

EXACT SCIENCES CORP  
Form 10-Q  
May 15, 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 March 31, 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)

**100 Campus Drive, Marlborough, Massachusetts**  
(Address of principal executive offices)

**01752**  
(Zip Code)

**(508) 683-1200**

(Registrant's telephone number, including area code)

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   
(Do not check if a smaller reporting company)

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 May 15, 2009, the registrant had 30,887,484 shares of Common Stock outstanding.

Table of Contents

EXACT SCIENCES CORPORATION

INDEX

	<b>Page Number</b>	
<b>Part I - Financial Information</b>		
Item 1.	Financial Statements	
	<u>Condensed Consolidated Balance Sheets (Unaudited) as of March 31, 2009 and December 31, 2008</u>	3
	<u>Condensed Consolidated Statements of Operations (Unaudited) for the Three Months Ended March 31, 2009 and 2008</u>	4
	<u>Condensed Consolidated Statements of Cash Flows (Unaudited) for the Three Months Ended March 31, 2009 and 2008</u>	5
	<u>Notes to Condensed Consolidated Financial Statements (Unaudited)</u>	6
<u>Item 2.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	20
<u>Item 3.</u>	<u>Quantitative and Qualitative Disclosures about Market Risk</u>	26
<u>Item 4T.</u>	<u>Controls and Procedures</u>	26
<b><u>Part II - Other Information</u></b>		
<u>Item 1A.</u>	<u>Risk Factors</u>	27
<u>Item 6.</u>	<u>Exhibits</u>	28
	<u>Signatures</u>	29
	<u>Exhibit Index</u>	30

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

	<b>March 31, 2009</b>	<b>December 31, 2008</b>
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 3,595	\$ 4,937
Marketable securities	17,018	
Prepaid expenses and other current assets	690	190
Total current assets	21,303	5,127
Property and Equipment, at cost:		
Laboratory equipment	174	174
Office and computer equipment	22	13
Leasehold improvements		
Furniture and fixtures	196	187
Less Accumulated depreciation and amortization	(123)	(111)
	73	76
Patent costs, net of accumulated amortization of \$2,820 at December 31, 2008		95
Restricted cash	600	600
	\$ 21,976	\$ 5,898
<b>LIABILITIES AND STOCKHOLDERS DEFICIT</b>		
Current Liabilities:		
Accounts payable	\$ 34	\$ 683
Accrued expenses	1,234	1,498
Third party royalty obligation, current portion	1,000	1,500
Deferred license fees, current portion	4,986	1,350
Total current liabilities	7,254	5,031
Third party royalty obligation, less current portion	965	1,950
Deferred license fees, less current portion	14,901	1,350
Commitments and contingencies		
Stockholders Deficit:		
Preferred stock, \$0.01 par value Authorized 5,000,000 shares Issued and outstanding 0 shares at March 31, 2009 and December 31, 2008, respectively		
Common stock, \$0.01 par value Authorized 100,000,000 shares Issued and outstanding 30,848,070 and 27,522,931 shares at March 31, 2009 and December 31, 2008, respectively	308	275
Additional paid-in capital	174,878	169,854
Treasury stock, at cost, 85,550 shares	(97)	(97)
Other comprehensive income	71	
Accumulated deficit	(176,304)	(172,465)
Total stockholders deficit	(1,144)	(2,433)
	\$ 21,976	\$ 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)**

	<b>Three Months Ended March 31,</b>	
	<b>2009</b>	<b>2008</b>
<b>Revenue:</b>		
Product royalty fees	\$ 7	\$ (292)
License fees	993	338
Product	5	5
	1,000	51
<b>Cost of revenue:</b>		
Product royalty fees		1
<b>Gross profit</b>	<b>1,000</b>	<b>50</b>
<b>Operating expenses:</b>		
Research and development (1)	108	859
General and administrative (1)	4,768	1,835
Restructuring	(3)	(2)
	4,873	2,692
<b>Loss from operations</b>	<b>(3,873)</b>	<b>(2,642)</b>
<b>Interest income</b>	<b>34</b>	<b>124</b>
<b>Net loss</b>	<b>\$ (3,839)</b>	<b>\$ (2,518)</b>
<b>Net loss per share basic and diluted</b>	<b>\$ (0.13)</b>	<b>\$ (0.09)</b>
<b>Weighted average common shares outstanding basic and diluted</b>	<b>30,230</b>	<b>27,145</b>

---

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

Research and development	\$	\$	44
General and administrative		623	257

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

Table of Contents**EXACT SCIENCES CORPORATION****Condensed Consolidated Statements of Cash Flows**

(Amounts in thousands - unaudited)

	<b>Three Months Ended March 31,</b>	
	<b>2009</b>	<b>2008</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (3,839)	\$ (2,518)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of fixed assets	12	59
Amortization and write-offs of patents	95	34
Stock-based compensation	623	301
Amortization of deferred license fees	(993)	(338)
Changes in assets and liabilities:		
Prepaid expenses and other current assets	(500)	(178)
Accounts payable	(649)	30
Accrued expenses	(264)	(743)
Third party royalty obligation	(1,485)	300
Net cash used in operating activities	(7,000)	(3,053)
<b>Cash flows from investing activities:</b>		
Purchases of marketable securities	(16,947)	(2,466)
Maturities of marketable securities		5,080
Purchases of property and equipment	(9)	
Increase in patent costs and other assets		(54)
Net cash (used in) provided by investing activities	(16,956)	2,560
<b>Cash flows from financing activities:</b>		
Proceeds from Genzyme Collaboration, License and Purchase Agreement	16,650	
Proceeds from sale of common stock to Genzyme	6,000	
Proceeds from exercise of common stock options and stock purchase plan	14	6
Payment to repurchase stock options	(50)	
Net cash provided by financing activities	22,614	6
Net decrease in cash and cash equivalents	(1,342)	(487)
Cash and cash equivalents, beginning of period	4,937	4,486
Cash and cash equivalents, end of period	\$ 3,595	\$ 3,999

*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 (the "Company") was incorporated in February 1995. The Company's purpose is to improve quality of life through the development of innovative diagnostics. The mission of the company is to save lives by launching an FDA-cleared, patient friendly colon cancer test that detects both 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. Both Conroy and Arora bring significant experience with molecular diagnostics and managing complex clinical trials to their new roles at the Company. They were most recently president and chief executive, and chief financial officer, respectively, of Third Wave Technologies Inc. Third Wave, a NASDAQ-traded molecular diagnostics company which was acquired last year by Hologic Inc. for \$582 million.

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 at Exact.

As more fully described in Note 3 below, the Company entered into a strategic transaction with Genzyme Corporation (the "Genzyme Strategic Transaction") on January 27, 2009, pursuant to which Genzyme acquired certain intellectual property assets related to the fields of prenatal and reproductive health and licensed certain intellectual property outside the fields of colorectal cancer screening and stool-based DNA detection. Genzyme also purchased 3.0 million shares of the Company's common stock. Pursuant to the strategic transaction, EXACT retained worldwide rights to its colorectal cancer screening and stool-based DNA testing intellectual property, and will receive a share of Genzyme's sublicensing income derived from the purchased intellectual property outside the fields of prenatal and reproductive health.

The Genzyme Strategic Transaction provides for the Company to receive up to \$24.5 million in cash in total. On January 27, 2009, the Company received \$16.65 million, with an additional \$1.85 million to be received over the next 18 months, contingent upon the non-occurrence of certain events, in exchange for the sale and license of certain of the Company's intellectual property assets, including those relating to reproductive and prenatal health. In addition, at closing, Genzyme purchased 3.0 million shares of EXACT common stock at \$2.00 per share for an aggregate purchase price of \$6.0 million.

The Company has licensed certain of its technologies, including improvements to such technologies, on an exclusive basis through December 2010 to Laboratory Corporation of America® Holdings ("LabCorp®") for use in a commercial testing service for the detection of colorectal cancer developed by LabCorp. The Company has devoted the majority of its efforts to date on research and development and commercialization support of its colorectal cancer detection technologies.



The Company expects that cash, cash equivalents and marketable securities on hand at March 31, 2009 will be sufficient to fund its current operations for at least the next twelve months, based on current operating plans. The projection is based on the Company's currently anticipated cost structure and operating assumptions and does not provide for the full funding of the development of the Company's stool-based DNA technology and related FDA submission and commercialization efforts or other programs and initiatives. The Company does not expect that product royalty payments or milestone payments from LabCorp will materially supplement its liquidity position in the next twelve months, if at all. Since the Company has no current sources of material ongoing revenue, it believes that it will need to raise additional capital to complete the development, FDA submission for clearance or approval, and commercialization of its technologies, including an FDA-approved in vitro diagnostic test for stool-based DNA colorectal cancer screening. If the Company is unable to obtain sufficient additional funds to enable it to fund its operations through the completion of the development of such a test, the submission to the FDA for clearance or approval of the test, and commercialization of the test, the Company's results of operations and financial condition would be materially adversely affected and it may be required to delay such efforts and otherwise scale back operations. Even if the Company successfully raises sufficient funds to continue its operations to fund the development, FDA submission, and commercialization of its technology, including an FDA-approved in vitro diagnostic test for stool-based DNA colorectal cancer screening, the Company cannot assure you that its business will ever generate sufficient cash flow from operations to become profitable.

### **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. These condensed consolidated financial statements assume that the Company will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business, and, in the opinion of management, include all normal and recurring adjustments which are necessary to present fairly the results of operations for the reported periods. 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.

Table of Contents

**(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 March 31, 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 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

## Edgar Filing: EXACT SCIENCES CORP - Form 10-Q

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 March 31, 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 three months ended March 31, 2009 and 2008.

### **Patent Costs**

Patent costs, which have historically consisted of related legal fees, are capitalized as incurred and 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. 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.

The following table summarizes activity with respect to the Company's capitalized patents for the three months ended March 31, 2009 and 2008. Amounts included in the table are in thousands.

Table of Contents

	Three Months Ended	
	March 31, 2009	March 31, 2008
Patents, net of accumulated amortization, Beginning of period	\$ 95	\$ 432
Patent costs capitalized		54
Amortization of patents		(34)
Write-offs of patents	(95)	
Patents, net of accumulated amortization, End of period	\$	\$ 452

**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.

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	March 31, 2008
Shares issuable upon exercise of stock options	6,636	4,433
Shares issuable upon exercise of outstanding warrants		1,000
	6,636	5,433

In conjunction with its strategic alliance with LabCorp, in June 2002, the Company issued to LabCorp a warrant (the LabCorp Warrant ) to purchase 1,000,000 shares of its common stock, exercisable over a three-year period at an exercise price of \$16.09 per share. At the time of issuance, the LabCorp Warrant had an expiration date of June 26, 2005. On June 24, 2005, the Company extended the expiration date of the LabCorp Warrant to August 13, 2008, which was the expiration date of the exclusive period at the time of the extension. On August 13, 2008, the LabCorp Warrant expired unexercised.

**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

Table of Contents

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 the License Fee Revenue line item in its statements of operations 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 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, Genzyme paid \$2.00 per share for the 3,000,000 million 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 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 the License Fee Revenue line item in its statements of operations over the initial five-year collaboration period ending in January 2014. The Company recognized approximately \$0.7 million in license fee revenue in connection with the amortization of the up-front payments from Genzyme during the quarter ended March 31, 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 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 5 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.

## Edgar Filing: EXACT SCIENCES CORP - Form 10-Q

**Product revenue.** Product revenue from the sale of certain components of the Company's Effipure technology to LabCorp was recognized upon transfer of the components provided that title passed, the price was fixed or determinable and collection of the receivable was probable. LabCorp has indicated that Effipure is not used as a component in LabCorp's ColoSure offering and the Company therefore does not expect to record product revenue in connection with Effipure sales in future periods.

**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 March 31, 2009 and 2008 was as follows:

(In thousands)	Three Months Ended March 31,	
	2009	2008
Net loss	\$ (3,839)	\$ (2,518)
Unrealized gain on marketable securities	71	1
Comprehensive loss	\$ (3,768)	\$ (2,517)

Table of Contents

**(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. Further, subject to the terms of the JHU Amendment (defined below), the Company assigned to Genzyme its rights under the license agreement between the Company and The Johns Hopkins University ("JHU") dated March 25, 2003, as amended (the "JHU Agreement") (collectively, with the licenses and assignment described herein, the "Sale Transaction"). The CLP Agreement also provides for the formation of a joint advisory committee to assist both parties in the achievement of product development and regulatory goals. The collaboration period under the CLP Agreement may be terminated upon certain events. Additional termination rights concerning the collaboration period arise after five years.

Under the CLP Agreement, the Company retained ownership of intellectual property rights other than the Transferred Intellectual Property. In addition, with respect to the Transferred Intellectual Property, Genzyme granted the Company an irrevocable, perpetual, exclusive, worldwide, fully-paid, royalty-free license to use and sublicense such intellectual property in the Company Field. The parties also granted to each other a perpetual (subject to termination for uncured material breaches), exclusive, worldwide, fully-paid, royalty-free license to use and sublicense any improvements Genzyme or the Company makes to the Transferred Intellectual Property that is applicable to the Company Field (in the case of the Company as licensee) or all fields other than the Company Field (the "Genzyme Field") (in the case of Genzyme as licensee). Further, the parties granted to each other a perpetual (subject to termination for uncured material breaches), exclusive, worldwide, fully-paid, royalty-free license to use and sublicense intellectual property jointly developed pursuant to the collaboration between the parties (the "Joint Technology"). The license to the Joint Technology granted by the Company to Genzyme is exclusive in the Genzyme Field and the license to the Joint Technology granted by Genzyme to the Company is exclusive in the Company Field. The Company also granted to Genzyme an exclusive option to obtain an exclusive license, in the Genzyme Core Field, to certain technology that the Company may develop or acquire that has applicability in the Genzyme Core Field. The CLP Agreement contains representations, warranties and covenants with respect to the Sale Transaction and provides, under certain circumstances, for the Company and Genzyme to indemnify each other for breaches of their respective representations, warranties and covenants.

As part of the Sale Transaction, the Company entered into an Assignment, Sublicense, Consent and Eighth Amendment to License Agreement with Genzyme and JHU (the "JHU Amendment") on January 27, 2009, whereby the Company assigned its rights under 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. The JHU Amendment also modified the minimum annual license fee due to JHU under the JHU Agreement. The JHU Agreement terminates upon the later of 20 years from the effective date of the JHU Agreement and the expiration of the last to expire of the patents for the licensed technology, or upon certain uncured defaults of JHU or Genzyme. Pursuant to the JHU Amendment, the sublicense to the Company terminates upon certain uncured defaults of the Company. The JHU Amendment also provides that, in the event the JHU Agreement terminates upon an uncured default of Genzyme, if the Company is in good standing under the JHU Agreement at such time, the sublicense to the Company will become a direct license from JHU to the Company.



Also as part of the Sale 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,

## Edgar Filing: EXACT SCIENCES CORP - Form 10-Q

### Table of Contents

1999, effective as of January 27, 2009. Pursuant to the Restated License, Genzyme 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 Sale 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.

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.

Pursuant to the Purchase Agreement, Genzyme has the right until December 31, 2010 to participate in certain future private offerings of equity securities by the Company up to the amount necessary to maintain Genzyme's pro-rata percentage ownership of the Company, at a price per share equal to the greater of \$2.00 or the closing price of the Common Stock on the Company's trading market on the day prior to the date that the Company notifies Genzyme of its right to purchase additional shares. This right is subject to certain customary exclusions, including issuances to employees pursuant to a stock plan, issuances in connection with a change of control transaction and issuances in connection with strategic partnerships. Under the Purchase Agreement, Genzyme also has the right to include the Shares on a registration statement filed by the Company or, under certain circumstances, cause the Company to file a registration statement covering the resale of the Shares by Genzyme with the Securities and Exchange Commission.

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, Genzyme paid \$2.00 per share for the 3,000,000 million shares of common stock purchased 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 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 \$0.7 million in license fee revenue in connection with the amortization of the up-front payments from Genzyme during the quarter ended March 31, 2009.

**(4) CHANGES IN SENIOR MANAGEMENT AND EMPLOYMENT AGREEMENTS**

*Former Chief Executive Officer and Former Chief Financial Officer*

Effective April 2, 2009, Jeffrey R. Lubert 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.

In connection with their departure, Messrs. Lubert 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. Lubert and Carelli that provided, in exchange for a general release in favor of the Company, for the accelerated payment of the salary continuation obligations on March 31, 2009. In addition, the release agreements also provided for

Table of Contents

the repurchase by the Company of options held by Messrs. Luber and Carelli for an aggregate of 895,000 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. Luber and Carelli approximately \$39,000 and \$11,000, respectively, to repurchase Mr. Luber's options to purchase 620,000 shares and Mr. Carelli's options to purchase 275,000 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. Luber and Carelli retained the balance of their existing options, the vesting of which accelerated by nine months.

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 its condensed consolidated financial statements 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 its condensed consolidated financial statements during the quarter ended March 31, 2009 in accordance with the provisions of SFAS No. 123(R) in connection with changes in vesting and period of exercise for options being retained by Messrs. Luber and Carelli.

A summary of options repurchased on March 31, 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 Repurchased
		Exercisable	Unexercisable	
11/18/2002	\$ 14.33	50,000		50,000
2/11/2004	\$ 7.72	80,000		80,000
12/23/2004	\$ 3.61	60,000		60,000
2/17/2005	\$ 4.22	20,000		20,000
2/16/2006	\$ 2.61	55,000		55,000
4/11/2006	\$ 3.07	29,166	834	30,000
2/15/2007	\$ 2.77	52,083	22,917	75,000
9/4/2007	\$ 2.90	125,000	125,000	250,000
		471,249	148,751	620,000

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 on March 31, 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 Repurchased
		Exercisable	Unexercisable	
11/9/2004	\$ 3.28	20,000		20,000
7/29/2005	\$ 2.65	27,499	2,501	30,000
2/16/2006	\$ 2.61	25,000		25,000
4/11/2006	\$ 3.07	24,305	695	25,000
2/15/2007	\$ 2.77	52,083	22,917	75,000
9/4/2007	\$ 2.90	50,000	50,000	100,000
		198,887	76,113	275,000

**Options Retained**

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

Table of Contents

*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 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.

Mr. Conroy's employment with the Company continues until terminated in accordance with the Conroy Agreement. Mr. Conroy may terminate his employment with the Company without "good reason" (as defined in the Conroy Agreement) upon 30 business days' written notice to the Company and with good reason at any time within ninety (90) days after the occurrence of an event constituting good reason. The Company may terminate Mr. Conroy's employment, with or without cause (as defined in the Conroy Agreement), upon written notice to Mr. Conroy. In the event of termination by the Company without cause or by Mr. Conroy for good reason, then Mr. Conroy will receive (i) salary continuation for a period of eighteen (18) months at his then-current base salary, (ii) any accrued but unpaid base salary as of the termination date, (iii) any accrued but unpaid bonus (including any performance-based bonus), (iv) twelve months' accelerated vesting of any unvested equity awards, and (v) the right to exercise any vested equity awards until the earlier of two (2) years from the date of termination or the date such equity award expires.

In the event of termination by the Company without cause or by Mr. Conroy for good reason, within twelve (12) months before, or if Mr. Conroy remains employed with the Company on the effective date of, a "Change of Control" (as defined in the Conroy Agreement), Mr. Conroy will receive a lump-sum payment equal to twenty-four (24) months (which period will be reduced under certain circumstances) of his then-current base salary. Upon a Change of Control and subject to Mr. Conroy's agreement to remain employed by the Company (or any successor), if requested, for a period of at least six (6) months following such Change of Control at his then current base salary, all of Mr. Conroy's outstanding stock options would become fully vested and exercisable. The foregoing change of control payments shall be subject to increase to cover any excise tax imposed by Section 4999 of the Internal Revenue Code of 1986, as amended. The Conroy Agreement also provides that Mr. Conroy will participate in a long-term incentive plan to be developed by the Company pursuant to which he will be eligible for a cash payment upon certain changes of control of the Company.

The Conroy Agreement prohibits Mr. Conroy from engaging in certain activities involving competition with the Company for an 18-month period following termination of his employment with the Company.

On March 18, 2009, the Company's Board of Directors appointed Maneesh 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.

Mr. Arora's employment with the Company continues until terminated in accordance with the Arora Agreement. Mr. Arora may terminate his employment with the Company without good reason (as defined in the Arora Agreement) upon 30 business days' written notice to the Company and with good reason at any time within ninety (90) days after the occurrence of an event constituting good reason. The Company may terminate Mr. Arora's employment, with or without cause (as defined in the Arora Agreement),

Table of Contents

upon written notice to Mr. Arora. In the event of termination by the Company without cause or by Mr. Arora for good reason, then Mr. Arora will receive (i) salary continuation for a period of fifteen (15) months at his then-current base salary, (ii) any accrued but unpaid base salary as of the termination date, (iii) any accrued but unpaid bonus (including any performance-based bonus), (iv) twelve months accelerated vesting of any unvested equity awards, and (v) the right to exercise any vested equity awards until the earlier of two (2) years from the date of termination or the date such equity award expires.

In the event of termination by the Company without cause or by Mr. Arora for good reason, within twelve (12) months before, or if Mr. Arora remains employed with the Company on the effective date of, a Change of Control (as defined in the Arora Agreement), Mr. Arora will receive a lump-sum payment equal to eighteen (18) months (which period will be reduced under certain circumstances) of his then-current base salary. Upon a Change of Control and subject to Mr. Arora's agreement to remain employed by the Company (or any successor), if requested, for a period of at least six (6) months following such Change of Control at his then current base salary, all of Mr. Arora's outstanding stock options would become fully vested and exercisable. The Arora Agreement also provides that Mr. Arora will participate in a long-term incentive plan to be developed by the Company pursuant to which he will be eligible for a cash payment upon certain changes of control of the Company.

The Arora Agreement prohibits Mr. Arora from engaging in certain activities involving competition with the Company for an 18-month period following termination of his employment with the Company.

**(5) 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.

**Potential**

**Potential**



Edgar Filing: EXACT SCIENCES CORP - Form 10-Q

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

Table of Contents

**(6) 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 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. The Company believes that such 1,100 square feet are adequate to meet our space requirements with respect to administrative needs. The Company believes that the development of an FDA-approved product for colorectal cancer screening will require that it lease additional space. In this regard, the Company is currently exploring additional space in Madison, Wisconsin.

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

Edgar Filing: EXACT SCIENCES CORP - Form 10-Q

condensed consolidated statements of operations.

Amounts remaining in the 2008 Restructuring accrual at March 31, 2009, which are expected to be paid out in cash through July 2010, are recorded under the caption "Accrued expenses" in the Company's consolidated balance sheets. The following table summarizes changes made to the restructuring accrual during the three months ended March 31, 2009 relating to the 2008 Restructuring. Amounts included in the table are in thousands.

Type of Liability	Balance, December 31, 2008	Charges	Cash Payments	Balance, March 31, 2009
Employee separation costs	\$ 16	\$ (2)	\$ (14)	\$ 121
Facility consolidation costs	165	(1)	(43)	121
Total	\$ 181	\$ (3)	\$ (57)	\$ 121

Table of Contents**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 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 impairment indicator under SFAS No. 144. 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 March 31, 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 quarter ended March 31, 2009. Amounts included in the table are in thousands.

Type of Liability	Balance, December 31, 2008	Charges	Cash Payments	Balance, March 31, 2009
Employee separation costs	\$	\$	\$	\$
Facility consolidation costs	161		(23)	138
Total	\$ 161	\$	\$ (23)	\$ 138

**(7) 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. Note 8 to the Company's consolidated financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2008, which has been filed with the SEC, includes a description of the Company's stock-based compensation plans.

**Stock-Based Compensation Expense**

The Company recorded \$0.6 million in stock-based compensation during the three months ended March 31, 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 certain stock option modifications discussed below. The Company recorded \$0.3 million in stock-based compensation during the three months ended March 31, 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 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 option-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 life 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 volatility from the time of its initial public offering in January 2001 through the measurement date 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 share-based compensation expense only for those awards that are expected to vest. The Company does not need to estimate forfeitures for awards prior to 2009 because all such share based awards vest monthly.

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 March 31,	
	2009	2008
<b>Option Plan Shares</b>		
Risk-free interest rates	1.76%	2.80%
Expected term (in years)	6	6
Expected volatility	85%	70%
Dividend yield	0%	0%
Weighted average fair value per share of options granted during the period	\$ 0.60	\$ 1.17

**Stock Option Activity**

## Edgar Filing: EXACT SCIENCES CORP - Form 10-Q

A summary of stock option activity under the 1995 Option Plan and the 2000 Option Plan during the three months ended March 31, 2009 is as follows:

Options (Aggregate intrinsic value in thousands)	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (1)
Outstanding, January 1, 2009	3,703,899	\$ 3.99	4.9	
Granted	4,053,790	\$ 0.77		
Exercised	(51,349)	\$ 0.27		
Cancelled or redeemed	(1,070,818)	\$ 4.30		
Outstanding, March 31, 2009	6,635,522	\$ 2.00	7.7	\$ 2,190
Exercisable, March 31, 2009	2,067,765	\$ 4.59	2.9	\$ 27
Vested and expected to vest, March 31, 2009	6,479,478	\$ 1.96	7.5	\$ 2,190

Table of Contents

---

(1) The aggregate intrinsic value of options outstanding, as well as options vested and expected to vest, at March 31, 2009 is calculated as the difference between the exercise price of the underlying options and the market price of the Company's common stock for the 4,289,790 options that had exercise prices that were lower than the \$1.25 market price of the Company's common stock at March 31, 2009. The aggregate intrinsic value of options exercisable at March 31, 2009 is calculated as the difference between the exercise price of the underlying options and the market price of the Company's common stock for the 50,307 options that had exercise prices that were lower than the \$1.25 market price of our common stock at March 31, 2009.

The table above includes outstanding restricted stock awards of 458,790 shares as of March 31, 2009. The Company granted 288,790 shares of common stock pursuant to restricted stock awards during the quarter ended March 31, 2009. There were 15,000 common stock awards that vested and were no longer subject to restriction during the quarter ended March 31, 2009.

As of March 31, 2009, there was \$2.6 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 2.4 years.

#### **(8) 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.



Edgar Filing: EXACT SCIENCES CORP - Form 10-Q

**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 March 31, 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 at March 31, 2009	Fair Value Measurement at March 31, 2009 Using:		
		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	\$ 17,018	\$	\$ 17,018	\$
Total	\$ 17,018	\$	\$ 17,018	\$

**(9) NEW ACCOUNTING PRONOUNCEMENTS**

In September 2006, the FASB issued SFAS No. 157. SFAS No. 157 establishes a common definition for fair value to be applied under GAAP requiring use of fair value, establishes a framework for measuring fair value, and expands disclosure about such fair value measurements. Issued in February 2008, FASB Staff Position No. SFAS 157-1, *Application of FASB Statement No. 157 to FASB Statement No. 13 and Other Accounting Pronouncements That Address Fair Value Measurements for Purposes of Lease Classification or Measurement under Statement 13*, removed leasing transactions accounted for under FASB Statement No. 13, *Accounting for Leases*, and related guidance from the scope of SFAS No. 157. Issued in February 2008, FASB Staff Position No. SFAS 157-2, *Effective Date of FASB Statement No. 157*, deferred the effective date of SFAS No. 157 for all nonfinancial assets and nonfinancial liabilities to fiscal years beginning after November 15, 2008. The adoption of FASB Staff Position No. SFAS 157-2 did not have a material effect on the Company's consolidated financial statements.

In December 2007, the FASB ratified the consensus reached by the EITF on EITF Issue No. 07-1, *Accounting for Collaborative Arrangements* ( EITF 07-1 ). EITF 07-1 requires collaborators to present the results of activities for which they act as the principal on a gross basis and report any payments received from (made to) other collaborators based on other applicable GAAP or, in the absence of other applicable GAAP, based on analogy to authoritative accounting literature or a reasonable, rational, and consistently applied accounting policy election. Further, EITF 07-1 clarified the determination of whether transactions within a collaborative arrangement are part of a vendor-customer (or analogous) relationship subject to EITF Issue No. 01-9, *Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor's Products)*. EITF 07-1 became effective for the Company beginning on January 1, 2009. The implementation of EITF 07-1 did not have a material effect on the Company's consolidated financial statements.

**(10) SUBSEQUENT EVENT****NASDAQ Compliance**

On March 6, 2009, the Company received notice from The NASDAQ Stock Market LLC ( NASDAQ ) that it was not in compliance with NASDAQ Marketplace Rule 4310(c)(3) (the Rule ), which requires an issuer to maintain a minimum \$35 million market value of its listed securities for continued listing on The NASDAQ Capital Market. NASDAQ also noted that the Company was not in compliance with either of the other alternatives for compliance with the Rule, which require minimum stockholders' equity of \$2,500,000 or net income from continuing operations of \$500,000 in the most recently completed fiscal year or in two of the last three most recently completed fiscal years, respectively. The Company was provided a period of 90 calendar days, or until June 4, 2009, to regain compliance with the Rule. On April 2, 2009, the Company received a determination from NASDAQ indicating that the Company had evidenced compliance with the Rule for continued listing on The NASDAQ Capital Market.



## **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.

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
- 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 laboratory adoption. Additionally, we intend to finalize plans for clinical trials in 2009 with the goal of confirming our trial protocols with the FDA.

Table of Contents

We have generated limited operating revenues since inception and, as of March 31, 2009, we had an accumulated deficit of approximately \$176.3 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**

*New Senior Management Team*

Effective April 2, 2009, Jeffrey R. Lubner 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 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 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.

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 895,000 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 620,000 shares and Mr. Carelli's options to purchase 275,000 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 at an exercise price of \$1.83, following the termination of their employment, respectively.

*Compliance with NASDAQ Listing Requirements*

On March 6, 2009, we received notice from The NASDAQ Stock Market LLC, or NASDAQ, that we were not in compliance with NASDAQ Marketplace Rule 4310(c)(3), or the Rule, which requires an issuer to maintain a minimum \$35 million market value of its listed securities for continued listing on The NASDAQ Capital Market. NASDAQ also noted that we were not in compliance with either of the other alternatives for compliance with the Rule, which require minimum stockholders' equity of \$2,500,000 or net

Table of Contents

income from continuing operations of \$500,000 in the most recently completed fiscal year or in two of the last three most recently completed fiscal years, respectively. On April 2, 2009, we received a determination from NASDAQ indicating that we had evidenced compliance with the Rule for continued listing on The NASDAQ Capital Market.

**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. Pursuant to the provisions of SEC Staff Accounting Bulletin No. 104 and EITF No. 00-21, which govern revenue recognition, 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 the License Fee Revenue line item in our statements of operations over the initial five-year collaboration period ending in January 2014. Receipt of any holdback amounts will similarly be deferred and amortized on a straight line basis into the License Fee Revenue line item in our statements of operations over the remaining term of the collaboration at the time of receipt.



## Edgar Filing: EXACT SCIENCES CORP - Form 10-Q

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. Under FASB Technical Bulletin No. 85-6, 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 the License Fee Revenue line item in our statements of operations over the initial five year collaboration period ending in January 2014. We recognized approximately \$0.7 million in license fee revenue in connection with the amortization of the up-front payments from Genzyme during the quarter ended March 31, 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.

Table of Contents

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 and 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 us to no longer pursue the patent or when the related intellectual property is either sold or deemed to be no longer of value to us. In connection with the Genzyme transaction, we sold our then-remaining capitalized intellectual property to Genzyme on January 27, 2009, and accordingly, we wrote-off the remaining unamortized capitalized patent costs at that time.

We apply SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets and for Long-Lived Assets*, or SFAS No. 144, which requires that we continually evaluate whether events or circumstances have occurred that indicate that the estimated remaining useful life of long-lived assets and certain identifiable intangibles and goodwill may warrant revision or that the carrying value of these assets may be impaired.

**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 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. 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*. Prior to January 1, 2006, we accounted for stock-based compensation under the provisions of Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees*.

***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 March 31, 2009, we had 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.

Table of Contents

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 September 2006, the FASB issued Statement No. 157, *Accounting for Fair Value Measurements*, or SFAS No. 157. SFAS No. 157 establishes a common definition for fair value to be applied under GAAP requiring use of fair value, establishes a framework for measuring fair value, and expands disclosure about such fair value measurements. Issued in February 2008, FASB Staff Position No. SFAS 157-1, *Application of FASB Statement No. 157 to FASB Statement No. 13 and Other Accounting Pronouncements That Address Fair Value Measurements for Purposes of Lease Classification or Measurement under Statement 13*, removed leasing transactions accounted for under FASB Statement No. 13, *Accounting for Leases*, and related guidance from the scope of SFAS No. 157. Issued in February 2008, FASB Staff Position No. SFAS 157-2, *Effective Date of FASB Statement No. 157*, deferred the effective date of SFAS No. 157 for all nonfinancial assets and nonfinancial liabilities to fiscal years beginning after November 15, 2008. The adoption of FASB Staff Position No. SFAS 157-2 did not have a material effect on our consolidated financial statements.

In November 2007, the FASB issued EITF Issue No. 07-1, *Accounting for Collaborative Arrangements*, or EITF 07-1, which defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties, including the appropriate income statement presentation and classification of, and the required disclosures related to, these arrangements. EITF 07-1 is effective January 1, 2009, to be applied retrospectively for collaborative arrangements existing as of the effective date. The adoption of EITF 07-1 did not have a material impact on our consolidated 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, or through 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 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 \$1.0 million for the quarter ended March 31, 2009, from \$0.1 million for the same period in 2008. The increase in net revenue for the quarter ended March 31, 2009, when compared to the quarter ended March 31, 2008, was primarily due to an increase of approximately \$0.7 million 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 in the quarter ended March 31, 2009 when compared to the quarter ended March 31, 2008 due to product royalty revenue charges of \$0.3 million recorded in the quarter ended March 31, 2008. These

## Edgar Filing: EXACT SCIENCES CORP - Form 10-Q

charges related to our third-party royalty reimbursement obligation to LabCorp, and resulted in negative product royalty revenue for the quarter ended March 31, 2008.

**Research and development expenses.** Research and development expenses decreased to \$0.1 million for the three months ended March 31, 2009 from \$0.9 million for the three months ended March 31, 2008. The decrease was primarily the result of the continuing effect of the cost reduction plans undertaken in 2007 and 2008. Research and development costs for the quarter ended March 31, 2009 were primarily comprised of external licensing costs and rent.

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.

Table of Contents

**General and administrative expenses.** General and administrative expenses increased to \$4.8 million for the quarter ended March 31, 2009, compared to \$1.8 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. Non-cash stock-based compensation expense included in general and administrative expense in the quarter ended March 31, 2009 also increased by \$0.4 million compared to the same period in 2008 primarily as a result of \$0.3 million in non-cash charges recorded in the first quarter of 2009 in connection with the option modifications made pursuant to separation and release agreements with Messrs. Luber and Carelli described elsewhere in this report. These increases were partially offset by a decrease in professional fees related to on-going operations of \$0.2 million in the first quarter of 2009 compared to the prior year period.

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 \$34,000 for the three months ended March 31, 2009 from \$0.1 million 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. As of March 31, 2009, we had approximately \$3.6 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 \$17.0 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 \$7.0 million for the quarter ended March 31, 2009 as compared to \$3.1 million for the quarter ended March 31, 2008. The principal use of cash in operating activities for the three months ended March 31, 2009 and 2008 was to fund our net loss. The increase in net cash used in operating activities for quarter ended March 31, 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 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 \$17.0 million for the quarter ended March 31, 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 \$2.6 million for the three months ended March 31, 2008 and primarily resulted from the maturity of marketable securities. Purchases of property and equipment were not material during the quarters ended March 31, 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.

## Edgar Filing: EXACT SCIENCES CORP - Form 10-Q

Net cash provided by financing activities was \$22.6 million for the quarter ended March 31, 2009 and was comprised primarily of the receipt of cash in connection with the Genzyme strategic 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 March 31, 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.

Table of Contents

The table below reflects our estimated fixed obligations and commitments as of March 31, 2009:

Description	Total	Less Than One Year	Payments Due by Period		More Than 5 Years
			1 - 3 Years (in Thousands)	3 - 5 Years	
Obligations under license and collaborative agreements	\$ 4,144	\$ 1,221	\$ 1,360	\$ 342	\$ 1,221
Operating lease obligations	1,367	1,023	344		
Severance obligations	75	75			
Purchase obligations	152	152			
<b>Total</b>	<b>\$ 5,738</b>	<b>\$ 2,471</b>	<b>\$ 1,704</b>	<b>\$ 342</b>	<b>\$ 1,221</b>

Obligations under license and collaboration agreements represent on-going commitments under various research collaborations and licensing agreements. This category includes a potential obligation to reimburse LabCorp for a certain third-party royalty, up to a remaining aggregate maximum of \$2.0 million, during two defined measurement periods between January 1, 2009 and December 31, 2010. Although payment of this potential obligation is dependent upon LabCorp's sales levels of ColoSure during the measurement periods, the total remaining potential \$2.0 million obligation has been included in the table above based on historical sales levels of PreGen-Plus and current sales levels of ColoSure as of March 31, 2009. Commitments under license agreements generally expire concurrent with the expiration of the intellectual property licensed from the third party. Operating leases reflect remaining obligations associated with leased facilities in Marlborough, Massachusetts. Purchase obligations primarily represent historical amounts owed in connection with our operations. Severance obligations represent remaining commitments to former personnel, including our former Chief Executive Officer and former Chief Financial Officer.

**Off-Balance Sheet Arrangements**

As of March 31, 2009, we had no off-balance sheet arrangements.

**Item 3. Quantitative and Qualitative Disclosures about Market Risk**

Our exposure to market risk is principally confined to our cash, cash equivalents and marketable securities. We invest our cash, cash equivalents and marketable securities in securities of the U.S. government and its agencies and in investment-grade, highly liquid investments consisting of commercial paper, bank certificates of deposit and corporate bonds, all of which are currently invested in the U.S. and are classified as available-for-sale. We place our cash equivalents and marketable securities with high-quality financial institutions, limit the amount of credit exposure to any one institution and have established investment guidelines relative to diversification and maturities designed to maintain safety and liquidity.

Based on a hypothetical ten percent adverse movement in interest rates, the potential losses in future earnings, fair value of risk-sensitive financial instruments, and cash flows are immaterial, although the actual effects may differ materially from the hypothetical analysis.



**Item 4T. 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 March 31, 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 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

**Part II - Other Information**

**Item 1A. Risk Factors**

**Factors That May Affect Future Results**

We operate in a rapidly changing environment that involves a number of risks that could materially affect our business, financial condition or future results, some of which are beyond our control. In addition to the other information set forth in this report, the risks and uncertainties that we believe are most important for you to consider are discussed in Part I, Item 1A. Risk Factors in our Annual Report on Form 10-K for the fiscal year ended December 31, 2008. There are no material changes to the risk factors described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2008. Additional risks and uncertainties not presently known to us, which we currently deem immaterial or which are similar to those faced by other companies in our industry or business in general, may also impair our business operations. If any of the foregoing risks or uncertainties actually occurs, our business, financial condition and operating results would likely suffer.

Table of Contents

**Item 6. Exhibits**

Exhibit Number	Description
3.1	Amended and Restated By-Laws of the Registrant, as amended.
10.1**	Collaboration, License and Purchase Agreement between Genzyme Corporation and the Registrant, dated January 27, 2009 (previously filed as Exhibit 10.1 to our Report on Form 8-K filed on January 28, 2009, which is incorporated herein by reference).
10.2**	Assignment, Sublicense, Consent and Eighth Amendment to License Agreement among the Registrant, Genzyme Corporation and The Johns Hopkins University, dated January 27, 2009 (previously filed as Exhibit 10.2 to our Report on Form 8-K filed on January 28, 2009, which is incorporated herein by reference).
10.3**	Amended and Restated License Agreement between Genzyme Corporation and the Registrant, dated January 27, 2009 (previously filed as Exhibit 10.3 to our Report on Form 8-K filed on January 28, 2009, which is incorporated herein by reference).
10.4	Common Stock Subscription Agreement between the Registrant and Genzyme Corporation, dated January 27, 2009 (previously filed as Exhibit 10.4 to our Report on Form 8-K filed on January 28, 2009, which is incorporated herein by reference).
10.5	Employment Agreement by and between Kevin T. Conroy and the Registrant, dated as of March 18, 2009 (previously filed as Exhibit 10.1 to our Report on Form 8-K filed on March 18, 2009, which is incorporated herein by reference).
10.6	Employment Agreement by and between Maneesh Arora and the Registrant, dated as of March 18, 2009 (previously filed as Exhibit 10.2 to our Report on Form 8-K filed on March 18, 2009, which is incorporated herein by reference).
10.7	Release Agreement between Jeffrey R. Lubber and the Registrant, dated as of March 31, 2009 (previously filed as Exhibit 10.36 to our Annual Report on Form 10-K for the period ended December 31, 2008, which is incorporated herein by reference).
10.8	Release Agreement between Charles R. Carelli, Jr. and the Registrant, dated as of March 31, 2009 (previously filed as Exhibit 10.37 to our Annual Report on Form 10-K for the period ended December 31, 2008, which is incorporated herein by reference).
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.

---

\*\* Confidential treatment has been requested for portions of this exhibit.

*Indicates a management contract or any compensatory plan, contract or arrangement.*

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: May 15, 2009

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

President and Chief Executive Officer  
(Authorized Officer)

Date: May 15, 2009

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

Chief Financial Officer  
(Authorized Officer and Principal Financial Officer)

Table of Contents

**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Description</b>
3.1	Amended and Restated By-Laws of the Registrant, as amended.
10.1**	Collaboration, License and Purchase Agreement between Genzyme Corporation and the Registrant, dated January 27, 2009 (previously filed as Exhibit 10.1 to our Report on Form 8-K filed on January 28, 2009, which is incorporated herein by reference).
10.2**	Assignment, Sublicense, Consent and Eighth Amendment to License Agreement among the Registrant, Genzyme Corporation and The Johns Hopkins University, dated January 27, 2009 (previously filed as Exhibit 10.2 to our Report on Form 8-K filed on January 28, 2009, which is incorporated herein by reference).
10.3**	Amended and Restated License Agreement between Genzyme Corporation and the Registrant, dated January 27, 2009 (previously filed as Exhibit 10.3 to our Report on Form 8-K filed on January 28, 2009, which is incorporated herein by reference).
10.4	Common Stock Subscription Agreement between the Registrant and Genzyme Corporation, dated January 27, 2009 (previously filed as Exhibit 10.4 to our Report on Form 8-K filed on January 28, 2009, which is incorporated herein by reference).
10.5	Employment Agreement by and between Kevin T. Conroy and the Registrant, dated as of March 18, 2009 (previously filed as Exhibit 10.1 to our Report on Form 8-K filed on March 18, 2009, which is incorporated herein by reference).
10.6	Employment Agreement by and between Maneesh Arora and the Registrant, dated as of March 18, 2009 (previously filed as Exhibit 10.2 to our Report on Form 8-K filed on March 18, 2009, which is incorporated herein by reference).
10.7	Release Agreement between Jeffrey R. Luber and the Registrant, dated as of March 31, 2009 (previously filed as Exhibit 10.36 to our Annual Report on Form 10-K for the period ended December 31, 2008, which is incorporated herein by reference).
10.8	Release Agreement between Charles R. Carelli, Jr. and the Registrant, dated as of March 31, 2009 (previously filed as Exhibit 10.37 to our Annual Report on Form 10-K for the period ended December 31, 2008, which is incorporated herein by reference).
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.

---

\*\* Confidential treatment has been requested for portions of this exhibit.

*Indicates a management contract or any compensatory plan, contract or arrangement.*