

EXACT SCIENCES CORP
Form 10-Q
August 13, 2009
Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended June 30, 2009

OR

- o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Commission File Number: 000-32179

EXACT SCIENCES CORPORATION

(Exact name of registrant as specified in its charter)

DELAWARE

02-0478229

Edgar Filing: EXACT SCIENCES CORP - Form 10-Q

(State or other jurisdiction of
incorporation or organization)

(I.R.S. Employer
Identification Number)

505 S. Rosa Road, Suite 123, Madison WI
(Address of principal executive offices)

53719
(Zip Code)

(608) 284-5700

(Registrant's telephone number, including area code)

100 Campus Drive, Marlborough, MA 01752

(Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report)

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

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

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

As of August 7, 2009, the registrant had 35,446,456 shares of Common Stock outstanding.

Table of Contents

EXACT SCIENCES CORPORATION

INDEX

	Page Number
Part I - Financial Information	
Item 1. Financial Statements	
<u>Condensed Consolidated Balance Sheets (Unaudited) as of June 30, 2009 and December 31, 2008</u>	3
<u>Condensed Consolidated Statements of Operations (Unaudited) for the Three and Six Months Ended June 30, 2009 and 2008</u>	4
<u>Condensed Consolidated Statements of Cash Flows (Unaudited) for the Six Months Ended June 30, 2009 and 2008</u>	5
<u>Notes to Condensed Consolidated Financial Statements (Unaudited)</u>	6
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	19
Item 4. <u>Controls and Procedures</u>	25
Part II - Other Information	
Item 6. <u>Exhibits</u>	26
<u>Signatures</u>	27
<u>Exhibit Index</u>	28

Table of Contents**EXACT SCIENCES CORPORATION****Condensed Consolidated Balance Sheets****(Amounts in thousands, except share data - unaudited)**

	June 30, 2009	December 31, 2008
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 12,288	\$ 4,937
Marketable securities	15,510	
Prepaid expenses and other current assets	426	190
Total current assets	28,224	5,127
Property and Equipment, at cost:		
Laboratory equipment	174	174
Office and computer equipment	57	13
Leasehold improvements	13	
Furniture and fixtures	10	
	254	187
Less Accumulated depreciation and amortization	(136)	(111)
	118	76
Patent costs, net of accumulated amortization of \$2,820 at December 31, 2008		95
Restricted cash	600	600
	\$ 28,942	\$ 5,898
LIABILITIES AND STOCKHOLDERS (DEFICIT) EQUITY		
Current Liabilities:		
Accounts payable	\$ 284	\$ 683
Accrued expenses	1,085	1,498
Third party royalty obligation	1,000	1,500
Deferred revenue	4,986	1,350
Total current liabilities	7,355	5,031
Third party royalty obligation, less current portion	965	1,950
Deferred revenue	13,654	1,350
Commitments and contingencies		
Stockholders (Deficit) Equity:		
Preferred stock, \$0.01 par value; 5,000,000 shares authorized; no shares issued and outstanding at June 30, 2009 and December 31, 2008		
Common stock, \$0.01 par value; 100,000,000 shares authorized; 35,267,069 and 27,522,931 shares issued and outstanding at June 30, 2009 and December 31, 2008	353	275
Additional paid-in capital	185,372	169,854
Treasury stock, at cost, 85,550 shares	(97)	(97)
Accumulated other comprehensive income	38	
Accumulated deficit	(178,698)	(172,465)
Total stockholders (deficit) equity	6,968	(2,433)
	\$ 28,942	\$ 5,898

The accompanying notes are an integral part of these condensed consolidated financial statements.

Table of Contents**EXACT SCIENCES CORPORATION****Condensed Consolidated Statements of Operations****(Amounts in Thousands, except per share data-unaudited)**

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
Revenue:				
Product royalty fees	\$ 11	\$ (495)	\$ 18	\$ (787)
License fees	1,247	338	2,240	676
Product		11		16
	1,258	(146)	2,258	(95)
Cost of revenue:				
Product royalty fees	8		8	1
Gross profit (loss)	1,250	(146)	2,250	(96)
Operating expenses:				
Research and development (1)	2,015	528	2,123	1,387
General and administrative (1)	1,638	1,495	6,406	3,330
Sales and marketing	40		40	
Restructuring		(5)	(3)	(7)
	3,693	2,018	8,566	4,710
Loss from operations	(2,443)	(2,164)	(6,316)	(4,806)
Interest income	49	64	83	188
Net loss	\$ (2,394)	\$ (2,100)	\$ (6,233)	\$ (4,618)
Net loss per share - basic and diluted	\$ (0.08)	\$ (0.08)	\$ (0.21)	\$ (0.17)
Weighted average common shares outstanding - basic and diluted	31,283	27,175	30,360	27,160

(1) Non-cash stock-based compensation expense included in these amounts are as follows:

Research and development	\$ 50	\$ 25	\$ 50	\$ 70
General and administrative	661	204	1,284	460

The accompanying notes are an integral part of these condensed consolidated financial statements.

Table of Contents**EXACT SCIENCES CORPORATION****Consolidated Statements of Cash Flows****(Amounts in thousands-unaudited)**

	Six Months Ended June 30,	
	2009	2008
Cash flows from operating activities:		
Net loss	\$ (6,233)	\$ (4,618)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	121	431
Stock-based compensation	1,334	530
Warrant expense for license fees	1,725	
Changes in assets and liabilities:		
Prepaid expenses and other current assets	(236)	(127)
Amortization of deferred revenue	(2,240)	(676)
Accounts payable	(399)	105
Accrued expenses	(381)	(1,185)
Third party royalty obligation	(1,485)	800
Net cash used in operating activities	(7,794)	(4,740)
Cash flows from investing activities:		
Purchases of marketable securities	(16,972)	(3,458)
Maturities of marketable securities	1,500	9,293
Purchases of property and equipment	(68)	
Increase in patent costs and other assets		(83)
Net cash (used in) provided by investing activities	(15,540)	5,752
Cash flows from financing activities:		
Proceeds from Genzyme Collaboration, License and Purchase Agreement	16,650	
Proceeds from sale of common stock to Genzyme	6,000	
Proceeds from sale of common stock, net of issuance costs	8,062	
Proceeds from exercise of common stock options and stock purchase plan	23	6
Payment to repurchase stock options	(50)	
Net cash provided by financing activities	30,685	6
Net increase in cash and cash equivalents	7,351	1,018
Cash and cash equivalents, beginning of period	4,937	4,486
Cash and cash equivalents, end of period	\$ 12,288	\$ 5,504

The accompanying notes are an integral part of these consolidated financial statements.

Table of Contents

EXACT SCIENCES CORPORATION

Notes to Condensed Consolidated Financial Statements

(Unaudited)

(1) ORGANIZATION AND BASIS OF PRESENTATION

Organization

EXACT Sciences Corporation (EXACT or the Company) was incorporated in February 1995. EXACT is a molecular diagnostics company focused on colorectal cancer. The Company s non-invasive stool-based DNA (sDNA) screening technology includes proprietary and patented methods that isolate and analyze human DNA present in stool to screen for the presence of colorectal pre-cancer and cancer. Effective April 2, 2009 the Company s board of directors appointed Kevin T. Conroy as president and chief executive, and Maneesh K. Arora as senior vice president and chief financial officer. They were most recently president and chief executive, and chief financial officer, respectively, of Third Wave Technologies Inc.

Basis of Presentation

The accompanying condensed consolidated financial statements of the Company are unaudited and have been prepared on a basis substantially consistent with the Company s audited financial statements and notes as of and for the year ended December 31, 2008 included in the Company s Annual Report on Form 10-K. These condensed consolidated financial statements are prepared in conformity with accounting principles generally accepted in the United States of America (GAAP) and follow the requirements of the Securities and Exchange Commission (SEC) for interim reporting. The results of the Company s operations for any interim period are not necessarily indicative of the results of the Company s operations for any other interim period or for a full fiscal year. The statements should be read in conjunction with the financial statements and footnotes thereto included in our audit for the year ended December 31, 2008.

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation

The accompanying condensed consolidated financial statements include the accounts of the Company s wholly-owned subsidiary, EXACT Sciences Securities Corporation, a Massachusetts securities corporation. All significant intercompany transactions and balances have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Cash and Cash Equivalents

The Company considers all highly-liquid investments with maturities of 90 days or less at the time of acquisition to be cash equivalents. Cash equivalents primarily consist of money market funds.

Restricted Cash

At June 30, 2009 and December 31, 2008, \$0.6 million of the Company's cash has been pledged as collateral for an outstanding letter of credit in connection with the lease for the Company's corporate headquarters.

Marketable Securities

The Company accounts for its investments in marketable securities in accordance with Statement of Financial Accounting Standards (SFAS) No. 115, *Accounting for Certain Investments in Debt and Equity Securities*. Management determines the appropriate classification of debt securities at the time of purchase and re-evaluates such

Table of Contents

designation as of each balance sheet date. Debt securities are classified as held-to-maturity when the Company has the positive intent and ability to hold the securities to maturity. Marketable equity securities and debt securities not classified as held-to-maturity are classified as available-for-sale. Available-for-sale securities are carried at fair value, with the unrealized gains and losses, net of tax, reported in other comprehensive income. The amortized cost of debt securities in this category is adjusted for amortization of premiums and accretion of discounts to maturity computed under the effective interest method. Such amortization is included in investment income. Realized gains and losses and declines in value judged to be other-than-temporary on available-for-sale securities are included in investment income. The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in investment income.

At June 30, 2009, the Company's investments were comprised of fixed income investments and all were deemed available-for-sale. At December 31, 2008, the Company held no marketable securities. The objectives of the Company's investment strategy are to provide liquidity and safety of principal while striving to achieve the highest rate of return consistent with these two objectives. The Company's investment policy limits investments to certain types of instruments issued by institutions with investment grade credit ratings and places restrictions on maturities and concentration by type and issuer. There were no realized gains or losses on the sale of available-for-sale securities during the six months ended June 30, 2009 and 2008.

Patent Costs

Patent costs, which have historically consisted of related legal fees, are capitalized as incurred, only if the Company determines that there is some probable future economic benefit derived from the transaction. The capitalized patents are amortized beginning when patents are approved over an estimated useful life of five years. Capitalized patent costs are expensed upon disapproval, upon a decision by the Company to no longer pursue the patent or when the related intellectual property is either sold or deemed to be no longer of value to the Company. During the second quarter of 2009 the Company determined that the patent costs incurred should be expensed and not capitalized as the future economic benefit derived from the transactions was indeterminate.

As more fully described in Note 3 below, in connection with the Genzyme Strategic Transaction the Company sold its then-remaining capitalized intellectual property to Genzyme on January 27, 2009, and accordingly, wrote off the remaining unamortized capitalized patent costs at that time. There are no capitalized patent costs recorded in the Company's financial statements as of June 30, 2009.

The following table summarizes activity with respect to the Company's capitalized patents for the six months ended June 30, 2009 and 2008. Amounts included in the table are in thousands.

	Six Months Ended June 30, 2009	Six Months Ended June 30, 2008
Patents, net of accumulated amortization, Beginning of period	\$ 95	\$ 432
Patent costs capitalized		83
Amortization of patents		(62)
Write-offs of patents	(95)	(253)

Patents, net of accumulated amortization, End of period	\$	\$	200
---	----	----	-----

Net Loss Per Share

Basic and diluted net loss per share is presented in conformity with SFAS No. 128, *Earnings per Share* (SFAS No. 128), for all periods presented. In accordance with SFAS No. 128, basic net loss per common share was determined by dividing net loss applicable to common stockholders by the weighted average common shares outstanding during the period. Basic and diluted net loss per share are the same because all outstanding common stock equivalents have been excluded, as they are anti-dilutive.

Table of Contents

The following potentially issuable common shares were not included in the computation of diluted net loss per share because they would have an anti-dilutive effect due to net losses for each period:

(In thousands)	2009	June 30, 2008
Shares issuable upon exercise of stock options	6,861	4,396
Shares issuable upon exercise of outstanding warrants	1,250	1,000
	8,111	5,396

Accounting for Stock-Based Compensation

The Company accounts for share-based payments to employees in accordance with SFAS No. 123(R), *Share-Based Payment* (SFAS No. 123(R)), which requires all share-based payments to employees, including grants of employee stock options and shares purchased under an employee stock purchase plan (if certain parameters are not met), to be recognized in the financial statements based on their fair values. Share-based payment transactions with parties other than employees are accounted for in accordance with EITF 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*.

Revenue Recognition

License fees. License fees for the licensing of product rights on initiation of strategic agreements are recorded as deferred revenue upon receipt and recognized as revenue on a straight-line basis over the license period. On June 27, 2007, the Company entered into an amendment to its exclusive license agreement with LabCorp (the Second Amendment) that, among other modifications to the terms of the license, extended the exclusive license period from August 2008 to December 2010, subject to carve-outs for certain named organizations. Accordingly, the Company amortizes the remaining deferred revenue balance resulting from its license agreement with LabCorp at the time of the Second Amendment (\$4.7 million) on a straight-line basis over the remaining exclusive license period, which ends in December 2010.

As more fully described in Note 3 below, in connection with the Genzyme Strategic Transaction, the Company received an up-front payment of \$16.65 million on January 27, 2009 in exchange for the assignment and licensing of certain intellectual property to Genzyme. Pursuant to the provisions of SEC Staff Accounting Bulletin No. 104 and EITF No. 00-21, *Revenue Arrangements with Multiple Deliverables*, which govern revenue recognition, the Company's on-going performance obligations to Genzyme under the Collaboration, License and Purchase Agreement (the CLP Agreement), as described below, including its obligation to deliver certain intellectual property improvements to Genzyme during the initial five-year collaboration period, were deemed to be undelivered elements of the CLP Agreement on the date of closing. Accordingly, the Company deferred the initial \$16.65 million in cash received at closing and will amortize that up-front payment on a straight line basis into revenue over the initial five-year collaboration period ending in January 2014. Receipt of any holdback amounts, as defined below, will similarly be deferred and amortized on a straight line basis into revenue over the remaining term of the collaboration at the time of receipt.

In addition, Genzyme paid \$2.00 per share for the 3,000,000 shares of common stock purchased from the Company on January 27, 2009, representing a premium of \$0.51 per share above the closing price of the Company's common stock on that date of \$1.49 per share. Under FASB Technical Bulletin No. 85-6, *Accounting for a Purchase of Treasury Shares at a Price Significantly in Excess of the Current Market Price of the Shares and the Income Statement Classification of Costs Incurred in Defending against a Takeover Attempt*, (FTB No. 85-6), the aggregate premium paid by Genzyme over the closing price of the Company's common stock on the date of the transaction of \$1.53 million is deemed to be

Edgar Filing: EXACT SCIENCES CORP - Form 10-Q

a part of the total consideration for the CLP Agreement. Accordingly, the Company deferred the aggregate \$1.53 million premium and will amortize that amount on a straight line basis into revenue over the initial five-year collaboration period ending in January 2014. The Company recognized approximately \$1.6 million in license fee revenue in connection with the amortization of the up-front payments from Genzyme during the six months ended June 30, 2009.

Product royalty fees. The Company has licensed certain of its technologies, including improvements to such technologies, on an exclusive basis through December 2010 to LabCorp. LabCorp developed and commercially offered PreGen-Plus, a non-invasive stool-based DNA colorectal cancer screening service for the average-risk population based on the Company's Version 1 technology, from August 2003 through June 2008. In June 2008, LabCorp stopped offering PreGen-Plus. On July 14, 2008, LabCorp began to commercially offer ColoSure, its next generation non-invasive, stool-based DNA

Table of Contents

testing service for the detection of colorectal cancer in the average-risk population, which is based on certain of the Company's intellectual property. The Company will be entitled to the same royalty and milestone structure on any sales of ColoSure as it was entitled to on sales of PreGen-Plus.

Prior to the effective date of the Second Amendment, the Company's product royalty fees were based on a specified contractual percentage of LabCorp's cash receipts from performing PreGen-Plus tests. Accordingly, the Company recorded product royalty fees based on this specified percentage of LabCorp's cash receipts, as reported to the Company each month by LabCorp. Subsequent to the effective date of the Second Amendment, the Company's product royalty fees are based on a specified contractual percentage of LabCorp's net revenues from sales of PreGen-Plus through June 1, 2008, when LabCorp stopped offering PreGen-Plus, and from sales of ColoSure from and after July 2008. Accordingly, subsequent to the effective date of the Second Amendment, the Company records product royalty fees based on the specified contractual percentage of LabCorp's net revenues from its sales of such colorectal cancer screening tests, as reported to the Company each month by LabCorp. The current royalty rate is 15%, subject to an increase to 17% in the event that LabCorp achieves a specified significant threshold of annual net revenues from the sales of such colorectal cancer screening tests.

Additionally, pursuant to the Second Amendment, the Company is potentially obligated to reimburse LabCorp for certain third-party royalty payments, as described in Note 6 below. To the extent the Company incurs liabilities in connection with this provision of the Second Amendment, the accretion of such liabilities will be recorded as a reduction in the product royalty fee line item in the Company's condensed consolidated statements of operations.

Other revenue. Revenue from milestone and other performance-based payments is recognized as revenue when the milestone or performance is achieved and collection of the receivable is estimable and probable.

Comprehensive Loss

SFAS No. 130, *Reporting Comprehensive Income*, establishes presentation and disclosure requirements for comprehensive income (loss). Comprehensive loss consists of net loss and the change in unrealized gains and losses on marketable securities. Comprehensive loss for the three months ended June 30, 2009 and 2008 was as follows:

(In thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
Net loss	\$ (2,394)	\$ (2,100)	\$ (6,233)	\$ (4,618)
Unrealized gain (loss) on marketable securities	(33)	(23)	38	(22)
Comprehensive loss	\$ (2,427)	\$ (2,123)	\$ (6,195)	\$ (4,640)

(3) GENZYME STRATEGIC TRANSACTION

Transaction summary

On January 27, 2009, the Company entered into a Collaboration, License and Purchase Agreement (the "CLP Agreement") with Genzyme Corporation ("Genzyme"). Pursuant to the CLP Agreement, the Company (i) assigned to Genzyme all of its intellectual property applicable to the fields of prenatal and reproductive health (the "Transferred Intellectual Property"), (ii) granted Genzyme an irrevocable, perpetual, exclusive, worldwide, fully-paid, royalty-free license to use and sublicense all of the Company's remaining intellectual property (the "Retained Intellectual Property") in the fields of prenatal and reproductive health (the "Genzyme Core Field"), and (iii) granted Genzyme an irrevocable, perpetual, non-exclusive, worldwide, fully-paid, royalty-free license to use and sublicense the Retained Intellectual Property in all fields other than the Genzyme Core Field and other than colorectal cancer detection and stool-based disease protection (the "Company Field"). Following the Genzyme Transaction, EXACT retains rights in its intellectual property to pursue only the fields of colorectal cancer detection and stool-based detection of any disease or condition. As part of the transaction, the Company entered into an Assignment, Sublicense, Consent and Eighth Amendment to License Agreement with Genzyme and JHU (the "JHU Amendment") (collectively, with the licenses and assignment described herein, the "Genzyme Strategic Transaction") on January 27, 2009, whereby the Company assigned its rights under the license agreement between the Company and The Johns Hopkins University ("JHU") dated March 25, 2003, as amended (the "JHU Agreement") to Genzyme. Pursuant to the JHU Amendment, Genzyme sublicensed to the Company the intellectual property subject to the JHU Agreement for colorectal cancer detection and stool-based disease detection, including the BEAMing technology for the detection of colorectal cancer. Under the JHU Amendment, the Company and Genzyme will share in the royalty and annual payment obligations to JHU.

Also as part of the Genzyme Strategic Transaction, the Company entered into an Amended and Restated License Agreement (the "Restated License") with Genzyme on January 27, 2009, which amends and restates the License Agreement between the parties dated March 25, 1999, effective as of January 27, 2009. Pursuant to the Restated License, Genzyme

Table of Contents

granted to the Company a non-exclusive license to use technology related to the use of certain genes, specifically APC and p53, and methodologies related thereto. In exchange for the license, which continues until the expiration of the last to expire licensed patent, the Company has agreed to pay Genzyme royalties based on net revenues received from performing tests that incorporate the licensed technology and sales of reagents and diagnostic test kits that incorporate the licensed technology, as well as certain minimum royalties, milestone payments and maintenance fees.

Pursuant to the Genzyme Strategic Transaction, Genzyme agreed to pay an aggregate of \$18.5 million to the Company, of which \$16.65 million was paid at closing and \$1.85 million (the Holdback Amount) is subject to a holdback by Genzyme to satisfy certain potential indemnification obligations of the Company. Subject to the terms and conditions of the CLP Agreement, one-half of the Holdback Amount will be released to the Company in 12 months and one-half will be released in 18 months. Genzyme also agreed to pay a double-digit royalty to the Company on income received by Genzyme as a result of any licenses or sublicenses to third parties of the Transferred Intellectual Property or the Retained Intellectual Property in any field other than the Genzyme Core Field or the Company Field.

Pursuant to the provisions of SEC Staff Accounting Bulletin No. 104 and EITF No. 00-21, which govern revenue recognition, the Company's on-going performance obligations to Genzyme under the CLP, including the obligation to deliver certain intellectual property improvements to Genzyme during the initial five year collaboration period, were deemed to be undelivered elements of the CLP Agreement on the date of closing. Accordingly, the Company deferred the initial \$16.65 million in cash received at closing and will amortize that up-front payment on a straight line basis into the License Fee Revenue line item in its statements of operations over the initial five year collaboration period. Receipt of any Holdback Amounts will similarly be deferred and amortized on a straight line basis into the License Fee Revenue line item in the Company's statements of operations over the remaining term of the collaboration at the time of receipt.

In addition, the Company entered into a Common Stock Subscription Agreement with Genzyme (the Purchase Agreement) on January 27, 2009, which provided for the private issuance and sale to Genzyme of 3,000,000 shares (the Shares) of the Company's common stock, \$0.01 par value per share (Common Stock), at a per share price of \$2.00, for an aggregate purchase price of \$6.0 million. The price paid by Genzyme for the Shares represented a premium of \$0.51 per share above the closing price of the Company's common stock on that date of \$1.49 per share. Under FTB No. 85-6 the aggregate premium paid by Genzyme over the closing price of the Company's common stock on the date of the transaction of \$1.53 million is included as a part of the total consideration for the CLP. Accordingly, the Company deferred the aggregate \$1.53 million premium and will amortize that amount on a straight line basis into the License Fee Revenue line item in the Company's statements of operations over the initial five-year collaboration period. The Company recognized approximately \$1.6 million in license fee revenue in connection with the amortization of the up-front payments from Genzyme during the six months ended June 30, 2009.

(4) MAYO LICENSING AGREEMENT

Overview

On June 11, 2009, the Company entered into a license agreement (the License Agreement) with MAYO Foundation for Medical Education and Research (MAYO). Under the License Agreement, MAYO granted the Company an exclusive, worldwide license within the field (the Field) of stool or blood based cancer diagnostics and screening (excluding a specified proteomic target) (the Proteomic Target) with regard to certain MAYO patents, and a non-exclusive worldwide license within the Field with regard to certain MAYO know-how. The License Agreement grants the Company an option to include the Proteomic Target within the Field upon written notice by the Company to MAYO during the first year of the term. The licensed patents cover advances in sample processing, analytical testing and data analysis associated with non-invasive, stool-based DNA screening for colorectal cancer. Under the License Agreement, the Company assumes the obligation and expense of

Edgar Filing: EXACT SCIENCES CORP - Form 10-Q

prosecuting and maintaining the licensed patents and is obligated to make commercially reasonable efforts to bring products covered by the licenses to market. Pursuant to the License Agreement, the Company granted MAYO two common stock purchase warrants with an exercise price of \$1.90 per share covering 1,000,000 and 250,000 shares of common stock, respectively. The Company will also make payments to MAYO for up-front fees, fees once certain milestones are reached by the Company, and other payments as outlined in the agreement. In addition to the license to intellectual property owned by MAYO, the Company will receive product development and research and development efforts from MAYO personnel. The Company determined that the payments made for intellectual property should not be capitalized as the future economic benefit derived from the transactions is uncertain. The Company is also liable to make royalty payments to MAYO on potential future net sales of any products developed from the licensed technology.

Table of Contents**Warrants**

The warrants granted to MAYO were valued based on a Black-Scholes pricing model at the date of the grant. The warrants were granted with an exercise price of \$1.90 per share of common stock. The grant to purchase 1,000,000 shares vested immediately and the grant to purchase 250,000 shares vest over a four year period. The total value of the warrants was calculated to be \$2.1 million and a non cash charge of \$1.7 million was recognized as research and development expense in the second quarter of 2009 and the remaining \$0.4 million non cash charge will be recognized straight-line over the four year vesting period. The assumptions for the Black-Scholes pricing model are represented in the table below.

Assumptions for Black-Scholes Pricing Model:

Exercise price	\$	1.90
Stock price	\$	1.99
Volatility		86.30%
Life of warrant (in years)		10
Treasury rate		3.88%
Yield		0%
Fair value per warrant	\$	1.72

Royalty Payments

The Company will make royalty payments to MAYO based on a percentage of net sales of products developed from the licensed technology starting in the third year of the agreement. Minimum royalty payments will be \$10,000 in 2012 and \$25,000 per year thereafter.

Other Payments

Other payments under the MAYO agreement include an upfront payment of \$80,000, a milestone payment of \$250,000 on the commencement of patient enrollment in a human cancer screening clinical, and a \$500,000 payment upon FDA approval of the Company's cancer screening test. The upfront payment of \$80,000 has been accrued for at June 30, 2009 and payment will be made in the third quarter of 2009. In addition, the Company will pay a minimum of \$659,516 to MAYO over the next 12 months for research and development efforts.

(5) CHANGES IN SENIOR MANAGEMENT AND EMPLOYMENT AGREEMENTS

Former Chief Executive Officer and Former Chief Financial Officer

Effective April 2, 2009, Jeffrey R. Lubber resigned as the Company's President and Chief Executive Officer and member of the Company's Board of Directors, and Charles R. Carelli, Jr. resigned as the Company's Chief Financial Officer. Mr. Carelli remained employed by the Company as a non-executive employee through April 30, 2009. The expenses related to the departure discussed below were recorded in the quarter ended March 31, 2009.

In connection with their departure, Messrs. Lubber and Carelli were entitled to receive severance benefits pursuant to their previously disclosed retention agreements, including salary continuation of \$472,500 and \$287,500, which is equal to eighteen months and fifteen months, respectively, of their base salaries as of the date of termination. On March 31, 2009, the Company entered into release agreements with Messrs. Lubber and Carelli that provided, in exchange for a general release in favor of the Company, for the accelerated payment of the salary continuation obligations. In addition, the release agreements also provided for the repurchase by the Company of options held by Messrs. Lubber and Carelli for an aggregate of 804,026 shares of common stock, in lieu of accelerated vesting and an extension of the option exercise period arising from the prior retention agreements. The Company paid Messrs. Lubber and Carelli approximately \$39,000 and \$11,000, respectively, to repurchase Mr. Lubber's options to purchase 553,333 shares and Mr. Carelli's options to purchase 250,693 shares. The purchase price of the outstanding options represented a 75 percent discount from the estimated fair value of the vested options as of March 31, 2009 and was recorded as a reduction to additional paid-in-capital. Messrs. Lubber and Carelli retained the balance of their existing options, the vesting of which was accelerated by nine months.

Edgar Filing: EXACT SCIENCES CORP - Form 10-Q

Table of Contents

In connection with the repurchase of options from Messrs. Luber and Carelli, the Company recorded non-cash stock-based compensation charges of approximately \$0.2 million in the quarter ended March 31, 2009 in accordance with the provisions of SFAS No. 123(R). In addition, the Company recorded non-cash stock-based compensation charges of approximately \$60,000 in the quarter ended March 31, 2009 in connection with modifications in vesting and period of exercise for options being retained by Messrs. Luber and Carelli.

A summary of options repurchased as of June 30, 2009 from Mr. Luber and options retained subsequent to Mr. Luber's termination is below.

Options Repurchased

Option Grant Date	Grant Price	Number of Securities Underlying Unexercised Options As of March 31, 2009		Total Options	Total Options Repurchased	Total Options Forfeited
		Exercisable	Unexercisable			
11/18/2002	\$ 14.33	50,000		50,000	50,000	
2/11/2004	\$ 7.72	80,000		80,000	80,000	
12/23/2004	\$ 3.61	60,000		60,000	60,000	
2/17/2005	\$ 4.22	20,000		20,000	20,000	
2/16/2006	\$ 2.61	55,000		55,000	55,000	
4/11/2006	\$ 3.07	29,166	834	30,000	30,000	
2/15/2007	\$ 2.77	52,083	22,917	75,000	70,833	4,167
9/4/2007	\$ 2.90	125,000	125,000	250,000	187,500	62,500
		471,249	148,751	620,000	553,333	66,667

Options Retained

Option Grant Date	Grant Price	Number of Options Retained	Expiration Date
2/21/2008	\$ 1.83	80,207	1/2/2011

A summary of options repurchased as of June 30, 2009 from Mr. Carelli and options retained subsequent to Mr. Carelli's termination is below.

Options Repurchased

Option Grant Date	Grant Price	Number of Securities Underlying Unexercised Options As of March 31, 2009		Total Options	Total Options Repurchased	Total Options Forfeited
		Exercisable	Unexercisable			
11/9/2004	\$ 3.28	20,000		20,000	20,000	
7/29/2005	\$ 2.65	27,499	2,501	30,000	30,000	

Edgar Filing: EXACT SCIENCES CORP - Form 10-Q

2/16/2006	\$	2.61	25,000		25,000	25,000	
4/11/2006	\$	3.07	24,305	695	25,000	25,000	
2/15/2007	\$	2.77	52,083	22,917	75,000	72,916	2,084
9/4/2007	\$	2.90	50,000	50,000	100,000	77,777	22,223
			198,887	76,113	275,000	250,693	24,307

Options Retained

Option Grant Date	Grant Price	Number of Options Retained	Expiration Date
2/21/2008	\$ 1.83	43,124	1/31/2011

New Chief Executive Officer and Chief Financial Officer

On March 18, 2009, the Company's Board of Directors appointed Kevin T. Conroy as President and Chief Executive Officer of the Company, effective April 2, 2009. Also on March 18, 2009, based on the recommendation of the Corporate Governance and Nominating Committee, the Board of Directors elected Mr. Conroy to the Board. In connection with his appointment, Mr. Conroy entered into an employment agreement with the Company on March 18, 2009 (the "Conroy Agreement"). Under the terms of the Conroy Agreement, Mr. Conroy serves as President and Chief Executive Officer of the Company at a base salary of \$340,000 and is eligible to earn up to 50% of his base salary in annual bonuses, with the exact amount of any such bonus to be determined by the Compensation Committee. Pursuant to the Conroy Agreement, Mr. Conroy was granted options to purchase 2.5 million shares of the common stock of the Company, par value \$0.01 per share (the "Common Stock"), at a price per share of \$0.83, which is equal to the closing price of the Common Stock on the NASDAQ Capital Market on March 18, 2009. Twenty-five percent (25%) of the

Table of Contents

shares underlying the stock options become exercisable on the one-year anniversary of the date of grant, with the remainder vesting quarterly over the subsequent three years.

On March 18, 2009, the Company's Board of Directors appointed Maneesh K. Arora as Senior Vice President and Chief Financial Officer of the Company, effective April 2, 2009. In connection with his appointment, Mr. Arora entered into an employment agreement with the Company on March 18, 2009 (the Arora Agreement). Under the terms of the Arora Agreement, Mr. Arora serves as Senior Vice President and Chief Financial Officer of the Company at a base salary of \$240,000 and is eligible to earn up to 40% of his base salary in annual bonuses, with the exact amount of any such bonus to be determined by the Compensation Committee. Pursuant to the Arora Agreement, Mr. Arora was granted options to purchase 1.25 million shares of Common Stock, at a price per share of \$0.83, which is equal to the closing price of the Common Stock on the NASDAQ Capital Market on March 18, 2009. Twenty-five percent (25%) of the shares underlying the stock options become exercisable on the one-year anniversary of the date of grant, with the remainder vesting quarterly over the subsequent three years.

(6) CONTINGENCIES**Third Party Royalty Obligation**

Pursuant to the terms of the Second Amendment to the Company's license agreement with LabCorp, the Company is obligated to reimburse LabCorp for certain third-party royalty payments if LabCorp's third-party royalty rate is greater than a specified royalty rate during the measuring period, as outlined in the table below. During the quarter ended March 31, 2009, the Company paid LabCorp approximately \$1.5 million related to its obligation for the first measurement period, which ended on December 31, 2008. The Company's future obligation to pay LabCorp pursuant to this provision of the Second Amendment is based on LabCorp's sales volumes of colorectal cancer screening tests using the Company's technology during two separate measurement periods, as defined below. A significant increase in such sales volumes during either measurement period, as compared to historical PreGen-Plus sales volumes, could reduce the Company's potential obligation during such measurement period, while test volumes consistent with historical PreGen-Plus sales levels could result in aggregate future payments to LabCorp totaling up to \$2.0 million during the remaining measurement periods. Until LabCorp's sales of colorectal cancer screening tests using the Company's technology increase to a level that would reduce this potential maximum obligation, if ever, the Company intends to record its estimated obligation under this provision of the Second Amendment as a reduction in the product royalty fee line item in its consolidated statements of operations, in accordance with EITF No. 01-09, Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor's Products). Based on sales volumes of PreGen-Plus through June 1, 2008 (when LabCorp ceased selling this service) and anticipated sales volumes of ColoSure, as of March 31, 2009, the Company had accrued a total of \$1.97 million related to the total potential \$2.0 million remaining obligation to LabCorp. The Company recorded charges of \$2.25 million and \$1.2 million during the years ended December 31, 2008 and 2007, respectively, in connection with this third-party royalty obligation. These charges were recorded under the caption Product royalty fees in the Company's consolidated statements of operations. Future increases in this obligation, to the extent necessary, will continue to be recorded as charges to the product royalty revenue line item of the Company's consolidated statements of operations. Amounts included in the table are in thousands.

Measurement period Start Date	Measurement period End Date	Payment Due Date for Measurement Period	Potential Minimum Third Party Royalty Obligation During Measurement Period	Potential Maximum Third Party Royalty Obligation During Measurement Period
January 1, 2009	December 31, 2009	January 30, 2010	\$	\$ 1,000
January 1, 2010	December 31, 2010	January 30, 2011		1,000
			\$	\$ 2,000

(7) RESTRUCTURING

2008 Restructuring

On July 16, 2008, the Company implemented certain cost reduction initiatives, including the suspension of the clinical validation study for its Version 2 technology and the elimination of eight positions, or 67% of the Company's

Table of Contents

workforce (the 2008 Restructuring), in connection with the Company's revised corporate strategy of reducing costs to better preserve existing cash.

In connection with the 2008 Restructuring, the Company recorded restructuring charges of approximately \$0.5 million during the three months ended September 30, 2008, including \$0.3 million in one-time termination benefits arising under retention and severance agreements with each of the terminated employees and \$0.2 million resulting from the write-off of leasehold improvements abandoned by the Company in connection with the reduction in force. The Company's decision to eliminate 67% of its workforce was deemed to be an impairment indicator under SFAS No. 144. As a result of performing the impairment evaluations, non-cash asset impairment charges of \$0.3 million were recorded to adjust the carrying value of the related leasehold improvements to their net realizable value.

In addition, in connection with the 2008 Restructuring, the Company accelerated the vesting of 15,523 shares under terminated employees previously unvested stock options, with a weighted average exercise price of \$2.65 per share, and extended the expiration date of all the terminated employees' outstanding options as of their date of termination, covering an aggregate of 181,828 shares with a weighted average exercise price of \$4.50 per share, through August 1, 2009. Pursuant to the measurement provisions of SFAS No. 123(R), the Company recorded one-time non-cash stock-based compensation charges of approximately \$3,000 in the Restructuring line item of the Company's condensed consolidated statements of operations during the quarter ended September 30, 2008.

During the fourth quarter of 2008, the Company entered into a sublease agreement (the 2008 Sublease Agreement) with QTEROS, Inc. (QTEROS) to sublease to QTEROS approximately 25,537 square feet of rentable area in the Company's corporate headquarters. The term of the 2008 Sublease Agreement, which commenced on December 9, 2008, is 20 months with a base rent of \$625,657 per year. Pursuant to the 2008 Sublease Agreement, QTEROS has no rights to renew or extend the 2008 Sublease Agreement. Under the terms of the 2008 Sublease Agreement, QTEROS is required to pay its pro rata share of any increases in building operating expenses and real estate taxes and to provide a security deposit in the form of an irrevocable, standby letter of credit from a national commercial bank reasonably acceptable to the Company in the amount of approximately \$52,000 naming the Company as beneficiary. The 2008 Sublease Agreement provides for the Company's employees to continue to occupy approximately 1,100 square feet in the premises subleased to QTEROS.

In connection with the 2008 Sublease Agreement, the Company also recorded the following restructuring charges during the fourth quarter of 2008 (included opposite the caption Facility consolidation costs in the table below): approximately \$0.1 million in future cash payments related to the difference between the Company's committed lease payments and the estimated sublease rental income under the 2008 Sublease Agreement; approximately \$0.1 million in one time real estate transaction and laboratory decommissioning fees; and approximately \$0.1 million of non-cash charges related to the write-off of leasehold improvements abandoned by the Company in connection with the 2008 Sublease Agreement. These charges were offset by cash receipts of approximately \$0.3 million received in connection with sales of fully depreciated fixed assets upon commencement of the 2008 Sublease Agreement. During the quarter ended March 31, 2009, certain of the cost estimates related to the 2008 Restructuring were adjusted, resulting in a credit of approximately \$3,000 to the restructuring line item in the Company's condensed consolidated statements of operations.

Amounts remaining in the 2008 Restructuring accrual at June 30, 2009, which are expected to be paid out in cash through July 2010, are recorded under the caption Accrued expenses in the Company's condensed consolidated balance sheets. The following table summarizes changes made to the restructuring accrual during the six months ended June 30, 2009 relating to the 2008 Restructuring. Amounts included in the table are in thousands.

Balance,

Balance,

Edgar Filing: EXACT SCIENCES CORP - Form 10-Q

Type of Liability	December 31, 2008		Charges	Cash Payments		June 30, 2009
Employee separation costs	\$	16	\$	(2)	\$	(14)
Facility consolidation costs		165		(1)		107
Total	\$	181	\$	(3)	\$	(71)

2007 Restructuring

During the third quarter of 2007, in connection with the Third Amendment to the LabCorp agreement, the Company notified six employees of their termination from the Company (the 2007 Restructuring). The 2007

Table of Contents

Restructuring was principally designed to eliminate the Company's sales and marketing functions to reduce costs and help preserve the Company's cash resources. In connection with the 2007 Restructuring, the Company recorded restructuring charges of approximately \$0.8 million during the three months ended September 30, 2007, primarily related to one-time termination benefits arising under retention and severance agreements with each of the terminated employees.

Restructuring charges recorded during the third quarter of 2007 of \$0.8 million included \$0.6 million in severance and related benefit costs which were paid in cash through May 2008, and \$0.2 million in non-cash stock-based compensation charges associated with extending the period of exercise for vested stock option awards for terminated employees.

During the fourth quarter of 2007, the Company entered into a sublease agreement (the 2007 Sublease Agreement) with INTRINSIX Corporation to sublease to INTRINSIX approximately 11,834 square feet of rentable area in the Company's corporate headquarters. The term of the 2007 Sublease Agreement, which commenced on December 15, 2007, is 32 months with a base rent of \$266,265 per year. Pursuant to the 2007 Sublease Agreement, INTRINSIX has no rights to renew or extend the 2007 Sublease Agreement. Under the terms of the 2007 Sublease Agreement, INTRINSIX was required to provide a security deposit of \$35,000 and is required to pay its pro rata share of any building operating expenses and real estate taxes.

In connection with the 2007 Sublease Agreement, the Company recorded restructuring charges of approximately \$0.4 million during the fourth quarter of 2007, which consist of approximately \$0.3 million in future cash payments related to the difference between the Company's committed lease payments and the estimated sublease rental income under the 2007 Sublease Agreement and approximately \$0.1 million of non-cash charges related to the write-off of leasehold improvements abandoned by the Company in connection with the Sublease Agreement. The Company's decision to enter into the 2007 Sublease Agreement was deemed to be an indicator of impairment. As a result of performing the impairment evaluations, asset impairment charges of \$0.1 million were recorded to adjust the carrying value of the related leasehold improvements to their net realizable value. Facility consolidation costs also include one time real estate transaction fees in connection with the Sublease Agreement.

Amounts remaining in the 2007 Restructuring accrual at June 30, 2009, which are expected to be paid out through July 2010, are recorded under the caption "Accrued expenses" in the Company's condensed consolidated balance sheets. The following table summarizes the 2007 Restructuring activities during the six months ended June 30, 2009. Amounts included in the table are in thousands.

Type of Liability	Balance, December 31, 2008	Charges	Cash Payments	Balance, June 30, 2009
Employee separation costs	\$	\$	\$	\$
Facility consolidation costs	161		(46)	115
Total	\$ 161	\$	\$ (46)	\$ 115

(8) STOCK-BASED COMPENSATION

Stock-Based Compensation Plans

The Company maintains the 1995 Stock Option Plan (1995 Option Plan), the 2000 Stock Option and Incentive Plan (2000 Option Plan) and the 2000 Employee Stock Purchase Plan.

Stock-Based Compensation Expense

The Company recorded \$0.7 million and \$1.3 million in stock-based compensation during the three and six months ended June 30, 2009 in connection with the amortization of restricted common stock awards and stock options granted to employees, non-employee directors and non-employee consultants as well as the modification of certain stock options. The Company recorded \$0.2 million and \$0.5 million, respectively, in stock-based compensation during the three and six months ended June 30, 2008 in connection with the amortization of awards of common stock, restricted common stock and stock options granted to employees, non-employee directors and non-employee consultants, as well as stock-based compensation expense of \$32,000 related to the Company's 2008 401(k) match.

Table of Contents**Determining Fair Value**

Valuation and Amortization Method - The fair value of each option award is estimated on the date of grant using the Black-Scholes pricing model based on the assumptions in the table below. The estimated fair value of employee stock options is amortized to expense using the straight-line method over the vesting period.

Expected Term - The Company uses the simplified calculation of expected life, described in the SEC's Staff Accounting Bulletins 107 and 110, as the Company does not currently have sufficient historical exercise data on which to base an estimate of expected term. Using this method, the expected term is determined using the average of the vesting period and the contractual life of the stock options granted.

Expected Volatility - Expected volatility is based on the Company's historical stock volatility data over the expected term of the awards.

Risk-Free Interest Rate - The Company bases the risk-free interest rate used in the Black-Scholes valuation method on the implied yield currently available on U.S. Treasury zero-coupon issues with an equivalent remaining term.

Forfeitures - As required by SFAS No. 123(R), the Company records stock-based compensation expense only for those awards that are expected to vest. The Company did not estimate forfeitures for awards prior to 2009 because all such share based awards vest monthly. Awards granted in 2009 that vest annually are all expected to vest and no forfeiture rate was utilized. The Company does not have significant history to calculate a forfeiture rate for awards that vest annually and the Company's best estimate is that all of these awards will vest.

The fair value of each option award is estimated on the date of grant using the Black-Scholes option-pricing model based on the assumptions in the following table.

	Three Months Ended		Six Months Ended		
	2009	June 30, 2008	2009	June 30, 2008	2008
Option Plan Shares					
Risk-free interest rates	2.54%	(1)	1.76% - 2.54%		2.80%
Expected term (in years)	6	(1)	6		6
Expected volatility	92%	(1)	85% - 92%		70%
Dividend yield	0%	(1)	0%		0%
Weighted average fair value per share of options granted during the period	\$ 0.99	(1)	\$ 0.64	\$	1.17

(1) The Company did not issue stock options or stock purchase rights under its stock-based compensation plans during the periods indicated.

Stock Option and Restricted Stock Activity

A summary of stock option and restricted stock activity under the 1995 Option Plan and the 2000 Option Plan during the six months ended June 30, 2009 is as follows:

Options	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (1)
<i>(Aggregate intrinsic value in thousands)</i>				
Outstanding, January 1, 2009	3,703,899	\$ 3.99	4.9	
Granted	4,463,754	\$ 0.81		
Exercised	(80,161)	\$ 0.26		
Cancelled or redeemed	(1,226,863)	\$ 3.98		
Outstanding, June 30, 2009	6,860,629	\$ 1.96	7.4	\$ 9,181
Exercisable, June 30, 2009	2,152,702	\$ 4.47	2.5	\$ 534
Vested and expected to vest, June 30, 2009	6,814,683	\$ 1.96	7	\$ 9,059

Table of Contents

(1) The aggregate intrinsic value of options outstanding, exercisable and vested and expected to vest is calculated as the difference between the exercise price of the underlying options and the market price of the Company's common stock for options that had exercise prices that were lower than the \$2.65 market price of the Company's common stock at June 30, 2009.

The table above includes outstanding restricted stock awards of 508,754 shares as of June 30, 2009 reflected as options with an exercise price of \$0. The Company granted 363,754 shares of common stock pursuant to restricted stock awards during the six months ended June 30, 2009. There were 40,000 common stock awards that vested and were no longer subject to restriction during the six months ended June 30, 2009.

As of June 30, 2009, there was \$2.5 million of total unrecognized compensation cost related to non-vested share-based compensation arrangements granted under all equity compensation plans. Total unrecognized compensation cost will be adjusted for future changes in forfeitures. The Company expects to recognize that cost over a weighted average period of 2.7 years.

(9) FAIR VALUE MEASUREMENTS

In September 2006, the FASB issued Statement No. 157, Accounting for Fair Value Measurements (SFAS No. 157). SFAS No. 157 clarifies the principle that fair value should be based on the assumptions market participants would use when pricing an asset or liability and establishes a fair value hierarchy that prioritizes the information used to develop those assumptions. Under the standard, fair value measurements are separately disclosed by level within the fair value hierarchy. SFAS No. 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. The Company adopted SFAS No. 157 on January 1, 2008 and it did not have any impact on its consolidated results of operations, financial position or cash flows.

SFAS No. 157 establishes a fair value hierarchy that prioritizes the inputs used to measure fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs. Observable inputs are inputs that reflect the assumptions that market participants would use in pricing the asset or liability developed based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the assumptions market participants would use in pricing the asset or liability developed based on the best information available in the circumstances.

The three levels of the fair value hierarchy established by SFAS No. 157 in order of priority are as follows:

- Level 1** Quoted prices (unadjusted) in active markets for identical assets or liabilities that the Company has the ability to access as of the reporting date. Active markets are those in which transactions for the asset or liability occur in sufficient frequency and volume to provide pricing information on an ongoing basis.
- Level 2** Pricing inputs other than quoted prices in active markets included in Level 1, which are either directly or indirectly observable as of the reporting date. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active.
- Level 3** Unobservable inputs that reflect the Company's assumptions about the assumptions that market participants would use in pricing the asset or liability. Unobservable inputs shall be used to measure fair value to the extent that observable inputs are not available.

In accordance with the disclosure provisions of SFAS No. 157, the following table presents the Company's fair value measurements as of June 30, 2009 along with the level within the fair value hierarchy prescribed by SFAS No. 157 in which the fair value measurements in their entirety fall, segregating fair value measurements using quoted prices in active markets for identical assets or liabilities (Level 1), significant other observable inputs (Level 2), and significant unobservable inputs (Level 3). Cash and cash equivalents are recorded at cost, which approximates fair value. Amounts in the table are in thousands.

Table of Contents

Description	Fair Value Measurement at June 30, 2009 Using:			
	Fair Value at June 30, 2009	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Available-for-Sale				
Marketable Securities	\$ 15,510	\$	\$ 15,510	\$
Total	\$ 15,510	\$	\$ 15,510	\$

(10) EQUITY FINANCING

On June 11, 2009, the Company completed a private placement transaction pursuant to which the Company sold 4,315,792 shares of common stock at a per share price of \$1.90 for net proceeds of \$8.1 million after issuance costs. Management intends to use the proceeds to fund future research and development efforts.

(11) NEW ACCOUNTING PRONOUNCEMENTS

In May 2009, the Financial Accounting Standards Board issued Statement 165, Subsequent Events, to incorporate the accounting and disclosure requirements for subsequent events into U.S. generally accepted accounting principles. Statement 165 introduces new terminology, defines a date through which management must evaluate subsequent events, and lists the circumstances under which an entity must recognize and disclose events or transactions occurring after the balance-sheet date. The Company adopted Statement 165 as of June 30, 2009, which was the required effective date. The Company evaluated its June 30, 2009 financial statements for subsequent events through August 13, 2009, the date the financial statements were available to be issued. The Company is not aware of any subsequent events which would require recognition or disclosure in the financial statements.

Table of Contents

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

The following discussion of the financial condition and results of operations of EXACT Sciences Corporation should be read in conjunction with the condensed consolidated financial statements and the related notes thereto included elsewhere in this Quarterly Report on Form 10-Q and the audited financial statements and notes thereto and Management's Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K for the year ended December 31, 2008, which has been filed with the Securities and Exchange Commission, or SEC.

Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities and Exchange Act of 1934, as amended, that are intended to be covered by the safe harbor created by those sections. Forward-looking statements, which are based on certain assumptions and describe our future plans, strategies and expectations, can generally be identified by the use of forward-looking terms such as believe, expect, may, will, should, could, seek, estimate, anticipate or other comparable terms. Forward-looking statements in this Quarterly Report on Form 10-Q may address the following subjects among others: statements regarding the sufficiency of our capital resources, expected operating losses, expected license fee revenues, expected research and development expenses, expected general and administrative expenses and our expectations concerning our business strategy. Forward-looking statements involve inherent risks and uncertainties which could cause actual results to differ materially from those in the forward-looking statements, as a result of various factors including those risks and uncertainties described in the Risk Factors and in Management's Discussion and Analysis of Financial Condition and Results of Operations sections of this report and our Annual Report on Form 10-K for the year ended December 31, 2008. We urge you to consider those risks and uncertainties in evaluating our forward-looking statements. We caution readers not to place undue reliance upon any such forward-looking statements, which speak only as of the date made. Except as otherwise required by the federal securities laws, we disclaim any obligation or undertaking to publicly release any updates or revisions to any forward-looking statement contained herein (or elsewhere) to reflect any change in our expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based.

Overview

EXACT Sciences Corporation is a molecular diagnostics company focused on colorectal cancer. Our non-invasive stool-based DNA (sDNA) screening technology includes proprietary and patented methods that isolate and analyze human DNA present in stool to screen for the presence of colorectal pre-cancer and cancer. We believe that our proprietary methods and technologies have several advantages over other screening options that may ultimately lead to decreased mortality associated with colorectal cancer, which is the third leading cause of cancer death overall, the second leading cause of death from cancers that affect both men and women, and the leading cause of cancer death among non-smokers in the United States.

The American Cancer Society estimates that 80-90 million people in the United States are eligible for colorectal cancer screening. The Company will approach this market opportunity by remaining focused on key priorities. The Company's priorities for 2009 are: 1) product development, 2) clinical trial planning and 3) creating a performance culture. Currently, we license certain of our colorectal cancer screening technologies on an exclusive basis in the U.S. and Canada through December 2010 to Laboratory Corporation of America® Holdings, or LabCorp®. LabCorp has developed and commercially offers a non-invasive stool-based DNA (sDNA) colorectal cancer screening service for the average-risk population, which is based on certain of our technologies.

Edgar Filing: EXACT SCIENCES CORP - Form 10-Q

Our primary goal is to become the market leader for a patient-friendly diagnostic screening product for the early detection of colorectal pre-cancer and cancer. Our strategic roadmap to achieve this goal includes the following key components:

- develop and refine our non-invasive sDNA colorectal pre-cancer and cancer screening test;
- advance our product through U.S. Food and Drug Administration, or FDA, clinical trials;
- secure insurance coverage and reimbursement for our product; and

Table of Contents

- commercialize an FDA-cleared product that detects colorectal pre-cancer and cancer.

We believe obtaining FDA approval is critical to building broad demand and successful commercialization for our sDNA colorectal cancer screening technologies. In 2009, we intend to focus on further refining our product design to demonstrate the clinical superiority of the test to detect pre-cancer and adenomas while balancing its product attributes to enable ease of commercialization and widespread adoption. Additionally, we intend to finalize plans for clinical trials in 2009 with the goal of confirming our trial protocols with the FDA.

We have generated limited operating revenues since inception and, as of June 30, 2009, we had an accumulated deficit of approximately \$178.7 million. Losses have historically resulted from costs incurred in conjunction with research, development and clinical study initiatives; salaries and benefits associated with the hiring of personnel; the initiation of marketing programs; and prior to August 31, 2007, the build-out of our sales infrastructure to support the commercialization of SDNA screening. We expect to continue to incur losses for the next several years, and it is possible we may never achieve profitability.

Recent Developments

Mayo Strategic Licensing Agreement

On June 11, 2009, we entered into a strategic transaction with the MAYO Foundation for Medical Education and Research (MAYO) to obtain a world-wide exclusive license to certain intellectual property. As part of the licensing agreement, we granted MAYO two common stock purchase warrants for 1,000,000 and 250,000 shares of common stock, respectively. We will also make payments to MAYO for up-front fees, fees upon our attainment of certain milestones, and other payments as outlined in the agreement. In addition to the license to intellectual property owned by MAYO, we will receive product development and research and development efforts from MAYO personnel. We determined that the payments made for intellectual property should not be capitalized as the future economic benefit derived from the transactions is uncertain. In addition to such payments, we are obligated to make royalty payments to MAYO on potential future net sales of any products developed from the licensed technology.

New Senior Management Team

Effective April 2, 2009, Jeffrey R. Luber resigned as our President, Chief Executive Officer and member of our board of directors and Charles R. Carelli, Jr. resigned as our Chief Financial Officer.

On March 18, 2009, our board of directors appointed Kevin T. Conroy as President and Chief Executive Officer, effective April 2, 2009. Also on March 18, 2009, based on the recommendation of our corporate governance and nominating committee, the board of directors appointed Mr. Conroy to fill a vacancy on our board. Our board of directors also appointed Maneesh K. Arora as our Senior Vice President and Chief Financial Officer, effective April 2, 2009.

Genzyme Strategic Transaction

In January 2009, we completed a strategic transaction with Genzyme Corporation, pursuant to which we assigned to Genzyme all of our intellectual property applicable to the fields of prenatal and reproductive health and granted Genzyme an irrevocable, perpetual, exclusive, worldwide, fully-paid, royalty-free license to use and sublicense all of our remaining intellectual property in all fields other than colorectal cancer detection and stool-based disease detection. We retained our rights in both the assigned and licensed intellectual property in the fields of colorectal cancer detection and stool-based disease detection. We and Genzyme also agreed to form a joint advisory committee to assist Genzyme in the achievement of product development goals related to the purchased intellectual property and to assist us with our regulatory goals.

Genzyme agreed to pay us an aggregate of \$18.5 million, of which \$16.65 million was paid at closing and \$1.85 million is subject to a holdback by Genzyme to satisfy certain of our potential indemnification obligations. Subject to terms of the strategic agreement, one-half of the holdback amount will be released to us in 12 months and one-half will be released in 18 months. Genzyme also agreed to pay a double-digit royalty to us on income received by Genzyme as a result of any licenses or sublicenses to third parties of the assigned or licensed intellectual property in any field other than prenatal and reproductive health or colorectal cancer detection and stool-based disease detection.

Table of Contents

In addition, we sold to Genzyme 3,000,000 shares of our common stock at a per share price of \$2.00, for a total purchase price of \$6.0 million.

Messrs. Luber and Carelli Severance

In connection with their departures in March 2009, Messrs. Luber and Carelli were entitled to receive severance benefits pursuant to their existing retention agreements, including salary continuation of \$472,500 and \$287,500, which is equal to eighteen months and fifteen months, respectively, of their base salaries as of the date of termination. On March 31, 2009, we entered into release agreements with Messrs. Luber and Carelli that provided, in exchange for a general release in favor of us, for the accelerated payment of the salary continuation obligations on March 31, 2009. In addition, the release agreements also provided for the repurchase by us of certain options held by Messrs. Luber and Carelli for an aggregate of 804,026 shares of common stock, in lieu of accelerated vesting and an extension of the option exercise period arising from their retention agreements. We paid Messrs. Luber and Carelli approximately \$39,000 and \$11,000, respectively, to repurchase Mr. Luber's options to purchase 553,333 shares and Mr. Carelli's options to purchase 250,693 shares. The purchase price of the outstanding options represented a 75 percent discount from the estimated fair value of the vested options as of March 31, 2009. Messrs. Luber and Carelli retained options to purchase 80,207 and 43,124 shares respectively at an exercise price of \$1.83, following the termination of their employment.

Private Placement Transaction

On June 11, 2009, we completed a private placement transaction pursuant to which we sold 4,315,792 shares of common stock at a per share price of \$1.90 for total proceeds of \$8.2 million.

Significant Accounting Policies

This management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments, including those related to revenue recognition and intangible assets. We base our estimates on historical experience and on various other factors that are believed to be appropriate under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

The notes to our consolidated financial statements included in our annual report on Form 10-K for the year ended December 31, 2008 include a summary of the significant accounting policies and methods used in the preparation of our consolidated financial statements. As described below, we believe that the following accounting policies and judgments are critical to fully understand and evaluate our reported financial results.

Revenue Recognition.

License fees. License fees for the licensing of product rights on initiation of strategic agreements are recorded as deferred revenue upon receipt and recognized as revenue on a straight-line basis over the license period. On June 27, 2007, we entered into an amendment to our exclusive license agreement with LabCorp, or the Second Amendment, that, among other modifications to the terms of the license, extended the exclusive license period from August 2008 to December 2010, subject to carve-outs for certain named organizations. Accordingly, we are amortizing the remaining deferred revenue balance resulting from our license agreement with LabCorp at the time of the Second Amendment (\$4.7 million) on a straight-line basis over the remaining exclusive license period, which ends in December 2010.

As more fully described under the heading "Genzyme Strategic Transaction" above, in connection with the Genzyme strategic transaction, we received an up-front payment of \$16.65 million on January 27, 2009 in exchange for the assignment and licensing of certain of our intellectual property to Genzyme. Our on-going performance obligations to Genzyme under the Collaboration, License and Purchase Agreement, or the CLP Agreement, including our obligation to deliver certain intellectual property improvements to Genzyme during the initial five year collaboration period, were deemed to be undelivered elements of the CLP Agreement on the date of closing. Accordingly, we deferred the initial \$16.65 million in cash received at closing and are amortizing that up-front payment on a straight line basis into revenue over the initial five-year collaboration period ending in January 2014. Receipt of any holdback amounts will similarly

Table of Contents

be deferred and amortized on a straight line basis into revenue over the remaining term of the collaboration at the time of receipt.

In addition, Genzyme paid \$2.00 per share for the 3.0 million shares purchased from us on January 27, 2009, representing a premium of \$0.51 per share above the closing price of the Company's common stock on that date of \$1.49 per share. The aggregate premium paid by Genzyme over the closing price of our common stock on the date of the transaction of \$1.53 million was deemed to be a part of the total consideration for the CLP Agreement. Accordingly, we deferred the aggregate \$1.53 million premium and will amortize that amount on a straight line basis into revenue over the initial five year collaboration period ending in January 2014. We recognized approximately \$1.6 million in license fee revenue in connection with the amortization of the up-front payments from Genzyme during the six months ended June 30, 2009.

Product royalty fees. We have licensed certain of our technologies, including improvements to such technologies, on an exclusive basis through December 2010 to LabCorp. LabCorp developed and commercially offered PreGen-Plus, a non-invasive sDNA colorectal cancer screening service for the average-risk population based on our Version 1 technology, from August 2003 through June 2008. In June 2008, LabCorp stopped offering PreGen-Plus. On July 14, 2008, LabCorp began to commercially offer ColoSure, its next generation non-invasive, sDNA testing service for the detection of colorectal cancer in the average-risk population, which is based on certain of our intellectual property. We are entitled to the same royalty and milestone structure on any sales of ColoSure as we were entitled to on sales of PreGen-Plus.

Prior to the effective date of the Second Amendment, our product royalty fees were based on a specified contractual percentage of LabCorp's cash receipts from performing PreGen-Plus tests. Accordingly, we recorded product royalty fees based on this specified percentage of LabCorp's cash receipts, as reported to us each month by LabCorp. Subsequent to the effective date of the Second Amendment, our product royalty fees are based on a specified contractual percentage of LabCorp's net revenues from sales of PreGen-Plus through June 1, 2008, when LabCorp stopped offering PreGen-Plus, and from sales of ColoSure from and after July 2008. Accordingly, subsequent to the effective date of the Second Amendment, we record product royalty fees based on the specified contractual percentage of LabCorp's net revenues from its sales of such colorectal cancer screening tests, as reported to us each month by LabCorp. The current royalty rate is 15%, subject to an increase to 17% in the event that LabCorp achieves a specified significant threshold of annual net revenues from the sales of such colorectal cancer screening tests.

Additionally, as described below under the heading **Critical Accounting Estimate Third Party Royalty Obligation**, pursuant to the Second Amendment, we are potentially obligated to reimburse LabCorp for certain third-party royalty payments. To the extent we incur liabilities in connection with this provision of the Second Amendment, the accretion of such liabilities will be recorded as a reduction in the product royalty fee line item in our statements of operations.

Other revenue. Revenue from milestone and other performance-based payments is recognized as revenue when the milestone or performance is achieved and collection of the receivable is estimable and probable.

Patent Costs. Patent costs, which have historically consisted of related legal fees, are capitalized as incurred, only if the Company determines that there is some probable future economic benefit derived from the transaction. The capitalized patents are amortized beginning when patents are approved over an estimated useful life of five years. Capitalized patent costs are expensed upon disapproval, upon a decision by the Company to no longer pursue the patent or when the related intellectual property is either sold or deemed to be no longer of value to the Company. During the quarter ended June 30, 2009, the Company determined that the patent costs incurred should not be capitalized as the future economic benefit derived from the transactions was not considered probable. In connection with the Genzyme Strategic Transaction, the Company sold its then-remaining capitalized intellectual property to Genzyme on January 27, 2009, and accordingly, wrote off the remaining unamortized capitalized patent costs at that time.

Stock-Based Compensation. We adopted SFAS No. 123(R) effective January 1, 2006 using the modified prospective transition method. SFAS No. 123(R) requires all stock-based payments to employees, including grants of employee stock options and shares purchased under an employee stock purchase plan (if certain parameters are not met), to be recognized in the financial statements based on their fair values. SFAS No. 123(R) did not change the accounting guidance for share-based payment transactions with parties other than employees provided in SFAS No. 123, as originally issued and EITF 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services.*

Table of Contents***Critical Accounting Estimate - Third Party Royalty Obligation***

Pursuant to the terms of the Second Amendment to our license agreement with LabCorp, we are obligated to reimburse LabCorp for certain third-party royalty payments if LabCorp's third-party royalty rate is greater than a specified royalty rate during the measuring period, as outlined in the table below. During the quarter ended March 31, 2009, we paid LabCorp approximately \$1.5 million related to our obligation for the first measurement period, which ended on December 31, 2008. Our future obligation to pay LabCorp pursuant to this provision of the Second Amendment is based on LabCorp's sales volumes of colorectal cancer screening tests using our technology during two separate measurement periods, as defined below. A significant increase in such sales volumes during either measurement period, as compared to historical PreGen-Plus sales volumes, could reduce our potential obligation during such measurement period, while test volumes consistent with historical PreGen-Plus sales levels could result in aggregate future payments to LabCorp totaling up to \$2.0 million during the remaining measurement periods. Until LabCorp's sales of colorectal cancer screening tests using our technology increase to a level that would reduce this potential maximum obligation, if ever, we intend to record our estimated obligation under this provision of the Second Amendment as a reduction in the product royalty fee line item in our statements of operations, in accordance with EITF No. 01-09, *Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor's Products)*. Based on sales volumes of PreGen-Plus through June 1, 2008 (when LabCorp ceased selling this service) and anticipated sales volumes of ColoSure, as of June 30, 2009, we have accrued a total of \$1.97 million related to the total potential \$2.0 million remaining obligation to LabCorp. Amounts included in the table are in thousands.

Measurement period Start Date	Measurement period End Date	Payment Due Date for Measurement Period	Potential Minimum Third Party Royalty Obligation During Measurement Period	Potential Maximum Third Party Royalty Obligation During Measurement Period
January 1, 2009	December 31, 2009	January 30, 2010	\$	\$ 1,000
January 1, 2010	December 31, 2010	January 30, 2011	\$	\$ 1,000
			\$	\$ 2,000

Recent Accounting Pronouncements

In May 2009, the Financial Accounting Standards Board issued Statement 165, Subsequent Events, to incorporate the accounting and disclosure requirements for subsequent events into U.S. generally accepted accounting principles. Statement 165 introduces new terminology, defines a date through which management must evaluate subsequent events, and lists the circumstances under which an entity must recognize and disclose events or transactions occurring after the balance-sheet date. The Company adopted Statement 165 as of June 30, 2009, which was the required effective date. The Company evaluated its June 30, 2009 financial statements for subsequent events through August 13, 2009, the date the financial statements were available to be issued. The Company is not aware of any subsequent events which would require recognition or disclosure in the financial statements.

Results of Operations

Revenue. Net revenue is primarily composed of the amortization of up-front technology license fees associated with our amended license agreement with LabCorp and our collaboration, license and purchase agreement with Genzyme. The unamortized LabCorp up-front payment is being amortized on a straight-line basis over the remaining exclusive license period, which ends in December 2010. The unamortized Genzyme up-front payment is being amortized on a straight-line basis over the initial Genzyme collaboration period, which ends in January 2014. While we expect license fee revenue resulting from the amortization of the up-front license payment from LabCorp in 2009 to be consistent with

Edgar Filing: EXACT SCIENCES CORP - Form 10-Q

amounts recorded in 2008, we expect that total license fee revenue for 2009 will be higher than amounts recorded in 2008 as a result of amortization of payments received from Genzyme in January 2009 in connection with the Genzyme strategic transaction.

Net revenue increased to \$1.3 million for the three months ended June 30, 2009, from (\$0.1) million for the same period in 2008 and increased to 2.3 million for the six months ended June 30, 2009 from (\$0.1) million for the same period in 2008. The increase in net revenue for the three and six months ended June 30, 2009 when compared to the same periods of 2008, was primarily due to an increase of approximately \$0.9 million and \$1.6 million, respectively, for

Table of Contents

the three and six months ended June 30, 2009 in license fee amortization as a direct result of the commencement of amortization of the upfront payment received from Genzyme in January 2009. In addition, product royalty revenues were higher for the three months and six months ended June 30, 2009 when compared to the same period in 2008 due to product royalty revenue charges of \$0.5 million and \$0.8 million recorded during the three months and six months ended June 30, 2008. These charges related to our third-party royalty reimbursement obligation to LabCorp, and resulted in negative product royalty revenue for the three and six months ended June 30, 2008.

Research and development expenses. Research and development expenses increased to \$2.0 million for the three months ended June 30, 2009 from \$0.5 million for the three months ended June 30, 2008, and increased to \$2.1 million for the six months ended June 30, 2009 from \$1.4 million for the six months ended June 30, 2008. The increase is primarily due to the \$1.7 million non-cash charge incurred as a result of the issuance of warrants pursuant to the Mayo licensing agreement and increased research and development efforts.

As a result of the activities anticipated in support of our objectives toward developing an FDA-approved in vitro diagnostic test, we expect research and development costs in 2009 to be higher than 2008 levels.

General and administrative expenses. General and administrative expenses increased to \$1.6 million for the three months ended June 30, 2009, compared to \$1.5 million for the same period in 2008. The increase is primarily due to a \$0.5 million increase in non-cash stock-based compensation expense included in general and administrative expense in the quarter ended June 30, 2009, which was partially offset by a decrease in general operating expenses in the second quarter of 2009 of \$0.3 million compared to the prior year period.

General and administrative expenses increased to \$6.4 million for the six months ended June 30, 2009, compared to \$3.3 million for the same period in 2008. This increase was primarily the result of \$1.9 million in transaction costs related to the Genzyme strategic transaction in January 2009, including legal, audit, and investment banking fees as well as approximately \$0.8 million in retention bonus payments made to employees pursuant to board-approved retention agreements. In addition, in connection with the departure of Jeffrey R. Luber, our former President and Chief Executive Officer, and Charles R. Carelli, Jr., our former Chief Financial Officer, we recorded approximately \$0.8 million in cash severance charges in the quarter ended March 31, 2009. Non-cash stock-based compensation expense included in general and administrative expense for the six months ended June 30, 2009 also increased by \$0.8 million compared to the same period in 2008. In the second quarter, these increases were partially offset by decreases in professional fees related to on-going operations and in general operating expenses.

We expect general and administrative expenses in 2009 to be higher than 2008 levels, primarily as a result of professional fees in connection with the Genzyme strategic transaction and the transition of our senior management team as described above.

Interest income. Primarily as a result of less favorable interest rates on investments held, interest income decreased to \$49,000 for the three months ended June 30, 2009 from \$64,000 for the same period in 2008 and decreased to \$83,000 for the six months ended June 30, 2009 from \$188,000 for the same period in 2008.

Liquidity and Capital Resources

We have financed our operations since inception primarily through private and public offerings of our equity securities, cash received from LabCorp in connection with our license agreement, and cash received in January 2009 from Genzyme in connection with the Genzyme strategic transaction described above. On June 11, 2009, we completed a private placement transaction pursuant to which we sold 4,315,792 shares of common stock at a per share price of \$1.90 for net proceeds of \$8.1 million after issuance costs. As of June 30, 2009, we had approximately \$12.3 million in unrestricted cash and cash equivalents, \$0.6 million in restricted cash, which has been pledged as collateral for an outstanding letter of credit in connection with the lease for our Marlborough, Massachusetts facility, and approximately \$15.5 million in investments in marketable securities. All of our investments in marketable securities are comprised of fixed income investments and all are deemed available-for-sale.

Net cash used in operating activities was \$7.8 million for six months ended June 30, 2009 as compared to \$4.7 million for the six months ended June 30, 2008. The principal use of cash in operating activities for the six months ended June 30, 2009 and 2008 was to fund our net loss. The increase in net cash used in operating activities for the six months ended June 30, 2009 as compared to the same period in 2008, was primarily due to the payment of the \$1.5 million to LabCorp to satisfy our third party royalty obligation for 2008, one-time transaction payments for professional fees in connection with the Genzyme strategic transaction of approximately \$1.1 million, one time retention bonus

Table of Contents

payments to employees pursuant to board-approved retention payments of approximately \$0.8 million, and one-time severance payments of approximately \$0.8 million to former executives, each as described elsewhere in this report. Cash flows from operations can vary significantly due to various factors, including changes in our operations, prepaid expenses, accounts payable and accrued expenses.

Net cash used in investing activities was \$15.5 million for the six months ended June 30, 2009 and represented the investment of a portion of the funds received in January 2009 from the Genzyme strategic transaction. Net cash provided by investing activities was \$5.8 million for the six months ended June 30, 2008 and primarily resulted from the maturity of marketable securities. Purchases of property and equipment were not material during the six months ended June 30, 2009 and 2008. As a result of the cash received in January 2009 in connection with the Genzyme strategic transaction, and based on our plans for further development of our sDNA technology for colorectal cancer detection, we expect that purchases of property and equipment during 2009 will be higher than amounts invested in 2008.

Net cash provided by financing activities was \$30.7 million for the six months ended June 30, 2009 and was comprised primarily of the receipt of \$22.6 million of cash in connection with the Genzyme strategic transaction and net proceeds after issuance costs of \$8.1 million from the issuance of common stock in the private placement transaction. We also paid \$50,000 to repurchase outstanding options from former executives as described elsewhere in this report.

We expect that cash, cash equivalents and marketable securities on hand at June 30, 2009 will be sufficient to fund our current operations for at least the next twelve months, based on current operating plans. This projection is based on our currently anticipated cost structure and operating assumptions and does not provide for the full funding of our current strategic plan, the centerpiece of which is the commercialization of our sDNA technology through completion of the development an FDA-approved in vitro diagnostic test for sDNA colorectal pre-cancer and cancer screening. We do not expect that product royalty payments or milestone payments from LabCorp will materially supplement our liquidity position in the next twelve months, if at all. Since we have no current sources of material ongoing revenue, we believe that we will need to raise additional capital to complete our strategic plan. If we are unable to obtain sufficient additional funds to enable us to fund our operations through the completion of such plan, our results of operations and financial condition would be materially adversely affected and we may be required to delay the implementation of our plan and otherwise scale back operations. Even if we successfully raise sufficient funds to continue the implementation of our strategic plan, we cannot assure you that our business will ever generate sufficient cash flow from operations to become profitable.

Off-Balance Sheet Arrangements

As of June 30, 2009, we had no off-balance sheet arrangements.

Item 4. Controls and Procedures

As of the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Rule 13a-15b promulgated under the Exchange Act of 1934, as amended. Based upon that evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that, as of June 30, 2009, our disclosure controls and procedures were effective in enabling us to record, process, summarize and report information required to be included in our periodic SEC

Edgar Filing: EXACT SCIENCES CORP - Form 10-Q

filings within the required time period. Our disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the periodic reports filed with the SEC is accumulated and communicated to our management, including our principal executive, financial and accounting officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

During the fiscal quarter covered by this report, there have been no significant changes in internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

Item 6. Exhibits

Exhibit Number	Description
4.1	Warrant No. W-1 issued to MAYO Foundation for Medical and Educational Research dated June 11, 2009
4.2	Warrant No. W-2 issued to MAYO Foundation for Medical and Educational Research dated June 11, 2009
10.1	Form of Securities Purchase Agreement, dated June 11, 2009 (previously filed as Exhibit 10 to our Report on Form 8-K filed on June 12, 2009, which is incorporated herein by reference).
10.2*	License Agreement, dated June 11, 2009, by and among the Registrant and MAYO Foundation for Medical and Educational Research
31.1	Certification Pursuant to Rule 13(a)-14(a) or Rule 15d-14(a) of Securities Exchange Act of 1934.
31.2	Certification Pursuant to Rule 13(a)-14(a) or Rule 15d-14(a) of Securities Exchange Act of 1934.
32.1	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

* *Portions of this document are confidential and have been omitted and filed separately with the Securities and Exchange Commission in connection with a request for confidential treatment of such omitted material in accordance with Rule 24b-2 under the Securities and Exchange Act of 1934.*

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.

EXACT SCIENCES CORPORATION

Date: August 13, 2009

By: /s/ Kevin T. Conroy
Kevin T. Conroy

President and Chief Executive Officer
(Authorized Officer)

Date: August 13, 2009

By: /s/ Maneesh K. Arora
Maneesh K. Arora

Chief Financial Officer
(Authorized Officer and Principal Financial Officer)

Table of Contents

EXHIBIT INDEX

Exhibit Number	Description
4.1	Warrant No. W-1 issued to MAYO Foundation for Medical and Educational Research dated June 11, 2009
4.2	Warrant No. W-2 issued to MAYO Foundation for Medical and Educational Research dated June 11, 2009
10.1	Form of Securities Purchase Agreement, dated June 11, 2009 (previously filed as Exhibit 10 to our Report on Form 8-K filed on June 12, 2009, which is incorporated herein by reference).
10.2*	License Agreement, dated June 11, 2009, by and among the Registrant and MAYO Foundation for Medical and Educational Research
31.1	Certification Pursuant to Rule 13(a)-14(a) or Rule 15d-14(a) of Securities Exchange Act of 1934.
31.2	Certification Pursuant to Rule 13(a)-14(a) or Rule 15d-14(a) of Securities Exchange Act of 1934.
32.1	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

* Portions of this document are confidential and have been omitted and filed separately with the Securities and Exchange Commission in connection with a request for confidential treatment of such omitted material in accordance with Rule 24b-2 under the Securities and Exchange Act of 1934.