

MYRIAD GENETICS INC
Form 10-Q
November 07, 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 September 30, 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

Edgar Filing: MYRIAD GENETICS INC - Form 10-Q

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

As of November 2, 2006 the registrant had 39,764,615 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 September 30, 2006 and June 30, 2006</u>	3
<u>Condensed Consolidated Statements of Operations (Unaudited) for the three months ended September 30, 2006 and 2005</u>	4
<u>Condensed Consolidated Statements of Cash Flows (Unaudited) for the three months ended September 30, 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>	9
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	16
Item 4. <u>Controls and Procedures</u>	17
PART II - Other Information	
Item 1. <u>Legal Proceedings</u>	18
Item 1A. <u>Risk Factors</u>	18
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	18
Item 3. <u>Defaults Upon Senior Securities</u>	18
Item 4. <u>Submission of Matters to a Vote of Security Holders</u>	18
Item 5. <u>Other Information</u>	18
Item 6. <u>Exhibits</u>	18
<u>Signatures</u>	19

Table of Contents

MYRIAD GENETICS, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)

	Sep. 30,	June 30,
	2006	2006
<i>(in thousands, except per share amounts)</i>		
Assets		
Current assets:		
Cash and cash equivalents	\$ 88,625	\$ 98,573
Marketable investment securities	123,490	129,171
Prepaid expenses	1,781	2,326
Trade accounts receivable, less allowance for doubtful accounts of \$1,950 at Sep. 30, 2006 and \$1,795 at June 30, 2006	23,162	20,820
Other receivables	746	1,397
Total current assets	237,804	252,287
Equipment and leasehold improvements:		
Equipment	49,477	47,255
Leasehold improvements	8,450	8,331
	57,927	55,586
Less accumulated depreciation and amortization	37,264	35,757
Net equipment and leasehold improvements	20,663	19,829
Other assets	4,349	4,487
	\$ 262,816	\$ 276,603
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	\$ 11,650	\$ 11,804
Accrued liabilities	11,239	14,901
Deferred revenue	58	117
Total current liabilities	22,947	26,822
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 39,735 at Sep. 30, 2006 and 39,683 at June 30, 2006	397	397
Additional paid-in capital	469,736	467,568
Accumulated other comprehensive loss	(401)	(746)
Accumulated deficit	(229,863)	(217,438)
Total stockholders equity	239,869	249,781
	\$ 262,816	\$ 276,603

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

Table of Contents

MYRIAD GENETICS, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)

<i>(in thousands, except per share amounts)</i>	Three Months Ended	
	Sep. 30, 2006	Sep. 30, 2005
Revenues:		
Molecular diagnostic revenue	\$ 30,851	\$ 21,529
Research revenue	2,692	3,585
Total revenues	33,543	25,114
Costs and expenses:		
Molecular diagnostic cost of revenue	8,105	5,803
Research and development expense	26,352	18,466
Selling, general and administrative expense	14,086	10,898
Total costs and expenses	48,543	35,167
Operating loss	(15,000)	(10,053)
Other income (expense):		
Interest income	2,602	811
Other	(27)	
	2,575	811
Net loss	\$ (12,425)	\$ (9,242)
Basic and diluted loss per share	\$ (0.31)	\$ (0.30)
Basic and diluted weighted average shares outstanding	39,700	30,886

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

Table of Contents

MYRIAD GENETICS, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

<i>(In thousands)</i>	Three Months Ended	
	Sep. 30, 2006	Sep. 30, 2005
Cash flows from operating activities:		
Net loss	\$ (12,425)	\$ (9,242)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,757	1,643
Loss on disposition of assets	27	
Bad debt expense	700	537
Share-based compensation expense	1,361	239
Changes in operating assets:		
Prepaid expenses	545	(1,308)
Trade accounts receivable	(3,042)	(2,048)
Other receivables	651	167
Accounts payable	(154)	(2,177)
Accrued liabilities	(3,662)	(1,508)
Deferred revenue	(59)	2,747
Net cash used in operating activities	(14,301)	(10,950)
Cash flows from investing activities:		
Capital expenditures	(2,480)	(914)
Purchases of marketable investment securities	(28,285)	(6,359)
Proceeds from sales and maturities of marketable investment securities	34,311	6,318
Net cash provided by (used in) investing activities	3,546	(955)
Cash flows from financing activities:		
Net proceeds from common stock issued under share-based compensation plans	807	1,124
Net cash provided by financing activities	807	1,124
Net decrease in cash and cash equivalents	(9,948)	(10,781)
Cash and cash equivalents at beginning of period	98,573	49,509
Cash and cash equivalents at end of period	\$ 88,625	\$ 38,728

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

Table of Contents

MYRIAD GENETICS, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

(1) Basis of Presentation

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

(2) Share-Based Compensation

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

In 2003 the Company adopted the 2003 Employee, Director and Consultant Stock Option Plan (the 2003 Plan), as amended most recently in January 2006, 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 September 30, 2006 the Company granted approximately 617,000 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 September 30, 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 months ended September 30, 2006 and 2005 was approximately \$1,361,000 and \$239,000, respectively. As of September 30, 2006, there was approximately \$17.6 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 3.3 years.

(3) Comprehensive Loss

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

	Three Months Ended Sep. 30,	
	2006	2005
Net loss	\$ (12,425)	\$ (9,242)
Unrealized gain (loss) on available-for-sale securities	345	(106)
Comprehensive loss	\$ (12,080)	\$ (9,348)

(4) Loss Per Common Share

As of September 30, 2006 and 2005, there were outstanding antidilutive potential common shares of 8,563,118 and 8,001,854, respectively. Because the computation of diluted loss per share does not include potential common shares that would have an antidilutive effect, the Company's calculation of the weighted average common shares outstanding utilized to calculate loss per common share was the same for both the basic and diluted calculation.

These potential common shares 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) molecular diagnostics, and (iii) drug development. The research segment is focused on the discovery of genes and protein pathways related to major common diseases. The molecular diagnostics segment provides testing to determine predisposition to common diseases. The drug development segment is focused on the development of therapeutic products for the treatment and prevention of major diseases.

The basis of presentation for the segments is the same as described in Note 1. The Company evaluates segment performance based on results from operations before interest income and expense and other income and expense.

Table of Contents

<i>(in thousands)</i>	Research	Molecular diagnostics	Drug development	Total
Three months ended Sep. 30, 2006:				
Revenues	\$ 2,692	\$ 30,851	\$	\$ 33,543
Depreciation and amortization	669	513	575	1,757
Segment operating income (loss)	(5,228)	13,070	(22,842)	(15,000)
Three months ended Sep. 30, 2005:				
Revenues	\$ 3,585	\$ 21,529	\$	\$ 25,114
Depreciation and amortization	644	516	483	1,643
Segment operating income (loss)	(2,502)	6,707	(14,258)	(10,053)

<i>(in thousands)</i>	Three Months Ended Sep. 30,	
	2006	2005
Total operating loss for reportable segments	\$ (15,000)	\$ (10,053)
Interest income	2,602	811
Other	(27)	
Net loss	\$ (12,425)	\$ (9,242)

Table of Contents

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

We are a leading biotechnology company focused on the development and marketing of novel therapeutic and molecular diagnostic products. We employ a number of proprietary technologies that permit us to understand the genetic basis of human disease and the role that genes and their related proteins play in the onset and progression of disease. We use this information to guide the development of new healthcare products that 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 molecular diagnostics 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.

Understanding the cause of disease at the molecular level can be very useful in determining how best to treat the disease. Historically, technologies used to discover pharmaceutical products that treat the symptoms of diseases have been less effective against complex diseases that arise through a combination of genetic and environmental factors, such as cancer and Alzheimer's disease. In order to treat complex diseases effectively, it is imperative to understand how the body uses its genetic information, how the disruption of important biological pathways can lead to disease, and how drugs can be developed to prevent, modify, or halt disease progression. As we learn more about the genetic basis of disease, we believe that we will be able to develop drugs that are more effective and have fewer side effects.

Our molecular diagnostic business encompasses efforts in both predictive medicine and personalized medicine. Predictive medicine analyzes genes and their mutations to assess an individual's risk for developing disease later in life. Personalized medicine analyzes genes and their mutations to assess a patient's risk of disease progression, disease recurrence, and drug response and toxicity. To date we have launched four commercial molecular diagnostic products. We market these products through our own 125-person sales force in the United States and we have entered into marketing collaborations with other organizations in selected foreign countries. Molecular diagnostic revenue was \$30.9 million for the three months ended September 30, 2006, an increase of 43% over revenue of \$21.5 million for the three months ended September 30, 2005. Our current commercial 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.

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

Table of Contents

polyps. Through proper application of screening and polyp removal, colon cancer is a preventable disease.

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.

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.

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

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

Flurizan : 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. We have initiated two Phase 3 clinical trials in patients with mild Alzheimer's disease. The first Phase 3 trial is a two-arm study (800 mg twice daily and placebo) which has enrolled 1,684 patients in 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 over an 18-month period with a 12-month interim look. The second Phase 3 trial is also a two-arm study (800 mg twice daily and placebo) and is currently enrolling 800 patients in 100 centers in Europe, Canada and the United States. This study is also designed to assess the ability of Flurizan to reduce the rate of cognitive decline and decline in overall function, such as judgment, problem-solving, behavior, and orientation over an 18-month period.

MPC-7869: drug candidate for prostate cancer. MPC-7869 is the subject of 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 MPC-7869 to delay the onset of metastatic cancer in patients with prostate cancer.

Azixa : drug candidate for solid cancer tumors and brain metastases. Azixa is a novel, small-molecule tubulin inhibitor that is being studied in two Phase 1 human clinical 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. In preclinical studies Azixa has demonstrated the ability to effectively cross the blood-brain barrier and is not subject

Table of Contents

to multiple drug resistance. This drug candidate has shown activity in preclinical studies against tumors of the prostate, breast, pancreas, colon and skin (melanoma).

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 hematologic cancers as well as refractory cancers that have 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.

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 non-selectivity, inability to effect thrombin-bound fibrin, and drug and food interactions.

MPI-49839: drug candidate for AIDS. MPI-49839, an orally available viral maturation inhibitor, is in late-stage preclinical development for the treatment of AIDS. As published in the scientific journal *Cell* in October 2001, our scientists and their collaborators discovered the viral budding and maturation mechanism in HIV and other viruses. This discovery led to the development of MPI-49839, 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.

We have also entered into strategic partnerships and collaborative relationships to discover genes and proteins associated with human disease, elucidate protein networks and disease pathways, screen small molecule libraries against drug target assays, develop novel drug candidates, and sequence the genome of entire organisms. We are currently undertaking collaborative research and development work with a number of organizations, including Abbott Laboratories, Istituto Agrario di San Michele all'Adigea and various entities within the National Institutes of Health. These collaborations allow us to further develop and utilize our technologies and to generate revenue.

We have devoted substantially all of our resources to undertaking our drug discovery and development programs, operating our molecular diagnostic business, and continuing our research and development efforts. We have three reportable operating segments: (1) research, (2) molecular diagnostics, and (3) drug development. See Note 5 Segment and Related Information in the notes to our condensed consolidated financial statements (unaudited) for information regarding these operating segments. Our revenues have consisted primarily of sales of molecular diagnostic products and research payments. We have yet to attain profitability and, for the three months ended September 30, 2006, we had a net loss of \$12.4 million. As of September 30, 2006 we had an accumulated deficit of \$229.9 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 molecular diagnostic products, the continuation of our internal research and development programs, and the expansion of our facilities. Additionally, we expect to incur substantial sales, marketing and other expenses in connection with building our pharmaceutical and molecular diagnostic businesses. We expect that losses will fluctuate from quarter to quarter and that such fluctuations may be substantial.

Table of Contents

Critical Accounting Policies

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

revenue recognition;

allowance for doubtful accounts; and

share-based payment expense.

Revenue Recognition. Molecular diagnostic revenue includes revenue from the sale of molecular diagnostic products, forensic DNA analysis fees, and related marketing agreements. Molecular diagnostic 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.

Research revenue includes revenue from research agreements, milestone payments, and technology licensing agreements. In applying the principles of Staff Accounting Bulletin 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, on a basis of costs incurred relative to the total estimated contract costs, or on the basis of contractually defined output measures such as units delivered. We make adjustments, if necessary, to the estimates used in our calculations as work progresses and we gain experience. The principal costs under these agreements are for personnel expenses to conduct research and development but also include costs for materials and other direct and indirect items necessary to complete the research under these agreements. Actual results may vary from our estimates. Payments received on uncompleted long-term contracts may be greater than or less than incurred costs and estimated earnings and have been recorded as other receivables or deferred revenues in the accompanying consolidated balance sheets. 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. GAAP requires us to make estimates and assumptions that affect the reported amount of assets at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Trade accounts receivable are comprised of amounts due from sales of our molecular diagnostic products. 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 require us to recognize in our consolidated statements of operations the grant-date fair value of our stock options and other equity-based compensation. The determination of grant-date fair value is estimated using an option-pricing model, which includes variables such as the expected volatility of our share price, the exercise behavior of our employees, interest rates, and dividend yields. These variables are projected based on our historical data, experience, and other factors. Changes in any of these variables could result in material adjustments to the expense recognized for share-based payments.

Table of Contents

Recent Accounting Pronouncements

In September 2006 the Financial Accounting Standards Board (FASB) issued SFAS No. 157, Fair Value Measurements. SFAS 157 defines fair value, establishes a framework for measuring fair value in GAAP, and expands disclosures about fair value measurements. SFAS 157 applies under other accounting pronouncements that require or permit fair value measurements, the FASB having previously concluded in those accounting pronouncements that fair value is the relevant measurement attribute. Accordingly, SFAS 157 does not require any new fair value measurements, but may change current practice for some entities. SFAS 157 is effective for fiscal years beginning after December 15, 2006. Our adoption of SFAS No. 157 is not expected to have a material effect on our consolidated financial position or results of operations.

In September 2006 the FASB also issued SFAS No. 158, Employers Accounting for Defined Benefit Pension and Other Postretirement Plans an amendment of FASB Statements No. 87, 88, 106, and 132(R). SFAS 158 requires an employer to recognize the overfunded or underfunded status of a defined benefit postretirement plan (other than a multiemployer plan) as an asset or liability in its statement of financial position and to recognize changes in that funded status in the year in which the changes occur through comprehensive income. SFAS 158 also requires an employer to measure the funded status of a plan as of the date of its year-end statement of financial position, with limited exceptions. An employer with publicly traded equity securities is required to initially recognize the funded status of a defined benefit postretirement plan and to provide the required disclosures as of the end of the fiscal year ending after December 15, 2006. Because we do not have a defined benefit pension plan or other qualifying post retirement plan our adoption of SFAS No. 158 is not expected to have a material effect on our consolidated financial position or results of operations.

In July 2006, the FASB issued FASB Interpretation No. 48 (FIN 48) Accounting for Income Tax Uncertainties. FIN 48 defines the threshold for recognizing the benefits of tax return positions in the financial statements as more-likely-than-not to be sustained by the taxing authority. FIN 48 provides guidance on the de-recognition, measurement and classification of income tax uncertainties, along with any related interest and penalties. FIN 48 also includes guidance concerning accounting for income tax uncertainties in interim periods and increases the level of disclosures associated with any recorded income tax uncertainties. FIN 48 is effective for fiscal years beginning after December 15, 2006. Our adoption of FIN 48 is not expected to have a material effect on our consolidated financial position or results of operations.

Results of Operations for the Three Months Ended September 30, 2006 and 2005

Molecular diagnostic revenue is comprised primarily of sales of molecular diagnostic products, and also includes some marketing fees and forensic DNA analysis fees. Molecular diagnostic revenue for the three months ended September 30, 2006 was \$30.9 million compared to \$21.5 million for the same three months in 2005, an increase of 43%. Increased sales, marketing, and education efforts have resulted in wider acceptance of our products by the medical community and increased revenue for the three months ended September 30, 2006. There can be no assurance that molecular diagnostic revenue will continue to increase at historical rates.

Research revenue is comprised of research payments received pursuant to collaborative agreements. Research revenue for the three months ended September 30, 2006 was \$2.7 million compared to \$3.6 million for the same three months in 2005. This 25% decrease in research revenue is primarily attributable to the successful completion of a research collaboration in the prior year quarter. Research revenue from our research collaboration agreements is recognized using a proportional performance methodology. Consequently, as these programs progress and outputs increase or decrease, revenue may increase or decrease proportionately.

Table of Contents

Molecular diagnostic cost of revenue for the three months ended September 30, 2006 was \$8.1 million compared to \$5.8 million for the same three months in 2005. This increase of 40% in molecular diagnostic cost of revenue is primarily due to the 43% increase in molecular diagnostic revenues for the three months ended September 30, 2006 compared to the same three months in 2005. Our gross profit margin was 74% for the three months ended September 30, 2006 compared to 73% for the same three months in 2005. There can be no assurance that molecular diagnostic 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 molecular diagnostic laboratory.

Research and development expenses for the three months ended September 30, 2006 were \$26.4 million compared to \$18.5 million for the same three months in 2005. This increase of 43% 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, customer service, 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 September 30, 2006 were \$14.1 million compared to \$10.9 million for the same three months in 2005. This increase of 29% was primarily attributable to general increases in costs to support the 43% growth in our molecular diagnostic 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 decreased \$15.6 million, or 7%, from \$227.7 million at June 30, 2006 to \$212.1 million at September 30, 2006. This decrease is primarily attributable to expenditures for our ongoing clinical trials, internal research and drug development programs, acquisition of capital assets, and other expenditures incurred in the ordinary course of business. These expenditures were partially offset by cash generated from our molecular diagnostic revenues.

In November 2005 we received \$139.7 million in net proceeds from an underwritten offering of 8.1 million shares of our common stock. Due to this increase in cash, cash equivalents, marketable investment securities, as well as increases in interest rates, interest income for the three months ended September 30, 2006 was \$2.6 million, compared to \$811,000 for the same three months in 2005, an increase of 221%.

Net cash used in operating activities was \$14.3 million during the three months ended September 30, 2006 compared to \$11.0 million used in operating activities during the same three months in 2005. Trade accounts receivable increased \$3.0 million between June 30, 2006 and September 30, 2006, primarily due to increases in molecular diagnostic sales during the same period. Accrued liabilities decreased by \$3.7 million between June 30, 2006 and September 30, 2006, primarily due to payments made for amounts related to our clinical trials.

Our investing activities provided cash of \$3.5 million during the three months ended September 30, 2006 and used cash of \$1.0 million during the same three months in 2005. Investing activities were comprised primarily of purchases and maturities of marketable investment securities and capital expenditures for research equipment.

Table of Contents

Financing activities provided cash of \$0.8 million during the three months ended September 30, 2006 and provided cash of \$1.1 million in the same three months in 2005. During the three months ended September 30, 2006 we received \$0.8 million from the exercise of stock options.

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

the progress and results of our current Phase 2b clinical trial of MPC-7869 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;

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

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

the progress, results and cost of developing personalized medicine products and additional predictive medicine products for our molecular diagnostic business;

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

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

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

Edgar Filing: MYRIAD GENETICS INC - Form 10-Q

the timing, receipt and amount of sales or royalties, if any, from Flurizan, MPC-7869, Azixa, MPC-2130, MPC-0920, and any other drug candidates.

We have an effective shelf registration statement on Form S-3 (Registration No. 333-123914) on file with the Securities and Exchange Commission for the sale of up to \$151.1 million of various types of securities upon filing of a prospectus supplement with the SEC. Because of our significant long-term capital requirements, we may access the public or private equity markets whenever conditions are favorable, even if we do not have an immediate need for additional capital at such time.

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

Table of Contents

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 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: 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 molecular diagnostic products that help assess which patients are subject to greater risk of developing diseases and who would therefore benefit from new preventive therapies; the possibility of delays in the research and 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 Risk Factors contained in Item 1A of our Annual Report on Form 10-K for the year ended June 30, 2006, 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 the Company or to any person acting on its 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 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 September 30, 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.

Table of Contents

Item 4. Controls and Procedures

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

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

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

Table of Contents

PART II - Other Information

Item 1. Legal Proceedings.

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

Item 1A. Risk Factors

There have been no material changes to the risk factors included in our Annual Report on Form 10-K for the fiscal year ended June 30, 2006.

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

None.

Item 3. Defaults Upon Senior Securities.

None.

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

None.

Item 5. Other Information.

None.

Item 6. Exhibits.

(a) Exhibits

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

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

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

Table of Contents

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

MYRIAD GENETICS, INC.

Date: November 3, 2006

By: /s/ Peter D. Meldrum
Peter D. Meldrum
President and Chief Executive Officer

(Principal executive officer)

Date: November 3, 2006

By: /s/ Jay M. Moyes
Jay M. Moyes
Chief Financial Officer

(Principal financial and chief accounting officer)