

MYRIAD GENETICS INC  
Form 10-Q  
November 04, 2009  
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, 2009

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)

Edgar Filing: MYRIAD GENETICS INC - Form 10-Q

<b>Delaware</b> (State or other jurisdiction of incorporation or organization)	<b>87-0494517</b> (I.R.S. Employer Identification No.)
<b>320 Wakara Way, Salt Lake City, UT</b> (Address of principal executive offices)	<b>84108</b> (Zip Code)
<b>Registrant's telephone number, including area code: (801) 584-3600</b>	

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 has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  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 the definitions of "accelerated filer," "large accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. Check one:

Large accelerated filer <input checked="" type="checkbox"/>	Accelerated filer <input type="checkbox"/>
Non-accelerated filer <input type="checkbox"/> (Do not check if smaller reporting company)	Smaller reporting company <input type="checkbox"/>

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 30, 2009 the registrant had 96,201,461 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, 2009 and June 30, 2009</u>	3
<u>Condensed Consolidated Statements of Operations (Unaudited) for the three months ended September 30, 2009 and 2008</u>	4
<u>Condensed Consolidated Statements of Cash Flows (Unaudited) for the three months ended September 30, 2009 and 2008</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>	13
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>	21
Item 3. <u>Defaults Upon Senior Securities</u>	21
Item 4. <u>Submission of Matters to a Vote of Security Holders</u>	21
Item 5. <u>Other Information</u>	21
Item 6. <u>Exhibits</u>	21
<u>Signatures</u>	22

**Table of Contents**

## MYRIAD GENETICS, INC. AND SUBSIDIARIES

## CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)

<i>(In thousands, except per share amounts)</i>	Sep. 30, 2009	Jun. 30, 2009
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 91,196	\$ 63,510
Marketable investment securities	266,433	253,345
Prepaid expenses	7,911	3,993
Trade accounts receivable, less allowance for doubtful accounts of \$4,000 at Sep. 30, 2009 and \$3,850 at Jun. 30, 2009	43,736	44,617
Other receivables	1,075	655
Total current assets	410,351	366,120
Equipment and leasehold improvements:		
Equipment	48,076	49,116
Leasehold improvements	12,011	11,942
	60,087	61,058
Less accumulated depreciation	37,873	38,435
Net equipment and leasehold improvements	22,214	22,623
Long-term marketable investment securities	59,370	75,370
Other assets	2,194	2,275
	\$ 494,129	\$ 466,388
<b>Liabilities and Stockholders Equity</b>		
Current liabilities:		
Accounts payable	\$ 7,648	\$ 14,177
Accrued liabilities	13,345	17,992
Total current liabilities	20,993	32,169
Stockholders equity:		
Preferred stock, \$0.01 par value, authorized 5,000 shares, issued and outstanding no shares		
Common stock, \$0.01 par value, authorized 150,000 shares at Sep. 30, 2009 and Jun. 30, 2009, issued and outstanding 96,174 at Sep. 30, 2009 and 95,896 at Jun. 30, 2009	962	959
Additional paid-in capital	559,000	550,432
Accumulated other comprehensive income	2,672	2,768
Accumulated deficit	(89,498)	(119,940)
Total stockholders equity	473,136	434,219
	\$ 494,129	\$ 466,388

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, 2009	Sep. 30, 2008
Molecular diagnostic revenue	\$ 85,122	\$ 69,965
Costs and expenses:		
Molecular diagnostic cost of revenue	11,062	9,790
Research and development expense	5,676	4,375
Selling, general, and administrative expense	38,672	32,411
Total costs and expenses	55,410	46,576
Operating income	29,712	23,389
Other income (expense):		
Interest income	1,913	3,434
Other	(215)	(2,005)
Total other income	1,698	1,429
Income from continuing operations before income taxes	31,410	24,818
Income tax provision	968	287
Income from continuing operations	\$ 30,442	\$ 24,531
Discontinued operations (Note 8)		
Loss from discontinued operations		(10,077)
Net income	\$ 30,442	\$ 14,454
Earnings (loss) per basic share:		
Continuing operations	\$ 0.32	\$ 0.27
Discontinued operations		(0.11)
Earnings per basic share	\$ 0.32	\$ 0.16
Earnings (loss) per diluted share:		
Continuing operations	\$ 0.31	\$ 0.25
Discontinued operations		(0.10)
Earnings per diluted share	\$ 0.31	\$ 0.15
Weighted average shares outstanding		
Basic	95,970	90,796
Diluted	99,492	96,618

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, 2009	Sep. 30, 2008
Cash flows from operating activities:		
Net income	\$ 30,442	\$ 14,454
Adjustments to reconcile net income to net cash provided by (used in) operating activities:		
Depreciation and amortization	1,779	2,256
Loss on disposition of assets	288	19
Share-based compensation expense	5,378	5,047
Bad debt expense	4,421	4,032
(Gain) loss on marketable investment securities	(73)	1,986
Changes in operating assets and liabilities:		
Prepaid expenses	(3,918)	41
Trade accounts receivable	(3,540)	(10,303)
Other receivables	(420)	(2,409)
Accounts payable	(6,529)	(9,885)
Accrued liabilities	(4,647)	(7,593)
Deferred revenue		(2,025)
Net cash provided by (used in) operating activities	23,181	(4,380)
Cash flows from investing activities:		
Capital expenditures for equipment and leasehold improvements	(1,577)	(953)
Purchase of other assets		(2,000)
Purchases of marketable investment securities	(55,168)	(63,056)
Proceeds from maturities of marketable investment securities	58,057	24,624
Net cash provided by (used in) investing activities	1,312	(41,385)
Cash flows from financing activities:		
Net proceeds from common stock issued under share-based compensation plans	3,193	38,264
Net cash provided by financing activities	3,193	38,264
Net increase (decrease) in cash and cash equivalents	27,686	(7,501)
Cash and cash equivalents at beginning of period	63,510	237,734
Cash and cash equivalents at end of period	\$ 91,196	\$ 230,233

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 (SEC). The condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, Myriad Genetics Laboratories, Inc., Myriad Financial, Inc., Myriad Therapeutics, Inc. and through June 30, 2009, Myriad Pharmaceuticals, Inc. (MPI). The financial statements presented herein reflect the spin-off of MPI on June 30, 2009 (see Note 8). 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, 2009, included in the Company's Annual Report on Form 10-K for the year ended June 30, 2009. Operating results for the three months ended September 30, 2009 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. The Company has evaluated subsequent events through November 4, 2009, which is the date these financial statements and Form 10-Q have been filed with the SEC. No material subsequent events have occurred since September 30, 2009 that required recognition or disclosure in these financial statements.

Until June 30, 2009, the Company's business included its research and drug development businesses which were spun-off to MPI. The separation resulted in MPI operating as an independent entity with its own publicly-traded stock. The results of operations for the former research and drug development businesses conducted by the Company and by MPI until June 30, 2009 are included as part of this report for the periods prior to that date as discontinued operations. The Company does not have any ownership or other form of interest in MPI subsequent to the separation (see Note 8).

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

(2) Marketable Investment Securities

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



**Table of Contents**

The amortized cost, gross unrealized holding gains, gross unrealized holding losses, and fair value for available-for-sale securities by major security type and class of security at September 30, 2009 and June 30, 2009 were as follows (in thousands):

	Amortized cost	Gross unrealized holding gains	Gross unrealized holding losses	Estimated fair value
<b>At September 30, 2009:</b>				
Available-for-sale:				
Corporate bonds and notes	\$ 218,531	\$ 2,629	\$ (83)	\$ 221,077
Federal agency issues	102,500	351	(15)	102,836
Auction rate securities	2,100		(210)	1,890
<b>Total</b>	<b>\$ 323,131</b>	<b>\$ 2,980</b>	<b>\$ (308)</b>	<b>\$ 325,803</b>

	Amortized cost	Gross unrealized holding gains	Gross unrealized holding losses	Estimated fair value
<b>At June 30, 2009:</b>				
Available-for-sale:				
Corporate bonds and notes	\$ 213,187	\$ 2,331	\$ (58)	\$ 215,460
Federal agency issues	110,660	705	0	111,365
Auction rate securities	2,100		(210)	1,890
<b>Total</b>	<b>\$ 325,947</b>	<b>\$ 3,036</b>	<b>\$ (268)</b>	<b>\$ 328,715</b>

Maturities of debt securities classified as available-for-sale are as follows at September 30, 2009 (in thousands):

	Amortized cost	Estimated fair value
Available-for-sale:		
Due within one year	\$ 264,654	\$ 266,433
Due after one year through three years	58,477	59,370
	<b>\$ 323,131</b>	<b>\$ 325,803</b>

In addition to the amounts above, the Company had cash equivalents of \$75.6 million at September 30, 2009 and \$32.8 million at June 30, 2009, respectively. Cash equivalents consist of highly liquid debt instruments with maturities at date of purchase of 90 days or less. As of September 30, 2009 and June 30, 2009, the carrying value of cash equivalents approximates fair value.

**(3) Share-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 2008 (the 2003 Plan), under which 16.8 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



**Table of Contents**

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, 2009, approximately 2.9 million shares represented by options that remain outstanding under the 2002 Plan 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 compensation committee of the board of directors 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, 2009, the Company granted approximately 1,322,000 options under the 2003 Plan. The Company also has an Employee Stock Purchase Plan under which a maximum of 2,000,000 shares of common stock may be purchased by eligible employees. Any shares are issued twice yearly at the end of each six month offering period on May 30 and November 30. During the three months ended September 30, 2009, the Company issued no shares of common stock under the Employee Stock Purchase Plan.

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

	<b>Three months ended Sep. 30,</b>	
	<b>2009</b>	<b>2008</b>
Molecular diagnostic cost of revenue	\$ 219	\$ 139
Research and development expense	906	668
Selling, general, and administrative expense	4,253	2,226
Discontinued operations		2,014
<b>Total share-based compensation expense</b>	<b>\$ 5,378</b>	<b>\$ 5,047</b>

During the three months ended September 30, 2009, 277,975 stock options were exercised at a weighted average price of \$11.48. As of September 30, 2009, there was approximately \$49.4 million of total unrecognized share-based compensation cost related to share-based awards granted under the Company's plans that will be recognized over a weighted-average period of 2.6 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.

**Table of Contents****(4) Comprehensive Income**

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

<i>(In thousands)</i>	<b>Three months ended Sep. 30,</b>	
	<b>2009</b>	<b>2008</b>
Net income	\$ 30,442	\$ 14,454
Unrealized gain (loss) on available-for-sale securities	(96)	(6,376)
<b>Comprehensive income</b>	<b>\$ 30,346</b>	<b>\$ 8,078</b>

**(5) Earnings Per Share**

Basic earnings per share is computed based on the weighted-average number of shares of the Company's common stock outstanding. Diluted earnings per share is computed based on the weighted-average number of shares of the Company's common stock, including common stock equivalents outstanding. Certain common shares consisting of stock options that would have an antidilutive effect were not included in the diluted earnings per share attributable to common stockholders for the three months ended September 30, 2009 and 2008.

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

<b>Denominator:</b>	<b>Three months ended Sep. 30,</b>	
	<b>2009</b>	<b>2008</b>
Weighted-average shares outstanding used to compute basic earnings per share	95,970	90,796
Effect of dilutive stock options	3,522	5,822
 Weighted-average shares outstanding and dilutive securities used to compute dilutive earnings per share	 99,492	 96,618

For the three months ended September 30, 2009, there were outstanding potential common equivalent shares of 4,453,927, compared to 1,630,835 in the same period in 2008, which were excluded from the computation of diluted earnings per share because the effect would have been anti-dilutive. These potential dilutive common equivalent shares may be dilutive to future diluted earnings per share.

**(6) Segment and Related Information**

The Company's business units from continuing operations have been aggregated into two reportable segments: (i) genetics and (ii) molecular diagnostics. The genetics segment is focused on the discovery of genes related to major common diseases and includes corporate services such as finance, human resources, legal, and information technology. The molecular diagnostics segment provides testing to assess an individual's risk for developing disease as well as testing to identify a patient's likelihood of responding to drug therapy and to help guide a patient's dosing to ensure optimal treatment.

**Table of Contents**

On June 30, 2009, the Company spun-off its research and drug development businesses to MPI. The results from the former research and drug development businesses are reflected as discontinued operations for periods prior to that date in the Condensed Consolidated Statements of Operations (see Notes 1 and 8).

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>Genetics</b>	<b>Molecular diagnostics</b>	<b>Total</b>
<b>Three months ended Sep. 30, 2009:</b>			
Revenue	\$	\$ 85,122	\$ 85,122
Depreciation and amortization	526	1,253	1,779
Segment operating income (loss) from continuing operations	(10,838)	40,550	29,712
<b>Three months ended Sep. 30, 2008:</b>			
Revenue		69,965	69,965
Depreciation and amortization	579	972	1,551
Segment operating income (loss) from continuing operations	(8,987)	32,376	23,389

<i>(In thousands)</i>	<b>Three months ended Sep. 30,</b>	
	<b>2009</b>	<b>2008</b>
Total operating income for reportable segments	\$ 29,712	\$ 23,389
Interest income	1,913	3,434
Other	(215)	(2,005)
Income tax provision	968	287
<b>Net income</b>	<b>\$ 30,442</b>	<b>\$ 24,531</b>

**(7) Fair Value Measurements**

The fair value of the Company's financial instruments reflects the amounts that the Company 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). The fair value hierarchy 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; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities. Some of the Company's marketable securities primarily utilize broker quotes in a non-active market for valuation of these securities.

Level 3 unobservable inputs.

**Table of Contents**

The substantial majority of our financial instruments are valued using quoted prices in active markets or based on other observable inputs. The following table sets forth the fair value of our financial assets that the Company re-measured at September 30, 2009:

<i>(In thousands)</i>	Level 1	Level 2	Level 3	Total
Cash and cash equivalents	\$ 81,162	\$ 10,034	\$	\$ 91,196
Securities available-for-sale		323,913	1,890	325,803
<b>Total</b>	<b>\$ 81,162</b>	<b>\$ 333,947</b>	<b>\$ 1,890</b>	<b>\$ 416,999</b>

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, 2009, the Company held \$1.9 million of investments which were measured using unobservable (Level 3) inputs. These investments represent less than 1% of our investments portfolio and were classified as Level 3 assets as of September 30, 2009. Our Level 3 assets consist of auction rate securities and the value is determined based on valuations which approximate fair value. As of September 30, 2009, the Company believes the unrealized losses in the auction rate securities are temporary and the Company does not intend to sell nor will it be required to sell the securities prior to maturity or recovery of the par value. As a result, the Company has recorded the unrealized losses in other comprehensive income in the accompanying condensed consolidated balance sheet. There were no changes in the composition or estimated fair value of our Level 3 financial assets, which are measured at fair value on a periodic basis, for the period ended September 30, 2009.

**(8) Separation of Research and Pharmaceutical Businesses**

On June 30, 2009, the Company separated its former research and drug development businesses from its molecular diagnostic business. The Company contributed substantially all of the assets and certain liabilities from the research and drug development businesses and \$188 million of cash and marketable securities to MPI. All outstanding shares of MPI were then distributed to the Company's stockholders of record on June 17, 2009 as a pro-rata, tax-free dividend of one MPI common stock for every four shares of the Company's common stock. The significant components of the research and drug development operations, which are presented as discontinued operations, were as follows (in thousands):

	Three Months ended Sep. 30,	
	2009	2008
Research and other revenues (1)	\$	\$ 3,685
Operating expenses (2)		(13,762)
<b>Total loss from discontinued operations</b>	<b>\$</b>	<b>\$ (10,077)</b>

- (1) Research revenue from discontinued operations includes revenue from research collaboration agreements, milestone payments, and technology licensing agreements.
- (2) Operating expenses from discontinued operations include costs associated with the development of clinical drug candidates and costs associated with the discontinuance of the Company's former Alzheimer's disease drug candidate.

**Table of Contents**

(9) Income Taxes

The Company's income tax expense from continuing operations for the three months ended September 30, 2009 and 2008 was \$968,000 and \$287,000, respectively. Income tax expense represents the Company's estimated alternative minimum tax and state tax liabilities.

---

**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 products. We employ a number of proprietary technologies that help us to understand the genetic basis of human disease and the role that genes and their related proteins may play in the onset, progression and treatment of disease. We use this information to guide the development of new molecular diagnostic products that are designed to assess an individual's risk for developing disease later in life (predictive medicine), identify a patient's likelihood of responding to drug therapy and help guide a patient's dosing to ensure optimal treatment (personalized medicine), or assess a patient's risk of disease progression and disease recurrence (prognostic medicine).

To date we have launched seven commercial molecular diagnostic products, including four predictive medicine and three personalized medicine products. We market these products through our own 300-person sales force in the United States and we have entered into marketing collaborations with other organizations in selected foreign countries for some of our predictive medicine products. Molecular diagnostic revenue was \$85.1 million for the three months ended September 30, 2009, an increase of 22% over revenues of \$70.0 million for the same period in the prior year. We launched our first molecular diagnostic product, BRACAnalysis®, in November 1996, and sales of BRACAnalysis account for most of our molecular diagnostic revenues.

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 later in life and who, therefore, would benefit from preventive therapies. We also believe that molecular diagnostic products will assist patient's physicians in managing their healthcare to ensure that patients receive the most appropriate treatment base on their individual genetic makeup and specific cause of disease.

The seven commercial molecular diagnostic products that we have launched to date are:

*BRACAnalysis®*, our predictive medicine product for hereditary breast and ovarian cancer;

*COLARIS®*, our predictive medicine product for hereditary colorectal and uterine cancer;

*COLARIS AP®*, our predictive medicine product for colon cancer;

*MELARIS®*, our predictive medicine product for hereditary melanoma;

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

*Prezeon*, our personalized medicine product to assess PTEN status for disease progression and drug response; and

*OnDose*, our personalized medicine product to measure chemotherapy exposure to 5FU.

During the three months ended September 30, 2009, devoted substantially all of our resources to supporting our molecular diagnostic products, as well as to the research and development of future molecular diagnostic product candidates. We have two reportable operating segments—genetics and molecular diagnostics. See Note 6—Segment and Related Information in the notes to our condensed consolidated financial statements (unaudited) for information regarding these operating segments. Our revenues consist of sales of our molecular diagnostic products.

We incurred research and development expenses from continuing operations of \$5.7 million and \$4.4 million for the three months ended September 30, 2009, and 2008, respectively. Our research and development expenses include costs incurred in maintaining and improving our seven current molecular diagnostic products and costs incurred for the discovery, development and validation of our pipeline of molecular diagnostic product candidates. Our sales and marketing expenses and general and administrative expenses include costs associated with building our molecular diagnostic business. We expect that these costs will fluctuate from quarter to quarter and that such fluctuations may be substantial.





---

## **Table of Contents**

For the three months ended September 30, 2009, we had net income from continuing operations of \$30.4 million compared to \$24.5 million for three months ended September 30, 2008. As of September 30, 2009, we had an accumulated deficit of \$89.5 million.

On June 30, 2009, we separated our molecular diagnostic business from our research and drug development businesses for the treatment of cancers and other diseases by transferring our research and drug development businesses along with \$188.0 million of cash into our then wholly-owned subsidiary, Myriad Pharmaceuticals, Inc. ( MPI ). All outstanding shares of MPI were then distributed to our stockholders as a pro-rata, tax-free dividend on June 30, 2009 by issuing one share of MPI common stock for every four shares of our common stock to stockholders of record on June 17, 2009. The separation resulted in MPI operating as an independent entity with its own publicly-traded stock. The results of operations for the former research and drug development activities conducted by us and by MPI until June 30, 2009 are included as part of this report for the periods prior to that date as discontinued operations. We do not have any ownership or other form of interest in MPI subsequent to the separation.

### **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;

share-based payment expense; and

income taxes.

*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.

*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.

As of September 30, 2009 and June 30, 2009, 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 \$400,000 and \$385,000, respectively.

*Share-Based Payment Expense.* We recognize expense related to 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.



## **Table of Contents**

*Income Taxes.* Significant estimates are required in determining our provision for income taxes. Some of these estimates are based on interpretations of existing tax laws or regulations, or the expected results from any future tax examinations. Various internal and external factors may have favorable or unfavorable effects on our future provision for income taxes. These factors include, but are not limited to, changes in tax laws, regulations and/or rates, the results of any future tax examinations, changing interpretations of existing tax laws or regulations, changes in estimates of prior years' items, past levels of research and development spending, acquisitions, changes in our corporate structure, and changes in overall levels of income before taxes all of which may result in periodic revisions to our provision for income taxes.

Our deferred tax assets are offset by a full valuation allowance. The determination of the amount and extent of the valuation allowance offsetting our deferred tax assets requires a substantial degree of judgment. If we continue to experience positive trends in operating results, this valuation allowance could reverse in part or in full in the near term based on whether or not, in our judgment, it becomes more likely than not that the underlying deferred tax assets will be realized.

### **Results of Operations for the Three Months Ended September 30, 2009 and 2008**

Revenue for the three months ended September 30, 2009 was \$85.1 million, compared to \$70.0 million for the same three months in 2008. This 22% increase in our 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 due to market penetration for the three months ended September 30, 2009. During three months ended September 30, 2009, we have initiated a direct-to-consumer ( DTC ) marketing campaign in strategic southern and midwestern states to increase our market penetration for BRACAnalysis in primarily 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, the markets in which we operate are experiencing unprecedented economic turmoil resulting in loss of jobs, loss of employer sponsored insurance coverage, reduced doctor visits, and poorer patient compliance in the area of preventive diagnostic testing. We believe that there has been negative impact on our revenue growth due to these difficult economic conditions. In addition, because BRACAnalysis and most of our molecular diagnostic products are only utilized once per patient, we will need to sell our services through physicians to new patients or develop new molecular diagnostic products in order to continue to generate revenue. Therefore, there can be no assurance that molecular diagnostic revenue will continue to increase at historical rates.

Molecular diagnostic cost of revenue for the three months ended September 30, 2009 was \$11.1 million, compared to \$9.8 million for the same three months in 2008. This increase of 13% in molecular diagnostic cost of revenue is primarily due to the 22% increase in revenue from our molecular diagnostic products, partially offset by technology improvements and efficiency gains in the operation of our molecular diagnostic laboratory. Our gross profit margin was 87% for the three months ended September 30, 2009 compared to 86% for the same three months in 2008. 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.

---

## **Table of Contents**

Research and development expenses from continuing operations are comprised primarily of salaries and related personnel costs, laboratory supplies, and equipment and facility costs. Research and development expenses for continuing operations incurred during the three months ended September 30, 2009 were \$5.7 million compared to \$4.4 million for same three months in 2008. This increase of 30% was primarily due to increased research and development associated with internal predictive, personalized and prognostic product development. We expect our research and development expenses will increase over the next several years as we work to develop our product pipeline and expand our offerings of molecular diagnostic products.

Selling, general and administrative expenses for continuing operations 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, 2009 were \$38.7 million, compared to \$32.4 million for the same three months in 2008. The increase in selling, general and administrative expense of 19% was due primarily to:

increase in sales and marketing expense of approximately \$3.0 million to support the continued expansion of our Ob/Gyn sales force from 100 to 150 sales representatives, acceleration of the mid-west DTC campaign launch, renewal of the southern DTC campaign, and other marketing initiatives;

increase in share-based compensation expense of approximately \$2.0 million;

general increase in administrative costs of approximately \$0.9 million to support the 22% growth in our molecular diagnostic business; and

increase in bad debt expense of approximately \$0.4 million associated with the increased molecular diagnostic sales.

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 and our efforts in support of our existing molecular diagnostic products.

Interest income for the three months ended September 30, 2009 was \$1.9 million, compared to \$3.4 million for the same three months in 2008. The decrease was due primarily to a lower market rates during the period. Other expense for the three months ended September 30, 2009 was \$0.2 million compared to \$2.0 million for the same three months in 2008. The decrease was due to a other-than-temporary impairment in 2008 on marketable investment securities from our holding of Lehman Brothers Holdings, Inc. ( Lehman ) bonds. Due to Lehman s bankruptcy filing we determined that our investment in certain Lehman bonds was not likely to be recoverable.

The tax expense of \$1.0 million for the three months ended September 30, 2009 represents our estimated alternative minimum tax and state tax liabilities.

## **Liquidity and Capital Resources**

Cash, cash equivalents, and marketable investment securities increased \$24.8 million, or 6%, from \$392.2 million at June 30, 2009 to \$417.0 million at September 30, 2009. This increase is primarily attributable to cash generated from sales of our molecular diagnostic products. This increase was partially offset by expenditures for our internal research and development programs, acquisition of capital assets, sales and marketing expense for our molecular diagnostic products, and other expenditures incurred in the ordinary course of business.

Net cash provided by operating activities was \$23.2 million during the three months ended September 30, 2009, compared to \$4.4 million used in operating activities during the same three months in 2008. Trade accounts receivable increased \$3.5 million between September 30, 2009 and June 30, 2009, primarily due to increases in molecular diagnostic sales. Prepaid expenses increased \$3.9 million due to increased sales and marketing efforts associated with our midwest and south DTC campaigns. Accrued liabilities and accounts payable decreased by \$4.6 million and \$6.5 million, respectively, between June 30, 2009 and September 30, 2009, primarily due to payments made following the spin-off of our former research and drug development businesses to MPI on June 30, 2009.



**Table of Contents**

Our investing activities provided cash of \$1.3 million during the three months ended September 30, 2009 and used cash of \$41.4 million during the same three months in 2008. Investing activities were comprised primarily of purchases and maturities of marketable investment securities. Capital expenditures for research equipment and facilities were \$1.6 million during the three months ended September 30, 2009.

Financing activities provided cash of \$3.2 million during the three months ended September 30, 2009 and provided cash of \$38.3 million in the same three months in 2008. Cash generated from financing activities was provided by the exercise of stock options.

We believe that with our existing capital resources and expected net cash to be generated for sales of our molecular diagnostic products, 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:

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

termination of the licenses underlying our molecular diagnostic products;

delays or other problems with operating our laboratory facilities;

public concern over our approved products and any product candidates;

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;

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

regulatory developments or enforcement in the United States and foreign countries;

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

changes in intellectual propriety laws of our patents or enforcement in the United States and foreign countries;

changes in structure of the healthcare system or healthcare payment systems;

the impact of current economic conditions and job loss resulting in fewer doctor visits and loss of employer provided insurance coverage;

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

the costs to satisfy our obligations under our existing and potential future collaborations.

### **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.



## **Table of Contents**

### **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 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 sales and profit margins of our existing molecular diagnostic products may decline or will not continue to increase at historical rates; the risk that we may be unable to develop additional molecular diagnostic products; the risk that licenses to the technology underlying our molecular diagnostic products and any future products are terminated or cannot be maintained on satisfactory terms; risks related to delays or other problems with operating our laboratory testing facilities; risks related to public concern over our products; risks related to regulatory developments or enforcement in the United States and foreign countries and changes in the structure of healthcare payment systems; 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 or our licensors may be unable to protect the proprietary technologies underlying our products; the risk of patent-infringement claims; challenges to intellectual property rights underlying our products or changes in intellectual property laws; 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, 2009, 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 adequate 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 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.

**Table of Contents**

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 our Lehman bonds and auction rate securities, has become difficult. Valuation and pricing of these securities has also become variable and subject to uncertainty.

**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 effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate, to allow timely decisions regarding required disclosure.

In designing and evaluating our disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and 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**

As previously disclosed in Part I, Item 3 of our Annual Report on Form 10-K for the fiscal year ended June 30, 2009, we are a defendant in a lawsuit brought by the Association for Molecular Pathology, *et al.* (the Plaintiffs) on May 12, 2009 in the United States District Court for the Southern District of New York. The Plaintiffs are seeking a declaratory ruling that seven claims of certain patents relating to the *BRCA1* and *BRCA2* genes, which patents are exclusively licensed to us, are invalid and unenforceable, and enjoining us (and the other defendants) from taking any actions to enforce these claims of these patents. These patents along with 16 other issued patents which are not subject to the lawsuit cover the intellectual property utilized in our BRACAnalysis predictive medicine product for breast and ovarian cancer. Myriad filed a motion to dismiss the lawsuit based on the Plaintiffs' lack of standing to bring this action. The Plaintiffs filed a motion for summary judgment. On November 1, 2009, the federal district court issued an order denying our motion to dismiss, and ordering that our opposition to Plaintiffs' motion for summary judgment is due by December 2, 2009. We believe that the Plaintiffs' claims are without merit and intend to vigorously defend this lawsuit.

We are not a party to any other legal proceedings that we believe will have a material impact on our financial position or results of operations.

**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, 2009, except as follows:

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

As of September 30, 2009, our patent portfolio included 211 issued patents owned or licensed by us and numerous patent applications in the United States and other countries with claims covering our intellectual property rights. Our commercial success will depend, in part, on our ability to obtain additional patents and licenses and protect our existing patent position, both in the United States and in other countries, for predisposing genes we identify and related technologies, processes, methods and other inventions that we believe are patentable. Our ability to preserve our trade secrets and other intellectual property is also critical to our long-term success. If we do not adequately protect our intellectual property, competitors may be able to use our technologies and erode or negate any competitive advantage we may have, which could harm our business and ability to maintain profitability. Patents may also issue to third parties which could interfere with our ability to bring our molecular diagnostic products to market. The laws of some foreign countries do not protect our proprietary rights to the same extent as U.S. laws, and we may encounter significant problems in protecting our proprietary rights in these countries.

The patent positions of diagnostic companies, including our patent position, are generally highly uncertain and involve complex legal and factual questions, and, therefore, any patents issued to us may be challenged, deemed unenforceable, invalidated or circumvented. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies and any future products are covered by valid and enforceable patents or are effectively maintained as trade secrets. To date there has not emerged from the U.S. Patent and Trademark Office, or PTO, the U.S. courts, or from patent offices or courts in foreign countries, a consistent policy regarding the breadth of claims allowed in genetic patents. Our patent applications may never issue as patents, and the claims of any issued patents may not afford meaningful protection for our technology or products. In addition, any patents issued to us or our licensors may be challenged, and subsequently narrowed, invalidated or circumvented. Specifically, as disclosed in Part II, Item 1 of this Quarterly Report on Form 10-Q, we are a defendant in a lawsuit brought by the Association for Medical Pathology and others, or the Plaintiffs, in the United States District Court for the Southern District of New York. The Plaintiffs are seeking a declaratory ruling that certain claims of seven patents relating to the *BRCA1* and *BRCA2* genes, which patents are exclusively licensed to us, are invalid and unenforceable, and enjoining us and the other defendants from taking any actions to enforce these claims of these patents. These patents along with 16 other issued patents which are not subject to the lawsuit cover the intellectual property utilized in our BRACAnalysis predictive medicine product for breast and ovarian cancer, which accounts for most of our revenues. While we believe that the Plaintiffs' claims are without merit and we intend to vigorously defend this lawsuit, if these patents are invalidated, others may be able to commercialize genetic tests that are competitive with our BRACAnalysis product, and our business could be seriously harmed.

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

Edgar Filing: MYRIAD GENETICS INC - Form 10-Q

we or our licensors were the first to make the inventions covered by each of our patent applications;

we or our licensors were the first to file patent applications for these inventions;

**Table of Contents**

others will not independently develop similar or alternative technologies or duplicate any of our technologies;

any of our or our licensors' patent applications will result in issued patents;

any of our or our licensors' patents will be valid or enforceable;

any patents issued to us or our licensors and collaborators will provide a basis for commercially viable products, will provide us with any competitive advantages or will not be challenged by third parties;

we will develop additional proprietary technologies or products that are patentable;

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

our patents or patents that we license from others will survive legal challenges, such as the lawsuit challenging the patents covering our BRACAnalysis predictive medicine product described above, and remain valid and enforceable.

If a third party files a patent application with claims to a gene, protein, or biomarker we have discovered, the PTO may declare an interference between competing patent applications. If an interference is declared, we may not prevail in the interference. If the other party prevails in the interference, we may be precluded from commercializing services or products based on the gene, protein, or biomarker or may be required to seek a license. A license may not be available to us on commercially acceptable terms, if at all.

We also rely upon unpatented proprietary technologies. Although we require employees, consultants and collaborators to sign confidentiality agreements, we may not be able to adequately protect our rights in such unpatented proprietary technologies, which could have a material adverse effect on our business. For example, others may independently develop substantially equivalent proprietary information or techniques or otherwise gain access to our proprietary technologies or disclose our technologies to our competitors.

**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, 2009

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

Date: November 4, 2009

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