MYRIAD GENETICS INC Form 10-Q May 08, 2013 Table of Contents

## **UNITED STATES**

## SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

## **FORM 10-Q**

(Mark One)

# x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended March 31, 2013

OR

# " TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from \_\_\_\_\_\_ to \_\_\_\_\_

Commission file number: 0-26642

## **MYRIAD GENETICS, INC.**

(Exact name of registrant as specified in its charter)

Delaware				
(State or other jurisdiction of				

incorporation or organization)

87-0494517 (I.R.S. Employer

Identification No.)

320 Wakara Way, Salt Lake City, UT84108(Address of principal executive offices)(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 x No  $\ddot{}$ 

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (\$232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No "

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

Large accelerated filer x

Accelerated filer

Non-accelerated filer" (Do not check if smaller reporting company)Smaller reporting companyIndicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).Yes " No x

As of May 2, 2013 the registrant had 79,654,860 shares of \$0.01 par value common stock outstanding.

# latures

2

## Table of Contents

#### Table of Contents

Financial Statements

Item 1.

#### MYRIAD GENETICS, INC.

#### INDEX TO FORM 10-Q

#### PART I - Financial Information

	Condensed Consolidated Balance Sheets (Unaudited) as of March 31, 2013 and June 30, 2012	3
	Condensed Consolidated Statements of Income and Comprehensive Income (Unaudited) for the three and nine months ended March 31, 2013 and 2012	4
	Condensed Consolidated Statements of Cash Flows (Unaudited) for the nine months ended March 31, 2013 and 2012	5
	Notes to Condensed Consolidated Financial Statements (Unaudited)	6
Item 2.	Management s Discussion and Analysis of Financial Condition and Results of Operations	14
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	21
Item 4.	Controls and Procedures	21
	PART II - Other Information	
Item 1.	Legal Proceedings	22
Item 1A.	Risk Factors	22
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	23
Item 3.	Defaults Upon Senior Securities	23
Item 4.	Mine Safety Disclosures	23
Item 5.	Other Information	23
Item 6.	Exhibits	23
<u>Signatures</u>		24

Page

#### MYRIAD GENETICS, INC. AND SUBSIDIARIES

#### CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)

(In thousands, except per share amounts)

(In thousands, except per share amounts)	March 31, 2013		June 30, 20	
Assets	1,111		<i>v</i> u	
Current assets:				
Cash and cash equivalents	\$	112,323	\$	86,352
Marketable investment securities		223,834		254,180
Prepaid expenses		1,541		1,713
		7,136		11,574
Trade accounts receivable, less allowance for doubtful accounts of \$6,300 at Mar. 31, 2013 and \$4,600		02 172		60 441
at Jun. 30, 2012		93,172		60,441
Deferred taxes		7,512		5,572
Other receivables		2,187		2,660
Total current assets		447,705		422,492
Equipment and leasehold improvements:				
Equipment		62,828		54,728
Leasehold improvements		18,246		17,800
		81,074		72,528
Less accumulated depreciation		54,199		48,297
Net equipment and leasehold improvements		26,875		24,231
Long-term marketable investment securities		126,120		113,692
Long-term deferred taxes		28,953		30,648
Note receivable		21,000		19,000
Other assets		8,000		8,000
Intangibles, net		13,525		15,722
Goodwill		56,850		56,850
Total assets	\$	729,028	\$	690,635
Liabilities and Stockholders Equity				
Current liabilities:				
Accounts payable	\$	12,238	\$	10,141
Accrued liabilities	Ŷ	38,352	Ŷ	32,772
Deferred revenue		3,031		2,054
Total current liabilities		53,621		44,967
		,-		, ·
Unrecognized tax benefits		10,478		10,008
Total liabilities		64,099		54,975
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 Mar. 31, 2013 and Jun. 30, 2012, issued and outstanding 79,816 at Mar. 31, 2013 and 82,569 at Jun. 30, 2012		797		826

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

Additional paid-in capital	662,541		647,680
Accumulated other comprehensive loss	(459	)	(162)
Retained earnings (accumulated deficit)	2,050	1	(12,684)
Total stockholders equity	664,929	I	635,660
	\$ 729,028	\$	690,635

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

#### MYRIAD GENETICS, INC. AND SUBSIDIARIES

#### CONDENSED CONSOLIDATED STATEMENTS OF INCOME AND COMPREHENSIVE INCOME (UNAUDITED)

(In thousands, except per share amounts)	Mar	onths Ended ch 31,	Nine Mon Marc	h 31,
	2013	2012	2013	2012
Molecular diagnostic testing	\$ 148,384	\$ 123,312	\$ 416,304	\$ 344,891
Companion diagnostic services	8,088	6,465	22,746	18,149
Total revenue	156,472	129,777	439,050	363,040
Costs and expenses:				
Cost of molecular diagnostic testing	16,462	13,465	45,960	37,580
Cost of companion diagnostic services	3,872	3,763	11,585	10,127
Research and development expense	13,618	11,753	39,125	30,502
Selling, general, and administrative expense	64,602	54,700	180,294	151,799
Total costs and expenses	98,554	83,681	276,964	230,008
Operating income	57,918	46,096	162,086	133,032
Other income (expense):				
Interest income	1,434	1,379	4,187	3,235
Other	(111)	6	(224)	(199)
	1 222	1 205	2.0(2	2.026
Total other income	1,323	1,385	3,963	3,036
Income before income taxes	59,241	47,481	166,049	136,068
Income tax provision	21,349	17,866	62,984	53,059
Net income	\$ 37,892	\$ 29,615	\$ 103,065	\$ 83,009
Earnings per share:				
Basic	\$ 0.47	\$ 0.35	\$ 1.27	\$ 0.98
Diluted	\$ 0.46	\$ 0.34	\$ 1.23	\$ 0.96
Weighted average shares outstanding				
Basic	80,375	84,403	81,219	84,715
Diluted	82,434	86,462	83,544	86,537
Net income	\$ 37,892	\$ 29,615	\$ 103,065	\$ 83,009
Comprehensive income:				
Unrealized gain (loss) on available-for-sale securities, net of tax	259	63	268	(138)
Change in foreign currency translation adjustment, net of tax	(497)	91	(566)	(112)
			(200)	()
Comprehensive income	\$ 37,654	\$ 29,769	\$ 102,767	\$ 82,759

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

#### MYRIAD GENETICS, INC. AND SUBSIDIARIES

#### CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

	Nine Mon Marc	
(In thousands)	2013	2012
Cash flows from operating activities:		
Net income	\$ 103,065	\$ 83,009
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	6,635	6,741
Loss on disposition of assets	4	206
Share-based compensation expense	20,435	19,859
Bad debt expense	23,103	17,491
Non-cash expense related to in-process research and development technology		750
Impairment of intangible asset	1,490	
Accreted interest on note receivable	(2,000)	(1,333)
Unrecognized tax benefits	470	560
Excess tax benefit from share-based compensation	(5,265)	(32,197)
Deferred income taxes	5,020	34,199
Gain on sale of marketable investment securities	,	(566)
Changes in operating assets and liabilities:		()
Prepaid expenses	178	776
Trade accounts receivable	(55,834)	(18,186)
Other receivables	473	(1,152)
Prepaid taxes		(10,633)
Inventory	4,438	(2,180)
Accounts payable	2,097	(3,456)
Accrued liabilities	5,580	6,150
Deferred revenue	977	63
Net cash provided by operating activities	110,866	100,101
Cash flows from investing activities:		
Capital expenditures for equipment and leasehold improvements	(8,582)	(7,216)
Acquisition of Myriad RBM, Inc.		(799)
Crescendo purchase option		(8,000)
Issuance of note receivable (Crescendo)		(17,000)
Purchase of in-process research and development technology		(750)
Purchase of other assets		(100)
Purchases of marketable investment securities	(281,774)	(290,854)
Proceeds from maturities and sales of marketable investment securities	299,395	294,005
Net cash provided by (used in) investing activities	9,039	(30,714)
Cash flows from financing activities:		
Net proceeds from common stock issued under share-based compensation plans	25,506	18,058
Excess tax benefit from share-based compensation	5,265	32,197
Repurchase and retirement of common stock	(124,705)	(67,471)
Net cash used in financing activities	(93,934)	(17,216)
Net increase in cash and cash equivalents	25,971	52,171

Cash and cash equivalents at beginning of period	86,352	52,681
Cash and cash equivalents at end of period	\$ 112,323	\$ 104,852

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

#### 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. 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, 2012, included in the Company s Annual Report on Form 10-K for the fiscal year ended June 30, 2012. Operating results for the three and nine months ended March 31, 2013 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) Marketable Investment Securities

The Company has classified its marketable investment securities as available-for-sale securities. 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 loss in stockholders equity until realized. Gains and losses on investment security transactions are reported on the specific-identification method. Dividend and interest income are recognized when earned.

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 March 31, 2013 and June 30, 2012 were as follows:

	Amortized	Gross unrealized holding	Gross unrealized holding	Estimated
(In thousands)	cost	gains	losses	fair value
At March 31, 2013:				
Cash and cash equivalents:				
Cash	\$ 31,119	\$	\$	\$ 31,119
Cash equivalents	81,202	2		81,204
Total cash and cash equivalents	112,321	2		112,323
Available-for-sale securities:				
Corporate bonds and notes	56,378	55	(4)	56,429
Municipal bonds	214,910	335	(4)	215,241
Federal agency issues	76,895	39		76,934
Auction rate securities	1,500		(150)	1,350
Total available-for-sale securities	349,683	429	(158)	349,954
Total cash, cash equivalents and available-for-sale securities	\$ 462,004	\$ 431	\$ (158)	\$ 462,277

	Amortized	Gross unrealized holding	Gross unrealized holding	Estimated
(In thousands)	cost	gains	losses	fair value
At June 30, 2012:		-		
Cash and cash equivalents:				
Cash	\$ 34,217	\$	\$	\$ 34,217
Cash equivalents	52,135			52,135
Total cash and cash equivalents	86,352			86,352
	, ,			
Available-for-sale securities:				
Corporate bonds and notes	116,581	112	(18)	116,675
Municipal bonds	141,299	85	(20)	141,364
Federal agency issues	108,478	33	(28)	108,483
Auction rate securities	1,500		(150)	1,350
Total available-for-sale securities	367,858	230	(216)	367,872
	,			
Total cash, cash equivalents and available-for-sale securities	\$ 454,210	\$ 230	\$ (216)	\$ 454,224

Cash, cash equivalents, and maturities of debt securities classified as available-for-sale securities are as follows at March 31, 2013:

(In thousands)	Amortized cost	Estimated fair value
Cash	\$ 31,119	\$ 31,119
Cash equivalents	81,202	81,204
Available-for-sale:		
Due within one year	223,711	223,834
Due after one year through five years	124,472	124,770
Due after five years	1,500	1,350
	\$ 462,004	\$462,277

#### (3) Share-Based Compensation

The Company maintains a share-based compensation plan, the 2010 Employee, Director and Consultant Equity Incentive Plan, as amended (the 2010 Plan ), that has been approved by the Company s shareholders. The 2010 Plan allows the Company, under the direction of the Compensation Committee of the Board of Directors, to make grants of stock options, restricted and unrestricted stock awards and other stock-based awards to employees, consultants and directors. On December 5, 2012, the shareholders approved an amendment to the 2010 Plan to set the number of shares available for grant to 4,500,000. At March 31, 2013, 4,519,590 shares were available for issuance. In addition, as of March 31, 2013, the Company may grant up to 8,811,530 additional shares under the 2010 Plan if options previously granted under the Company s 2003 Employee, Director and Consultant Option Plan and 2002 Amended and Restated Employee, Director and Consultant Stock Option Plan are cancelled or expire without the issuance of shares of common stock by the Company.

The number of shares, terms, and vesting period of awards under the 2010 Plan are determined by the Compensation Committee of the Board of Directors for each equity award. Options under the plan generally vest ratably over four years and expire ten years from the grant date. On December 5, 2012, the shareholders approved an amendment to the 2010 Plan to change the term of all future awards to eight years. The exercise price of options granted is equivalent to the fair market value of the stock on the grant date.

The Company also had an Employee Stock Purchase Plan that was approved by shareholders in 1995 (the 1995 Purchase Plan ), and subsequently amended, under which 2,000,000 shares of common stock had been authorized. As of December 5, 2012, a total of 1,990,000 shares of common stock had been issued under the 1995 Purchase Plan when it was terminated. On December 5, 2012, the shareholders

approved the 2012

Employee Stock Purchase Plan (the 2012 Purchase Plan ) under which 2,000,000 shares of common stock has been authorized. Shares are issued under the 2012 Purchase Plan twice yearly at the end of each offering period. As of March 31, 2013, no shares of common stock have been issued under the 2012 Purchase Plan.

A summary of the stock option activity under the Company s plans for the nine months ended March 31, 2013 is as follows:

	Number of shares	Weighted average exercise price
Options outstanding at June 30, 2012	15,233,281	\$ 19.32
Options granted	2,897,623	27.11
Less:		
Options exercised	1,818,004	13.14
Options canceled or expired	238,296	22.18
Options outstanding at March 31, 2013	16,074,604	\$ 21.38

As of March 31, 2013, options to purchase 9,122,023 shares were vested and exercisable at a weighted average price of \$20.11. As of March 31, 2013, there was \$42,009,000 of total unrecognized share-based compensation expense related to share-based awards granted under the Company s plans that will be recognized over a weighted-average period of 2.5 years.

Share-based compensation expense recognized and included in the condensed consolidated statements of income was allocated as follows:

(In thousands)	Three months ended March 31, 2013 2012				arch 31, March 31,	
	2010	2012	2010	2012		
Cost of molecular diagnostic testing	\$ 252	\$ 285	\$ 811	\$ 878		
Cost of companion diagnostic services	54	20	159	39		
Research and development expense	818	818	2,496	2,574		
Selling, general, and administrative expense	5,607	5,465	16,969	16,368		
Total share-based compensation expense	\$ 6,731	\$ 6,588	\$ 20,435	\$ 19,859		

#### (4) <u>Stockholders Equity</u>

#### Stock Repurchase Program

In January 2013, the Company completed its fourth share repurchase program, which authorized the repurchase of up to \$200 million of the Company s common stock. In February 2013, the Company s Board of Directors authorized a fifth share repurchase program of \$200 million of the Company s outstanding common stock. The Company plans to repurchase the \$200 million of its common stock from time to time or on an accelerated basis through open market transactions or privately negotiated transactions as determined by the Company s management. The amount and timing of stock repurchases under the program will depend on business and market conditions, stock price, trading restrictions, acquisition activity and other factors. As of March 31, 2013, approximately \$174.9 million remained available for repurchases under the fifth program. The Company uses the par value method of accounting for its stock repurchases. As a result of the stock repurchases, the Company reduced common stock and additional paid-in capital and recorded charges to retained earnings (accumulated deficit). The shares retired, aggregate common stock and additional paid-in capital reductions, and related

charges to retained earnings (accumulated deficit) for the repurchases for the three and nine months ended March 31, 2013 and 2012 were as follows:

(In thousands)		ths ended h 31,	Nine months ended March 31,		
	2013	2012	2013	2012	
Shares purchased and retired	1,738	502	4,805	3,114	
Common stock and additional paid-in-capital reductions	\$ 13,252	\$ 3,732	\$ 36,374	\$ 23,004	
Charges to retained earnings (accumulated deficit)	\$ 31,571	\$ 8,273	\$ 88,331	\$ 44,468	

#### (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 the dilutive effect of common stock equivalents outstanding.

The following is a reconciliation of the denominators of the basic and diluted earnings per share computations:

(In thousands)	Three months ended March 31,		March 31	
	2013	2012	2013	2012
Denominator:				
Weighted-average shares outstanding used to compute basic earnings per share	80,375	84,403	81,219	84,715
Effect of dilutive stock options	2,059	2,059	2,325	1,822
Weighted-average shares outstanding and dilutive securities used to compute dilutive earnings per share	82,434	86,462	83,544	86,537

Certain outstanding stock options were excluded from the computation of diluted earnings per share for the three and nine months ended March 31, 2013 and 2012 because the effect would have been anti-dilutive. These potential dilutive common shares, which may be dilutive to future diluted earnings per share, are as follows:

	Three months end	led Nine m	nonths ended,
	March 31,	March 31, March 3	
(In thousands)	2013 201	2 2013	2012
Anti-dilutive options excluded from EPS computation	5,797 7,5	689 4,975	5 8,639

#### (6) Segment and Related Information

The Company s business units have been aggregated into three reportable segments: (i) research, (ii) molecular diagnostics and (iii) companion diagnostics. The research segment is focused on the discovery of genes, biomarkers and proteins related to major common diseases and includes corporate services such as finance, human resources, legal, and information technology. The molecular diagnostics segment provides testing that is designed to assess an individual s risk for developing disease later in life, identify a patient s likelihood of responding to drug therapy and guide a patient s dosing to ensure optimal treatment, or assess a patient s risk of disease progression and disease recurrence. The companion diagnostics segment provides testing products and services to the pharmaceutical, biotechnology and medical research industries. The Company evaluates segment performance based on results from operations before interest income and expense and other income and expense.

(In thousands) Three months ended March 31, 2013:	Research	Molecular diagnostics	Companion diagnostics	Total
Revenue	\$	\$ 148,384	\$ 8,088	\$ 156,472
Depreciation and amortization	1,210	2,424	821	4,455
Segment operating income (loss)	(17,224)	76,165	(1,023)	57,918
Three months ended March 31, 2012:				
Revenue	\$	\$ 123,312	\$ 6,465	\$ 129,777
Depreciation and amortization	567	1,310	426	2,303
Segment operating income (loss)	(15,199)	63,282	(1,987)	46,096
Nine months ended March 31, 2013:				
Revenue	\$	\$ 416,304	\$ 22,746	\$ 439,050
Depreciation and amortization	1,818	3,543	1,274	6,635
Segment operating income (loss)	(47,989)	214,195	(4,120)	162,086
Nine months ended March 31, 2012:				
Revenue	\$	\$ 344,891	\$ 18,149	\$ 363,040
Depreciation and amortization	1,591	3,909	1,241	6,741
Segment operating income (loss)	(40,500)	179,200	(5,668)	133,032

	Three months ended		Nine mon	ths ended
	Marc	h 31,	Marc	h 31,
(In thousands)	2013	2012	2013	2012
Total operating income for reportable segments	\$ 57,918	\$ 46,096	\$ 162,086	\$ 133,032
Interest income	1,434	1,379	4,187	3,235
Other	(111)	6	(224)	(199)
Income tax provision	21,349	17,866	62,984	53,059
Net income	\$ 37,892	\$ 29,615	\$ 103,065	\$ 83,009

#### (7) Fair Value Measurements

The fair value of the Company s financial instruments reflects the amounts that the Company estimates it will receive in connection with the sale of an asset or pay 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. This category generally includes U.S. Government and agency securities; municipal securities; mutual funds and securities sold and not yet settled. The Company s marketable securities primarily utilize broker quotes in a non-active market for valuation of these securities.
- Level 3 unobservable inputs.

The substantial majority of the Company s financial instruments are valued using quoted prices in active markets or based on other observable inputs. For Level 2 securities, the Company uses a third party pricing service which provides documentation on an ongoing basis that includes, among other things, pricing information with respect to reference data, methodology, inputs summarized by asset class, pricing application and corroborative information. The Company reviews, tests and validates this information. The following table sets forth the fair value of the financial assets that the Company re-measured on a regular basis:

(In thousands)	Level 1	Level 2	Level 3	Total
at March 31, 2013				
Money market funds (a)	\$ 3,169	\$	\$	\$ 3,169
Corporate bonds and notes		126,427		126,427
Municipal bonds		223,278		223,278
Federal agency issues		76,934		76,934
Auction rate securities			1,350	1,350
Total	\$ 3,169	\$ 426,639	\$ 1,350	\$ 431,158
(In thousands)	Level 1	Level 2	Level 3	Total
at June 30, 2012				
Money market funds (a)	\$ 38,835	\$	\$	\$ 38,835
Corporate bonds and notes		129,975		129,975
Municipal bonds		141,364		141,364
Federal agency issues		108,483		108,483
Auction rate securities			1,350	1,350

(a) Money market funds are primarily comprised of exchange traded funds and accrued interest

#### (8) Commitments and Contingencies

The Company is subject to various claims and legal proceedings covering matters that arise in the ordinary course of its business activities. As of March 31, 2013, the management of the Company believes any liability that may ultimately result from the resolution of these matters will not have a material adverse effect on the Company s consolidated financial position, operating results, or cash flows.

#### (9) Income Taxes

In order to determine the Company s quarterly provision for income taxes, the Company used an estimated annual effective tax rate that is based on expected annual income and statutory tax rates in the various jurisdictions in which the Company operates. Certain significant or unusual items are separately recognized in the quarter during which they occur and can be a source of variability in the effective tax rates from quarter to quarter.

Income tax expense for the three months ended March 31, 2013 was \$21,349,000, or approximately 36% of pre-tax income, compared to \$17,866,000, for the three months ended March 31, 2012, or approximately 38% of pre-tax income. Income tax expense for the nine months ended March 31, 2013 was \$62,984,000, or approximately 38% of pre-tax income, compared to \$53,059,000 for the nine months ended March 31, 2012, or approximately 38% of pre-tax expense for the nine months ended March 31, 2012, or approximately 39% of pre-tax income. Income tax expense for the three and nine months ended March 31, 2013 is based on

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

the Company s estimated annual effective tax rate for the full fiscal year ending June 30, 2013, adjusted by discrete items recognized during the period. The Company s effective tax rate differs from the U.S. federal statutory rate of 35% primarily due to state income taxes, research and development credits realized from the retro-active extension of the credit in January 2013, as well as timing differences related to the recognition of the tax effect of equity compensation expense from incentive stock options and the deduction realized if those options are disqualified upon exercise and sale.

The Company files U.S., U.K., France and state income tax returns in jurisdictions with various statutes of limitations. The Company s New York State income tax returns for the years ended June 30, 2007, 2008 and 2009 are currently under examination by the New York State Department of Taxation and Finance. Annual and interim tax provisions include amounts considered necessary to pay assessments that may result from examination

of prior year tax returns; however, the amount ultimately paid upon resolution of issues may differ materially from the amount accrued. The Company s U.S. federal tax return, U.K. and France income tax returns and all other state tax returns are not currently under examination.

#### (10) <u>Goodwill and Intangible Assets</u> Goodwill

At March 31, 2013, the Company had recorded goodwill of \$56,850,000 related to the acquisition of Myriad RBM, Inc. on May 31, 2011 (formerly Rules-Based Medicine, Inc.). There were no events or circumstances that indicated that impairment exists: therefore, the Company recorded no impairment of goodwill for the three months and nine months ended March 31, 2013.

#### Intangible Assets

Intangible assets primarily consist of amortizable assets of purchased licenses and technologies, and customer relationships as well as non-amortizable intangible assets of in-process technologies, research and development and trademarks. Certain of these intangible assets were recorded as part of the Company s purchase of Rules-Based Medicine, Inc. on May 31, 2011. In December 2012, the Company notified the licensor of the Company s OnDose product of the Company s intent to terminate the license agreement, and as a result, recorded an impairment charge of approximately \$1,490,000 associated with the purchased license agreement. The fair value was estimated for the license agreement using the undiscounted future cash flows method, under which the Company determined that the fair value was less than the carrying value. The impairment is included in research and development in the condensed consolidated statement of income and is part of the molecular diagnostic segment. The following summarizes the amounts reported as intangible assets:

(In thousands) March 31, 2013	Gross Carrying Amount		cumulated	Net
Purchased licenses and technologies	\$ 4,500	\$	(2,565)	\$ 1,935
6	. ,	φ		
Customer relationships	4,650		(860)	3,790
Total amortizable intangible assets	9,150		(3,425)	5,725
Trademarks	3,000			3,000
In-process research and development	4,800			4,800
Total non-amortizable intangible assets	7,800			7,800
Total intangible assets	\$ 16,950	\$	(3,425)	\$ 13,525

(In thousands) June 30, 2012	Gross Carrying Amount	Accumulated Amortization	Net
Purchased licenses and technologies	\$ 6,500	\$ (2,724)	\$ 3,776
Customer relationships	4,650	(504)	4,146
Total amortizable intangible assets	11,150	(3,228)	7,922
Trademarks	3,000		3,000
In-process research and development	4,800		4,800
Total non-amortizable intangible assets	7,800		7,800

Total intangible assets	\$ 18,950	\$ (3,228)	\$ 15,722

The Company recorded amortization during the respective periods for these intangible assets as follows:

(In thousands)		Three months ended March 31,		Nine months ended March 31,	
	2013	2012	2013	2012	
Amortization on intangible assets	\$ 194	\$ 275	\$ 701	\$ 825	

#### (11) Term Loan and Option Agreement

On September 8, 2011, the Company issued a \$25,000,000 term loan to Crescendo Bioscience, Inc. (Crescendo) of South San Francisco, CA under a Loan and Security Agreement (Loan Agreement) and also secured an exclusive three-year option to acquire the company pursuant to a definitive merger agreement (the Option Agreement). During the fiscal quarter ended September 30, 2012, the Loan Agreement was amended to increase the stated interest rate from 6% to 7% per year. The fair value of the Option Agreement of \$8,000,000 was determined utilizing valuation models at the time of the issuance, including the market and income based approaches, which utilize various inputs including projected income, volatility, risk free rates and projected terms. The Company periodically evaluates the Option Agreement for impairment. No impairment indicators were noted at March 31, 2013.

The residual \$17,000,000 value of the term loan has been classified as a note receivable at its accreted value of \$21,000,000 on the condensed consolidated balance sheet as of March 31, 2013. The Company recorded interest income related to accretion of the note receivable and the stated interest rate for the three and nine months ended March 31, 2013 of \$1,104,000 and \$3,306,000, respectively, in the condensed consolidated statement of income. The Company is utilizing the effective interest method to accrete the discount portion of the note receivable through interest income over the three-year term of the Company s option to acquire Crescendo under the Option Agreement. The note receivable is evaluated for collectability each reporting period. If the Company determines that the note receivable and any accrued interest is not collectible, such amount will be written off in the period that determination is made. No amounts related to the note receivable or accrued interest were written off during the three or nine months ended March 31, 2013.

#### (12) Subsequent Event

In April 2013, the Company acquired approximately 28 million shares of Series E preferred stock of RainDance Technologies (RainDance) of Lexington, Massachusetts, for \$5.0 million. The Series E shares represent less than 5% of the total shares outstanding of RainDance s capital stock. The Company will record the investment at cost and periodically evaluate the investment for impairment. RainDance provides high-throughput picodroplet-based technology that can encapsulate a single molecule, cell or reaction and be digitally analyzed and sorted one at a time.

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

We are a leading molecular diagnostic company dedicated to making a difference in patients lives through the discovery and commercialization of transformative tests which assess a person s risk of developing disease, guide treatment decisions and assess risk of disease progression and recurrence. We believe in improving healthcare for patients by providing physicians with critical information to solve unmet medical needs. By understanding the underlying genetic basis of disease, we believe that individuals who have a greater risk of developing disease can be identified and physicians may be able to use this information to improve patient outcomes and better manage patient healthcare. In addition, by understanding the RNA expression levels of certain genes, we believe that we can improve patient healthcare by providing information on the aggressiveness of their disease. Further, we believe that the analysis of the expression of groups of proteins may provide a physician with life-saving information to guide treatment decisions for their patients with cancer and other major diseases.

Our goal is to provide physicians with this critical information that may guide the healthcare management of their patients to prevent disease, diagnose the disease at an earlier stage, determine the most appropriate therapy, or assess the aggressiveness of their disease. We employ a number of proprietary technologies, including DNA, RNA and protein analysis, 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 and progression of disease. We use this information to guide the development of new molecular diagnostic tests that are designed to assess an individual s risk for developing disease later in life (predictive medicine), identify a patient s likelihood of responding to drug therapy and guide a patient s dosing to ensure optimal treatment (personalized medicine), or assess a patient s risk of disease progression and disease recurrence (prognostic medicine).

Our business strategy for future growth is focused on three key initiatives. First, we are working to grow and expand our existing products and markets. Second, we are developing our business internationally and have recently established operations in Europe. Finally, we intend to launch new transformative products across a diverse set of disease indications, complementing our current businesses in oncology, women s health and urology.

#### Products and Services

We offer nine primary commercial molecular diagnostic tests, including six predictive medicine tests, two personalized medicine tests, and one prognostic medicine test. We market these tests through our own sales force of approximately 390 people in the United States. We have also established offices in France, Spain, United Kingdom and Italy; laboratory operations and a sales and administrative office in Germany; and international headquarters in Switzerland. We market our BRAC*Analysis*<sup>®</sup>, COLARIS<sup>®</sup>, and COLARIS AP<sup>®</sup> products through our own European sales force, and as of March 31, 2013, we have entered into distributor agreements with organizations in select Latin American, European, Asian and African countries.

Our nine commercial molecular diagnostic tests include:

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

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

COLARIS AP<sup>®</sup>, our predictive medicine test for hereditary colorectal cancer;

MELARIS®, our predictive medicine test for hereditary melanoma;

PANEXIA , our predictive medicine test for pancreatic cancer;

PREZEON®, our personalized medicine test to assess PTEN status for disease progression and drug response;

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

Prolaris®, our prognostic medicine test for prostate cancer;

Theraguide® 5-FU, our personalized medicine test for chemotherapy toxicity to 5-FU; and

*BART*, our predictive medicine test for detecting large genomic rearrangements in the genes involved in hereditary breast and ovarian cancer patients, for which we have received increased testing requests from physicians and affected patients.

Through our wholly owned subsidiary, Myriad RBM, Inc., we provide biomarker discovery and companion diagnostic services to the pharmaceutical, biotechnology, and medical research industries utilizing our multiplexed immunoassay technology. Our technology enables us to efficiently screen large sets of clinical samples from both diseased and non-

diseased populations against our extensive menu of biomarkers. By analyzing the data generated from these tests, we attempt to discover biomarker patterns that indicate a particular disease or disorder with a high degree of accuracy or may be used to identify patients who would likely respond to a particular therapy. In addition to the companion diagnostic research revenue received from analyzing these samples, we also use this information to create and validate new biomarkers that can aid us in the development of novel molecular diagnostic tests that could aid a physician in making diagnostic and treatment decisions.

#### Use of Resources

During the three and nine months ended March 31, 2013, we devoted substantially all of our resources to supporting our molecular diagnostic and companion diagnostic businesses, as well as to the research and development of future molecular and companion diagnostic opportunities. We also pursued in-licensing opportunities where we acquire rights to new products and technologies from third parties. We have three reportable operating segments research, molecular diagnostics and companion diagnostics. See Note 6 Segment and Related Information in the notes to our condensed consolidated financial statements (unaudited) for information regarding these operating segments.

For the three and nine months ended March 31, 2013, we had net income of \$37.9 million and \$103.1 million and diluted earnings per share of \$0.46 and \$1.23, compared to net income of \$29.6 million and \$83.0 million and diluted earnings per share of \$0.34 and \$0.96 per share in the same periods in the prior year. Net income and diluted earnings per share results for the three and nine months ended March 31, 2013 included income tax expense of \$21.3 million and \$63.0 million compared to \$17.9 million and \$53.1 million for the same periods in the prior year.

#### Share Repurchase

Between May 2010 and January 2013, we repurchased \$500 million of our outstanding common stock. In February 2013, we announced that our board of directors authorized us to repurchase an additional \$200 million of our outstanding common stock and have repurchased an additional \$25.1 million of our outstanding common stock under this repurchase plan during the three months ended March 31, 2013. In connection with this fifth stock repurchase authorization, we have been authorized to repurchase shares from time to time or on an accelerated basis through open market transactions or privately negotiated transactions as determined by the our management. The amount and timing of stock repurchases under the program will depend on business and market conditions, stock price, trading restrictions, acquisition activity and other factors. See also Part II, Item 2. Unregistered Sales of Equity Securities and Use of Proceeds Issuer Purchases of Equity Securities.

#### **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. No significant changes to our accounting policies took place during the period. For a further discussion of our critical accounting policies, see our Annual Report on Form 10-K for the fiscal year ended June 30, 2012.

#### Results of Operations for the Three Months Ended March 31, 2013 and 2012

#### Revenue

Revenue is comprised of sales of our molecular diagnostic tests and our companion diagnostic services. Total revenue for the three months ended March 31, 2013 was \$156.5 million, compared to \$129.8 million for the same three months in 2012. This 21% increase in revenue is primarily due to increased molecular diagnostic testing volume for our BRACAnalysis, Colaris and Colaris AP, a significant increase in BART testing volume, and a significant increase in companion diagnostic services due to increased research collaborations, as disclosed in the table below. We believe that our increased sales, marketing, and education efforts resulted in wider acceptance of our molecular diagnostic tests by the medical community and increased patient testing volumes. However, there can be no assurance that our revenue will continue to increase or remain at current levels.

Total revenue of our molecular diagnostic tests and companion diagnostic services and revenue by product as a percent of total revenue for the three months ended March 31, 2013 and 2012 were as follows:

		onths ended rch 31,		% of Total	Revenue
(In thousands)	2013	2012	% Change	2013	2012
Molecular diagnostic testing revenues:			-		
BRACAnalysis	\$ 115,387	\$ 105,894	9%	74%	81%
COLARIS & COLARIS AP	13,280	11,189	19%	8%	9%
BART	16,923	3,442	392%	11%	3%
Other	2,794	2,787	0%	2%	2%
Total molecular diagnostic testing revenues	148,384	123,312	20%		
Companion diagnostic service revenues	8,088	6,465	25%	5%	5%
Total revenues	\$ 156,472	\$ 129,777	21%	100%	100%

Our molecular diagnostic sales force is focused on two major markets, oncology and women s health. Oncology and women s health revenues were 65% and 35% of total molecular diagnostic testing revenues, respectively, during the three months ended March 31, 2013. Sales of molecular diagnostic tests in each market for the three months ended March 31, 2013 and 2012 were as follows:

	Three mor	Three months ended			
	Marc	h 31,			
(In thousands)	2013	2012	% Change		
Molecular diagnostic testing revenues:					
Oncology	\$ 95,776	\$ 84,416	13%		
Women s health	52,608	38,896	35%		
Total molecular diagnostic testing revenues	\$ 148,384	\$ 123,312	20%		

Certain prior period reclassifications to oncology and women s health revenue have been made to conform to current period presentation.

#### Costs and Expenses

Cost of revenue is comprised primarily of salaries and related personnel costs, laboratory supplies, royalty payments, equipment costs and facilities expense. Cost of molecular diagnostic testing revenue for the three months ended March 31, 2013 was \$16.5 million, compared to \$13.5 million for the same three months in 2012. This increase of 22% in molecular diagnostic testing cost of revenue is due to an increase in testing volumes. Our costs of companion diagnostic services include similar items. Cost of companion diagnostic services for the three months ended March 31, 2013 was \$3.9 million, compared to \$3.8 million for the same three months in 2012. This 3% increase in companion diagnostic testing cost of revenue is to support the 25% increase in companion diagnostic revenues. Many of the costs associated with the performance of our companion diagnostic services are fixed; consequently, gross margins will vary as we experience fluctuations in our companion diagnostic service revenue.

Our cost of revenue may also fluctuate from quarter to quarter based on the introduction of new molecular diagnostic tests, testing volumes, changes in companion diagnostic services, price changes of existing tests and services, changes in our costs associated with such tests and services, the adoption of new technologies and operating systems in our molecular diagnostic laboratories and costs associated with operating our German laboratory. There can be no assurance that gross profit margins will remain at current levels.

Our research and development expenses include costs incurred in maintaining and improving our current molecular diagnostic tests and costs incurred for the discovery, validation and development of our pipeline of molecular and companion diagnostic test candidates. Research and development expenses are comprised primarily of salaries and related personnel costs, laboratory supplies, clinical trial costs, equipment, and

#### Table of Contents

facilities costs. Research and development

expenses incurred during the three months ended March 31, 2013 were \$13.6 million compared to \$11.8 million for same three months in 2012. This increase of 16% was primarily due to the following:

an increase of approximately \$0.7 million due to the internal development of future molecular diagnostic product candidates

an increase of approximately \$0.6 million in internal development activities and clinical studies to support our existing molecular diagnostic testing products; and

an increase of approximately \$0.6 million in internal development activities to support our companion diagnostic services business. We expect that our research and development expenses will increase over the next several years as we continue to develop our pipeline and expand our offerings of molecular diagnostic tests and companion diagnostic services.

Our sales, general and administrative expenses include costs associated with building our molecular diagnostic and companion diagnostic businesses domestically and internationally. Selling, general and administrative expenses consist primarily of salaries, commissions and related personnel costs for sales, marketing, customer service, billing and collection, executive, legal, finance and accounting, information technology, human resources, and allocated facilities expenses. Selling, general and administrative expenses for the three months ended March 31, 2013 were \$64.6 million, compared to \$54.7 million for the same three months in 2012. The increase in selling, general and administrative expense of 18% was due primarily to supporting the 21% increase in revenue and include:

an increase in sales and marketing expense of approximately \$5.8 million due to various marketing initiatives, added sales force headcount and increased sales commissions associated with the increase in revenues;

an increase of approximately \$1.5 million in international administrative costs from our international operations;

an increase of approximately \$1.5 million in bad debt expense; and

an increase of approximately \$1.1 million in other general administrative expenses.

We expect that our selling, general and administrative expenses will continue to fluctuate from quarter to quarter and that such increases may be substantial, depending on the number and scope of any new molecular diagnostic and companion diagnostic launches, our efforts in support of our existing molecular diagnostic tests and companion diagnostic services as well as our continued international expansion efforts.

#### Other Income (Expense)

Interest income was \$1.4 million for both the three months ended March 31, 2013 and March 31, 2012. Interest income consists primarily of interest income recorded from the note receivable from Crescendo Bioscience, Inc.

#### Income Tax Provision

Income tax expense for the three months ended March 31, 2013 was \$21.3 million, for an effective income tax rate of approximately 36%, compared to income tax expense of \$17.9 million or a 38% effective income tax rate in the same period in 2012. Our quarterly effective tax rate is a sum of the U.S. federal statutory rate of 35% and a blended state income tax rate of 4% offset by certain discrete items that are required to be separately recognized during the quarter in which they occurred. In January 2013, the research and development tax credit was reinstated and was retroactive for research and development activities from January 1, 2012 through the current period. As a result of this reinstituted credit, during the period ended March 31, 2013 we recognized approximately \$1.0 million in additional R&D tax credit benefits that offset our current period tax expense. In addition, the current period income tax expense was benefited from the recognition of deductions from permanent

#### Table of Contents

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

differences generated from the exercise and disqualification of incentive stock options. Certain significant or unusual items are separately recognized during the period in which they occur and can be a source of variability in the effective tax rates from quarter to quarter.

#### Results of Operations for the Nine Months Ended March 31, 2013 and 2012

#### Revenue

Total revenue for the nine months ended March 31, 2013 was \$439.1 million, compared to \$363.0 million for the same nine months in 2012. This 21% increase is primarily due to increased molecular diagnostic testing volume for our BRACAnalysis, Colaris and Colaris AP, BART and other tests, as well as an increase in companion diagnostic testing revenues as a result of increased research collaborations, as disclosed in the table below.

Total revenue of our molecular diagnostic tests and companion diagnostic services for the nine months ended March 31, 2013 and 2012 were as follows:

	Nine months ended				
	March 31,			% of Total Revenue	
(In thousands)	2013	2012	% Change	2013	2012
Molecular diagnostic testing revenues:					
BRACAnalysis	\$ 330,626	\$ 296,789	11%	75%	82%
COLARIS & COLARIS AP	37,424	31,736	18%	9%	9%
BART	40,327	8,998	348%	9%	2%
Other	7,927	7,368	8%	2%	2%
Total molecular diagnostic testing revenues	416,304	344,891	21%		
Companion diagnostic service revenues	22,746	18,149	25%	5%	5%
Total revenues	\$ 439,050	\$ 363,040	21%	100%	100%

Oncology and women s health revenues were 65% and 35% of total molecular diagnostic testing revenues, respectively, during the nine months ended March 31, 2013. Sales of molecular diagnostic tests in each market for the nine months ended March 31, 2013 and 2012 were as follows:

(In thousands)	Nine months ended March 31,				
	2013	2012	% Change		
Molecular diagnostic testing revenues:					
Oncology	\$ 270,009	\$ 236,131	14%		
Women s health	146,295	108,760	35%		
Total molecular diagnostic testing revenues	\$ 416,304	\$ 344,891	21%		

Certain prior period reclassifications to oncology and women s health revenue have been made to conform to current period presentation.

#### Costs and Expenses

Cost of molecular diagnostic testing revenue for the nine months ended March 31, 2013 was \$46.0 million, compared to \$37.6 million for the same nine months in 2012. This increase of 22% in molecular diagnostic testing cost of revenue is primarily due to an increase in testing volumes. Cost of companion diagnostic services was \$11.6 million for the nine months ended March 31, 2013, compared to \$10.1 million for the nine months ended March 31, 2013. This 14% increase in companion diagnostic services cost of revenue is primarily due to an increase in companion diagnostic research revenue.

Research and development expenses incurred during the nine months ended March 31, 2013 were \$39.1 million compared to \$30.5 million for same nine months in 2012. This increase of 28% was primarily due to the following:

#### Table of Contents

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

an increase of approximately \$2.4 million due to the internal development of future molecular diagnostic product candidates;

an increase of approximately \$2.2 million in internal development activities and clinical studies to support our existing molecular diagnostic testing products;

an increase of approximately \$1.7 million in internal development activities to support our companion diagnostic services business;

an increase of approximately \$1.5 million related to the impairment of an intangible asset for the license agreement related to the OnDose product; and

an increase of approximately \$0.8 million for the acquisition of new products and licenses.

Selling, general and administrative expenses for the nine months ended March 31, 2013 were \$180.3 million, compared to \$151.8 million for the same nine months in 2012. The increase in selling, general and administrative expense of 19% was due primarily to support the increase in revenue and include:

an increase in sales and marketing expense of approximately \$18.6 million due to marketing initiatives, added sales force headcount and increased sales commissions associated with increased revenues;

an increase of approximately \$5.5 million in bad debt expense;

an increase of approximately \$3.8 million in international administrative costs from our international operations; and

an increase in share-based compensation expense of approximately \$0.6 million. *Other Income (Expense)* 

Interest income for the nine months ended March 31, 2013 was \$4.2 million, compared to \$3.2 million for the same nine months in 2012, an increase of 31%. The increase was due primarily to interest income recorded from the note receivable from Crescendo.

#### Income Tax Provision

Income tax expense for the nine months ended March 31, 2013 was \$63.0 million, for an effective income tax rate of approximately 38%, compared to income tax expense of \$53.1 million or a 39% effective income tax rate in the same period in 2012. Income tax expense for the nine months ended March 31, 2013 is based on our estimated annual effective tax rate for the full fiscal year ending June 30, 2013 adjusted by discrete items recognized during the period. Our annual effective tax rate is a sum of the U.S. federal statutory rate of 35% and a blended state income tax rate of 4% offset by certain discrete items. The nine month effective tax rate is primarily impacted by the reinstituted research and development tax credit as well as the from the recognition of deductions from permanent differences generated from the exercise and disqualification of incentive stock options. Certain significant or unusual items are separately recognized during the period in which they occur and can be a source of variability in the effective tax rates from period.

#### Liquidity and Capital Resources

Cash, cash equivalents, and marketable investment securities were \$462.3 million at March 31, 2013 compared to \$454.2 million at June 30, 2012, which is an increase of \$8.1 million, or 2%. This increase was attributable to increased collections from higher sales, partially offset by the purchase of \$124.7 million of our common stock under our share repurchase programs.

Net cash provided by operating activities was \$110.9 million during the nine months ended March 31, 2013, compared to \$100.1 million during the same nine months in 2012. Our net income was reduced by non-cash charges in the form of share-based compensation, intangible asset impairment and depreciation and amortization, which totaled \$20.4 million, \$1.5 million and \$6.6 million, respectively, during the nine months ended March 31, 2013. In addition, operating cash was reduced by an increase of \$55.8 million in trade accounts receivable due to an increase in days sales outstanding primarily due to delays in payment by Noridian Administrative Services, Inc., our Medicare administrative contractor for BRAC*Analysis* testing, while awaiting the finalization of revised Medicare pricing. Now that Medicare pricing has been determined for the new BRAC*Analysis* billing code, we expect our accounts receivable balance to normalize over the next few quarters and our days sales outstanding to return to more normalized levels of 45 days.

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

Our investing activities provided cash of \$9.0 million during the nine months ended March 31, 2013 and used cash of \$30.7 million during the same nine months in 2012. Investing activities were comprised primarily of purchases and sales and maturities of marketable investment securities. Capital expenditures for equipment and facilities for the nine months ended March 31, 2013 were \$8.6 million.

Financing activities used cash of \$93.9 million during the nine months ended March 31, 2013 and used cash of \$17.2 million in the same nine months in 2012. Cash utilized in financing activities during the nine months ended March 31, 2013 was primarily due to the purchase of \$124.7 million of our common stock through our share repurchase programs, partially offset by \$25.5 million from cash provided primarily by the exercise of stock options.

We believe that our existing capital resources and net cash expected to be generated from sales of our molecular diagnostic tests and companion diagnostic services will be adequate to fund our current and planned operations for the foreseeable future, although no assurance can be given that changes will not occur that would consume available capital resources more quickly than we currently expect and that we may need or want to raise additional funds. 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 testing and companion diagnostic services businesses;

termination of the licenses underlying our molecular diagnostic tests and companion diagnostic services or failure to enter into product or technology licensing or other arrangements favorable to us;

delays or other problems with operating our laboratory facilities;

the costs and expenses incurred in supporting our existing molecular diagnostic tests and companion diagnostic services;

the progress, results and cost of developing and launching additional molecular diagnostic tests and offering additional companion diagnostic services;

potential business development activities, in-licensing agreements and acquisitions, such as our acquisition of Myriad RBM and our strategic debt investment and option to acquire Crescendo Biosciences, Inc., and our ability to successfully integrate and achieve the expected benefits of our business development activities, in-licensing agreements and acquisitions;

changes in the government regulatory approval process for our tests;

the progress, costs and results of our international expansion efforts;

the costs, timing, outcome, and enforcement of any regulatory review of our existing or future molecular diagnostic tests and companion diagnostic services;

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;

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

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

changes in intellectual property laws covering our molecular diagnostic tests and companion diagnostic services and patents or enforcement in the United States and foreign countries;

changes in the governmental or private insurers reimbursement levels for our tests; and

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

Words such as may, anticipate, estimate, expects, projects, intends, plans, believes and words and terms of similar substance used in 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 tests and companion diagnostic services may decline or will not continue to increase at historical rates; risks related to changes in the governmental or private insurers reimbursement levels for our tests; the risk that we may be unable to develop or achieve commercial success for additional molecular diagnostic tests and companion diagnostic services in a timely manner, or at all; the risk that we may not successfully develop new markets for our molecular diagnostic tests and companion diagnostic services, including our ability to successfully generate revenue outside the United States; the risk that licenses to the technology underlying our molecular diagnostic tests and companion diagnostic services tests and any future tests 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 genetic testing in general or our tests in particular; risks related to regulatory requirements or enforcement in the United States and foreign countries and changes in the structure of the healthcare system or healthcare payment systems; risks related to our ability to obtain new corporate collaborations or licenses and acquire new technologies or businesses on satisfactory terms, if at all; risks related to our ability to successfully integrate and derive benefits from any technologies or businesses that we license or acquire; the development of competing tests and services; the risk that we or our licensors may be unable to protect the proprietary technologies underlying our tests; the risk of patent-infringement claims or challenges to the validity of our patents; 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 fiscal year ended June 30, 2012, 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

There have been no material changes in our market risk during the three and nine months ended March 31, 2013 compared to the disclosures in Part II, Item 7A of our Annual Report on Form 10-K for the fiscal year ended June 30, 2012, which is incorporated by reference herein.

#### **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 the 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.

#### **PART II - Other Information**

#### **Item 1. Legal Proceedings**

We are a defendant in a lawsuit brought by the Association for Molecular Pathology, *et al.*, the Plaintiffs, originally filed on May 12, 2009 in the United States District Court for the Southern District of New York (the District Court) seeking a declaratory ruling that 15 claims in patents relating to the *BRCA1* and *BRCA2* genes are invalid and unenforceable under 35 U.S.C Section 101. The 15 claims at issue in the lawsuit are part of the intellectual property relating to our BRACAnalysis predictive medicine test for breast and ovarian cancer. The District Court ruled that the claims were invalid; however, on appeal, the United States Court of Appeals for the Federal Circuit (the Federal Circuit) ruled that the nine composition of matter claims relating to isolated DNA molecules and one method claim relating to screening potential cancer therapeutics via changes in cell growth rates are patent eligible. The Plaintiffs appealed the decision of the Federal Circuit to the United States Supreme Court (the Supreme Court) as it related to the composition of matter claims. The Supreme Court vacated the Federal Circuit s decision and remanded the case for a redetermination as to the composition of matter claims. Following remand from the Supreme Court, on August 16, 2012, the Federal Circuit again ruled that the nine composition of matter claims relating to isolated DNA molecules and one method claim relating to screening potential cancer therapeutics are patent eligible under 35 U.S.C. Section 101. The Plaintiffs again sought review by the Supreme Court of the Federal Circuit s decision on remand. On November 30, 2012, the Supreme Court granted *certiorari*, agreeing to hear the case. The Supreme Court heard oral arguments on April 15, 2013 and a decision by the Supreme Court is expected by June 30, 2013.

Apart from the nine claims being challenged in this lawsuit, there are over 500 separate claims under 24 patents, and various propriety technologies and information, which cover the intellectual property utilized in, or relating to, our BRCA*nalysis* predictive medicine test for breast and ovarian cancer which are not subject to this lawsuit. Accordingly, we do not believe that this lawsuit will have a material adverse impact on our business, financial position or results of operations.

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

#### Item 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, 2012.

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

#### **Issuer Purchases of Equity Securities**

In January 2013, we completed our stock repurchase authorization for \$200 million, which was approved in August 2011. In February 2013, our board of directors authorized a new stock repurchase program for an additional \$200 million. We are authorized to complete the repurchase from time to time or on an accelerated basis through open market transactions or privately negotiated transactions as determined by the Company s management. The amount and timing of stock repurchases under the program will depend on business and market conditions, stock price, trading restrictions, acquisition activity and other factors. There is no specified term or expiration date for this program.

The details of the activity under our stock repurchase program during the fiscal quarter ended March 31, 2013 were as follows:

#### **Issuer Purchases of Equity Securities**

	(a)		(b)	(c)	(d)		
				Total Number of Shares Purchased as Part of Publicly	Approximate Dollar Value of Shares that May Yet Be		
	Total Number of	Averag	e Price Paid	Announced Plans or	Purchased Under the		
Period	Shares Purchased	per Share		per Share		Programs	Plans or Programs
January 1, 2013 to January 31, 2013	735,377	\$	26.88	735,377	\$		
February 1, 2013 to February 28, 2013	507,155	\$	24.80	507,155	187,420,981		
March 1, 2013 to March 31, 2013	495,931	\$	25.16	495,931	174,943,751		
Total	1,738,463			1,738,463	\$ 174,943,751		

Item 3. Defaults Upon Senior Securities.

None.

#### Item 4. Mine Safety Disclosures.

None.

#### Item 5. Other Information.

None.

#### Item 6. 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.
- 101@ The following materials from Myriad Genetics, Inc. s Quarterly Report on Form 10-Q for the quarter ended March 31, 2013, formatted in XBRL (Extensible Business Reporting Language): (i) the unaudited Condensed Consolidated Balance Sheets, (ii) the unaudited Condensed Consolidated Statements of Income, (iii) the unaudited Condensed Consolidated Statements of Cash Flows, and (iv) Notes to Condensed Consolidated Financial Statements.

#### 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.

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

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

24

Date: May 8, 2013

Date: May 8, 2013