

EXACT SCIENCES CORP  
Form 10-Q  
November 01, 2013  
[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 September 30, 2013

OR

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

Commission File Number: 001-35092

**EXACT SCIENCES CORPORATION**

(Exact name of registrant as specified in its charter)

Edgar Filing: EXACT SCIENCES CORP - Form 10-Q

**DELAWARE**  
(State or other jurisdiction of  
incorporation or organization)

**02-0478229**  
(I.R.S. Employer  
Identification Number)

**441 Charmany Drive, Madison WI**  
(Address of principal executive offices)

**53719**  
(Zip Code)

**(608) 284-5700** (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 <input type="checkbox"/>	Accelerated filer <input checked="" type="checkbox"/>
Non-accelerated filer <input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company <input type="checkbox"/>

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 October 30, 2013, the registrant had 70,917,521 shares of common stock outstanding.

Table of Contents

EXACT SCIENCES CORPORATION

INDEX

	<b>Page Number</b>
<b><u>Part I - Financial Information</u></b>	
Item 1. Financial Statements	
<u>Condensed Consolidated Balance Sheets (Unaudited) as of September 30, 2013 and December 31, 2012</u>	4
<u>Condensed Consolidated Statements of Operations (Unaudited) for the Three and Nine Months Ended September 30, 2013 and 2012</u>	5
<u>Condensed Consolidated Statements of Comprehensive Loss (Unaudited) for the Three and Nine Months Ended September 30, 2013 and 2012</u>	6
<u>Condensed Consolidated Statements of Cash Flows (Unaudited) for the Nine Months Ended September 30, 2013 and 2012</u>	7
<u>Notes to Condensed Consolidated Financial Statements (Unaudited)</u>	8
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	21
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	29
Item 4. <u>Controls and Procedures</u>	30
<b><u>Part II - Other Information</u></b>	
Item 1. <u>Legal Proceedings</u>	30
Item 1A. <u>Risk Factors</u>	30
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	30
Item 3. <u>Defaults Upon Senior Securities</u>	30
Item 4. <u>Mine Safety Disclosures</u>	30
Item 5. <u>Other Information</u>	30
Item 6. <u>Exhibits</u>	30
<u>Signatures</u>	31
<u>Exhibit Index</u>	32

Table of Contents

Part I Financial Information

Table of Contents**EXACT SCIENCES CORPORATION****Condensed Consolidated Balance Sheets**

(Amounts in thousands, except share data - unaudited)

	September 30, 2013	December 31, 2012
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 9,710	\$ 13,345
Marketable securities	138,131	94,776
Prepaid expenses and other current assets	904	593
Total current assets	148,745	108,714
Property and Equipment, at cost:		
Laboratory equipment	4,546	4,051
Assets under construction	3,668	
Office and computer equipment	855	824
Leasehold improvements	339	283
Furniture and fixtures	28	28
	9,436	5,186
Less Accumulated depreciation	(2,685)	(1,781)
	6,751	3,405
	\$ 155,496	\$ 112,119
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current Liabilities:		
Accounts payable	\$ 605	\$ 3,652
Accrued expenses	5,725	3,327
Capital lease obligation, current portion	347	333
Lease incentive obligation, current portion	495	
Deferred license fees, current portion	1,330	4,143
Total current liabilities	8,502	11,455
Long-term debt	1,000	1,000
Long-term accrued interest	79	63
Capital lease obligation, less current portion	449	711
Lease incentive obligation, less current portion	376	
Deferred license fees, less current portion		295
Commitments and contingencies		
Stockholders Equity:		
Preferred stock, \$0.01 par value Authorized 5,000,000 shares Issued and outstanding no shares at September 30, 2013 and December 31, 2012		
Common stock, \$0.01 par value Authorized 100,000,000 shares Issued and outstanding 70,897,521 and 63,909,800 shares at September 30, 2013 and December 31, 2012	709	639
Additional paid-in capital	452,836	372,123
Other comprehensive income	118	78
Accumulated deficit	(308,573)	(274,245)
Total stockholders equity	145,090	98,595
	\$ 155,496	\$ 112,119

Edgar Filing: EXACT SCIENCES CORP - Form 10-Q

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
License fees	1,036	1,036	3,108	3,108
Operating expenses:				
Research and development	6,982	10,491	20,965	31,692
General and administrative	3,686	2,547	9,962	7,085
Sales and marketing	1,615	1,006	6,676	2,931
	12,283	14,044	37,603	41,708
Loss from operations	(11,247)	(13,008)	(34,495)	(38,600)
Investment income	103	67	220	188
Interest expense	(16)	(11)	(53)	(21)
Net loss	\$ (11,160)	\$ (12,952)	\$ (34,328)	\$ (38,433)
Net loss per share basic and diluted	\$ (0.16)	\$ (0.21)	\$ (0.52)	\$ (0.66)
Weighted average common shares outstanding basic and diluted	70,559	60,531	66,389	58,104

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

Table of Contents**EXACT SCIENCES CORPORATION****Condensed Consolidated Statements of Comprehensive Loss****(Amounts in thousands - unaudited)**

	<b>Three Months Ended September 30,</b>		<b>Nine Months September 30,</b>	
	<b>2013</b>	<b>2012</b>	<b>2013</b>	<b>2012</b>
Net loss	\$ (11,160)	\$ (12,952)	\$ (34,328)	\$ (38,433)
Other comprehensive loss, net of tax				
Unrealized holding gain on available-for-sale investments	101	39	40	106
Comprehensive loss	\$ (11,059)	\$ (12,913)	\$ (34,288)	\$ (38,327)

*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, except share data - unaudited)**

	<b>Nine Months Ended September 30,</b>	
	<b>2013</b>	<b>2012</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (34,328)	\$ (38,433)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of property and equipment	976	666
Loss on disposal of property and equipment	91	
Stock-based compensation	5,660	4,024
Amortization of deferred license fees	(3,108)	(3,108)
Warrant licensing expense		152
Restricted stock licensing expense		1,000
Amortization of premium on short-term investments	458	359
Changes in assets and liabilities:		
Prepaid expenses and other current assets	(311)	(218)
Accounts payable	(3,047)	265
Accrued expenses	3,013	1,483
Lease incentive obligation	871	
Accrued interest	16	15
Net cash used in operating activities	(29,709)	(33,795)
<b>Cash flows from investing activities:</b>		
Purchases of marketable securities	(89,261)	(90,408)
Maturities of marketable securities	45,488	41,823
Purchases of property and equipment	(4,413)	(586)
Net cash used in investing activities	(48,186)	(49,171)
<b>Cash flows from financing activities:</b>		
Proceeds from sale of common stock, net of issuance costs	73,296	57,755
Proceeds from exercise of common stock options and stock purchase plan	1,212	2,090
Payments on capital lease obligations	(248)	
Net cash provided by financing activities	74,260	59,845
Net increase (decrease) in cash and cash equivalents	(3,635)	(23,121)
Cash and cash equivalents, beginning of period	13,345	35,781
Cash and cash equivalents, end of period	\$ 9,710	\$ 12,660
<b>Supplemental disclosure of non-cash investing and financing activities:</b>		
Unrealized gain (loss) on available-for-sale investments	\$ 40	\$ 106
Issuance of 30,534 and 32,872 shares of common stock to fund the Company's 401(k) matching contribution for 2012 and 2011, respectively	\$ 354	\$ 274
Conversion of accrued expenses into 34,442 and 34,336 shares of common stock in connection with the Company's Employee Stock Purchase Plan for 2013 and 2012, respectively.	\$ 261	\$ 194
Laboratory equipment acquired with a capital lease	\$	\$ 1,151

*The accompanying notes are an integral part of these condensed 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 was incorporated in February 1995. Exact is a molecular diagnostics company currently focused on the early detection and prevention of colorectal cancer. The Company's non-invasive stool-based DNA (sDNA) screening technology includes proprietary and patented methods that isolate and analyze human DNA present in stool to screen for the presence of colorectal pre-cancer and cancer.

**Basis of Presentation**

The accompanying condensed consolidated financial statements include the accounts of the Company and those of its wholly-owned subsidiary, Exact Sciences Laboratories, LLC., are unaudited and have been prepared on a basis substantially consistent with the Company's audited financial statements and notes as of and for the year ended December 31, 2012 included in the Company's Annual Report on Form 10-K (the 2012 Form 10-K). These condensed consolidated financial statements are prepared in conformity with accounting principles generally accepted in the United States of America (GAAP) and follow the requirements of the Securities and Exchange Commission (SEC) for interim reporting. In the opinion of management, all adjustments (consisting only of adjustments of a normal and recurring nature) considered necessary for a fair presentation of the results of operations have been included. The results of the Company's operations for any interim period are not necessarily indicative of the results of the Company's operations for any other interim period or for a full fiscal year. The statements should be read in conjunction with the audited financial statements and related notes included in the 2012 Form 10-K. Management has evaluated subsequent events for disclosure or recognition in the accompanying financial statements up to the filing of this report.

References to Exact, we, us, our, or the Company refer to Exact Sciences Corporation and its subsidiary, Exact Sciences Laboratories, LLC.

**(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**Use of Estimates**

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

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 cash on hand, demand deposits in bank, money market funds, and all highly liquid investments with an original maturity of 90 days or less to be cash and cash equivalents. The Company had no restricted cash at September 30, 2013 and December 31, 2012.

### **Marketable 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 carried at amortized cost 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 loss. The

Table of Contents

amortized cost of debt securities in this category is adjusted for amortization of premiums and accretion of discounts to maturity computed under the straight-line method, which approximates 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 September 30, 2013 and December 31, 2012, the Company's investments were comprised of fixed income investments and all were deemed available-for-sale. 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. Investments in which the Company has the ability and intent, if necessary, to liquidate in order to support its current operations (including those with a contractual term greater than one year from the date of purchase) are classified as current. All of the Company's investments are considered current. There were no realized losses for the nine months ended September 30, 2013 and September 30, 2012. Realized gains were \$5.1 thousand and \$4.2 thousand for the nine months ended September 30, 2013 and 2012, respectively. Unrealized gains or losses on investments are recorded in other comprehensive loss.

Available-for-sale securities at September 30, 2013 consisted of the following:

(In thousands)	Amortized Cost	September 30, 2013		Estimated Fair Value
		Gains in Accumulated Other Comprehensive Income	Losses in Accumulated Other Comprehensive Income	
U.S. government agency securities	\$ 44,477	\$ 56	\$	\$ 44,533
Corporate bonds	80,973	52		81,025
Certificates of deposit	7,565	9		7,574
Commercial paper	4,998	1		4,999
Total available-for-sale securities	\$ 138,013	\$ 118	\$	\$ 138,131

Available-for-sale securities at December 31, 2012 consisted of the following:

Table of Contents

(In thousands)	December 31, 2012			
	Amortized Cost	Gains in Accumulated Other Comprehensive Income	Losses in Accumulated Other Comprehensive Income	Estimated Fair Value
U.S. government agency securities	\$ 44,270	\$ 38	\$	\$ 44,308
Corporate bonds	43,303	27		43,330
Certificates of deposit	5,926	13		5,939
Commercial paper	1,199			1,199
Total available-for-sale securities	\$ 94,698	\$ 78	\$	\$ 94,776

**Property and Equipment**

Property and equipment are stated at cost and depreciated using the straight-line method over the assets' estimated useful lives. Maintenance and repairs are expensed when incurred; additions and improvements are capitalized. The estimated useful lives of fixed assets are as follows:

Asset Classification	Estimated Useful Life
Laboratory equipment	3 - 5 years
Office and computer equipment	3 years
Leasehold improvements	Lesser of the remaining lease term or useful life
Furniture and fixtures	3 years

At September 30, 2013, the Company had \$3.7 million of assets under construction which consisted of \$1.7 million of leasehold improvements for the Company's new commercial lab facility, \$1.2 million of capitalized costs related to software projects, and \$0.8 million of costs related to equipment under construction. Depreciation will begin on these assets once they are placed into service. The Company expects that it will cost \$3.2 million to complete the construction of the new lab facility. The Company has committed to pay \$1.4 million of this amount and the landlord for the facility has committed to pay the remaining \$1.8 million as part of the lease incentive obligation outlined in the lease. See Note 6 (Operating Lease).

**Net Loss Per Share**

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 due to the Company's losses.

Table of Contents

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

(In thousands)	September 30,	
	2013	2012
Shares issuable upon exercise of stock options	6,108	6,282
Shares issuable upon exercise of outstanding warrants (1)	155	325
Shares issuable upon the release of restricted stock awards	1,264	945
Shares issuable upon the vesting of restricted stock awards related to a licensing agreement	49	73
	7,576	7,625

(1) At September 30, 2013, represents warrants to purchase 80,000 shares of common stock issued under a license agreement and warrants to purchase 75,000 shares of common stock issued under a consulting agreement. At September 30, 2012, represents warrants to purchase 250,000 shares of common stock issued under a license agreement and warrants to purchase 75,000 shares of common stock issued under a consulting agreement.

**Revenue Recognition**

**License fees.** License fees for the licensing of product rights are recorded as deferred revenue upon receipt of cash and recognized as revenue on a straight-line basis over the license period. As more fully described in the 2012 Form 10-K, in connection with the Company's January 2009 strategic transaction with Genzyme Corporation, Genzyme agreed to pay the Company a total of \$18.5 million, of which \$16.65 million was paid on January 27, 2009 and \$1.85 million was subject to a holdback by Genzyme to satisfy certain potential indemnification obligations in exchange for the assignment and licensing of certain intellectual property to Genzyme. 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 through licenses certain intellectual property improvements to Genzyme, if improvements are made 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 is amortizing that up-front payment on a straight-line basis into revenue over the initial five-year collaboration period ending in January 2014. The Company received the first holdback amount of \$1.0 million, which included accrued interest due, from Genzyme during the first quarter of 2010. The Company received the second holdback amount of \$0.9 million, which included accrued interest due, from Genzyme during the third quarter of 2010. The amounts were deferred and are being amortized on a straight-line basis into revenue over the remaining term of the collaboration at the time of receipt.

In addition, Genzyme purchased 3,000,000 shares of common stock on January 27, 2009 for \$2.00 per share, representing a premium of \$0.51 per share above the closing price of the Company's common stock on that date of \$1.49 per share. The aggregate premium paid by Genzyme over the closing price of 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 is amortizing that amount on a straight-line basis into revenue over the initial five-year collaboration period ending in January 2014.

Table of Contents

The Company recognized approximately \$1.0 million in license fee revenue in connection with the amortization of the up-front payments from Genzyme, during each of the three month periods ended September 30, 2013 and September 30, 2012. The Company recognized approximately \$3.1 million in license fee revenue in connection with the amortization of up-front payments from Genzyme during each of the nine month periods ended September 30, 2013 and September 30, 2012.

**(3) MAYO LICENSE AGREEMENT**

**Overview**

On June 11, 2009, the Company entered into a license agreement (the License Agreement ) with MAYO Foundation for Medical Education and Research ( MAYO ). Under the License Agreement, MAYO granted the Company an exclusive, worldwide license within the field (the Field ) of stool or blood based cancer diagnostics and screening (excluding a specified proteomic target) with regard to certain MAYO patents, and a non-exclusive worldwide license within the Field with regard to certain MAYO know-how. The licensed patents cover advances in sample processing, analytical testing and data analysis associated with non-invasive, stool-based DNA screening for colorectal cancer. Under the License Agreement, the Company assumes the obligation and expense of prosecuting and maintaining the licensed patents and is obligated to make commercially reasonable efforts to bring products covered by the license to market. Pursuant to the License Agreement, the Company granted MAYO two common stock purchase warrants with an exercise price of \$1.90 per share covering 1,000,000 and 250,000 shares of common stock, respectively. The Company is also required to make payments to MAYO for up-front fees, fees once certain milestones are reached by the Company, and other payments as outlined in the License Agreement. In addition to the license to intellectual property owned by MAYO, the Company receives product development and research and development efforts from MAYO personnel. The Company is also obligated to make royalty payments to MAYO on potential future net sales of any products developed from the licensed technology. The Company sought rights to the Mayo intellectual property for the specific purpose of developing a non-invasive, stool-based DNA screening test for colorectal cancer. At the time the license agreement was executed, the sole focus of the Company was the development of such a test. Accordingly, the Company recognized the initial payments and expense related to the warrants at the time of the transaction and the amounts were expensed to research and development as there were no anticipated alternative future uses associated with the intellectual property.

**Warrants**

The warrants granted to MAYO were valued based on a Black-Scholes pricing model at the date of the grant. The warrants were granted with an exercise price of \$1.90 per share of common stock. The grant to purchase 1,000,000 shares was immediately exercisable and the grant to purchase 250,000 shares vests and becomes exercisable over a four year period.

In March of 2010, MAYO partially exercised its warrant covering 1,000,000 shares by utilizing the cashless exercise provision contained in the warrant. As a result of this exercise for a gross amount of 200,000 shares, in lieu of paying a cash exercise price, MAYO forfeited its rights with respect to 86,596 shares leaving it with a net amount of 113,404 shares.

In September of 2010, MAYO partially exercised this warrant by utilizing the cashless exercise provision contained in the warrant. As a result of this exercise for a gross amount of 300,000 shares, in lieu of paying a cash exercise price, MAYO forfeited its rights with respect to 97,853 shares leaving it with a net amount of 202,147 shares.



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

In June of 2011, MAYO partially exercised this warrant by utilizing the cashless exercise provision contained in the warrant. As a result of this exercise for a gross amount of 250,000 shares, in lieu of paying a cash exercise price, MAYO forfeited its rights with respect to 60,246 shares leaving it with a net amount of 189,754 shares.

In September of 2011, MAYO partially exercised this warrant by utilizing the cashless exercise provision contained in the warrant. As a result of this exercise for a gross amount of 250,000 shares, in lieu of paying a cash exercise price, MAYO forfeited its right with respect to 56,641 shares leaving it with a net amount of 193,359 shares. Following this exercise, the warrant covering 1,000,000 shares was fully exercised.

In January of 2013, MAYO partially exercised its warrant covering 250,000 shares by utilizing the cashless exercise provision contained in the warrant. As a result of this exercise for a gross amount of 85,000 shares, in lieu of paying a cash exercise price, MAYO forfeited its right with respect to 14,008 shares leaving it with a net amount of 70,992 shares.

Table of Contents

In June of 2013, MAYO partially exercised this warrant by utilizing the cashless exercise provision contained in the warrant. As a result of this exercise for a gross amount of 85,000 shares, in lieu of paying a cash exercise price, MAYO forfeited its right with respect to 12,765 shares leaving it with a net amount of 72,235 shares. The warrant now covers a total of 80,000 shares.

**Royalty Payments**

The Company will make royalty payments to MAYO based on a percentage of net sales of products developed from the licensed technology starting in the third year of the agreement. Minimum royalty payments were \$10,000 in 2012 and will be \$25,000 per year through 2029, the year the last patent expires.

**Other Payments**

Other payments under the MAYO agreement include an upfront payment of \$80,000, a milestone payment of \$250,000 on the commencement of patient enrollment in FDA trials for the Company's Cologuard pre-cancer and cancer screening test, and a \$500,000 payment upon FDA approval of the Company's Cologuard test. The upfront payment of \$80,000 was made in the third quarter of 2009 and expensed to research and development in the second quarter of 2009. The Company began enrollment in its FDA trial in June of 2011 and the milestone payment of \$250,000 was made in June of 2011 and expensed to research and development in the second quarter of 2011. It is uncertain as to when the FDA will approve the Company's pre-cancer and cancer screening test. Therefore, the \$500,000 milestone payment has not been recorded as a liability. The Company evaluates the status of the FDA trial at each reporting date to determine if a liability should be recorded for the milestone payment.

In addition, the Company is making payments to MAYO for research and development efforts. During the three and nine months ended September 30, 2013, the Company made payments of \$0.3 million and \$0.6 million, respectively. At September 30, 2013 the Company recorded an estimated liability in the amount of \$0.7 million for research and development efforts. During the three and nine months ended September 30, 2012, the Company made payments of \$0.3 million and \$0.6 million, respectively. At September 30, 2012 the Company recorded an estimated liability in the amount of \$0.2 million for research and development efforts.

**May 2012 Amendment**

In May 2012 the Company expanded the relationship with MAYO through an amendment to the License Agreement. As part of the amendment, MAYO expanded the Company's license to include all gastrointestinal cancers and diseases, and new cancer screening applications of stool- and blood-based testing. As consideration for the expanded license, the Company granted MAYO 97,466 shares of restricted stock, one quarter of which vested immediately, with the remainder to vest in three equal annual installments. The Company recognized \$1.0 million in research and development licensing expense during the twelve months ended December 31, 2012 in connection with the restricted stock grant. The Company sought rights to the Mayo intellectual property for the specific purpose of developing future non-invasive, stool-based DNA screening tests for gastrointestinal diseases other than colorectal cancer. The Company does not believe there are alternative future uses for the intellectual property. In addition, at the time the restricted stock grant expense was recorded for the intellectual property license, the Company believed it was unlikely they would proceed with the tests for other gastrointestinal diseases unless the significant risks related to the colorectal cancer screening test receiving FDA approval were mitigated. Because of the significant uncertainty of receiving FDA approval for the colorectal

cancer diagnostic, coupled with the uncertainty associated with funding future development of tests for other gastrointestinal diseases, the Company could not conclude that commencement of any future projects related to the acquired intellectual property was reasonably expected at the time of this license agreement amendment.

As part of the amendment, the Company will also be responsible for making additional restricted stock grants to MAYO as certain milestones are met with respect to commercial launch of the Company's second and third licensed products. Additionally, the Company will make milestone payments once certain sales levels are reached on the second and third licensed products. It is uncertain as to when these milestones will be met; therefore, the milestone payments have not been recorded as a liability. The Company evaluates the status of the milestone payments at each reporting date to determine if a liability should be recorded for the milestone payment.

#### **(4) STOCK-BASED COMPENSATION**

##### **Stock-Based Compensation Plans**

The Company maintains the 2010 Omnibus Long-Term Incentive Plan, the 2010 Employee Stock Purchase Plan, the 2000 Stock Option and Incentive Plan and the 2000 Employee Stock Purchase Plan (collectively, the "Stock Plans"). In July 2013 the Company's stockholders approved an amendment to the 2010 Omnibus Long-Term Incentive Plan to increase the number of shares reserved for issuance thereunder by 2,800,000 shares and to increase the fungible share ratio to 1.55 (from 1.35) so that each share of common stock covered by an award other than an option or stock appreciation right will reduce the shares available under the plan by 1.55 shares.

Table of Contents

**Stock-Based Compensation Expense**

The Company recorded \$1.8 million and \$5.7 million in stock-based compensation expense during the three and nine months ended September 30, 2013 in connection with the amortization of restricted stock and restricted stock unit awards, stock purchase rights granted under the Company's employee stock purchase plan and stock options granted to employees, non-employee consultants and non-employee directors. The Company recorded \$1.5 million and \$4.0 million in stock-based compensation expense during the three and nine months ended September 30, 2012 in connection with the amortization of restricted stock and restricted stock unit awards, stock purchase rights granted under the Company's employee stock purchase plan and stock options granted to employees and non-employee directors.

In connection with the June 7, 2013 resignation of Laura Stoltenberg, the Company's former Chief Commercial Officer, the Company modified the vesting of 100,000 shares of Ms. Stoltenberg's previously unvested restricted stock units of which 41,250 of the restricted stock units vested upon the execution of the separation agreement, 10,000 will vest in March 2014, and the remaining 48,750 will vest in twenty-four equal monthly installments beginning in April 2014, subject to Ms. Stoltenberg's continuing compliance with the terms of the separation agreement. Ms. Stoltenberg forfeited all other unvested restricted stock units and stock option awards. It was determined that the continuing compliance and service to be provided to the Company under the separation agreement was not substantive and, as a result, the Company recorded the full value of the modified restricted stock units as additional stock-based compensation expense in the second quarter of 2013.

**Determining Fair Value**

**Valuation and Recognition** - 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 recognized 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 life. Using this method, the expected term is determined using the average of the vesting period and the contractual life of the stock options granted.

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

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

**Forfeitures** - The Company records stock-based compensation expense only for those awards that are expected to vest. A forfeiture rate is estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from initial estimates. The Company's forfeiture rate used in the nine months ended September 30, 2013 was 2.76%. The Company's forfeiture rate used in the nine months ended September 30, 2012 was 1.38%.

The fair value of each restricted stock and restricted stock unit award is determined on the date of grant using the closing stock price on that day.

Table of Contents

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
<b>Option Plan Shares</b>				
Risk-free interest rates	1.73%	0.81% - 0.89%	0.94% - 1.73%	0.81% - 0.89%
Expected term (in years)	6	6	6	6
Expected volatility	82.9%	86.0%	82.9% - 84.0%	86.0% - 92.0%
Dividend yield	0%	0%	0%	0%
Weighted average fair value per share of options granted during the period	\$ 10.34	\$ 7.47	\$ 8.12	\$ 6.90
<b>ESPP Shares</b>				
Risk-free interest rates	(1)	(1)	0.11% - 0.20%	0.19% - 0.27%
Expected term (in years)	(1)	(1)	0.5-2	0.5-2
Expected volatility	(1)	(1)	39.1% - 45.6%	40% - 55%
Dividend yield	(1)	(1)		
Weighted average fair value per share of stock purchase rights granted during the period	(1)	(1) \$	2.80	\$ 3.47

(1) The Company did not issue stock purchase rights under its 2010 Purchase Plan during the respective period.

**Stock Option and Restricted Stock Activity**

A summary of stock option activity under the Stock Plans during the nine months ended September 30, 2013 is as follows:

Table of Contents

<b>Options</b> <b>(Aggregate intrinsic value in thousands)</b>	<b>Shares</b>	<b>Weighted Average Exercise Price</b>	<b>Weighted Average Remaining Contractual Term (Years)</b>	<b>Aggregate Intrinsic Value (1)</b>
Outstanding, January 1, 2013	6,181,996	\$ 2.62	6.6	
Granted	290,570	\$ 11.36		
Exercised	(234,544)	\$ 5.17		
Forfeited	(129,625)	\$ 10.15		
Outstanding, September 30, 2013	6,108,397	\$ 2.78	6.5	\$ 55,277
Exercisable, September 30, 2013	5,237,044	\$ 1.79	5.7	\$ 52,461
Vested and expected to vest September 30, 2013	6,057,354	\$ 2.74	6.5	\$ 55,142

(1)The aggregate intrinsic value of options outstanding, exercisable and vested and expected to vest is calculated as the difference between the exercise price of the underlying options and the market price of the Company's common stock for options that had exercise prices that were lower than the \$11.80 market price of the Company's common stock at September 30, 2013. The total intrinsic value of options exercised during the three and nine months ended September 30, 2013 was \$1.0 million and \$1.6 million, respectively. The total intrinsic value of options exercised during the three and nine months ended September 30, 2012 was \$0.4 million and \$3.8 million, respectively.

As of September 30, 2013, there was \$14.4 million of total unrecognized compensation cost related to non-vested share-based compensation arrangements granted under all Stock 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 2.72 years.

A summary of restricted stock activity under the Stock Plans during the nine months ended September 30, 2013 is as follows:

	<b>Restricted Shares</b>	<b>Weighted Average Grant Date Fair Value</b>
Outstanding, January 1, 2013	813,955	\$ 8.51
Granted	998,102	\$ 11.80
Released	(188,981)	\$ 9.06
Forfeited	(358,981)	\$ 9.45
Outstanding, September 30, 2013	1,264,095	\$ 10.76

Table of Contents

During the first quarter of 2012, the Company granted a total of 262,500 restricted stock units to certain executives that would have vested based upon the satisfaction of certain service and performance conditions. These performance conditions were not met and the awards were forfeited during the first quarter of 2013. The expense recorded through December 31, 2012 for these awards totaling \$0.6 million was reversed during the first quarter of 2013 due to the forfeiture.

During the first quarter of 2013, the Company granted a total of 180,750 restricted stock units to certain executives that will vest based upon the satisfaction of certain service and performance conditions. The Company performed an evaluation of internal and external factors, and determined the number of shares that are most likely to vest based on the probability of which performance conditions will be met. The expense for the fair value of the awards that are expected to vest is being recognized ratably over the vesting period.

Warrants to purchase 75,000 shares of common stock were issued in connection with a consulting agreement in 2009. The warrants contain a performance condition and vest if the Company successfully receives FDA approval for its Cologuard test. The Company is uncertain if the performance conditions will be attained, and therefore no expense has been recorded on this warrant as of September 30, 2013. The exercise price of the warrant is \$0.01.

**(5) FAIR VALUE MEASUREMENTS**

The FASB has issued authoritative guidance which requires 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. The fair value hierarchy establishes and 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 are as follows:

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



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

Fixed-income securities and mutual funds are valued using a third party pricing agency. The valuation is based on observable inputs including pricing for similar assets and other observable market factors. There has been no material change from period to period. The estimated fair value of the Company's long-term debt based on a market approach was approximately \$1.0 million as of September 30, 2013 and December 31, 2012 and represent Level 2 measurements. When determining the estimated fair value of the Company's long-term debt, the Company used market-based risk measurements, such as credit risk.

The following table presents the Company's fair value measurements as of September 30, 2013 along with the level within the fair value hierarchy in which the fair value measurements in their entirety fall. Amounts in the table are in thousands.

Table of Contents

Description	Fair Value Measurement at September 30, 2013 Using:			
	Fair Value at September 30, 2013	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash and cash equivalents				
Cash and money market	\$ 9,710	\$ 9,710	\$	\$
Available-for-Sale				
Marketable securities				
U.S. government agency securities	44,533		44,533	
Corporate bonds	81,025		81,025	
Certificates of deposit	7,574		7,574	
Commercial paper	4,999		4,999	
Total	\$ 147,841	\$ 9,710	\$ 138,131	\$

The following table presents the Company's fair value measurements as of December 31, 2012 along with the level within the fair value hierarchy in which the fair value measurements in their entirety fall. Amounts in the table are in thousands.

Table of Contents

Description	Fair Value Measurement at December 31, 2012 Using:			
	Fair Value at December 31, 2012	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>Cash and cash equivalents</b>				
Cash and money market	\$ 13,095	\$ 13,095	\$	\$
Corporate bonds	250		250	
<b>Available-for-Sale</b>				
<b>Marketable securities</b>				
U.S. government agency securities	44,308		44,308	
Certificates of deposit	5,939		5,939	
Corporate bonds	43,330		43,330	
Commercial paper	1,199		1,199	
<b>Total</b>	<b>\$ 108,121</b>	<b>\$ 13,095</b>	<b>\$ 95,026</b>	<b>\$</b>

As of September 30, 2013 and December 31, 2012 the Company held available-for-sale securities which had been in a continuous unrealized loss position for less than twelve months, the total unrealized losses of which were \$14.8 thousand, as of September 30, 2013, and \$4.8 thousand, as of December 31, 2012. At September 30, 2013 and December 31, 2012 there were no available-for-sale securities in a continuous loss position for greater than twelve months.

The following summarizes contractual underlying maturities of the Company's available-for-sale investments in debt securities at September 30, 2013 (in thousands):

	Cost		Fair Value	
Due in one year or less	\$	85,409	\$	85,452
Due after one year through two years		52,604		52,679
	\$	138,013	\$	138,131

**(6) OPERATING LEASE**

During the second quarter of 2013, the Company entered into a five year lease for a 29,000 square foot facility in Madison, Wisconsin to house its commercial lab operations. This lease contains periodic rent escalation adjustments and includes provisions for tenant improvements. The Company has two options to extend the term of the lease for five years each.

Future minimum payments under the operating lease are as follows as of September 30, 2013. Amounts included in the table are in thousands.

Table of Contents

Year Ending December 31,		
2013	\$	112
2014		676
2015		680
2016		684
2017		689
2018		578
Total lease obligations	\$	3,419

During the third quarter of 2013, the Company began to make leasehold improvements to the 29,000 square foot facility in Madison, Wisconsin that is to house its commercial lab operations. At September 30, 2013 total leasehold improvements were \$1.7 million and were included in assets under construction on the balance sheet. As part of the lease agreement, the landlord has agreed to pay for a portion of leasehold improvements constructed. These payments will be recorded as a lease incentive obligation and will be amortized over the term of the lease as a reduction of rent expense. The Company will begin to amortize the leasehold improvements upon completion of the improvements. As of September 30, 2013, the lease incentive obligation was \$0.9 million.

The Company expects that it will cost \$3.2 million to complete the construction of the new lab facility. The Company has committed to pay \$1.4 million of this amount and the landlord for the facility has committed to pay the remaining \$1.8 million as part of the lease incentive obligation outlined in the lease.

**(7) EQUITY**

In February 2011, we adopted a rights agreement and subsequently distributed to our stockholders preferred stock purchase rights. Under certain circumstances, each right can be exercised for one one-thousandth of a share of Series A Junior Participating Preferred Stock. In general, the rights will become exercisable in the event of an announcement of an acquisition of 15% or more of our outstanding common stock or the commencement or announcement of an intention to make a tender offer or exchange offer for 15% or more of our outstanding common stock. If any person or group acquires 15% or more of our common stock, our stockholders, other than the acquiror, will have the right to purchase additional shares of our common stock (in lieu of the Series A Junior Participating Preferred Stock) at a substantial discount to the then prevailing market price. The rights agreement could significantly dilute such acquiror's ownership position in our shares, thereby making a takeover prohibitively expensive and encouraging such acquiror to negotiate with our board of directors. The ability to exercise these rights is contingent on events that the Company has determined to be unlikely at this time, and therefore this provision has not been considered in the computation of equity or earnings per share.

**(8) RELATED PARTY TRANSACTIONS**

During the three months ended September 30, 2013, the Company entered into a one year consulting agreement with a non-employee director under which the director provides advisory services in support of the Company's commercialization activities. In accordance with the agreement, the Company granted a restricted stock award for 4,277 shares of common stock that vests over one year, and will make cash payments totaling \$60.0 thousand over the one year term of the agreement.

**(9) INCOME TAXES**

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

The Company is subject to taxation in the U.S. and various state jurisdictions. All of the Company's tax years are subject to examination by the U.S. and state tax authorities due to the carryforward of unutilized net operating losses.

Under financial accounting standards, deferred tax assets or liabilities are computed based on the differences between the financial statement and income tax bases of assets and liabilities using the enacted tax rates. Deferred income tax expense or benefit represents the change in the deferred tax assets or liabilities from period to period.

A valuation allowance to reduce the deferred tax assets is reported if, based on the weight of the evidence, it is more likely than not that some portion or all of the deferred tax assets will not be realized. The Company has incurred significant losses since its inception and due to the uncertainty of the amount and timing of future taxable income, management has determined that a full valuation allowance at September 30, 2013 is necessary to reduce the tax assets to the amount that is more likely than not to be realized. Due to the existence of the valuation allowance, future changes in the Company's unrecognized tax benefits will not impact the Company's effective tax rate.

The Company recognizes the financial statement benefit of a tax position only after determining that the relevant tax authority would more likely than not sustain the position following an audit. For tax positions meeting the more-likely-than-not threshold, the amount recognized in the financial statements is the largest benefit that has a greater than 50 percent likelihood of being realized upon ultimate settlement with the relevant tax authority. At September 30, 2013 the Company had no unrecognized tax benefits, nor are there any tax positions where it is reasonably possible that the

Table of Contents

total amounts of unrecognized tax benefits will significantly increase or decrease within the 12 months following September 30, 2013.

**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 and its subsidiary ( Exact, we, us, our or the Company ) 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, 2012, which has been filed with the SEC (the 2012 Form 10-K ).

**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, timing and anticipated results of our pivotal clinical trial and our related FDA submissions, estimated markets for our products and expected 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 our 2012 Form 10-K and our subsequently filed Quarterly Reports on Form 10-Q. 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**

We are a molecular diagnostics company currently focused on the early detection and prevention of colorectal cancer. We have developed an accurate, non-invasive, patient friendly screening test to meet our primary goal of becoming the market leader for a 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:

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

- advance our product through U.S. Food and Drug Administration (FDA) clinical approval process;
- commercialize an FDA-approved product that detects colorectal pre-cancer and cancer; and
- secure favorable reimbursement for our product from payors.

Our Cologuard test is a non-invasive, stool-based DNA (sDNA) screening test designed to detect DNA markers, which in published studies have been shown to be associated with colorectal cancer. In addition to DNA markers, our test includes a protein marker to detect blood in the stool utilizing an antibody-based fecal immunochemical test (FIT).

Colorectal cancer is the second leading cause of cancer deaths in the United States and the leading cause of cancer deaths among nonsmokers.

Table of Contents

It is widely accepted that colorectal cancer is among the most preventable, yet least prevented cancers. Colorectal cancer can take up to 10-15 years to progress from a pre-cancerous lesion to metastatic cancer and death. Patients who are diagnosed early in the progression of the disease with pre-cancerous lesions or polyps, or early-stage cancer are more likely to have a complete recovery and to be treated less expensively. Accordingly, the American Cancer Society recommends that all people age 50 and older undergo regular colorectal cancer screening. Of the more than 80 million people in the United States for whom routine colorectal cancer screening is recommended, nearly 47 percent have not been screened according to current guidelines. Poor compliance has meant that nearly two-thirds of colorectal cancer diagnoses are made in the disease's late stages. The five-year survival rates for stages 3 and 4 are 67 percent and 12 percent, respectively.

We believe the large population of unscreened and inadequately screened patients represents a significant opportunity for a patient friendly screening test like ours. A powerful preventive tool that detects pre-cancerous polyps and early stage colorectal cancer could significantly reduce colorectal cancer deaths and the health care costs associated with the disease. Pre-cancerous polyps are present in approximately 6 percent of average risk people 50 years of age and older who undergo routine colorectal cancer screening.

The competitive advantages of sDNA screening provide a significant market opportunity. Assuming a 30-percent test adoption rate and a three-year screening interval, we estimate the potential U.S. market for sDNA screening to be more than \$2 billion and we estimate the potential global market opportunity to be greater than \$3 billion.

Our current focus is on seeking FDA approval for our Cologuard test. We believe obtaining FDA approval is important to building broad demand and successfully commercializing our sDNA colorectal cancer screening technology. We are also in the process of developing our strategy for the ultimate commercialization of our Cologuard test.

In November 2012 we completed enrollment for our pivotal FDA clinical trial with over 10,000 patients enrolled at 90 enrollment sites in the U.S. and Canada. All patients provided a sample to be tested with our Cologuard test, and received a FIT test and a colonoscopy.

Preliminary, top-line data from the clinical trial showed that our Cologuard test demonstrated 92 percent sensitivity for the detection of colorectal cancer and 42 percent sensitivity for the detection of pre-cancerous polyps, including 66 percent sensitivity for pre-cancerous polyps equal to or greater than 2 centimeters. The test achieved a specificity of 87 percent during the clinical trial.

The clinical trial achieved all of its endpoints. The co-primary endpoints for the study were the sensitivity and specificity of the Cologuard screening test for colorectal adenocarcinoma. The clinical trial included two sets of co-secondary endpoints. The first included sensitivity and specificity of the test for advanced adenomas. The second included superiority of Cologuard to FIT for cancer and advanced adenoma sensitivity.

Each patient result from the Cologuard test was compared to the patient's colonoscopy result and the histopathologic diagnosis of any lesions that were discovered during colonoscopy and biopsied. The study population included 65 cancer patients and 752 patients with pre-cancerous polyps.



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

We submitted the results of our clinical trial to the FDA through a three part submission of a manufacturing module, analytical module, and clinical module. The manufacturing module was submitted to the FDA in December 2012, the analytical module was submitted to the FDA in February 2013, and the clinical module was submitted to the FDA in June 2013. Our submission is currently under review by the FDA.

We believe that obtaining a favorable national coverage decision and a favorable reimbursement rate from the Centers for Medicare & Medicaid Services (CMS) for our Cologuard test will be a necessary element in achieving material commercial success.

With the goal of expediting receipt of a favorable coverage decision, we are working with CMS to coordinate the CMS coverage review with the FDA pre-market approval through a parallel review process. This program provides a pathway to a potential CMS national coverage determination shortly after an FDA approval, should it occur.

Table of Contents

We plan to focus marketing efforts on primary care physicians who prescribe a high volume of fecal occult blood testing (FOBT) and FIT tests since this physician group has displayed a partiality for stool based screening methods. Six percent of primary care physician prescribers are responsible for 60% of FOBT/FIT volume.

We have generated limited operating revenues since inception and, as of September 30, 2013, we had an accumulated deficit of approximately \$308.6 million. We expect to continue to incur losses for the next several years, and it is possible we may never achieve profitability.

**2013 Priorities**

Our top priorities for 2013 include completing the FDA submission and advancing our dialogue with CMS regarding our planned national coverage application for our Cologuard test. We submitted the final module of our FDA submission in June 2013. If for any reason the FDA does not approve our premarket approval application (PMA) or such approval is substantially delayed, our business and prospects would likely be materially adversely impacted. Likewise it would be a material adverse event for our business if we do not receive a positive national coverage decision and favorable reimbursement rate from CMS or if for any other reason we are unable to successfully commercialize our Cologuard test.

An additional focus for us in 2013 is building our manufacturing capacity which includes continuous improvements to our FDA compliant quality management system.

Another 2013 priority for us is establishing a lab facility to process Cologuard tests and provide patient results. We have leased a 29,000 square foot facility in Madison, Wisconsin to house our commercial lab operations and construction of the lab in that facility is currently underway.

In addition, in 2013 we plan to work toward launch readiness through building and deploying a marketing team and continuing our outreach and education efforts to physicians, third party payors and advocates.

We also have identified a new opportunity for our sDNA technology focused on the inflammatory bowel disease (IBD) patient population. We initiated an IBD clinical trial in the first quarter of 2013 that will focus on this specific patient group, and plan on enrolling approximately 300 IBD patients into the trial. Furthermore, we will work on developing enhancements to our Cologuard test and identifying and conducting research on other potential pipeline products targeting other cancers, such as esophageal and pancreatic cancer.

**Financial Overview**

**Revenue.** Our revenue is comprised of the amortization of up-front license fees for the licensing of certain patent rights to Genzyme. We expect that license fees for 2013 will be consistent with amounts recorded in 2012.

**Our Cost Structure.** Our selling, general and administrative expenses consist primarily of non-research personnel salaries, office expenses, professional fees, sales and marketing expenses incurred in support of our commercialization efforts and non-cash stock-based compensation.

#### **Critical Accounting Policies and Estimates**

Management's discussion and analysis of our financial condition and results of operations is based on our condensed financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States (GAAP). 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, tax positions and stock-based compensation. We base our estimates on historical experience and on various other factors that are believed to be appropriate under the

Table of Contents

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.

While our significant accounting policies are more fully described in Note 2 of our financial statements included in the 2012 Form 10-K, we believe that the following accounting policies and judgments are most critical to aid in fully understanding and evaluating 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 of cash and recognized as revenue on a straight-line basis over the license period.

In connection with our January 2009 strategic transaction with Genzyme Corporation, Genzyme agreed to pay us a total of \$18.5 million, of which \$16.65 million was paid on January 27, 2009 and \$1.85 million was subject to a holdback by Genzyme to satisfy certain potential indemnification obligations in exchange for the assignment and licensing of certain intellectual property to Genzyme. Our on-going performance obligations to Genzyme under the Collaboration, License and Purchase Agreement (the CLP Agreement), as described below, including our obligation to deliver certain intellectual property improvements to Genzyme, if improvements are made during the initial five-year collaboration period, were deemed to be undelivered elements of the CLP Agreement on the date of closing. Accordingly, we deferred the initial \$16.65 million in cash received at closing and are amortizing that up-front payment on a straight-line basis into revenue over the initial five-year collaboration period ending in January 2014. We received the first holdback amount of \$962,000, which included accrued interest due, from Genzyme during the first quarter of 2010 and the second holdback amount of \$934,250, which included accrued interest, due from Genzyme during the third quarter of 2010. The amounts were deferred and are being amortized on a straight-line basis into revenue over the remaining term of the collaboration at the time of receipt.

In addition, Genzyme purchased 3,000,000 shares of our common stock on January 27, 2009, for \$2.00 per share, representing a premium of \$0.51 per share above the closing price of our common stock on that date of \$1.49 per share. The aggregate premium paid by Genzyme over the closing price of our common stock on the date of the transaction of \$1.53 million is deemed to be a part of the total consideration for the CLP Agreement. Accordingly, we deferred the aggregate \$1.53 million premium and are amortizing that amount on a straight-line basis into revenue over the initial five-year collaboration period ending in January 2014.

In total, we recognized approximately \$1.0 million in license fee revenue in connection with the amortization of the up-front payments and holdback amounts from Genzyme during each of the three month periods ended September 30, 2013 and 2012 and approximately \$3.1 million for each of the nine month periods ended September 30, 2013 and 2012.

**Stock-Based Compensation.** In accordance with GAAP, all stock-based payments, including grants of employee stock options, restricted stock and restricted stock units and shares purchased under an employee stock purchase plan (ESPP) (if certain parameters are not met), are recognized in the financial statements based on their fair values. The following assumptions are used in determining fair value for stock options, restricted stock and ESPP shares:

- **Valuation and Recognition** - The fair value of each option award is estimated on the date of grant using the Black-Scholes option pricing model. The estimated fair value of employee stock options is recognized to expense using the straight-line method over the vesting period.
- **Expected Term** - The Company uses the simplified calculation of expected life, described by the SEC's Staff Accounting Bulletins 107 and 110, as the Company does not currently have sufficient historical exercise data on which to base an estimate of expected term. Using this method, the expected term is determined using the average of the vesting period and the contractual life of the stock options granted.
- **Expected Volatility** - Expected volatility is based on the Company's historical stock volatility data over the expected term of the awards.
- **Risk-Free Interest Rate** - The Company bases the risk-free interest rate used in the Black-Scholes valuation method on the implied yield currently available on U.S. Treasury zero-coupon issues with an equivalent remaining expected term.

Table of Contents

- **Forfeitures** - The Company records stock-based compensation expense only for those awards that are expected to vest. A forfeiture rate is estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from initial estimates. The Company's forfeiture rate used in the nine months ended September 30, 2013 was 2.76%. The Company's forfeiture rate used in the nine months ended September 30, 2012 was 1.38%.

The fair value of each restricted stock award and restricted stock unit is determined on the date of grant using the closing stock price on that day. 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 Note 4 to our condensed financial statements.

**Results of Operations**

**Revenue.** Total revenue was \$1.0 million for each of the three month periods ended September 30, 2013 and September 30, 2012. Total revenue was \$3.1 million for each of the nine month periods ended September 30, 2013 and September 30, 2012. Total revenue is composed of the amortization of up-front technology license fee payments associated with our collaboration, license and purchase agreement with Genzyme. The unamortized Genzyme up-front payment and holdback amounts are being amortized on a straight-line basis over the initial Genzyme collaboration period, which ends in January 2014.

**Research and development expenses.** Research and development expenses decreased to \$7.0 million for the three months ended September 30, 2013 from \$10.5 million for the three months ended September 30, 2012. Research and development expenses decreased to \$21.0 million for the nine months ended September 30, 2013 from \$31.7 million for the nine months ended September 30, 2012. This decrease was primarily due to a decrease in clinical trial costs, lab expenses, and professional fees due to the completion of the FDA clinical trial for our Cologuard test in April 2013 and was slightly offset by an increase in personnel expenses due to increased headcount.

Research and development expenses for the three months ended September 30, 2013 consisted of the following:

	Three Months Ended September 30,				
	2013		2012		Change
Personnel expenses	\$	2.2	\$	1.8	\$ 0.4
Other research and development		1.4		0.5	0.9
Clinical trial expenses		1.0		5.1	(4.1)
Lab expenses		0.9		1.3	(0.4)
Stock-based compensation		0.7		0.5	0.2
Research collaborations		0.4		0.3	0.1
Professional fees		0.3		0.9	(0.6)
License and royalty fees		0.1		0.1	
Total research and development expenses	\$	7.0	\$	10.5	\$ (3.5)

Research and development expenses for the nine months ended September 30, 2013 consisted of the following:



Table of Contents

	Nine Months Ended September 30,		
	2013	2012	Change
Personnel expenses	\$ 6.9	\$ 5.3	\$ 1.6
Clinical trial expenses	4.2	13.4	(9.2)
Other research and development	3.4	1.3	2.1
Lab expenses	2.0	4.1	(2.1)
Stock-based compensation	1.8	1.6	0.2
Research collaborations	1.4	0.8	0.6
Professional fees	1.0	3.9	(2.9)
License and royalty fees	0.3	1.3	(1.0)
Total research and development expenses	\$ 21.0	\$ 31.7	\$ (10.7)

**General and administrative expenses.** General and administrative expenses increased to \$3.7 million for the three months ended September 30, 2013 compared to \$2.5 million for the three months ended September 30, 2012. General and administrative expenses increased to \$10.0 million for the nine months ended September 30, 2013 compared to \$7.1 million for the nine months ended September 30, 2012. The increase in general and administrative expenses was primarily a result of increased legal and professional fees, increased personnel costs due to increased headcount, and other general and administrative expenses to support the overall growth of the Company.

General and administrative expenses for the three months ended September 30, 2013 consisted of the following:

	Three Months Ended September 30,		
	2013	2012	Change
Other general and administrative	\$ 1.0	\$ 0.7	\$ 0.3
Stock-based compensation	1.0	0.8	0.2
Legal and professional fees	0.9	0.4	0.5
Personnel expenses	0.6	0.5	0.1
Facility costs	0.2	0.1	0.1
Total general and administrative expenses	\$ 3.7	\$ 2.5	\$ 1.2

General and administrative expenses for the nine months ended September 30, 2013 consisted of the following:

	Nine Months Ended September 30,		
	2013	2012	Change
Legal and professional fees	\$ 3.1	\$ 1.2	\$ 1.9
Other general and administrative	2.5	2.4	0.1
Personnel expenses	2.0	1.4	0.6
Stock-based compensation	2.0	1.9	0.1
Facility costs	0.4	0.2	0.2
Total general and administrative expenses	\$ 10.0	\$ 7.1	\$ 2.9



Table of Contents

**Sales and marketing expenses.** Sales and marketing expenses increased to \$1.6 million for the three months ended September 30, 2013, from \$1.0 million for the three months ended September 30, 2012. Sales and marketing expenses increased to \$6.7 million for the nine months ended September 30, 2013 from \$2.9 million for the nine months ended September 30, 2012. The increase in sales and marketing expense was a result of hiring additional marketing personnel and increasing our efforts to prepare for the commercialization of our Cologuard test. The increase in sales and marketing expenses for the nine months ended September 30, 2013 was the result of higher stock-based compensation and personnel costs related to the June 7, 2013 resignation of Laura Stoltenberg, the Company's former Chief Commercial Officer.

Sales and marketing expenses for the three months ended September 30, 2013 consisted of the following:

	Three Months Ended September 30,		
	2013	2012	Change
Professional fees	\$ 0.7	\$ 0.4	\$ 0.3
Personnel expenses	0.6	0.3	0.3
Other sales and marketing	0.2	0.1	0.1
Stock-based compensation	0.1	0.2	(0.1)
Total sales and marketing expenses	\$ 1.6	\$ 1.0	\$ 0.6

Sales and marketing expenses for the nine months ended September 30, 2013 consisted of the following:

	Nine Months Ended September 30,		
	2013	2012	Change
Personnel expenses	\$ 2.4	\$ 1.0	\$ 1.4
Professional fees	1.9	1.4	0.5
Stock-based compensation	1.7	0.4	1.3
Other sales and marketing	0.7	0.1	0.6
Total sales and marketing expenses	\$ 6.7	\$ 2.9	\$ 3.8

**Investment income.** Investment income increased to \$103.0 thousand for the three months ended September 30, 2013 compared to \$67.0 thousand for the three months ended September 30, 2012. Investment income increased to \$220.0 thousand for the nine months ended September 30, 2013 compared to \$188.0 thousand for the nine months ended September 30, 2012. This is

Table of Contents

primarily due to an increase in the average investment balance and a higher return on investment during the current year when compared to the same period in 2012.

**Interest expense.** Interest expense increased to \$16.0 thousand for the three months ended September 30, 2013 from \$11.0 thousand for the three months ended September 30, 2012. Interest expense increased to \$53.0 thousand for the nine months ended September 30, 2013 from \$21.0 thousand for the nine months ended September 30, 2012. This increase is primarily due to interest expense recognized for our capital lease during the three and nine months ended September 30, 2013 which was entered into during September 2012.

***Liquidity and Capital Resources***

We have financed our operations since inception primarily through private and public offerings of our common stock. As of September 30, 2013, we had approximately \$9.7 million in unrestricted cash and cash equivalents and approximately \$138.1 million in marketable securities.

All of our investments in marketable securities are comprised of fixed income investments and all are deemed available-for-sale. The objectives of this portfolio are to provide liquidity and safety of principal while striving to achieve the highest rate of return, consistent with these two objectives. Our 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.

Net cash used in operating activities was \$29.7 million for the nine months ended September 30, 2013 as compared to \$33.8 million for the nine months ended September 30, 2012. The principal use of cash in operating activities for the nine months ended September 30, 2013 was to fund our net loss which decreased from the nine months ended September 30, 2012 primarily due to decreased research and development efforts as our clinical trial was completed in April 2013.

Net cash used by investing activities was \$48.2 million for the nine months ended September 30, 2013 as compared to \$49.2 million for the nine months ended September 30, 2012. The decrease in cash used by investing activities for the nine months ended September 30, 2013 compared to the same period in 2012 was primarily the result of the timing of purchases and maturities of marketable securities. Excluding the impact of purchases and maturities of marketable securities, net cash used in investing activities consisted of purchases of property and equipment of \$4.4 million for the nine months ended September 30, 2013 and \$0.6 million for the same period in 2012. The increase in property and equipment purchases during the nine months ended September 30, 2013 was primarily the result of increased laboratory equipment purchases and software costs and the build out of our commercial lab operation as part of our commercialization efforts for Cologuard.

Net cash provided by financing activities was \$74.3 million for the nine months ended September 30, 2013, as compared to net cash provided by financing activities of \$59.8 million for the nine months ended September 30, 2012. The increase in cash provided by financing activities for the nine months ended September 30, 2013 was due to the receipt of \$73.3 million of cash from our June 2013 common stock offering, \$1.2 million of cash inflows from stock options exercises slightly offset by capital lease payments of \$0.2 million compared to the receipt of \$57.8 million of cash from our August 2012 common stock offering and \$2.1 million of cash inflows from stock option exercises for the same period in 2012.

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

We expect that cash and cash equivalents on hand at September 30, 2013 will be sufficient to fund our 2013 priorities and our current operations for at least the next twelve months, based on current operating plans. However, since we have no current sources of material ongoing revenue, we may need to raise additional capital to fund our strategic plan, the primary goal of which is obtaining FDA approval and successfully commercializing our Cologuard test. We have incurred significant expenditures in the process of completing the clinical trial for our Cologuard test which was completed in April 2013. We do not expect additional significant clinical costs related to obtaining approval for our Cologuard test. In addition, we are in the process of developing our strategy for the ultimate commercialization of our Cologuard test which will also take significant time and require significant expenditures. The timing of those expenditures is uncertain and depends in part upon the timeline for obtaining FDA approval.

We expect that it will cost \$3.2 million to complete the construction of the new lab facility. We have committed to pay \$1.4 million of this amount and the landlord for the facility has committed to pay the remaining \$1.8 million as part of the lease incentive obligation outlined in the lease.

Table of Contents**Contractual Obligations**

During the second quarter of 2013, we entered into a five year lease for a 29,000 square foot facility in Madison, Wisconsin to house our commercial lab operations. This lease contains periodic rent escalation adjustments and includes provisions for tenant improvements. We have two options to extend the term of the lease for five years each. Future minimum payments under the operating lease are as follows. Amounts included in the table are in thousands.

Year Ending December 31,		
2013	\$	112
2014		676
2015		680
2016		684
2017		689
2018		578
Total lease obligations	\$	3,419

During the third quarter of 2013, we began to make leasehold improvements to this facility. As part of the lease agreement, the landlord has agreed to pay for a portion of leasehold improvements constructed. We expect that it will cost \$3.2 million to complete the construction of the new lab facility. We have committed to pay \$1.4 million of this amount and the landlord for the facility has committed to pay the remaining \$1.8 million as part of the lease incentive obligation outlined in the lease.

**Off-Balance Sheet Arrangements**

As of September 30, 2013, 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, which, as of September 30, 2013 were 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.

Table of Contents

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 4. Controls and Procedures**

As of the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and our Principal Financial Officer, of the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934, as amended). Based upon that evaluation, our Chief Executive Officer and our Principal Financial Officer concluded that, as of September 30, 2013, our disclosure controls and procedures were effective. Disclosure controls and procedures enable 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 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.

**Part II - Other Information**

**Item 1. Legal Proceedings**

Not applicable.

**Item 1A. Risk Factors**

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 most recent Annual Report on Form 10-K. There have been no material changes to the risk factors described in that report.

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

Not applicable.

**Item 3. Defaults Upon Senior Securities**

Not applicable.

**Item 4. Mine Safety Disclosures**

Not applicable.

**Item 5. Other Information**

Not applicable.

**Item 6. Exhibits**

The exhibits required to be filed as a part of this report are listed in the Exhibit Index.

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: November 1, 2013

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

President and Chief Executive Officer (Principal Executive Officer)

Date: November 1, 2013

By: /s/ William J. Megan  
William J. Megan

Principal Financial Officer

Table of Contents

**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Description</b>
10.1	Employment Letter Agreement by and between William J. Megan and Exact Sciences Corporation, dated as of August 7, 2013.
10.2	Consulting Agreement dated August 27, 2013 between the Registrant and James P. Connelly.
10.3	First Amendment to the Exact Sciences Corporation 2010 Omnibus Long-Term Incentive Plan (previously filed as Appendix A to the Proxy Statement for the Company's 2013 Annual Meeting of Stockholders filed on June 26, 2013), which is incorporated herein by reference)
10.4	Exact Sciences Corporation Non-employee Director Compensation Policy dated July 25, 2013
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.
101	Interactive Data Files