

MYRIAD GENETICS INC
Form 10-Q
May 02, 2006
Table of Contents

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

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended March 31, 2006

OR

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

Commission file number: 0-26642

MYRIAD GENETICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction

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

of incorporation or organization)

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

84108
(Zip Code)

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

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

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

Large accelerated filer ☐

Accelerated filer ☒

Non-accelerated filer ☐

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

Edgar Filing: MYRIAD GENETICS INC - Form 10-Q

As of April 27, 2006 the registrant had 39,474,624 shares of \$0.01 par value common stock outstanding.

Table of Contents

MYRIAD GENETICS, INC.

INDEX TO FORM 10-Q

	Page
PART I - Financial Information	
Item 1. Financial Statements:	
<u>Condensed Consolidated Balance Sheets (Unaudited) as of March 31, 2006 and June 30, 2005</u>	3
<u>Condensed Consolidated Statements of Operations (Unaudited) for the three and nine months ended March 31, 2006 and 2005</u>	4
<u>Condensed Consolidated Statements of Cash Flows (Unaudited) for the nine months ended March 31, 2006 and 2005</u>	5
<u>Notes to Condensed Consolidated Financial Statements (Unaudited)</u>	6
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	10
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	18
Item 4. <u>Controls and Procedures</u>	19
PART II - Other Information	
Item 1. <u>Legal Proceedings</u>	20
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	20
Item 3. <u>Defaults Upon Senior Securities</u>	20
Item 4. <u>Submission of Matters to a Vote of Security Holders</u>	20
Item 5. <u>Other Information</u>	20
Item 6. <u>Exhibits</u>	20
<u>Signatures</u>	21

Table of Contents

MYRIAD GENETICS, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)

<i>(in thousands, except per share amounts)</i>	Mar. 31, 2006	Jun. 30, 2005
Assets		
Current assets:		
Cash and cash equivalents	\$ 106,407	\$ 49,509
Marketable investment securities	122,927	64,334
Prepaid expenses	3,097	3,331
Trade accounts receivable, less allowance for doubtful accounts of \$1,795 at Mar. 31, 2006 and \$1,395 at June 30, 2005	20,514	17,236
Other receivables	1,074	1,145
Total current assets	254,019	135,555
Equipment and leasehold improvements:		
Equipment	45,609	40,160
Leasehold improvements	8,200	8,004
	53,809	48,164
Less accumulated depreciation and amortization	34,159	29,698
Net equipment and leasehold improvements	19,650	18,466
Other assets	4,624	4,937
	\$ 278,293	\$ 158,958
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 10,492	\$ 11,897
Accrued liabilities	9,999	10,136
Deferred revenue	1,102	1,252
Total current liabilities	21,593	23,285
Stockholders' equity:		
Preferred stock, \$0.01 par value, 5,000 shares authorized, no shares issued and outstanding		
Common stock, \$0.01 par value, 60,000 shares authorized; issued and outstanding 39,430 at Mar. 31, 2006 and 30,862 at June 30, 2005	394	309
Additional paid-in capital	463,058	315,147
Accumulated other comprehensive loss	(738)	(534)
Accumulated deficit	(206,014)	(179,249)
Total stockholders' equity	256,700	135,673
	\$ 278,293	\$ 158,958

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

Table of Contents

MYRIAD GENETICS, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)

<i>(in thousands, except per share amounts)</i>	Three Months Ended		Nine Months Ended	
	Mar. 31, 2006	Mar. 31, 2005	Mar. 31, 2006	Mar. 31, 2005
Revenues:				
Predictive medicine revenue	\$ 26,867	\$ 18,386	\$ 71,788	\$ 50,350
Research revenue	2,942	1,575	10,466	5,960
Total revenues	29,809	19,961	82,254	56,310
Costs and expenses:				
Predictive medicine cost of revenue	7,505	5,297	19,581	14,667
Research and development expense	21,967	15,540	59,463	43,218
Selling, general and administrative expense	12,291	9,834	34,818	30,429
Total costs and expenses	41,763	30,671	113,862	88,314
Operating loss	(11,954)	(10,710)	(31,608)	(32,004)
Other income (expense):				
Interest income	2,407	724	4,867	2,044
Other	(24)		(24)	(66)
	2,383	724	4,843	1,978
Net loss	\$ (9,571)	\$ (9,986)	\$ (26,765)	\$ (30,026)
Basic and diluted loss per share	\$ (0.24)	\$ (0.32)	\$ (0.76)	\$ (0.98)
Basic and diluted weighted average shares outstanding	39,232	30,749	35,192	30,693

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

Table of Contents

MYRIAD GENETICS, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

<i>(In thousands)</i>	Nine Months Ended	
	Mar. 31, 2006	Mar. 31, 2005
Cash flows from operating activities:		
Net loss	\$ (26,765)	\$ (30,026)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	5,051	4,546
Loss on disposition of assets	24	66
Bad debt expense	1,625	1,413
Share-based compensation expense	1,616	
Changes in operating assets:		
Prepaid expenses	234	1,891
Trade accounts receivable	(4,903)	(3,592)
Other receivables	71	(562)
Accounts payable	(1,405)	(39)
Accrued liabilities	(137)	1,372
Deferred revenue	(150)	126
Net cash used in operating activities	(24,739)	(24,805)
Cash flows from investing activities:		
Capital expenditures	(5,846)	(2,442)
Purchases of other assets	(100)	(100)
Purchases of marketable investment securities	(115,754)	(42,904)
Proceeds from sales and maturities of marketable investment securities	56,957	33,298
Net cash used in investing activities	(64,743)	(12,148)
Cash flows from financing activities:		
Net proceeds from public offering of common stock	139,739	
Net proceeds from common stock issued under share-based compensation plans	6,641	1,363
Net cash provided by financing activities	146,380	1,363
Net increase (decrease) in cash and cash equivalents	56,898	(35,590)
Cash and cash equivalents at beginning of period	49,509	83,983
Cash and cash equivalents at end of period	\$ 106,407	\$ 48,393

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 for interim financial information and pursuant to the applicable rules and regulations of the Securities and Exchange Commission. The condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation. In the opinion of management, the accompanying financial statements contain all adjustments (consisting of normal and recurring accruals) necessary to present fairly all financial statements in accordance with U.S. generally accepted accounting principles. 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, 2005, included in the Company's Annual Report on Form 10-K for the year ended June 30, 2005. Operating results for the three and nine month periods ended March 31, 2006 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. generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements, as well as the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

(2) Share-Based Compensation

On July 1, 2005 the Company adopted the provisions of Financial Accounting Standards Board Statement No. 123R, *Share-Based Payment* (Statement 123R). Statement 123R sets accounting requirements for share-based compensation to employees, including employee stock purchase plans, and requires companies to recognize in the statement of operations the grant-date fair value of stock options and other equity-based compensation.

In 2003 the Company adopted the 2003 Employee, Director and Consultant Stock Option Plan (the 2003 Plan) under which 3.9 million shares of common stock have been reserved for issuance upon the exercise of options that the Company grants from time to time. Additional shares represented by options previously granted under the Company's 2002 Amended and Restated Employee, Director and Consultant Stock Option Plan (the 2002 Plan) which are canceled or expire after the date of stockholder approval of the 2003 Plan without delivery of shares of stock by the Company and any shares which have been reserved but not granted under the 2002 Plan as of the date of stockholder approval of the 2003 Plan are available for grant under the 2003 Plan.

The number of shares, terms, and exercise period are determined by 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. The exercise price of options granted is equivalent to the fair market value of the stock at the date of grant. During the quarter ended March 31, 2006 the Company granted approximately 686,000 options under the 2003 Plan. The Company also has an Employee Stock Purchase Plan under which a maximum of 600,000 shares of common stock may be purchased by eligible employees. During the quarter ended March 31, 2006, the Company issued no shares of common stock under the Employee Stock Purchase Plan.

Table of Contents

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

Share-based compensation expense included in the consolidated statements of operations for the three and nine months ended March 31, 2006 was approximately \$887,000 and \$1,616,000, respectively. As of March 31, 2006, there was approximately \$13.8 million of total unrecognized share-based compensation cost related to share-based compensation granted under our plans that will be recognized over a weighted-average period of 3.6 years.

Statement 123R applies only to awards granted after the required effective date. Awards granted prior to the Company's implementation of Statement 123R were accounted for under the recognition and measurement principles of APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and related Interpretations. Accordingly, no stock-based employee compensation cost is reflected in net loss in the accompanying condensed consolidated statement of operations for the three and nine months ended March 31, 2005, as all options granted under the Company's plans had exercise prices equal to the market value of the underlying common stock on the date of grant.

The following table illustrates the effect on net loss and loss per share if the Company had applied the fair value recognition provisions of SFAS No. 123, *Accounting for Stock-Based Compensation*, to stock-based employee compensation for periods presented prior to the Company's adoption of Statement 123R:

<i>(in thousands, except per share amounts)</i>	Three months ended Mar. 31, 2005	Nine months ended Mar. 31, 2005
Net loss, as reported	\$ (9,986)	\$ (30,026)
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards, net of tax related effects	(6,198)	(19,090)
Pro forma net loss	\$ (16,184)	\$ (49,116)
Loss per share:		
Basic and diluted as reported	\$ (0.32)	\$ (0.98)
Basic and diluted pro forma	\$ (0.53)	\$ (1.60)

Stock-based employee compensation expense included in the statements of operations for the three and nine months ended March 31, 2006 decreased from the compensation expense included in the pro forma net loss of the three and nine months ended March 31, 2005 due to the acceleration of vesting of the Company's unvested options in April 2005.

Table of Contents**(3) Comprehensive Loss**

The components of the Company's comprehensive loss are as follows (in thousands):

	Three Months Ended Mar. 31,		Nine Months Ended Mar. 31,	
	2006	2005	2006	2005
Net loss	\$ (9,571)	\$ (9,986)	\$ (26,765)	\$ (30,026)
Unrealized loss on available-for-sale securities	(66)	(381)	(204)	(572)
Comprehensive loss	\$ (9,637)	\$ (10,367)	\$ (26,969)	\$ (30,598)

(4) Net Loss Per Common Share

Loss per common share is computed based on the weighted-average number of common shares and, as appropriate, dilutive potential common shares outstanding during the period. Stock options and warrants are considered to be potential common shares. Basic loss per common share is the amount of loss for the period available to each share of common stock outstanding during the reporting period. Diluted loss per share is the amount of loss for the period available to each share of common stock outstanding during the reporting period and to each share that would have been outstanding assuming the issuance of common shares for all dilutive potential common shares outstanding during the period. In calculating loss per common share the net loss and the weighted average common shares outstanding were the same for both the basic and diluted calculation.

As of March 31, 2006 and 2005, there were antidilutive potential common shares of 8,271,460 and 7,455,375, respectively. Accordingly, these potential common shares were not included in the computation of diluted loss per share for the periods presented, but may be dilutive to future basic and diluted earnings per share.

(5) Segment and Related Information

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

Table of Contents

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

<i>(in thousands)</i>	Research	Predictive medicine	Drug development	Total
Three months ended Mar. 31, 2006:				
Revenues	\$ 2,942	\$ 26,867	\$	\$ 29,809
Depreciation and amortization	651	529	536	1,716
Segment operating income (loss)	(4,744)	9,608	(16,818)	(11,954)
Three months ended Mar. 31, 2005:				
Revenues	1,575	18,386		19,961
Depreciation and amortization	516	520	487	1,523
Segment operating income (loss)	(4,403)	4,603	(10,910)	(10,710)
Nine months ended Mar. 31, 2006:				
Revenues	10,466	71,788		82,254
Depreciation and amortization	1,947	1,577	1,527	5,051
Segment operating income (loss)	(11,005)	23,527	(44,130)	(31,608)
Nine months ended Mar. 31, 2005:				
Revenues	5,960	50,350		56,310
Depreciation and amortization	1,620	1,510	1,416	4,546
Segment operating income (loss)	(11,454)	10,550	(31,100)	(32,004)

<i>(in thousands)</i>	Three Months Ended Mar. 31,		Nine Months Ended Mar. 31,	
	2006	2005	2006	2005
Total operating loss for reportable segments	\$ (11,954)	\$ (10,710)	\$ (31,608)	\$ (32,004)
Interest income	2,407	724	4,867	2,044
Other	(24)		(24)	(66)
Net loss	\$ (9,571)	\$ (9,986)	\$ (26,765)	\$ (30,026)

(6) Public Offering of Common Stock

In November 2005, the Company received \$139.7 million in net proceeds from an underwritten public offering of 8,050,000 shares of common stock pursuant to the Company's outstanding shelf registration on Form S-3 (Registration No. 333-123914). The Company has approximately \$151.1 million of securities available for sale under the shelf registration statement.

Table of Contents

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

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

We believe that the future of medicine lies in the creation of new classes of drugs that treat the underlying cause, not just the symptoms, of disease and that may be useful in disease prevention. By understanding the genetic basis of disease, we believe we will be able to develop drugs that are safer and more efficacious. In addition, we believe that advances in the emerging field of predictive medicine will improve our ability to determine which patients are subject to a greater risk of developing these diseases and who therefore would benefit from preventive therapies.

Myriad researchers have made important discoveries in the fields of cancer, Alzheimer's disease and infectious diseases such as AIDS. These discoveries point to novel disease pathways that may pave the way for the development of new classes of drugs. We intend to develop and, subject to regulatory approval, market our therapeutic products in the areas of cancer, Alzheimer's disease and viral disease.

Therapeutic products in development

We currently have four drug candidates in seven clinical trials and a number of drug candidates in late-stage preclinical development. Our most advanced drug development programs are described below:

Flurizan (R-flurbiprofen): drug candidate for Alzheimer's disease. Flurizan, our lead therapeutic candidate for the treatment of Alzheimer's disease, is the first in a new class of drug candidates known as selective amyloid beta lowering agents, or SALAs. In April 2005, we completed a Phase 2 human clinical trial of Flurizan in 207 patients with mild to moderate Alzheimer's disease. The study found that patients with mild Alzheimer's disease who received the 800 mg twice-daily dose of Flurizan achieved between 34 and 45% slowing in decline on the three primary endpoints (activities of daily living, overall function and cognitive ability). A 20% or greater slowing in decline is generally regarded as clinically relevant. Flurizan appeared to be well tolerated by Alzheimer's patients in the Phase 2 study and adverse events were generally mild and non-specific and did not differ significantly between placebo and treated groups. Since April 2005, we have continued a Phase 2 follow-on study, gathering longer-term data from the same patients who elected to continue beyond the 12 months of the original study.

We have also initiated enrollment in a Phase 3 study in patients with mild Alzheimer's disease. The Phase 3 trial is a two-arm study (800 mg twice daily and placebo) that will enroll 800 patients per arm in over 130 centers in the United States and is designed to assess the ability of Flurizan to reduce the rate of cognitive decline and decline in activities of daily living in patients with mild Alzheimer's disease over an 18 month period. Alzheimer's disease is a degenerative neurological condition affecting up to 50% of all people aged 85 or older, with an estimated four million cases in the United States alone.

Flurizan (R-flurbiprofen): drug candidate for prostate cancer. Flurizan is also in a Phase 2b human clinical trial for the treatment of patients with pre-metastatic prostate cancer. This clinical trial is a three arm (800 mg twice daily, 800 mg once daily and placebo), 82 patient per arm study being conducted at 56 centers in the United States and Canada and is designed to assess the ability of Flurizan to delay the onset of metastatic cancer in patients with prostate cancer. Approximately 232,000 men in the United States were diagnosed with prostate cancer in 2005. It is the second leading cause of death from cancer in men.

Azixa : drug candidate for solid cancer tumors and brain metastases. Azixa, also known as MPC-6827, is a novel, small-molecule tubulin inhibitor that is being studied in two Phase 1 human clinical

Table of Contents

trials. These trials use an escalating dose regimen designed to evaluate the safety and pharmacokinetic profile of Azixa in patients with advanced solid tumors and metastatic brain tumors, respectively. In preclinical studies, Azixa showed better activity against a range of human tumors in mouse xenografts than the standard of care treatments for those cancers. In addition, Azixa demonstrated the ability to effectively cross the blood-brain barrier and was not subject to multiple drug resistance. This drug candidate has demonstrated activity in preclinical studies against tumors of the prostate, breast, pancreas, colon and skin (melanoma). According to the American Cancer Society, these cancers are expected to account for approximately 642,000 new cases in 2005 in the United States alone. In addition, according to the National Cancer Institute, it is estimated that there were as many as 170,000 new cases of brain metastases in 2005.

MPC-2130: drug candidate for blood cancers. Our drug candidate MPC-2130, a novel apoptosis inducing small molecule, is also in the Phase 1 clinical trial stage. The study is designed to evaluate the safety and pharmacokinetic profile of MPC-2130 in patients with advanced metastatic tumors or blood cancers as well as refractory cancer that has progressed despite previous chemotherapy. In preclinical studies, MPC-2130 demonstrated cancer cell killing activity in ovarian cancer and prostate cancer as well as two lymphoma cell lines, Burkitt's lymphoma and T-cell lymphoma. In addition, MPC-2130 was not subject to multiple drug resistance and was able to cross the blood-brain barrier. According to the American Cancer Society, approximately 98,000 Americans were diagnosed with blood cancers in 2005.

MPC-0920: drug candidate for thrombosis. In April 2006 we initiated a Phase 1 human clinical trial for our drug candidate MPC-0920, an orally available direct thrombin inhibitor. The study uses an escalating dose regimen designed to evaluate the safety and pharmacokinetic profile of MPC-0920 in healthy volunteers. MPC-0920 has demonstrated characteristics that may offer improvements over traditional anticoagulants, which have limitations such as nonselectivity, inability to effect thrombin-bound fibrin and drug interactions. We believe that deep-vein thrombosis and arterial fibrillation represent two large potential markets.

MPI-49839: drug candidate for AIDS. As published in the scientific journal *Cell* in October 2001, our scientists and their collaborators discovered the viral budding mechanism in HIV and other viruses. This discovery led to the development of MPI-49839, an orally available viral budding/maturation inhibitor, which is one of a new class of drug candidates for the treatment of AIDS. MPI-49839 has demonstrated strong anti-HIV activity and has been shown to be active against many of the drug resistant strains of HIV. MPI-49839 is in late-stage preclinical development in preparation for human clinical testing in the future, and we may submit an Investigational New Drug application, or IND, as early as the end of our fiscal year ending June 30, 2006.

MPC-4505: drug candidate for chemotherapy induced emesis. Our drug candidate MPC-4505, a small molecule that has demonstrated solubility and oral bioavailability, is an NK1 receptor antagonist for chemotherapy induced emesis (nausea and vomiting). We believe these characteristics of MPC-4505 make it suitable for both an oral formulation and a sterile IV formulation. MPC-4505 has shown central nervous system penetration, a long half-life and a favorable safety profile in preclinical testing. MPC-4505 is in late-stage preclinical development in preparation for human clinical testing in the future.

Table of Contents**Therapeutic product pipeline**

Molecule	Therapeutic Area	Status
Flurizan	Alzheimer's disease	Phase 3
Flurizan	Alzheimer's disease	Phase 2 Follow-on
Flurizan	Prostate cancer	Phase 2b
Azixa	Brain metastases	Phase 1
Azixa	Solid tumors	Phase 1
MPC-2130	Blood cancers and metastatic tumors	Phase 1
MPC-0920	Thrombosis	Phase 1
MPI-49839	AIDS	Preclinical
MPC-4505	Emesis	Preclinical

Predictive medicine products

Predictive medicine analyzes genes and their mutations to assess an individual's risk for developing disease later in life. Armed with this risk assessment information, individuals can increase surveillance and take action to prevent or delay the onset of disease.

To date, we have launched four commercial predictive medicine products. We market these products through our own 115-person sales force in the United States and we have entered into marketing collaborations with other organizations in selected foreign countries. Predictive medicine revenues were \$26.9 million and \$71.8 million for the three and nine months ended March 31, 2006, respectively, which represented increases of 46% and 43% over the same three and nine months in 2005. Our current commercial predictive medicine products are described below:

BRACAnalysis®: predictive medicine product for breast and ovarian cancer. BRACAnalysis is a comprehensive analysis of the BRCA1 and BRCA2 genes for assessing a woman's risk for breast and ovarian cancer. A woman who tests positive with the BRACAnalysis test has an 82% risk of developing breast cancer during her lifetime and up to a 54% risk of developing ovarian cancer. BRACAnalysis provides important information that we believe will help the patient and her physician make better informed lifestyle, surveillance, preventive medication and treatment decisions. As published in the *Journal of the National Cancer Institute*, researchers have shown that pre-symptomatic individuals who have a high risk of developing breast cancer can reduce their risk by approximately 50% with appropriate preventive therapies. Additionally, as published in the *New England Journal of Medicine*, researchers have shown that pre-symptomatic individuals who carry gene mutations can lower their risk of developing ovarian cancer by approximately 60% with appropriate preventive therapies. It is estimated that in 2005 there were approximately 235,000 women in the United States diagnosed with breast or ovarian cancer. This year in the United States, an estimated 57,000 women died from these cancers. The test is currently priced at \$3,120 and is covered by all major health maintenance organizations and health insurance providers in the United States.

COLARIS®: predictive medicine product for colon cancer and uterine cancer. COLARIS is a comprehensive analysis of the MLH1 and MSH2 genes for determining a person's risk of developing colon cancer or uterine cancer. Individuals who carry a deleterious mutation in one of the two colon cancer genes in the COLARIS test have a greater than 80% lifetime risk of developing colon cancer and women have a 60% lifetime chance of developing uterine cancer. Highly effective preventive measures include colonoscopy and the removal of precancerous polyps. Through proper screening and polyp removal, colon cancer is a preventable disease. Colorectal cancer is the second leading cause of cancer deaths in the United States, with approximately 145,000 new cases diagnosed in 2005. Familial forms of colorectal cancer are estimated to account for 10% to 30% of all cases according to the American Society of Clinical Oncologists. The test is currently priced at \$2,050 and is covered by all major health maintenance organizations and health insurance providers in the United States.

Table of Contents

COLARIS AP®: predictive medicine product for colon cancer. COLARIS AP detects mutations in the APC and MYH genes, which cause a colon polyp-forming syndrome known as familial adenomatous polyposis (FAP) and a more common variation of the syndrome known as attenuated FAP. Individuals who carry a deleterious mutation in the APC or MYH gene may have a greater than 90% lifetime risk of developing colon cancer. Effective preventive measures include colonoscopy and the removal of pre-cancerous polyps and prophylactic surgery. The test is currently priced at \$1,795 and is covered by all major health maintenance organizations and health insurance providers in the United States.

MELARIS®: predictive medicine product for melanoma. MELARIS analyzes mutations in the p16 gene to determine genetic susceptibility to malignant melanoma, a deadly form of skin cancer. Individuals who test positive for MELARIS have a 75-fold increased risk of developing melanoma during their lifetimes as compared to the general population. MELARIS, which assesses a person's risk of developing melanoma, provides important information that we believe will be useful in the surveillance and prevention of melanoma. Melanoma can be prevented through appropriate screening and a specific threshold of action for mutation carriers, in which pre-cancerous lesions are removed before cancer can develop. Melanoma is lethal within five years in 86% of cases where it has spread to another site in the body. However, when melanoma is diagnosed at an early stage, fewer than 10% of patients die within five years. MELARIS is currently priced at \$745 and is covered by certain health maintenance organizations and health insurance providers in the United States.

We have devoted substantially all of our resources to undertaking our drug discovery and development programs, operating our predictive medicine business, and continuing our research and development efforts. Our revenues have consisted primarily of sales of predictive medicine products and research payments. We have yet to attain profitability and, for the three and nine months ended March 31, 2006, we had net losses of \$9.6 million and \$26.8 million, respectively. As of March 31, 2006 we had an accumulated deficit of \$206.0 million.

We expect to incur losses for at least the next several years, primarily due to the expansion of our drug discovery and development efforts, the initiation and continuing conduct of human clinical trials, the launch of new predictive medicine products, the continuation of our internal research and development programs, and expansion of our facilities. Additionally, we expect to incur substantial sales, marketing and other expenses in connection with building our pharmaceutical and predictive medicine businesses. We expect that losses will fluctuate from quarter to quarter and that such fluctuations may be substantial.

Critical Accounting Policies

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

revenue recognition;

allowance for doubtful accounts; and

shared-based payment expense.

Revenue Recognition. Predictive medicine revenues include revenues from the sale of predictive medicine products, related marketing agreements, and forensic DNA analysis fees. Predictive medicine revenue is recognized upon completion of the test or analysis and communication of results and when collectibility is reasonably assured. Up-front payments related to marketing agreements are deferred and recognized ratably over the life of the agreement.

Table of Contents

Research revenues include revenues from research agreements, milestone payments, and technology licensing agreements. In applying the principles of SAB 104 to research and technology license agreements we consider the terms and conditions of each agreement separately to arrive at a proportional performance methodology of recognizing revenue. Such methodologies involve recognizing revenue on a straight-line basis over the term of the agreement and based on costs incurred relative to the total estimated contract costs (cost-to-cost method). We make adjustments, if necessary, to the estimates used in our cost-to-cost calculations as work progresses and we gain experience. The principal costs under these agreements are for personnel expenses to conduct research and development but also include costs for materials and other direct and indirect items necessary to complete the research under these agreements. Actual results may vary from our estimates. Payments received on uncompleted long-term contracts may be greater than or less than incurred costs and estimated earnings and have been recorded as other receivables or deferred revenues in the accompanying condensed consolidated balance sheets. We recognize revenue from milestone payments as agreed-upon events representing the achievement of substantive steps in the development process are achieved and where the amount of the milestone payments approximates the value of achieving the milestone. We recognize revenue from up-front nonrefundable license fees on a straight-line basis over the period of our continued involvement in the research and development project.

Allowance for Doubtful Accounts. The preparation of our financial statements in accordance with U.S. generally accepted accounting principles 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 predictive medicine products. We analyze trade accounts receivable and consider historic experience, customer creditworthiness, facts and circumstances specific to outstanding balances, and payment term changes when evaluating the adequacy of the allowance for doubtful accounts. Changes in these factors could result in material adjustments to the expense recognized for bad debt.

Share-Based Payment Expense. Financial Accounting Standards Board Statement No. 123R, *Share-Based Payment* (Statement 123R) and Staff Accounting Bulletin No. 107 set accounting requirements for share-based compensation to employees, including employee stock purchase plans, and requires us to recognize in our condensed consolidated statements of operations the grant-date fair value of our stock options and other equity-based compensation. The determination of grant-date fair value is estimated using an option-pricing model, which includes variables such as the expected volatility of our share price, the exercise behavior of our employees, interest rates, and dividend yields. These variables are projected based on our historical data and experience. Changes in any of these variables could result in material adjustments to the expense recognized for share-based payments.

New Accounting Pronouncements

In May 2005, the Financial Accounting Standards Board Statement issued SFAS No. 154, *Accounting Changes and Error Corrections* a replacement of APB Opinion No. 20 and FASB Statement No. 3. SFAS No. 154 requires retrospective application to prior periods financial statements for changes in accounting principle, unless it is impracticable to determine either the period-specific effects or the cumulative effect of the change. SFAS No. 154 also requires that retrospective application of a change in accounting principle be limited to the direct effects of the change. Indirect effects of a change in accounting principle should be recognized in the period of the accounting change. SFAS No. 154 also requires that a change in depreciation, amortization, or depletion method for long-lived non-financial assets be accounted for as a change in accounting estimate affected by a change in accounting principle. SFAS No. 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. Our adoption of SFAS No. 154 is not expected to have a material effect on our consolidated financial position or results of operations.

Table of Contents

Results of Operations for the Three Months Ended March 31, 2006 and 2005

Predictive medicine revenue is comprised primarily of sales of predictive medicine products, and also includes some marketing fees and forensic DNA analysis fees. Predictive medicine revenues for the three months ended March 31, 2006 were \$26.9 million compared to \$18.4 million for the same three months in 2005, an increase of 46%. Increased sales, marketing, and education efforts have resulted in wider acceptance of our products by the medical community and increased revenues for the three months ended March 31, 2006. There can be no assurance that predictive medicine revenues will continue to increase at historical rates.

Research revenues are comprised of research payments received pursuant to collaborative agreements and amortization of upfront technology license fees. Research revenues for the three months ended March 31, 2006 were \$2.9 million compared to \$1.6 million for the same three months in 2005. This 87% increase in research revenue is primarily attributable to revenues associated with the delivery of research data pursuant to a research collaboration. We expect that our continued focus will be on our internal drug development and predictive medicine programs and we plan to continue to de-emphasize external research collaborations. Research revenue from our research collaboration agreements is recognized using a proportional performance methodology. Consequently, as these programs progress and costs increase or decrease, revenues may increase or decrease proportionately.

Predictive medicine cost of revenue for the three months ended March 31, 2006 was \$7.5 million compared to \$5.3 million for the same three months in 2005. This increase of 42% in predictive medicine cost of revenue is primarily due to the 46% increase in predictive medicine revenues for the three months ended March 31, 2006 compared to the same three months in 2005. Our gross profit margin was 72% for the three months ended March 31, 2006 compared to 71% for the same three months in 2005. There can be no assurance that predictive medicine gross profit margins will increase and we expect that our gross profit margins will fluctuate from quarter to quarter based on the introduction of new technology and operating systems in our predictive medicine laboratory.

Research and development expenses for the three months ended March 31, 2006 were \$22.0 million compared to \$15.5 million for the same three months in 2005. This increase of 41% was primarily due to increased costs associated with our ongoing clinical trials as well as increased costs associated with our drug discovery and drug development programs. We expect to incur significant increases in our research and development expenses over the next several years as we expand clinical trials for our product candidates currently in clinical development, including Flurizan and Azixa, advance our other product candidates into clinical trials, and expand our research and development activities. We expect that these expenses will continue to fluctuate from quarter to quarter based on changes in our research programs and the progression of our drug development programs.

Selling, general and administrative expenses consist primarily of salaries, commissions and related personnel costs for sales, marketing, executive, legal, finance, accounting, human resources, business development, allocated facilities expenses and other corporate expenses. Selling, general and administrative expenses for the three months ended March 31, 2006 were \$12.3 million compared to \$9.8 million for the same three months in 2005. This increase of 25% was primarily attributable to general increases in costs to support the 46% growth in our predictive medicine business and our therapeutic development efforts. We expect our selling, general and administrative expenses will continue to fluctuate depending on the number and scope of new product launches and our drug discovery and drug development efforts.

Results of Operations for the Nine Months Ended March 31, 2006 and 2005

Predictive medicine revenues for the nine months ended March 31, 2006 were \$71.8 million compared to \$50.4 million for the same nine months in 2005, an increase of 43%. Increased sales, marketing, and

Table of Contents

education efforts, coupled with publications concerning the clinical utility of our products have resulted in wider acceptance of our products by the medical community and increased revenues for the nine months ended March 31, 2006. There can be no assurance that predictive medicine revenues will continue to increase at historical rates.

Research revenues for the nine months ended March 31, 2006 were \$10.5 million compared to \$6.0 million for the same nine months in 2005. This 76% increase in research revenue is primarily attributable to revenues associated with the delivery of research data pursuant to two research collaborations which resulted in increased research revenues of approximately \$7.4 million for the nine months ended March 31, 2006 compared to the same nine months in 2005. This increase was partially offset by the successful completion of research collaborations in the prior year, which resulted in decreased research revenues of approximately \$2.9 million. Research revenue from our research collaboration agreements is recognized using a proportional performance methodology. Consequently, as these programs progress and costs increase or decrease, revenues may increase or decrease proportionately.

Predictive medicine cost of revenue for the nine months ended March 31, 2006 was \$19.6 million compared to \$14.7 million for the same nine months in 2005. This increase of 34% in predictive medicine cost of revenue is primarily due to the 43% increase in predictive medicine revenues for the nine months ended March 31, 2006 compared to the same nine months in 2005. Our gross profit margin was 73% for the nine months ended March 31, 2006 compared to 71% for the same nine months in 2005. There can be no assurance that predictive medicine gross profit margins will increase and we expect that our gross profit margins will fluctuate based on the introduction of new technology and operating systems in our predictive medicine laboratory.

Research and development expenses for the nine months ended March 31, 2006 were \$59.5 million compared to \$43.2 million for the same nine months in 2005. This increase of 38% was due in part to increased costs associated with our ongoing clinical trials as well as increases in our drug discovery and drug development programs. These increases added approximately \$13.0 million to our research and development costs for the nine months ended March 31, 2006 compared to the same nine months in 2005. Increased costs associated with a new research collaboration as well as technology development in our clinical laboratory added approximately \$3.3 million to our research and development costs for the nine months ended March 31, 2006 compared to the same nine months in 2005.

Selling, general and administrative expenses for the nine months ended March 31, 2006 were \$34.8 million compared to \$30.4 million for the same nine months in 2005. This increase of 14% was primarily attributable to general increases in costs to support the 43% growth in our predictive medicine business and our therapeutic development efforts. We expect our selling, general and administrative expenses will continue to fluctuate depending on the number and scope of new product launches and our drug discovery and drug development efforts.

Liquidity and Capital Resources

Cash, cash equivalents, and marketable investment securities increased \$115.5 million, or 101%, from \$113.8 million at June 30, 2005 to \$229.3 million at March 31, 2006. This increase is primarily attributable to the public offering of \$139.7 million (net proceeds) of our common stock in November 2005. This increase was partially offset by expenditures for our ongoing clinical trials, internal research and drug development programs and other expenditures incurred in the ordinary course of business. As a result of changes in cash, cash equivalents, marketable investment securities, and interest rates, interest income for the three and nine months ended March 31, 2006 was \$2.4 million and \$4.9 million, respectively, compared to \$724,000 and \$2.0 million for the same three and nine months in 2004, increases of 232% and 138%, respectively.

Table of Contents

Net cash used in operating activities was \$24.7 million during the nine months ended March 31, 2006 compared to \$24.8 million used in operating activities during the same nine months in 2005. Trade accounts receivable increased \$4.9 million between June 30, 2005 and March 31, 2006, primarily due to increases in predictive medicine sales during the same period. Accounts payable decreased by \$1.4 million between June 30, 2005 and March 31, 2006, primarily due to payments made for lab supplies, equipment, and amounts related to our clinical trials.

Our investing activities used cash of \$64.7 million during the nine months ended March 31, 2006 and used cash of \$12.1 million during the same nine months in 2005. Investing activities were comprised primarily of purchases and maturities of marketable investment securities and capital expenditures for research equipment.

Financing activities provided cash of \$146.4 million during the nine months ended March 31, 2006 and provided cash of \$1.4 million during the same nine months in 2005. In November 2005 we received \$139.7 million in net proceeds from an underwritten offering of 8.1 million shares of our common stock pursuant to our outstanding shelf registration statement on Form S-3 (Registration No. 333-123914). Following the offering we have approximately \$151.1 million of securities available for sale under the shelf registration statement. During the nine months ended March 31, 2006 we received \$6.6 million from the exercise of stock options and the purchase of our common stock from our Employee Stock Purchase Plan.

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

the progress and results of our current Phase 3 clinical trial of Flurizan for the treatment of Alzheimer's disease;

the progress and results of our current Phase 2b clinical trial of Flurizan for the treatment of prostate cancer and any additional trials that may be required by the FDA or that we may initiate on our own;

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

the progress and results of our Phase 1 clinical trials for Azixa, MPC-2130, and MPC-0920 and any future trials we may initiate based on the Phase 1 results;

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

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

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

the progress, results and cost of developing personalized medicine products and additional predictive medicine products;

Edgar Filing: MYRIAD GENETICS INC - Form 10-Q

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

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

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

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

Table of Contents

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 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 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: our inability to further identify, develop and achieve commercial success for new products and technologies; our ability to discover drugs that are safer and more efficacious than our competitors; our ability to develop predictive medicine products that help assess which patients are subject to greater risk of developing diseases and who would therefore benefit from new preventive therapies; the possibility of delays in the research and development necessary to select drug development candidates and delays in clinical trials; the risk that clinical trials may not result in marketable products; the risk that we may be unable to successfully finance and secure regulatory approval of and market our drug candidates, or that clinical trials will be completed on the timelines we have estimated; uncertainties about our ability to obtain new corporate collaborations and acquire new technologies on satisfactory terms, if at all; the development of competing products and services; our ability to protect our proprietary technologies; patent-infringement claims; risks of new, changing and competitive technologies and regulations in the United States and internationally; and other factors discussed under the heading Item 8.01 Other Events - Risk Factors in our Current Report on Form 8-K filed with the Securities and Exchange Commission on October 28, 2005.

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. You are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date of this Quarterly Report or the date of any document incorporated by reference in 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 Investment Policy. The primary objectives of our Investment Policy are to preserve principal, maintain proper liquidity to meet operating needs and maximize yields. Our Investment Policy specifies credit quality standards for our investments and limits the amount of credit exposure to any single issue, issuer or type of investment.

Our investments consist of securities of various types and maturities of three years or less, with a maximum average maturity of 12 months. These securities are classified as available-for-sale, which are recorded on the balance sheet at fair market value with unrealized gains or losses reported as part of accumulated other comprehensive income. Gains and losses on investment security transactions are

Table of Contents

reported on the specific-identification method. Dividend and interest income are recognized when earned. A decline in the market value of any marketable investment security below cost that is deemed other than temporary results in a charge to earnings and establishes a new cost basis for the security.

The securities held in our investment portfolio are subject to interest rate risk. Changes in interest rates affect the fair market value of the marketable investment securities. After a review of our marketable securities as of March 31, 2006, we have determined that in the event of a hypothetical ten percent increase in interest rates, the resulting decrease in fair market value of our marketable investment securities would be insignificant to the consolidated financial statements as a whole.

Item 4. Controls and Procedures

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

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

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

Table of Contents

PART II - Other Information

Item 1. Legal Proceedings.

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

Item 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.

On January 6, 2006, the Company held a Special Meeting of Stockholders (the "Special Meeting"). A quorum of 24,930,291 shares of Common Stock of the Company (of a total of 39,016,728 shares outstanding as of the record date, or 63.90%) was represented at the Special Meeting in person or by proxy, which was held to vote on the following proposal:

To approve a proposed amendment to the Company's 2003 Employee, Director and Consultant Stock Option Plan to increase by 1,200,000 the number of shares of our common stock available for issuance under this plan.

The proposal was adopted, with the vote totals as follows:

For	16,702,377
Against	6,409,873
Abstain	1,818,041
Broker Non-vote	

Item 5. Other Information.

None.

Item 6. Exhibits.

(a) Exhibits

- 10.1 Myriad Genetics, Inc. 2003 Employee, Director and Consultant Stock Option Plan, as amended (previously filed and incorporated herein by reference from the Form 8-K filed on January 9, 2006).
- 31.1 Certification of Chief Executive Officer pursuant to Section 302(a) of the Sarbanes-Oxley Act of 2002.

Edgar Filing: MYRIAD GENETICS INC - Form 10-Q

- 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: April 28, 2006

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

President and Chief Executive Officer

(Principal executive officer)

Date: April 28, 2006

By: /s/ Jay M. Moyes
Jay M. Moyes

Chief Financial Officer

(Principal financial and chief accounting officer)