

MYRIAD GENETICS INC  
Form 10-Q  
May 06, 2008  
Table of Contents

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
**Washington, D.C. 20549**  
**FORM 10-Q**

(Mark One)

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the quarterly period ended March 31, 2008

OR

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

Commission file number: 0-26642

**MYRIAD GENETICS, INC.**

*(Exact name of registrant as specified in its charter)*

**Delaware**  
*(State or other jurisdiction  
of incorporation or organization)*

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

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

**84108**  
*(Zip Code)*

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

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

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

Edgar Filing: MYRIAD GENETICS INC - Form 10-Q

Large accelerated filer  Accelerated filer

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

Smaller reporting company

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

As of May 1, 2008 the registrant had 44,636,518 shares of \$0.01 par value common stock outstanding.

**Table of Contents**

**MYRIAD GENETICS, INC.**

INDEX TO FORM 10-Q

	<b>Page</b>
PART I - Financial Information	
Item 1. Financial Statements	
<u>Condensed Consolidated Balance Sheets (Unaudited) as of March 31, 2008 and June 30, 2007</u>	3
<u>Condensed Consolidated Statements of Operations (Unaudited) for the three and nine months ended March 31, 2008 and 2007</u>	4
<u>Condensed Consolidated Statements of Cash Flows (Unaudited) for the nine months ended March 31, 2008 and 2007</u>	5
<u>Notes to Condensed Consolidated Financial Statements (Unaudited)</u>	6
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	10
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	18
Item 4. <u>Controls and Procedures</u>	19
PART II - Other Information	
Item 1. <u>Legal Proceedings</u>	20
Item 1A. <u>Risk Factors</u>	20
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	20
Item 3. <u>Defaults Upon Senior Securities</u>	20
Item 4. <u>Submission of Matters to a Vote of Security Holders</u>	20
Item 5. <u>Other Information</u>	20
Item 6. <u>Exhibits</u>	20
<u>Signatures</u>	21

**Table of Contents**

## MYRIAD GENETICS, INC. AND SUBSIDIARIES

## CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)

<i>(In thousands, except per share amounts)</i>	Mar. 31, 2008	Jun. 30, 2007
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 142,392	\$ 143,432
Marketable investment securities	61,802	70,679
Prepaid expenses	7,032	5,972
Trade accounts receivable, less allowance for doubtful accounts of \$3,950 at Mar. 31, 2008 and \$2,600 at Jun. 30, 2007	39,704	31,103
Other receivables	2,018	1,348
<b>Total current assets</b>	<b>252,948</b>	<b>252,534</b>
Equipment and leasehold improvements:		
Equipment	61,515	54,868
Leasehold improvements	10,750	9,826
	72,265	64,694
Less accumulated depreciation	44,154	39,806
<b>Net equipment and leasehold improvements</b>	<b>28,111</b>	<b>24,888</b>
Long-term marketable investment securities	106,294	94,201
Other assets	3,604	3,917
	<b>\$ 390,957</b>	<b>\$ 375,540</b>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 12,009	\$ 15,763
Accrued liabilities	23,594	19,031
Deferred revenue	2,058	383
<b>Total current liabilities</b>	<b>37,661</b>	<b>35,177</b>
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 44,624 at Mar. 31, 2008 and 43,440 at Jun. 30, 2007	446	434
Additional paid-in capital	621,682	592,727
Accumulated other comprehensive income (loss)	1,264	(398)
Accumulated deficit	(270,096)	(252,400)
<b>Total stockholders' equity</b>	<b>353,296</b>	<b>340,363</b>
	<b>\$ 390,957</b>	<b>\$ 375,540</b>

See accompanying notes to condensed consolidated financial statements (unaudited).



**Table of Contents**

## MYRIAD GENETICS, INC. AND SUBSIDIARIES

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)

<i>(In thousands, except per share amounts)</i>	Three Months Ended		Nine Months Ended	
	Mar. 31, 2008	Mar. 31, 2007	Mar. 31, 2008	Mar. 31, 2007
<b>Revenue:</b>				
Molecular diagnostic revenue	\$ 59,023	\$ 37,991	\$ 158,176	\$ 103,017
Research and other revenue	2,742	2,979	8,597	8,631
<b>Total revenue</b>	<b>61,765</b>	<b>40,970</b>	<b>166,773</b>	<b>111,648</b>
<b>Costs and expenses:</b>				
Molecular diagnostic cost of revenue	8,263	7,577	23,289	23,211
Research and development expense	31,161	22,890	84,490	73,899
Selling, general, and administrative expense	30,157	19,595	87,127	49,999
<b>Total costs and expenses</b>	<b>69,581</b>	<b>50,062</b>	<b>194,906</b>	<b>147,109</b>
Operating loss	(7,816)	(9,092)	(28,133)	(35,461)
<b>Other income (expense):</b>				
Interest income	3,250	3,123	10,774	8,298
Other	(65)	32	(337)	5
	3,185	3,155	10,437	8,303
<b>Net loss</b>	<b>\$ (4,631)</b>	<b>\$ (5,937)</b>	<b>\$ (17,696)</b>	<b>\$ (27,158)</b>
Basic and diluted loss per share	\$ (0.10)	\$ (0.14)	\$ (0.40)	\$ (0.67)
Basic and diluted weighted average shares outstanding	44,448	41,503	44,035	40,329

See accompanying notes to condensed consolidated financial statements (unaudited).

**Table of Contents**

## MYRIAD GENETICS, INC. AND SUBSIDIARIES

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

<i>(In thousands)</i>	Nine Months Ended	
	Mar. 31, 2008	Mar. 31, 2007
Cash flows from operating activities:		
Net loss	\$ (17,696)	\$ (27,158)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	6,522	5,536
Loss (gain) on disposition of assets	337	(5)
Share-based compensation expense	10,580	5,220
Bad debt expense	8,347	3,840
Changes in operating assets and liabilities:		
Prepaid expenses	(1,060)	(462)
Trade accounts receivable	(16,948)	(8,481)
Other receivables	(670)	(733)
Accounts payable	(3,754)	(806)
Accrued liabilities	4,563	(3,346)
Deferred revenue	1,675	290
<b>Net cash used in operating activities</b>	<b>(8,104)</b>	<b>(26,105)</b>
Cash flows from investing activities:		
Capital expenditures for equipment and leasehold improvements	(9,669)	(8,658)
Sales (purchases) of other assets	(100)	20
Purchases of marketable investment securities	(158,280)	(90,698)
Proceeds from maturities of marketable investment securities	156,726	111,006
<b>Net cash provided by (used in) investing activities</b>	<b>(11,323)</b>	<b>11,670</b>
Cash flows from financing activities:		
Net proceeds from public offering of common stock		105,282
Net proceeds from common stock issued under share-based compensation plans	18,387	5,451
<b>Net cash provided by financing activities</b>	<b>18,387</b>	<b>110,733</b>
Net decrease in cash and cash equivalents	(1,040)	96,298
Cash and cash equivalents at beginning of period	143,432	98,573
<b>Cash and cash equivalents at end of period</b>	<b>\$ 142,392</b>	<b>\$ 194,871</b>

See accompanying notes to condensed consolidated financial statements (unaudited).

**Table of Contents**

MYRIAD GENETICS, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

(1) Basis of Presentation

The accompanying condensed consolidated financial statements have been prepared by Myriad Genetics, Inc. (the Company) in accordance with U.S. generally accepted accounting principles (GAAP) for interim financial information and pursuant to the applicable rules and regulations of the Securities and Exchange Commission. The condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation. In the opinion of management, the accompanying financial statements contain all adjustments (consisting of normal and recurring accruals) necessary to present fairly all financial statements in accordance with GAAP. The condensed consolidated financial statements herein should be read in conjunction with the Company's audited consolidated financial statements and notes thereto for the fiscal year ended June 30, 2007, included in the Company's Annual Report on Form 10-K for the year ended June 30, 2007. Operating results for the three and nine months ended March 31, 2008 may not necessarily be indicative of results to be expected for any other interim period or for the full year.

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements, as well as the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Certain reclassifications have been made to prior period amounts to conform to the current period presentation.

(2) Share-Based Compensation

The Company accounts for share-based compensation pursuant to the provisions of Statement of Financial Accounting Standards (SFAS) No. 123R, *Share-Based Payment* (SFAS 123R). SFAS 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.

In 2003, the Company adopted and the shareholders approved the 2003 Employee, Director and Consultant Stock Option Plan, as amended most recently in November 2007 (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 were reserved but not granted under the 2002 Plan as of the date of stockholder approval of the 2003 Plan are available for grant under the 2003 Plan. As of March 31, 2008 approximately 3.1 million shares represented by options remain outstanding under the 2002 Plan that would be transferred to the 2003 Plan if they are cancelled or expire without delivery of the shares of stock by the Company.

The number of shares, terms, and exercise period are determined by the board of directors or a committee thereof on an option-by-option basis. Options generally vest ratably over four years and expire ten years from the date of grant. Options are granted to members of the board of directors under the terms of the 2003 Plan and vest on the first anniversary of the date of grant.



**Table of Contents**

The exercise price of options granted is equivalent to the fair market value of the stock on the date of grant. During the three and nine months ended March 31, 2008, the Company granted approximately 960,000 and 1,857,000 options under the 2003 Plan. The Company also has an Employee Stock Purchase Plan under which a maximum of 1,000,000 shares of common stock may be purchased by eligible employees. During the three and nine months ended March 31, 2008, the Company issued 35,391 shares of common stock under the Employee Stock Purchase Plan.

The fair value of each option grant is estimated on the grant date using the Black-Scholes option-pricing model. Expected option lives and volatilities used in fair valuation calculations are based on historical data of the Company and the related expense is recognized on a straight-line basis over the vesting period.

Share-based compensation expense included in the condensed consolidated statements of operations for the three and nine months ended March 31, 2008 and 2007 was approximately \$4.4 million and \$10.6 million compared to approximately \$2.1 million and \$5.2 million, respectively. As of March 31, 2008, there was approximately \$44.1 million of total unrecognized share-based compensation cost related to share-based compensation granted under the Company's plans that will be recognized over a weighted-average period of 2.9 years.

**(3) Comprehensive Loss**

The components of the Company's comprehensive loss are as follows:

<i>(In thousands)</i>	<b>Three months ended</b>		<b>Nine months ended</b>	
	<b>Mar. 31,</b>		<b>Mar. 31,</b>	
	<b>2008</b>	<b>2007</b>	<b>2008</b>	<b>2007</b>
Net loss	\$ (4,631)	\$ (5,937)	\$ (17,696)	\$ (27,158)
Unrealized gain on available-for-sale securities	748	148	1,662	613
<b>Comprehensive loss</b>	<b>\$ (3,883)</b>	<b>\$ (5,789)</b>	<b>\$ (16,034)</b>	<b>\$ (26,545)</b>

**(4) Loss Per Common Share**

Basic and diluted loss per common share is computed using the weighted average number of shares of common stock outstanding during the period. Potentially dilutive common shares consisting of stock options and warrants were not included in the diluted loss per share attributable to common stockholders for all periods presented because the inclusion of such shares would have had an antidilutive effect.

As of March 31, 2008 and 2007, there were outstanding potential common shares of 8,942,934 and 8,871,200, respectively. These potential dilutive common shares may be dilutive to future diluted earnings per share.

**(5) Segment and Related Information**

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 and protein pathways related to major common diseases. The molecular diagnostics segment provides testing to determine predisposition to common diseases and risk associated with drug toxicity and response. The drug development segment is focused on the development of therapeutic products for the treatment and prevention of major diseases.

**Table of Contents**

The Company evaluates segment performance based on results from operations before interest income and expense and other income and expense.

<i>(In thousands)</i>	<b>Research</b>	<b>Molecular diagnostics</b>	<b>Drug development</b>	<b>Total</b>
<b>Three months ended Mar. 31, 2008:</b>				
Revenue	\$ 867	\$ 59,023	\$ 1,875	\$ 61,765
Depreciation and amortization	600	955	731	2,286
Segment operating income (loss)	(8,060)	27,701	(27,457)	(7,816)
<b>Three months ended Mar. 31, 2007:</b>				
Revenue	2,979	37,991		40,970
Depreciation and amortization	645	656	654	1,955
Segment operating income (loss)	(5,140)	16,212	(20,164)	(9,092)
<b>Nine months ended Mar. 31, 2008:</b>				
Revenue	5,472	158,176	3,125	166,773
Depreciation and amortization	1,802	2,602	2,118	6,522
Segment operating income (loss)	(21,988)	66,931	(73,076)	(28,133)
<b>Nine months ended Mar. 31, 2007:</b>				
Revenue	8,631	103,017		111,648
Depreciation and amortization	1,975	1,715	1,846	5,536
Segment operating income (loss)	(15,568)	44,285	(64,178)	(35,461)

<i>(In thousands)</i>	<b>Three months ended Mar. 31,</b>		<b>Nine months ended Mar. 31,</b>	
	<b>2008</b>	<b>2007</b>	<b>2008</b>	<b>2007</b>
Total operating loss for reportable segments	\$ (7,816)	\$ (9,092)	\$ (28,133)	\$ (35,461)
Interest income	3,250	3,123	10,774	8,298
Other	(65)	32	(337)	5
Net loss	\$ (4,631)	\$ (5,937)	\$ (17,696)	\$ (27,158)

The following table sets forth a comparison of balance sheet items by operating segment at March 31, 2008 and June 30, 2007:

<i>(In thousands)</i>	<b>Mar. 31, 2008</b>	<b>Jun. 30, 2007</b>
<b>Net equipment and leasehold improvements:</b>		
Research	\$ 7,014	\$ 8,200
Molecular diagnostics	12,042	9,576
Drug development	9,055	7,112
<b>Total</b>	<b>\$ 28,111</b>	<b>\$ 24,888</b>
<b>Total Assets:</b>		
Research	\$ 14,130	\$ 14,150
Molecular diagnostics	53,058	42,142
Drug development	13,281	10,936
<b>Total</b>	<b>\$ 80,469</b>	<b>\$ 67,228</b>



**Table of Contents**

The following table reconciles assets by operating segment to total assets at March 31, 2008 and June 30, 2007:

<i>(In thousands)</i>	<b>Mar. 31, 2007</b>	<b>Jun. 30, 2007</b>
Total assets by segment	\$ 80,469	\$ 67,228
Cash, cash equivalents, and marketable investment securities (1)	310,488	308,312
<b>Total</b>	<b>\$ 390,957</b>	<b>\$ 375,540</b>

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

(6) Recent Accounting Pronouncements

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.

(7) Subsequent Event

On April 10, 2008, the Company acquired NaturNorth Technologies, LLC. The Company purchased NaturNorth to acquire key technology. The preliminary aggregate purchase price was approximately \$1,350,000, which represented cash consideration. The acquisition will be accounted for under the purchase method of accounting. The acquisition of NaturNorth is not anticipated to have a material impact on our revenues or results of operations.

---

**Table of Contents**

**Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations**

We are a leading biotechnology company focused on the development and marketing of novel therapeutic and molecular diagnostic 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 disease and assess a person's risk of disease later in life.

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 insure the patient receives the most appropriate drug at the optimal dose.

Understanding the cause of disease at the molecular level can be very useful in determining how best to treat the disease. Historically, technologies used to discover pharmaceutical products that treat the symptoms of diseases have been less effective against complex diseases that arise through a combination of genetic and environmental factors, such as cancer and Alzheimer's disease. 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.

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:

*BRACAnalysis*<sup>®</sup>, our predictive medicine product for breast and ovarian cancer

*COLARIS*<sup>®</sup>, our predictive medicine product for colorectal and uterine cancer

*COLARIS AP*<sup>®</sup>, our predictive medicine product for colon cancer

*MELARIS*<sup>®</sup>, our predictive medicine product for melanoma

*Theraguide 5FU*, our personalized medicine product for chemotherapy toxicity

We market these products through our own sales force of approximately 200 people in the United States and we have entered into marketing collaborations with other organizations in other countries. Molecular diagnostic revenue was \$59.0 million and \$158.2 million for the three and nine months ended March 31, 2008, an increase of 55% and 54% over revenues of \$38.0 and \$103.0 million for the same periods in the prior year.

Myriad researchers have made important discoveries in the fields of cancer, Alzheimer's disease, 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. We intend to develop and, subject to regulatory approval, market our therapeutic products in the areas of cancer, Alzheimer's disease and viral disease. We currently have five drug candidates in six clinical trials and a number of drug candidates in late-stage preclinical development, including:

*Flurizan*<sup>®</sup> (*tarenflurbil*), our lead therapeutic candidate for the treatment of Alzheimer's disease, is being investigated in two Phase 3 clinical trials in patients with mild Alzheimer's disease. All patients participating in our U.S. phase 3 trial have completed the 18-month study period. We are currently in the process of collecting and preparing for analysis the data from the U.S.



---

**Table of Contents**

Phase 3 trial. We anticipate that we may report top-line results of this study in June 2008, and that we may present detailed results of the trial at the International Conference on Alzheimer's Disease in July 2008. Flurizan is also proceeding on schedule in an international Phase 3 clinical trial in patients with mild Alzheimer's disease. The 18-month study period is scheduled to conclude in October 2008;

*Azixa*, our drug candidate for solid primary tumors and metastatic brain tumors, is being tested in multiple Phase 2 clinical trials. These trials follow an adaptive design protocol and are designed as pivotal studies;

*Vivecon*, our drug candidate for the treatment of AIDS, is in a Phase 1 clinical trial;

*MPC-2130*, our drug candidate for hematologic cancers, is in a Phase 1 clinical trial;

*MPC-0920*, our drug candidate for thrombosis, recently completed a Phase 1 clinical trial; and

*MPC-3100*, our drug candidate for the treatment of cancer, is in the late-stage pre-clinical testing.

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. We have three reportable operating segments: (1) research, (2) molecular diagnostics, and (3) drug development. See Note 5 Segment and Related Information in the notes to our condensed consolidated financial statements (unaudited) for information regarding these operating segments. Our revenues have consisted primarily of sales of molecular diagnostic products and research payments. We have yet to attain profitability and, for the three and nine months ended March 31, 2008, we had net losses of \$4.6 million and \$17.7 million, respectively. As of March 31, 2008 we had an accumulated deficit of \$270.1 million.

Our research and development expenses include costs incurred for our drug candidates currently in human clinical trials, including Flurizan, Azixa, Vivecon, MPC-0920, and MPC-2130. 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 by individual drug candidate. 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.

Our lead drug candidate, Flurizan, comprises the majority of our research and development costs for our clinical drug candidates. All participants participating in our U.S. Phase 3 trial of Flurizan have completed the 18-month study period, and based upon our current estimates, we anticipate we may report results in mid-2008. Development costs associated with a follow-on open label study will continue until we obtain regulatory approval from the FDA, if at all. We anticipate our European Phase 3 trial of Flurizan will be completed in late 2008, and that development costs associated with this trial will end shortly thereafter. Any future revenue and cash flow from potential sales of Flurizan are subject to a number of factors, including results from our ongoing clinical trials, regulatory approval, market acceptance of our product, manufacturing and supply of our product and other factors. If we receive regulatory approval and are able to successfully commercialize Flurizan, we anticipate revenues and cash flows from sales of this product to commence sometime in mid- to-late 2009.

The timing and amount of any future expenses, completion dates, and revenues for our other 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

## **Table of Contents**

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 other than Flurizan. 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

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

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.

We expect to incur losses for at least the next several years, primarily due to the expansion of our drug discovery and development efforts, the initiation and continuing conduct of human clinical trials, the preparation for launch and the launch of any drug candidates that receive regulatory approval, the launch of new molecular diagnostic products, the continuation of our internal research and development programs, and the expansion of our facilities. Additionally, we expect to incur substantial sales, marketing and other expenses in connection with building our pharmaceutical and molecular diagnostic businesses. We expect that losses 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.



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

*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 collectibility is reasonably assured.

Research revenue includes revenue from research agreements and technology licensing agreements. In applying the principles of SAB 104 and EITF 00-21 to research and technology license agreements we

## **Table of Contents**

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 the basis of contractually defined output measures such as units delivered or as underlying research costs are incurred. We make adjustments, if necessary, to the estimates used in our calculations as work progresses and we gain experience. 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.

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.

*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 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.

After a review of our allowance for doubtful accounts as of March 31, 2008 and June 30, 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 \$395,000 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.

## **Results of Operations for the Three Months Ended March 31, 2008 and 2007**

Molecular diagnostic revenue is comprised primarily of sales of our five molecular diagnostic products. Molecular diagnostic revenue for the three months ended March 31, 2008 was \$59.0 million compared to \$38.0 million for the same three months in 2007. This 55% increase in molecular diagnostic revenue is primarily attributable to increased testing volume resulting from our expanded sales force, launching a direct-to-consumer marketing campaign for our *BRCAAnalysis*<sup>®</sup> predictive medicine product, and working to increase our market penetration in the Ob/Gyn market. Through these efforts we are attempting to broaden 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 or that it will continue to do so at historical rates.

---

**Table of Contents**

Research and other revenue is comprised of research and license payments received pursuant to collaborative agreements. Research revenue for the three months ended March 31, 2008 was \$2.7 million compared to \$3.0 million for the same three months in 2007. This 8% decrease in research revenue is primarily attributable to the successful completion of research collaborations. 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. We continue to focus our research efforts on internal programs to develop molecular diagnostic and therapeutic products and to de-emphasize external research collaborations.

Molecular diagnostic cost of revenue for the three months ended March 31, 2008 was \$8.3 million compared to \$7.6 million for the same three months in 2007. This increase of 9% in molecular diagnostic cost of revenue is primarily due to the 55% increase in sales volume of our molecular diagnostic products, and was offset by technology improvements and efficiency gains in the operation of our molecular diagnostic laboratory. Our gross profit margin was 86% for the three months ended March 31, 2008 compared to 80% for the same three months in 2007. Our gross profit margins may fluctuate from quarter to quarter based on the introduction of any new molecular diagnostic products, changes in our costs associated with such products, and any new technologies and operating systems in our molecular diagnostic laboratory.

Research and development expenses for the three months ended March 31, 2008 were \$31.2 million compared to \$22.9 million for the same three months in 2007. This increase of 36% in research and development expense was due primarily to:

increased costs of approximately \$4.7 million associated with our pharmaceutical development programs;

increased costs of approximately \$1.9 million associated with our molecular diagnostic research programs; and

increased share-based payment expense under SFAS 123R of approximately \$1.7 million.

We expect to increase our research and development expenses over the next several years as we conduct additional clinical trials to support the potential commercialization of our product candidates currently in clinical development, including Flurizan, Azixa, MPC-2130, MPC-0920 and Vivecon, advance our other product candidates into clinical trials, and expand our research and development activities. We expect that these expenses will continue to fluctuate based on changes in our research programs and the progression of our drug development programs.

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 resources, and allocated facilities expenses. Selling, general and administrative expenses for the three months ended March 31, 2008 were \$30.2 million compared to \$19.6 million for the same three months in 2007. The increase in selling, general and administrative expense was due primarily to:

increased sales and marketing expense of approximately \$4.8 million to support the 55% 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 a potential product launch of Flurizan resulted in an increase of approximately \$2.7 million;

general increases in costs of approximately \$1.4 million to support growth in our molecular diagnostic business and therapeutic development efforts;

growth in our molecular diagnostic sales which resulted in an increase of \$1.2 million in bad debt expense; and



## Table of Contents

increased share-based payment expense under SFAS 123R of approximately \$0.5 million;  
We expect our selling, general and administrative expenses will continue to fluctuate depending on the number and scope of any new product launches and our drug discovery and drug development efforts.

### **Results of Operations for the Nine Months Ended March 31, 2008 and 2007**

Molecular diagnostic revenue for the nine months ended March 31, 2008 was \$158.2 million compared to \$103.0 million for the same nine months in 2007, an increase of 54%. Increased sales, marketing, and education efforts, including our direct-to-consumer advertising campaign, have resulted in increased testing volumes, wider acceptance of our products by the medical community, and increased revenue for the nine months ended March 31, 2008. There can be no assurance that molecular diagnostic revenue will continue to increase at historical rates.

Research and other revenue for the nine months ended March 31, 2008 was \$8.6 million compared to \$8.6 million for the same nine months in 2007. We continue to focus our research efforts on internal programs to develop molecular diagnostic and therapeutic products and to de-emphasize external research collaborations.

Molecular diagnostic cost of revenue for the nine months ended March 31, 2008 was \$23.3 million compared to \$23.2 million for the same nine months in 2007. Molecular diagnostic cost of revenue remained stable as to technology improvements and efficiency gains in the operation of our molecular diagnostic laboratory, which were offset by increased sales of our molecular diagnostic products. Our gross profit margin was 85% for the nine months ended March 31, 2008 compared to 77% for the same nine months in 2007.

Research and development expenses for the nine months ended March 31, 2008 were \$84.5 million compared to \$73.9 million for the same nine months in 2007. This increase of 14% was due primarily to:

increased costs of approximately \$4.1 million associated with our molecular diagnostic research programs;

increased share-based payment expense under SFAS 123R of approximately \$3.5 million; and

increased costs of approximately \$3.0 million associated with our pharmaceutical development programs.

Selling, general and administrative expenses for the nine months ended March 31, 2008 were \$87.1 million compared to \$50.0 million for the same nine months in 2007. The increase in selling, general and administrative expense for the nine months ended March 31, 2008 compared to same nine months in 2007 was due primarily to:

increased sales and marketing expense of approximately \$19.3 million to support the 54% 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 a potential product launch of Flurizan which resulted in an increase of approximately \$5.5 million;

increased marketing costs of approximately \$4.5 million associated with the launch of our direct-to-consumer and public awareness campaign for our *BRACAnalysis*<sup>®</sup> predictive medicine product;

growth in our molecular diagnostic sales which resulted in an increase of \$4.5 million in bad debt expense;

increased share-based payment expense of approximately \$1.7 million; and

---

**Table of Contents**

general increases in costs of approximately \$1.6 million to support growth in our molecular diagnostic business and therapeutic development efforts.

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.

**Liquidity and Capital Resources**

Cash, cash equivalents, and marketable investment securities increased \$2.2 million, or 1%, from \$308.3 million at June 30, 2007 to \$310.5 million at March 31, 2008. This increase is primarily attributable to cash generated from sales of our molecular diagnostic products and proceeds from the exercise of stock options. This increase was partially offset by expenditures for our ongoing clinical trials, internal research and drug development programs, acquisition of new equipment, and other expenditures incurred in the ordinary course of business.

Interest income for the three and nine months ended March 31, 2008 was \$3.3 million and \$10.8 million, compared to \$3.1 million and \$8.3 million for the same three and nine months in 2007. This increase of 4% and 30% is due primarily to increases in cash, cash equivalents, and marketable investment securities over the same periods in 2007.

Net cash used in operating activities was \$8.1 million during the nine months ended March 31, 2008 compared to \$26.1 million used in operating activities during the same nine months in 2007. Trade accounts receivable increased \$16.9 million between June 30, 2007 and March 31, 2008, primarily due to increases in molecular diagnostic sales. Prepaid expenses increased \$1.1 million between June 30, 2007 and March 31, 2008, primarily due to prepayments related to our ongoing clinical trials for Flurizan. Accrued liabilities increased by \$4.6 million between June 30, 2007 and March 31, 2008, primarily due to accrued sales commissions and amounts accrued for our ongoing clinical trials.

Our investing activities used cash of \$11.3 million during the nine months ended March 31, 2008 and provided cash of \$11.7 million during the same nine months in 2007. Investing activities were comprised primarily of purchases and maturities of marketable investment securities and capital expenditures for research equipment and facilities.

Financing activities provided cash of \$18.4 million during the nine months ended March 31, 2008 and provided cash of \$110.7 million in the same nine months in 2007. During the nine months ended March 31, 2008 we received \$18.4 million from the exercise of stock options and sales of our shares under our Employee Stock Purchase Plan. In the prior year we received \$105.3 million in net proceeds from a public offering of our common stock.

We have an effective shelf registration statement on Form S-3 (Registration No. 333-123914) on file with the Securities and Exchange Commission. We have approximately \$43.4 million of various types of securities available for sale under this registration statement. Because of our significant 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 such time.

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 3 clinical trials of Flurizan for the treatment of Alzheimer's disease and any additional trials that may be required by the FDA or that we may initiate on our own;

**Table of Contents**

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;

any future trials that we may initiate based on results of our Phase 1 clinical trial for MPC-0920;

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;

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 Flurizan, Azixa, Vivecon, MPC-2130, MPC-0920, and any other 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.

**Effects of Inflation**



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

We do not believe that inflation has had a material impact on our business, sales, 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 Quarterly Report on Form 10-Q contains such forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995.

Words such as may, anticipate, estimate, expects, projects, intends, plans, believes and words and terms of similar substance used in conjunction with any discussion of future operating or financial performance, identify forward-looking statements. All forward-looking statements are management's present expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those described in the forward-looking statements. These risks include, but are not limited to: 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 those of our competitors; the risk we may be

---

**Table of Contents**

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 predictive medicine products that help assess which patients are subject to greater risk of developing diseases and who would therefore benefit from new preventive therapies; the risk that we may be unable to develop or market additional personalized medicine products that may help identify appropriate drug selection and dose; the possibility of delays in the research and development necessary to select drug development candidates and delays in clinical trials, including the expected timing for the conclusion of the U.S. Phase 3 trial for Flurizan and the initial report of results from that trial; 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 our Annual Report on Form 10-K for the year ended June 30, 2007, which has been filed with the Securities and Exchange Commission, as well as any updates to those risk factors filed from time to time in our Quarterly Reports on Form 10-Q or Current Reports on Form 8-K.

In light of these assumptions, risks and uncertainties, the results and events discussed in the forward-looking statements contained in this Quarterly 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 Quarterly 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 3. 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 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 March 31, 2008, we have determined that in the event of a hypothetical 10 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 4. Controls and Procedures**

- (a) *Evaluation of Disclosure Controls and Procedures.* Our principal executive officer and principal financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of the end of period covered by this Quarterly Report on Form 10-Q, have concluded that, based on such evaluation, our disclosure controls and procedures were adequate and effective to ensure that material information relating to us, including our consolidated subsidiaries, was made known to them by others within those entities, particularly during the period in which this Quarterly Report on Form 10-Q was being prepared.

In designing and evaluating our disclosure controls and procedures, our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

- (b) *Changes in Internal Controls.* There were no changes in our internal control over financial reporting, identified in connection with the evaluation of such internal control that occurred during our last fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Table of Contents**

**PART II - Other Information**

**Item 1. Legal Proceedings.**

Neither the Company nor any of its subsidiaries is a party to any material legal proceedings.

**Item 1A. Risk Factors**

There have been no material changes to the risk factors included in our Annual Report on Form 10-K for the fiscal year ended June 30, 2007.

**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.**

None.

**Item 3. Defaults Upon Senior Securities.**

None.

**Item 4. Submission of Matters to a Vote of Security Holders.**

None.

**Item 5. Other Information.**

None.

**Item 6. Exhibits.**

(a) Exhibits

31.1 Certification of Chief Executive Officer pursuant to Section 302(a) of the Sarbanes-Oxley Act of 2002.

31.2 Certification of Chief Financial Officer pursuant to Section 302(a) of the Sarbanes-Oxley Act of 2002.

32.1 Certifications pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

**Table of Contents**

**SIGNATURES**

Pursuant to the requirements 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.

MYRIAD GENETICS, INC.

Date: May 6, 2008

By: /s/ Peter D. Meldrum  
Peter D. Meldrum  
President and Chief Executive Officer  
(Principal executive officer)

Date: May 6, 2008

By: /s/ James S. Evans  
James S. Evans  
Chief Financial Officer  
(Principal financial and chief accounting officer)