

MYRIAD GENETICS INC  
Form 10-Q  
November 04, 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 September 30, 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*

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

*of incorporation or organization)*

**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

Smaller reporting company

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 October 31, 2008 the registrant had 46,499,660 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 September 30, 2008 and June 30, 2008</u>	3
<u>Condensed Consolidated Statements of Operations (Unaudited) for the three months ended September 30, 2008 and 2007</u>	4
<u>Condensed Consolidated Statements of Cash Flows (Unaudited) for the three months ended September 30, 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>	11
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>	Sep. 30, 2008	Jun. 30, 2008
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 230,233	\$ 237,734
Marketable investment securities	78,107	90,994
Prepaid expenses	3,102	3,143
Trade accounts receivable, less allowance for doubtful accounts of \$4,400 at Sep. 30, 2008 and \$4,100 at Jun. 30, 2008	46,934	40,663
Other receivables	7,178	4,769
Total current assets	365,554	377,303
Equipment and leasehold improvements:		
Equipment	63,340	63,095
Leasehold improvements	11,738	11,701
	75,078	74,796
Less accumulated depreciation	46,293	44,770
Net equipment and leasehold improvements	28,785	30,026
Long-term marketable investment securities	134,285	91,328
Other assets	2,604	685
	\$ 531,228	\$ 499,342
<b>Liabilities and Stockholders Equity</b>		
Current liabilities:		
Accounts payable	\$ 14,999	\$ 24,884
Accrued liabilities	39,177	46,770
Deferred revenue	8	2,033
Total current liabilities	54,184	73,687
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 46,443 at Sep. 30, 2008 and 44,744 at Jun. 30, 2008	464	447
Additional paid-in capital	673,294	630,000
Accumulated other comprehensive loss	(6,613)	(237)
Accumulated deficit	(190,101)	(204,555)
Total stockholders equity	477,044	425,655
	\$ 531,228	\$ 499,342

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	
	Sep. 30, 2008	Sep. 30, 2007
Revenue:		
Molecular diagnostic revenue	\$ 69,965	\$ 46,056
Research and other revenue	3,685	2,210
Total revenue	73,650	48,266
Costs and expenses:		
Molecular diagnostic cost of revenue	9,790	7,335
Research and development expense	17,149	26,025
Selling, general, and administrative expense	33,399	26,488
Total costs and expenses	60,338	59,848
Operating income (loss)	13,312	(11,582)
Other income (expense):		
Interest income	3,434	3,857
Other	(2,005)	(274)
Total other income	1,429	3,583
Income (loss) before taxes	14,741	(7,999)
Income tax provision	287	
Net income (loss)	\$ 14,454	\$ (7,999)
Earnings (loss) per share		
Basic	\$ 0.32	\$ (0.18)
Diluted	\$ 0.30	\$ (0.18)
Weighted average shares outstanding		
Basic	45,398	43,568
Diluted	48,309	43,568

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>	Three Months Ended	
	Sep. 30, 2008	Sep. 30, 2007
Cash flows from operating activities:		
Net income (loss)	\$ 14,454	\$ (7,999)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization	2,256	2,068
Loss on disposition of assets		274
Share-based compensation expense	5,047	2,426
Bad debt expense	4,032	2,141
Other than temporary impairment on marketable investment securities	1,986	
Changes in operating assets and liabilities:		
Prepaid expenses	41	(5,789)
Trade accounts receivable	(10,303)	(4,526)
Other receivables	(2,409)	(1,211)
Accounts payable	(9,885)	(1,770)
Accrued liabilities	(7,593)	2,062
Deferred revenue	(2,025)	(374)
Net cash used in operating activities	(4,399)	(12,698)
Cash flows from investing activities:		
Capital expenditures for equipment and leasehold improvements	(934)	(3,282)
Purchase of other assets	(2,000)	
Purchases of marketable investment securities	(63,056)	(80,826)
Proceeds from maturities of marketable investment securities	24,624	54,093
Net cash used in investing activities	(41,366)	(30,015)
Cash flows from financing activities:		
Net proceeds from common stock issued under share-based compensation plans	38,264	6,497
Net cash provided by financing activities	38,264	6,497
Net decrease in cash and cash equivalents	(7,501)	(36,216)
Cash and cash equivalents at beginning of period	237,734	143,432
Cash and cash equivalents at end of period	\$ 230,233	\$ 107,216

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, 2008, included in the Company's Annual Report on Form 10-K for the year ended June 30, 2008. Operating results for the three months ended September 30, 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 U.S. 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.

(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 September 30, 2008 approximately 2.2 million shares represented by options remain outstanding under the 2002 Plan that will transfer 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. The exercise price of options granted is equivalent to the fair market value of the stock on the date of grant. During the three months ended September 30, 2008, the Company granted approximately 910,000 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 months ended September 30, 2008, the Company issued no shares of common stock under the Employee Stock Purchase Plan.



**Table of Contents**

Employee stock-based compensation expense recognized under FAS 123R was allocated as follows (*in thousands*):

	<b>Three months ended Sep. 30,</b>	
	<b>2008</b>	<b>2007</b>
Cost of revenue	\$ 139	\$ 22
Research and development	2,682	1,266
Selling, general, and administrative	2,226	1,138
 Total employee stock-based compensation expense	 \$ 5,047	 \$ 2,426

As of September 30, 2008, there was approximately \$55.2 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.

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.

(3) Comprehensive Loss

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

<i>(In thousands)</i>	<b>Three months ended Sep. 30,</b>	
	<b>2008</b>	<b>2007</b>
Net income (loss)	\$ 14,454	\$ (7,999)
Change in unrealized gain (loss) on available-for-sale securities	(6,376)	461
 Comprehensive income (loss)	 \$ 8,078	 \$ (7,538)

(4) Earnings (Loss) Per Share

Basic earnings (loss) per share is computed based on the weighted-average number of shares of our common stock outstanding. Diluted earnings (loss) per share 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 were not included in the diluted loss per share attributable to common stockholders for the three months ended September 30, 2007 because the inclusion of such shares would have had an antidilutive effect.

**Table of Contents**

The following is a reconciliation of the numerators and denominators of the basic and diluted earnings (loss) per share computations (*in thousands*):

	Three months ended Sep. 30,	
	2008	2007
<b>Numerator:</b>		
Net income (loss)	\$ 14,454	\$ (7,999)
<b>Denominator:</b>		
Weighted-average shares outstanding used to compute basic earnings (loss) per share	45,398	43,568
Effect of dilutive stock options	2,911	
 Weighted-average shares outstanding and dilutive securities used to compute dilutive earnings (loss) per share	 48,309	 43,568

As of September 30, 2008 and 2007, there were outstanding potential common shares of 1,630,835 and 8,766,223, respectively, which were excluded from the computation of diluted earnings (loss) per share because the effect would have been anti-dilutive. These potential dilutive common shares may be dilutive to future diluted earnings (loss) 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) pharmaceutical 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 risks associated with drug toxicity and response. The pharmaceutical development segment is focused on the development of therapeutic products for the treatment and prevention of major diseases.

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

<i>(In thousands)</i>	Research	Molecular diagnostics	Pharmaceutical development	Total
Three months ended Sep. 30, 2008:				
Revenue	\$ 3,685	\$ 69,965	\$	\$ 73,650
Depreciation and amortization	579	705	972	2,256
Segment operating income (loss)	(5,856)	32,376	(13,208)	13,312
Three months ended Sep. 30, 2007:				
Revenue	2,210	46,056		48,266
Depreciation and amortization	592	800	676	2,068
Segment operating income (loss)	(6,694)	18,465	(23,353)	(11,582)

<i>(In thousands)</i>	2008	2007
Total operating income (loss) for reportable segments	\$ 13,312	\$ (11,582)
Interest income	3,434	3,857
Other	(2,005)	(274)
Income tax provision	287	
 Net income (loss)	 \$ 14,454	 \$ (7,999)



**Table of Contents**

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

<i>(In thousands)</i>	Sep. 30, 2008	Jun. 30, 2008
<i>Net equipment and leasehold improvements:</i>		
Research	\$ 6,949	\$ 6,959
Molecular diagnostics	12,067	12,717
Pharmaceutical development	9,769	10,350
<b>Total</b>	<b>28,785</b>	<b>30,026</b>
<i>Total Assets:</i>		
Research	12,452	10,435
Molecular diagnostics	62,670	54,604
Pharmaceutical development	13,481	14,247
<b>Total</b>	<b>\$ 88,603</b>	<b>\$ 79,286</b>

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

<i>(In thousands)</i>	Sep. 30, 2008	Jun. 30, 2008
Total assets by segment	\$ 88,603	\$ 79,286
Cash, cash equivalents and marketable investment securities (1)	442,625	420,056
<b>Total</b>	<b>\$ 531,228</b>	<b>\$ 499,342</b>

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

(6) Fair Value Measurements

On July 1, 2008, we adopted SFAS 157 *Fair Value Measurement* ( FAS 157 ), which established a framework for measuring fair value in GAAP and clarified the definition of fair value within that framework. FAS 157 does not require assets and liabilities that were previously recorded at cost to be recorded at fair value. For assets and liabilities that are already required to be disclosed at fair value, FAS 157 introduced, or reiterated, a number of key concepts which form the foundation of the fair value measurement approach to be used for financial reporting purposes. The fair value of our financial instruments reflects the amounts that we estimate to receive in connection with the sale of an asset or paid in connection with the transfer of a liability in an orderly transaction between market participants at the measurement date (exit price). FAS 157 also established a fair value hierarchy that prioritizes the use of inputs used in valuation techniques into the following three levels:

Level 1 quoted prices in active markets for identical assets and liabilities.

Level 2 observable inputs other than quoted prices in active markets for identical assets and liabilities.

Level 3 unobservable inputs.

The adoption of FAS 157 did not have an effect on our financial condition or results of operations, but FAS 157 requires new disclosures about how we value certain assets and liabilities. Much of the disclosure is focused on the inputs used to measure fair value, particularly in instances where the measurement uses significant unobservable (Level 3) inputs. The substantial majority of our financial instruments are valued using quoted prices in active markets or based on other observable inputs.



**Table of Contents**

<i>(In thousands)</i>	Sep. 30, 2008	Jun. 30, 2008
Cash and cash equivalents	\$ 230,233	\$ 237,734
Short-term marketable investment securities	78,107	90,994
Long-term marketable investment securities	134,285	91,328
Total	\$ 442,625	\$ 420,056

The following table sets forth the fair value of our financial assets that were measured on a recurring basis during the three months ended September 30, 2008:

<i>(In thousands)</i>	Level 1	Level 2	Level 3	Total
Cash and cash equivalents	\$ 75,801	\$ 154,432	\$	\$ 230,233
Securities available-for-sale		210,502	1,890	212,392
Total	\$ 75,801	\$ 364,934	\$ 1,890	\$ 442,625

Our Level 1 assets include cash and money market instruments. Level 2 assets consist of our marketable investment securities that include federal agency issues, commercial paper, corporate bonds, and euro bonds. As of September 30, 2008, we held \$1.9 million of investments which were measured using unobservable (Level 3) inputs. These investments represent less than 1% of our total fair value investments portfolio and were classified as Level 3 assets for the three months ended September 30, 2008. Our Level 3 assets consist of certain marketable investment securities, with an auction reset feature (auction rate securities) and value determined based on valuations which approximate fair value. In February 2008, the auction-rate securities market experienced a number of failed auctions, including those we held and continue to hold, which severely limited the liquidity for these securities. As of September 30, 2008, we believe the unrealized losses in the auction-rate securities are temporary and we have the ability and intent to hold the assets to maturity. As a result, we have recorded the unrealized losses in other comprehensive loss in the accompanying condensed consolidated balance sheet. There were no changes in the fair value of our Level 3 financial assets, which are measured at fair value on a recurring basis, for the three months ended September 30, 2008.

**(7) Subsequent Event**

On October 20, 2008, we announced that Myriad's Board of Directors had authorized management to proceed with preparations to separate our research and pharmaceutical development businesses from our molecular diagnostic business. It is anticipated that the separation will be completed as a pro-rata tax free dividend distribution to shareholders of Myriad. We plan to seek an independent opinion that the dividend distribution would be tax-free to Myriad and its shareholders. We expect to file a Form 10 registration statement for the new research and pharmaceutical development company in the second calendar quarter of 2009.

## Table of Contents

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

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 major 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, or 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 250-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 \$70.0 million for the three months ended September 30, 2008, an increase of 52% over revenues of \$46.1 million for the same period in the prior year.

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 date we have launched five commercial molecular diagnostic products:

*BRCA*Analysis<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 also focus our efforts on the development of therapeutic products to treat disease. To treat complex diseases effectively we believe that 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. 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 therefore be able to develop drugs that are more effective and have fewer side effects.

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 solid primary and metastatic brain tumors;

*Vivecon* for the treatment of AIDS;

Edgar Filing: MYRIAD GENETICS INC - Form 10-Q

*MPC-2130* for the treatment of hematologic cancers;

*MPC-3100* for the treatment of solid tumors; and



---

**Table of Contents**

*MPC-0920* for the treatment of thrombosis.

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) pharmaceutical 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, together with a \$100.0 million upfront fee for Flurizan recognized as pharmaceutical revenue in fiscal 2008. For the three months ended September 30, 2008, we had net income of \$14.5 million compared to a net loss of \$8.0 million for the period ended September 30, 2007. As of September 30, 2008, we had an accumulated deficit of \$190.1 million.

Our research and development expenses include costs incurred for our drug candidates currently in human clinical trials, including 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.

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

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.

---

## **Table of Contents**

On October 20, 2008, we announced that our Board of Directors has authorized management to proceed with preparations to separate our research and drug development businesses from our molecular diagnostics business to form two well-capitalized, highly-focused, independent public companies. If completed, the transaction is intended to enable each of the companies to excel in their respective fields, acknowledging the different needs of a high-growth, profitable molecular diagnostics business and research and pharmaceutical development businesses. By separating the businesses, we believe each company will better pursue its long-term strategic initiatives and compete more effectively in its respective markets. We anticipate the proposed separation will be completed as a pro-rata dividend to shareholders. We plan to seek an independent opinion that the dividend distribution would be a tax free to Myriad and its shareholders. We expect to file a Form 10 registration statement for the new research and pharmaceutical development company in second calendar quarter of fiscal 2009.

### **Critical Accounting Policies**

Critical accounting policies are those policies which are both important to the presentation 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.

Pharmaceutical 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.

## **Table of Contents**

*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.

After a review of our allowance for doubtful accounts as of September 30, 2008 and June 30, 2008, 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 \$440,000 and \$410,000, 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 September 30, 2008 and 2007**

Molecular diagnostic revenue for the three months ended September 30, 2008 was \$70.0 million, compared to \$46.1 million for the same three months in 2007. This 52% 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 three months ended September 30, 2008. During the past quarter we expanded our sales force to 250 full-time sales representatives, initiated a public awareness marketing campaign in strategic southern states, and increased our market penetration in both the oncology and 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 at historical rates.

Research and other revenue is comprised of research and license payments received pursuant to collaborative agreements. Research revenue for the three months ended September 30, 2008 was \$3.7 million, compared to \$2.2 million for the same three months in 2007. This 67% increase in research revenue is primarily attributable to the completion of the final phase of a research collaboration. 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.

---

## **Table of Contents**

Molecular diagnostic cost of revenue for the three months ended September 30, 2008 was \$9.8 million, compared to \$7.3 million for the same three months in 2007. This increase of 33% in molecular diagnostic cost of revenue is primarily due to the 52% increase in sales revenue 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 September 30, 2008 compared to 84% 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. There can be no assurance that molecular diagnostic gross profit margins will continue to increase or remain at current levels, and we expect that our gross profit margins will fluctuate from quarter to quarter.

Research and development expenses for the three months ended September 30, 2008 were \$17.1 million, compared to \$26.0 million for the same three months in 2007. This decrease of 34% was due primarily to decreased pharmaceutical development costs of approximately \$11.1 million from our former drug candidate Flurizan. This decrease was partially offset by increased SFAS 123R share-based payment expense of approximately \$1.4 million and increased development costs of our other diagnostic and pharmaceutical programs of approximately \$0.8 million.

We expect our research and development expenses will fluctuate as we conduct additional clinical trials to support the potential commercialization of our product candidates currently in clinical development, including Azixa and Vivecon, advance our other product candidates into clinical trials, develop additional molecular diagnostic products, and expand our research and development activities.

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 September 30, 2008 were \$33.4 million, compared to \$26.5 million for the same three months in 2007. The increase in selling, general and administrative expense of 26% was due primarily to:

increased sales and marketing expense of approximately \$3.7 million to support the 52% growth in our molecular diagnostic revenues, which includes the continued expansion of our Ob/Gyn sales force, commissions, travel, and initiative programs;

increase in bad debt expense of approximately \$1.9 million that resulted from growth in our molecular diagnostic sales and an increase in our bad debt allowance;

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

increased SFAS 123R share-based payment expense of approximately \$1.1 million.

These increases were partially offset by a reduction in commercialization costs of approximately \$1.4 million from the discontinuation of Flurizan. We expect our selling, general and administrative expenses will continue to fluctuate depending on the number and scope of any new molecular diagnostic product launches, our efforts in support of our existing molecular diagnostic products, and our drug discovery and drug development efforts.

Interest income for the three months ended September 30, 2008 was \$3.4 million, compared to \$3.9 million for the same three months in 2007. The decrease was due primarily to changing interest rates.

## **Liquidity and Capital Resources**

Cash, cash equivalents, and marketable investment securities increased \$22.5 million, or 5%, from \$420.1 million at June 30, 2008 to \$442.6 million at September 30, 2008. This increase is primarily attributable to cash generated from our molecular diagnostic revenue and, to a lesser extent, research collaboration payments 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 capital assets, increased sales and marketing expense for our molecular diagnostic products and other expenditures incurred in the ordinary course of business.



**Table of Contents**

Other expense for the three months ended September 30, 2008 was comprised primarily of other than temporary impairment on marketable investment securities. Based on the bankruptcy filing of Lehman Brothers Holdings, Inc. ( Lehman ), we determined that our investment in certain Lehman bonds was not likely to be recoverable. Based on this determination we expensed the full value of all Lehman holdings resulting in another than temporary impairment loss of approximately \$2.0 million.

Net cash used in operating activities was \$4.4 million during the three months ended September 30, 2008, compared to \$12.7 million used in operating activities during the same three months in 2007. Trade accounts receivable increased \$10.3 million between June 30, 2008 and September 30, 2008, primarily due to increases in molecular diagnostic revenue. Accrued liabilities decreased by \$7.6 million between June 30, 2008 and September 30, 2008, primarily due to the reduction in accrued sales commissions and salaries and was partially offset by amounts accrued for the purchase of a technology license. Deferred revenue decreased by \$2.0 million between June 30, 2008 and September 30, 2008, primarily due to the completion of the final phase of a research collaboration agreement.

Our investing activities used cash of \$41.4 million during the three months ended September 30, 2008 and used cash of \$30.0 million during the same three months in 2007. Investing activities were comprised primarily of purchases and maturities of marketable investment securities and capital expenditures for research equipment and facilities, as well as the purchase of a technology license.

Financing activities provided cash of \$38.3 million during the three months ended September 30, 2008 and provided cash of \$6.5 million in the same three months in 2007. During the three months ended September 30, 2008 we received \$38.3 million from the exercise of stock options and sales of our shares under our Employee Stock Purchase Plan. In the prior year we received \$6.5 million in net proceeds from the exercise of stock options.

We have an effective shelf registration statement on Form S-3 (Registration No. 333-123914) on file with the Securities and Exchange Commission ( SEC ). We have approximately \$43.4 million of various types of securities available for sale under this registration statement on or before December 1, 2008. 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 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 2a clinical trials for Vivecon and our Phase 1 trial for MPC-2130 and any future trials that we may initiate based on the 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;

**Table of Contents**

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

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

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.

The October 2008 announcement of our plans to proceed with preparations to separate our research and pharmaceutical development business from our molecular diagnostic business will impact our current liquidity and capital resources. At the time of separation, we intend to allocate our liquidity and capital resources to each business in a manner appropriate for its financial profile, however specific amounts remain undetermined.

**Effects of Inflation**

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.

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

Words such as may, anticipate, estimate, expects, projects, intends, plans, believes and words and terms of similar substance used in connection 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 our competitors; the risk we may be unable to develop manufacturing capability for approved products; the risk that sales of or profit margins for 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



## **Table of Contents**

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; the risk that we may not be able to effectuate the spin off of our research and development businesses as contemplated; 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, 2008, 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. Investors 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.

Although our investment policy guidelines are intended to ensure the preservation of principal, current market conditions have resulted in high levels of uncertainty. Our ability to trade or redeem the marketable investment securities in which we invest, including certain corporate bonds and auction rate securities, has become difficult. Valuation and pricing of these securities has also become variable and subject to uncertainty.

As of September 30, 2008 we have estimated unrealized losses of \$6.6 million in our investment portfolio, primarily from our investments in bonds of financial institutions currently experiencing credit difficulties and unrealized losses in the fair value changes in auction rate securities. We have determined that these losses are temporary in nature. We also recorded a \$2.0 million other than temporary impairment on marketable investment securities for Lehman. However, the ultimate value that we realize from our marketable investment securities may change substantially. Due to our positive cash flows we do not anticipate that market conditions will adversely impact the operation of our business or current strategic plans.

**Table of Contents**

The securities held in our investment portfolio are also 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 September 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.

**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, 2008.

**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: November 4, 2008

By: /s/ Peter D. Meldrum  
Peter D. Meldrum

President and Chief Executive Officer

(Principal executive officer)

Date: November 4, 2008

By: /s/ James S. Evans  
James S. Evans

Chief Financial Officer

(Principal financial and chief accounting officer)