented the maximum amount that may be payable to a third party, which was recorded as research and development expense.

F-21

**Table of Contents**

**MYRIAD GENETICS, INC.**

**AND SUBSIDIARIES**

Notes to Consolidated Financial Statements - Continued

On June 30, 2008, based on results from the Company's U.S. phase III clinical trial, the Company announced its intention to discontinue all Flurizan development activities. Both the Company and Lundbeck concluded that Flurizan had no future economic value and that the Company had no continuing substantive obligations to Lundbeck. Based on this conclusion, the Company recognized the \$100 million as pharmaceutical revenue in the accompanying consolidated statement of operations for the year ended June 30, 2008.

Due to the termination of Flurizan development the Company canceled certain agreements relating to clinical trials, drug manufacturing, and other activities. The Company estimated the cancellation costs that will be incurred under the respective contracts that will not provide economic benefit to the Company. The Company estimated and recorded approximately \$3.0 million of research and development expense for the cancellation of these development agreements in the year ended June 30, 2008.

F-22