

EXACT SCIENCES CORP  
Form 10-Q  
November 04, 2011  
[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, 2011**

**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)

**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

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 November 4, 2011, the registrant had 52,929,772 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 Balance Sheets (Unaudited) as of September 30, 2011 and December 31, 2010</u>	3
<u>Condensed Statements of Operations (Unaudited) for the Three and Nine Months Ended September 30, 2011 and 2010</u>	4
<u>Condensed Statements of Cash Flows (Unaudited) for the Nine Months Ended September, 2011 and 2010</u>	5
<u>Notes to Condensed Financial Statements (Unaudited)</u>	6
<u>Item 2.</u>	
<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	17
<u>Item 3.</u>	
<u>Quantitative and Qualitative Disclosures About Market Risk</u>	22
<u>Item 4.</u>	
<u>Controls and Procedures</u>	23
<b><u>Part II - Other Information</u></b>	
<u>Item 1.</u>	
<u>Legal Proceedings</u>	23
<u>Item 1A.</u>	
<u>Risk Factors</u>	23
<u>Item 2.</u>	
<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	23
<u>Item 3.</u>	
<u>Defaults Upon Senior Securities</u>	24
<u>Item 4.</u>	
<u>(Removed and Reserved)</u>	24
<u>Item 5</u>	
<u>Other Information</u>	24
<u>Item 6.</u>	
<u>Exhibits</u>	25
<u>Signatures</u>	26
<u>Exhibit Index</u>	27

Table of Contents

## Part I Financial Information

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

	September 30, 2011	December 31, 2010
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 4,995	\$ 78,752
Marketable securities	70,436	16,663
Prepaid expenses and other current assets	867	246
Total current assets	76,298	95,661
Property and Equipment, at cost:		
Laboratory equipment	2,189	943
Office and computer equipment	528	188
Leasehold improvements	99	89
Furniture and fixtures	23	20
	2,839	1,240
Less Accumulated depreciation	(648)	(386)
	2,191	854
	\$ 78,489	\$ 96,515
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current Liabilities:		
Accounts payable	\$ 977	\$ 1,028
Accrued expenses	2,266	1,987
Deferred license fees, current portion	4,143	4,143
Total current liabilities	7,386	7,158
Long-term debt	1,000	1,000
Long-term accrued interest	36	21
Deferred license fees, less current portion	5,475	8,582
Commitments and contingencies		
Stockholders Equity:		
Preferred stock, \$0.01 par value		
Authorized 5,000,000 shares		
Issued and outstanding no shares at September 30, 2011 and December 31, 2010		
Common stock, \$0.01 par value		
Authorized 100,000,000 shares		
Issued and outstanding 52,910,773 and 52,163,629 shares at September 30, 2011 and December 31, 2010	529	522
Additional paid-in capital	276,033	272,380
Other comprehensive income (loss)	(50)	1
Accumulated deficit	(211,920)	(193,149)
Total stockholders equity	64,592	79,754

\$ 78,489 \$ 96,515

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Revenue:				
Product royalty fees	\$ 4	\$ 5	\$ 14	\$ 24
License fees	1,035	1,351	3,107	3,945
	1,039	1,356	3,121	3,969
Cost of revenue:				
Product royalty fees	6	6	18	18
Gross profit	1,033	1,350	3,103	3,951
Operating expenses:				
Research and development	6,110	2,635	14,296	6,553
General and administrative	1,951	1,796	5,931	4,647
Sales and marketing	815	315	1,763	754
	8,876	4,746	21,990	11,954
Loss from operations	(7,843)	(3,396)	(18,887)	(8,003)
Interest income	75	19	131	35
Interest expense	(5)	(5)	(15)	(15)
Net loss	\$ (7,773)	\$ (3,382)	\$ (18,771)	\$ (7,983)
Net loss per share basic and diluted	\$ (0.15)	\$ (0.08)	\$ (0.36)	\$ (0.21)
Weighted average common shares outstanding basic and diluted	52,443	40,155	52,129	38,293

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

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

	<b>Nine Months Ended September 30,</b>	
	<b>2011</b>	<b>2010</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (18,771)	\$ (7,983)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>		
Depreciation of property and equipment	262	167
Stock-based compensation	2,855	1,675
Amortization of deferred license fees	(3,107)	(3,944)
Warrant licensing expense	80	80
<b>Changes in assets and liabilities:</b>		
Prepaid expenses and other current assets	(621)	145
Accounts payable	(51)	224
Accrued expenses	448	370
Accrued interest	15	15
Net cash used in operating activities	(18,890)	(9,251)
<b>Cash flows from investing activities:</b>		
Purchases of marketable securities	(71,202)	(18,740)
Maturities of marketable securities	17,378	7,098
Purchases of property and equipment	(1,599)	(502)
Net cash used in investing activities	(55,423)	(12,144)
<b>Cash flows from financing activities:</b>		
Proceeds from Genzyme Collaboration, License and Purchase Agreement		1,896
Proceeds from sale of common stock, net of issuance costs		17,597
Proceeds from exercise of common stock options and stock purchase plan	556	293
Decrease in restricted cash		500
Net cash provided by financing activities	556	20,286
Net decrease in cash and cash equivalents	(73,757)	(1,109)
Cash and cash equivalents, beginning of period	78,752	21,924
Cash and cash equivalents, end of period	\$ 4,995	\$ 20,815
<b>Supplemental disclosure of non-cash investing and financing activities:</b>		
Unrealized loss on available-for-sale investments	\$ (51)	\$ (20)
Issuance of 27,872 and 15,460 shares of common stock to fund the Company's 401(k) matching contribution for 2010 and 2009, respectively	\$ 169	\$ 65

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

Table of Contents

**EXACT SCIENCES CORPORATION**

**Notes to Condensed Financial Statements**

**(Unaudited)**

**(1) ORGANIZATION AND BASIS OF PRESENTATION**

**Organization**

Exact Sciences Corporation ( Exact, we, us or the Company ) was incorporated in February 1995. Exact is a molecular diagnostics company 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 financial statements of the Company are unaudited and have been prepared on a basis substantially consistent with the Company's audited financial statements and notes as of and for the year ended December 31, 2010 included in the Company's Annual Report on Form 10-K. These condensed 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 our Annual Report on Form 10-K for the year ended December 31, 2010 (the 2010 Form 10-K ).

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

**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 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.

Table of Contents**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 income. The amortized cost of debt securities in this category is adjusted for amortization of premiums and accretion of discounts to maturity computed under the straight-line 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 interest income.

At September 30, 2011 the Company's investments were comprised of fixed income investments and all were deemed available-for-sale. At December 31, 2010, the Company's investments were comprised of fixed income investments and mutual funds 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. Realized losses for the nine months ended September 30, 2011 were \$477. Realized losses for the nine months ended September 30, 2010 were \$3,792. There were no realized gains for the nine months ended September 30, 2011 or 2010. Unrealized gains or losses on investments are recorded in other comprehensive income.

Available-for-sale securities at September 30, 2011 consist of the following:

(In thousands)	September 30, 2011				
	Amortized Cost	Gains in Accumulated Other Comprehensive Income	Losses in Accumulated Other Comprehensive Income		Estimated Fair Value
U.S. government agency securities	\$ 29,050	\$	\$ (17)	\$	\$ 29,033
Corporate bonds	27,674		(34)		27,640
Certificates of deposit	12,363	1			12,364
Commercial paper	1,399				1,399
Total available-for-sale securities	\$ 70,486	\$ 1	\$ (51)	\$	\$ 70,436

Available-for-sale securities at December 31, 2010 consist of the following:

(In thousands)	December 31, 2010				
	Amortized Cost	Gains in Accumulated Other Comprehensive Income	Losses in Accumulated Other Comprehensive Income		Estimated Fair Value
Certificates of deposit	\$ 6,662	\$ 1	\$	\$	\$ 6,663

Edgar Filing: EXACT SCIENCES CORP - Form 10-Q

Mutual funds		10,000				10,000
Total available-for-sale securities	\$	16,662	\$	1	\$	16,663

**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 is the same

Table of Contents

because all outstanding common stock equivalents have been excluded, as they are anti-dilutive as a result of the Company's losses.

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,	
	2011	2010
Shares issuable upon exercise of stock options	6,678	6,241
Shares issuable upon exercise of outstanding warrants (1)	325	825
Shares of restricted stock awards outstanding	504	157
	7,507	7,223

---

(1) At September 30, 2011, represents warrants to purchase 250,000 shares of common stock issued under a licensing agreement and warrants to purchase 75,000 shares of common stock issued under a consulting agreement. At September 30, 2010, represents warrants to purchase 750,000 shares of common stock issued under a licensing 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. 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 amortized 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 ended in December 2010.

As more fully described in the 2010 Form 10-K, 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. 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 \$962,000, which included accrued interest due, from Genzyme during the first quarter of 2010. The Company received the second holdback amount of \$934,250, which

Table of Contents

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 paid \$2.00 per share for the 3,000,000 shares of common stock purchased from the Company on January 27, 2009, representing a premium of \$0.51 per share above the closing price of the Company's common stock on that date of \$1.49 per share. 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.

The Company recognized approximately \$1.0 million and \$1.4 million in license fee revenue in connection with the amortization of the up-front payments from LabCorp and Genzyme during the three months ended September 30, 2011 and September 30, 2010, respectively. The Company recognized approximately \$3.1 million and \$3.9 million in license fee revenue in connection with the amortization of up-front payments from LabCorp and Genzyme during the nine months ended September 30, 2011 and September 30, 2010, respectively.

**Comprehensive Loss**

Comprehensive loss consists of net loss and the change in unrealized gains and losses on marketable securities. Comprehensive loss for the three and nine months ended September 30, 2011 and 2010 was as follows:

(In thousands)	Three Months September 30,		Nine Months September 30,	
	2011	2010	2011	2010
Net loss	\$ (7,773)	\$ (3,382)	\$ (18,771)	\$ (7,983)
Unrealized loss on marketable securities	(38)	(18)	(51)	(20)
Comprehensive loss	\$ (7,811)	\$ (3,400)	\$ (18,822)	\$ (8,003)

**(3) MAYO LICENSING AGREEMENT****Overview**

On June 11, 2009, the Company entered into a license agreement (the "License Agreement") with MAYO Foundation for Medical Education and Research ("MAYO"). Under the License Agreement, MAYO granted the Company an exclusive, worldwide license within the field (the "Field") of stool or blood based cancer diagnostics and screening (excluding a specified proteomic target) 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 licenses to market. Pursuant to the License Agreement, the Company granted MAYO two common stock purchase warrants with an exercise price of \$1.90 per share covering 1,000,000 and 250,000 shares of common stock, respectively. The Company is also required to make payments to MAYO for up-front fees, fees once certain milestones are

Edgar Filing: EXACT SCIENCES CORP - Form 10-Q

reached by the Company, and other payments as outlined in the agreement. In addition to the license to intellectual property owned by MAYO, the Company will receive product development and research and development efforts from MAYO personnel. The Company determined that the payments made for intellectual property should not be capitalized as the future economic benefit derived from the transactions is

Table of Contents

uncertain. The Company is also liable to make royalty payments to MAYO on potential future net sales of any products developed from the licensed technology.

**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. The total value of the warrants was calculated to be \$2.1 million and a non-cash charge of \$1.7 million was recognized as research and development expense in the second quarter of 2009 and the remaining \$0.4 million non-cash charge is being recognized straight-line over the four year vesting 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.

Following this exercise, the warrant covered 800,000 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. Following this exercise, the warrant covered 500,000 shares.

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.

Following this exercise, the warrant covered 250,000 shares. In September 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 was fully exercised.

**Royalty Payments**

The Company will make royalty payments to MAYO based on a percentage of net sales of products developed from the licensed technology starting in the third year of the agreement. Minimum royalty payments will be \$10,000 in 2012 and \$25,000 per year thereafter 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. It is uncertain as to when the FDA will approve the Company's cancer screening test. Therefore, the \$500,000 milestone payment has not been recorded as a liability. The Company periodically evaluates the status of the FDA trial.

In addition, the Company is making payments to MAYO for research and development efforts. During the nine months ended September 2011, the Company made payments of \$1.0 million and at September 30, 2011 the Company recorded an estimated liability in the amount of \$0.3 million for research and development efforts. During the nine months ended September 2010, the Company made payments of \$0.9 million and at September 30, 2010 the Company recorded an estimated liability in the amount of \$0.5 million for research and development efforts. During the three months ended September 30, 2011 and September 30, 2010 the Company made payments of \$0.3 million and \$0.2 million, respectively.



Table of Contents

**(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 ).

**Stock-Based Compensation Expense**

The Company recorded \$1.2 million and \$2.7 million, respectively, in stock-based compensation expense during the three and nine months ended September 30, 2011 in connection with the amortization of restricted common stock awards, stock purchase rights granted under the Company's employee stock purchase plan and stock options granted to employees, non-employee directors and non-employee consultants. The Company recorded \$0.6 million and \$1.6 million, respectively, in stock-based compensation expense during the three and nine months ended September 30, 2010 in connection with the amortization of restricted common stock awards, stock purchase rights granted under the Company's employee stock purchase plan and stock options granted to employees, non-employee directors and non-employee consultants.

**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. The fair value of each restricted stock award is determined on the date of grant using the closing stock price on that day. The fair value of restricted stock awards is recognized to expense using the straight-line method over the vesting period.

**Expected Term** - The Company uses the simplified calculation of expected term 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 expected term.

*Forfeitures* - The Company records stock-based compensation expense only for those awards that are expected to vest. Awards granted in the nine months ended September 30, 2011 are all expected to vest and no forfeiture rate was utilized.

Table of Contents

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
<b>Option Plan Shares</b>				
Risk-free interest rates	1.12% - 1.52%	1.6%-1.70%	1.12% - 2.3%	1.60%-2.69%
Expected term (in years)	6	6	6	6
Expected volatility	91% - 92%	92%	91% - 92%	91% - 92%
Dividend yield	0%	0%	0%	0%
Weighted average fair value per share of options granted during the period	\$ 5.92	\$ 3.02	\$ 4.76	\$ 2.99
<b>ESPP Shares</b>				
Risk-free interest rates	(1)	(1)	0.22% - 0.61%	0.17%-0.38%
Expected term (in years)	(1)	(1)	0.5 - 2	0.5-1
Expected volatility	(1)	(1)	48% - 63%	53%-127%
Dividend yield	(1)	(1)	0%	0%
Weighted average fair value per share of options granted during the period	(1)	(1)	\$ 2.88	\$ 1.07

(1) The Company did not issue stock purchase rights under its 2000 Employee Stock Purchase Plan or its 2010 Employee Stock Purchase Plan during the period indicated.

**Stock Option and Restricted Stock Activity**

A summary of stock option activity under the Stock Plans during the nine months ended September 30, 2011 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, 2011	6,217,199	\$ 1.93	7.9	
Granted	797,424	\$ 6.22		
Exercised	(265,443)	\$ 2.09		
Forfeited	(71,252)	\$ 11.57		
Outstanding, September 30, 2011	6,677,928	\$ 2.34	7.5	\$ 29,619
Exercisable, September 30, 2011	3,589,164	\$ 1.88	7.0	\$ 17,713
Vested and expected to vest, September 30, 2011	6,677,928	\$ 2.34	7.5	\$ 29,619

Table of Contents

(1)The aggregate intrinsic value of options outstanding, exercisable and vested and expected to vest is calculated as the difference between the exercise price of the underlying options and the market price of the Company's common stock for options that had exercise prices that were lower than the \$6.63 market price of the Company's common stock at September 30, 2011.

As of September 30, 2011, there was \$8.5 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 2.65 years.

A summary of restricted stock activity under the Stock Plans during the nine months ended September 30, 2011 is as follows:

	<b>Restricted Shares</b>		<b>Weighted Average Grant Date Fair Value</b>
Outstanding, January 1, 2011	263,630	\$	6.20
Granted	335,716	\$	6.06
Released	(92,508)	\$	5.15
Forfeited	(2,500)	\$	5.61
Outstanding, September 30, 2011	504,338	\$	6.31

During the first quarter of 2011, the Company granted a total of 213,300 restricted stock units to certain executives that will vest based upon the satisfaction of certain service and performance conditions. The performance condition is based on the Company meeting certain performance targets in 2011. The Company performed an evaluation of internal and external factors, and determined that it is probable that the performance condition will be met and these shares will vest in full. Therefore, the Company is recording expense for the fair value of these awards ratably over the vesting period.

**(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. This guidance was adopted in 2009 for non-financial assets and liabilities. Under the standard, fair value measurements are separately disclosed by level within the fair value hierarchy. The fair value hierarchy established 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:



Table of Contents

- 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.

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 following table presents the Company's fair value measurements as of September 30, 2011 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.

Description	Fair Value at September 30, 2011	Fair Value Measurement at September 30, 2011 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				
U.S. government agency securities	\$ 29,033	\$	\$ 29,033	\$
Certificates of deposit	12,364		12,364	
Corporate bonds	27,640		27,640	
Commercial paper	1,399		1,399	
Total	\$ 70,436	\$	\$ 70,436	\$

Table of Contents

The following table presents the Company's fair value measurements as of December 31, 2010 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.

Description	Fair Value at December 31, 2010	Fair Value Measurement at December 31, 2010 Using:		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>Available-for-Sale</b>				
Marketable securities				
Certificates of deposit	6,663		6,663	
Mutual Funds	10,000	10,000		
<b>Total</b>	<b>\$ 16,663</b>	<b>\$ 10,000</b>	<b>\$ 6,663</b>	<b>\$</b>

**(6) INCOME TAXES**

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, 2011 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 our 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, 2011 the Company had no unrecognized tax benefits, nor are there any tax positions where it is reasonably possible that the total amounts of unrecognized tax benefits will significantly increase or decrease within the 12 months following September 30, 2011.

**(7) RECENT ACCOUNTING PRONOUNCEMENTS***Presentation of Comprehensive Income*

In June 2011, the FASB issued an accounting standard update which requires the presentation of components of other comprehensive income with the components of net income in either (1) a continuous statement of comprehensive income that contains two sections, net income and other comprehensive income, or (2) two separate but consecutive statements. This accounting standard update eliminates the option to present components of other comprehensive income



Table of Contents

as part of the statement of stockholders' equity, and is effective for interim and annual periods beginning after December 15, 2011, and shall be applied retrospectively. Other than a change in presentation, the implementation of this accounting pronouncement is not expected to have a material impact on our financial statements.

***Amendments to Fair Value Measurements***

In May 2011, the FASB issued an accounting standard update that amends the accounting standard on fair value measurements. The accounting standard update provides for a consistent definition and measurement of fair value, as well as similar disclosure requirements between GAAP and International Financial Reporting Standards (IFRS). The accounting standard update changes fair value measurement principles, clarifies the application of existing fair value measurement, and expands the fair value disclosure requirements, particularly for Level 3 fair value measurements. The amendments in this accounting standard update are to be applied prospectively and are effective for interim and annual periods beginning after December 15, 2011. We do not expect the adoption of this accounting standard update will have a material effect on our financial statements, but it may require certain additional disclosures.

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 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, 2010, which has been filed with the SEC (the 2010 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, anticipated results of our pivotal clinical trial, 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 our Annual Report on Form 10-K for the year ended December 31, 2010 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**

Exact Sciences Corporation is a molecular diagnostics company focused on the early detection and prevention of colorectal cancer. We have exclusive intellectual property protecting our non-invasive, molecular screening technology for the detection of colorectal cancer. 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 Cologuard® stool-based DNA (sDNA) colorectal pre-cancer and cancer screening test;
- advance our Cologuard test through U.S. Food and Drug Administration (FDA) clinical trials; and

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

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

Our product includes DNA markers, which in published studies have been shown to be associated with colorectal cancer. In addition to DNA markers, our test will also detect blood in stool, utilizing an antibody-based fecal immunochemical test (FIT).

Our current focus is on seeking U.S. Food and Drug Administration clearance or approval for our Cologuard test. We also are in the process of developing our strategy for the ultimate commercialization of our Cologuard test. We believe obtaining FDA clearance or approval is critical to building broad demand and successful commercialization for our sDNA colorectal cancer screening technologies. As part of our product development efforts, product performance, throughput and cost are among the elements that will need to be addressed in the design and development of a commercial product based on our technology.

Table of Contents

Our Cologuard test is designed to detect pre-cancerous lesions or polyps, and each of the four stages of colorectal cancer. Pre-cancerous polyps are present in approximately 6 percent of the population over 50 years of age in the United States.

We are designing our test with a goal of detecting both pre-cancers and cancers. The target sensitivity rate for cancer is equal to or greater than 85 percent at a specificity of 90 percent. On October 28, 2010 we announced the results of a validation study involving a total of 1,178 stool samples. In this study, the current version of our Cologuard test was able to detect cancers at or above this target sensitivity rate and we were also able to demonstrate strong pre-cancer detection.

It is widely accepted that colorectal cancer is among the most preventable, yet least prevented cancers. Colorectal cancer typically takes up to 10-15 years to progress from a pre-cancerous lesion to metastatic cancer and death. However, it is the second-leading cause of cancer death in the United States, killing almost 50,000 people each year.

There is a significant unmet clinical need related to the diagnosis of colorectal cancer. Approximately 40 percent of those who should be screened for colorectal cancer are not screened according to current guidelines.

Poor compliance has meant that nearly two-thirds of colon 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.

Our Cologuard test can detect pre-cancers and cancers early, and is expected to be a powerful, preventive tool. By detecting pre-cancers and cancers early with our test, affected patients can be referred to colonoscopy, during which the polyp or lesion can be removed. The sDNA screening model has the potential to significantly reduce colorectal cancer deaths. The earlier the pre-cancer or cancer can be detected, the greater the reduction in mortality.

The benefits of sDNA-based screening are clear. It detects both pre-cancers and cancers. The target sensitivity for cancer is equal to or greater than 85 percent at a specificity of 90 percent. sDNA-based screening is non-invasive and requires no bowel preparation or dietary restriction like other methods. The sample for sDNA-based screening can be collected easily at home and mailed to the appropriate laboratory, where the testing would be conducted. sDNA-based screening is also affordable, particularly relative to colonoscopy.

The competitive landscape is favorable to sDNA-based screening. All of the colorectal cancer detection methods in use today are constrained by some combination of poor sensitivity, poor compliance and cost. Colonoscopy is uncomfortable and expensive. A recent study shows that seven out of ten people age 50 and older who have been told they should get a colonoscopy still have not had the test primarily due to fears and aversion to completing the bowel preparation. Current fecal blood testing suffers from poor sensitivity, including 66 percent detection rates for cancer and 27 percent detection rates for pre-cancers, and poor compliance. Blood-based DNA testing is also disadvantaged by its sensitivity. Data from a clinical trial of one blood-based test was released in early 2010. It demonstrated only 52-67 percent sensitivity across all stages of cancer, with little sensitivity for pre-cancer.

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

The competitive advantages of sDNA-based 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 \$1.2 billion, and the total available U.S. market to be more than \$5 billion.

Our intellectual property portfolio positions us to be the leading player to develop and market tests for the detection of colorectal cancer from stool samples. Our portfolio of issued and pending patents broadly protects our position from competitors and yields freedom to operate in this market. We have intellectual property pertaining to: sample type, sample preparation, sample preservation, biomarkers and related methods and formulations. In 2009, we expanded our intellectual property estate through our collaboration with the Mayo Clinic and licensed Invader detection technology from Hologic, which we plan to incorporate into our Cologuard test. We have an extensive license to markers, digital PCR and other technologies applicable to the detection of colon cancer from Johns Hopkins University, and have additional licensed intellectual property from MDx Health (formerly Oncomethylome) and Case Western Reserve University.

Table of Contents

We have generated limited operating revenues since inception and, as of September 30, 2011, we had an accumulated deficit of approximately \$211.9 million. We expect to continue to incur losses for the next several years, and it is possible we may never achieve profitability.

**2011 Priorities**

On June 30, 2011 we began enrolling patients in the pivotal FDA clinical trial for our Cologuard test. We are planning to have approximately 60 sites in the United States and Canada participate in the study. Those sites are expected to enroll more than 10,000 patients between the ages of 50 and 84 who are at average risk for colorectal cancer. If for any reason this trial is not successful or is substantially delayed or for any other reason we are unable to successfully commercialize our Cologuard test, our business and prospects would likely be materially adversely impacted.

As part of the goal of expediting receipt of a favorable coverage decision, we are working with the Center for Medicare and Medicaid (CMS) to coordinate the conduct of our clinical trial with the CMS coverage review process for our Cologuard test.

We also plan to focus on developing the market for our Cologuard test during 2011. During the first quarter of 2011 we hired John Krayacich as Senior Vice President, Sales and Marketing. We expect our market development efforts to include conducting additional product validation studies, publishing scientific papers regarding our sDNA colorectal cancer screening technology and expanding our outreach to physicians, third-party payors and advocates. We plan to concentrate our commercialization efforts initially on key opinion leader physicians who are strongly focused on the diagnosis and treatment of colorectal cancer.

**Financial Overview**

**Revenue.** Our revenue is comprised of the amortization of up-front license fees for the licensing of certain patent rights to LabCorp and Genzyme and product royalty fees on tests sold by LabCorp utilizing our technology. We expect that product royalty fees for 2011 will be consistent with amounts recorded in 2010. We expect that license fee revenue resulting from the amortization of the up-front license payments in 2011 will be less than amounts recorded in 2010 since we ceased amortizing revenues under our license agreement with LabCorp in December 2010.

**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**

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

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. 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, certain third party royalty obligations and stock-based compensation. 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.

While our significant accounting policies are more fully described in Note 2 of our condensed financial statements included in the 2010 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.

Table of Contents

**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. On June 27, 2007, we entered into an amendment to our exclusive license agreement with LabCorp which, among other modifications to the terms of the license, extended the exclusive license period of the license with LabCorp from August 2008 through December 2010. Accordingly, we amortized the remaining deferred revenue balance at the time of the amendment of \$4.7 million on a straight-line basis over the remaining exclusive license period, which ended in December 2010.

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 paid \$2.00 per share for the 3,000,000 shares of our common stock purchased on January 27, 2009, 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 and \$1.4 million in license fee revenue in connection with the amortization of the up-front payments and holdback amounts from Genzyme and LabCorp during the three months ended September 30, 2011 and 2010, respectively. In total, we recognized approximately \$3.1 million and \$3.9 million in license fee revenue in connection with the amortization of the up-front payments and holdback amounts from Genzyme and LabCorp during the nine months ended September 30, 2011 and September 30, 2010, respectively.

**Stock-Based Compensation.** In accordance with GAAP, all stock-based payments, including grants of employee stock options, restricted stock, 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 employee stock options, restricted stock and ESPP shares:

- **Valuation and Recognition** The fair value of each restricted stock award 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. The estimated fair value of employee stock options and the fair value of restricted stock awards are recognized to expense using the straight-line method over the vesting period.



- **Expected Term** - The Company uses the simplified calculation of expected term as the Company does not currently have sufficient historical exercise data on which to base an estimate of expected term. Using this method, the expected term is determined using the average of the vesting period and the contractual life of the stock options granted.
- **Expected Volatility** - Expected volatility is based on the Company's historical stock volatility data over the expected term of the awards.
- **Risk-Free Interest Rate** - The Company bases the risk-free interest rate used in the Black-Scholes valuation method on the implied yield currently available on U.S. Treasury zero-coupon issues with an equivalent remaining term.

Table of Contents

- **Forfeitures** - The Company records stock-based compensation expense only for those awards that are expected to vest. Awards granted in the nine months ended September 30, 2011 are all expected to vest and no forfeiture rate was utilized.

**Results of Operations**

**Revenue.** Total revenue decreased to \$1.0 million for the three months ended September 30, 2011 from \$1.4 million for the same period in 2010, and decreased to \$3.1 million for the nine months ended September 30, 2011 from \$4.0 million for the same period in 2010. Total revenue is primarily composed of the amortization of up-front technology license fee payments associated with our amended license agreement with LabCorp and our collaboration, license and purchase agreement with Genzyme. The reduction in revenues for the three and nine months ended September 30, 2011 is primarily due to the expiration of the license period under the LabCorp license agreement in December 2010 and our ceasing amortization of revenues under the agreement at that time. 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. Revenues also include royalties on LabCorp's sales of ColoSure as well as charges for our third-party royalty reimbursement obligation to LabCorp which are recorded as reductions to revenue under financial accounting guidance.

**Research and development expenses.** Research and development expenses increased to \$6.1 million for the three months ended September 30, 2011 from \$2.6 million for the three months ended September 30, 2010, and increased to \$14.3 million for the nine months ended September 30, 2011 from \$6.6 million for the same period in 2010. The increase for the three months ended September 30, 2011 was primarily due to an increase of \$1.6 million in professional fee expenses primarily related to our clinical trial, \$0.8 million in clinical trial related expenses, \$0.5 million in compensation expenses, \$0.3 million of lab expenses, \$0.2 million in stock-based compensation expenses, and \$0.2 million in other research and development expenses, compared to the same period in 2010 offset by a decrease of \$0.1 million in license and royalty fees. The increase for the nine months ended September 30 2011 was primarily due to an increase of \$3.5 million in professional fee expenses primarily related to our clinical trial, \$1.6 million in compensation expenses, \$0.9 million in clinical trial related expenses, \$0.7 million of lab expenses, \$0.5 million in stock-based compensation expenses, \$0.4 million in license and royalty fees, \$0.3 million in other research and development expenses, compared to the same period in 2010 offset by a decrease of \$0.2 million in research collaboration expense. The increase in these categories was the result of increased research and development activities in support of our efforts to develop and seek FDA approval for our Cologuard test, which included hiring additional research and development personnel and administering our clinical trial. As a result of these efforts, we expect research and development costs in 2011 to continue to be higher than 2010 levels.

**General and administrative expenses.** General and administrative expenses increased to \$2.0 million for the three months ended September 30, 2011, compared to \$1.8 million for the same period in 2010, and increased to \$5.9 million for the nine months ended September 30, 2011 from \$4.6 million for the same period in 2010. The increase for the three months ended September 30, 2011 was primarily due to an increase of \$0.2 million in stock-based compensation expenses, \$0.1 million in compensation expenses compared to the same period in 2010, offset by a \$0.1 million decrease and legal and professional fees. The increase for the nine months ended September 30, 2011 was primarily due to an increase of \$0.4 million in legal and professional fees, \$0.4 million in stock-based compensation expenses, \$0.3 million in compensation expenses, and \$0.2 million in other general and administrative expenses consisting primarily of office expenses, facility costs and information technology expenses. Overall increases in these reporting periods are due to increased personnel and facility costs compared to the same period in 2010.

**Sales and marketing expenses.** Sales and marketing expenses increased to \$0.8 million for the three months ended September 30, 2011 from \$0.3 million for the same period in 2010, and \$1.8 million for the nine months ended September 30, 2011 from \$0.8 million for the same period in 2010 as a result of increased sales and marketing efforts in support of our efforts to develop and commercialize our Cologuard test which included hiring additional personnel and increased market research activities.

Edgar Filing: EXACT SCIENCES CORP - Form 10-Q

**Interest income.** Interest income increased to \$75,000 for the three months ended September 30, 2011 from \$19,000 for the same period in 2010, and increased to \$131,000 for the nine months ended September 30, 2011 from \$35,000 for the same period in 2010. This increase is primarily due to larger cash and investment balances when compared to the same period in 2010.

Table of Contents

*Liquidity and Capital Resources*

We have financed our operations since inception primarily through private and public offerings of our common stock, cash received from LabCorp in connection with our license agreement with LabCorp, and cash received in January 2009 from Genzyme in connection with the Genzyme strategic transaction. As of September 30, 2011, we had approximately \$75.4 million in cash equivalents and 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. As of September 30, 2011 we had approximately \$70.4 million in marketable securities.

Net cash used in operating activities was \$18.9 million for the nine months ended September 30, 2011 as compared to \$9.3 million for the nine months ended September 30, 2010. The principal use of cash in operating activities for the nine months ended September 30, 2011 and 2010 was to fund our net loss which increased primarily due to increased research and development activities which included the start of our clinical trial in June 2011.

Net cash used in investing activities was \$55.4 million for the nine months ended September 30, 2011 as compared to \$12.1 million for the nine months ended September 30, 2010. The increase in cash used in investing activities for the nine months ended September 30, 2011 compared to the same period in 2010 was primarily the result of purchase and maturity activity 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 \$1.6 million for the nine months ended September 30, 2011 and \$0.5 million for the nine months ended September 30, 2010. Increased purchases of property and equipment during the nine months ended September 30, 2011 were a result of increased research and development activities. Based on our plans for further development of our sDNA technology for colorectal cancer detection, we expect that purchases of property and equipment during 2011 will be higher than amounts invested in 2010.

Net cash provided by financing activities was \$0.6 million for the nine months ended September 30, 2011, as compared to \$20.3 million for the nine months ended September 30, 2010. The decrease in cash provided by financing activities for the nine months ended September 30, 2011 was primarily related to the receipt during the nine months ended September 30, 2010 of approximately \$17.6 million in proceeds from the sale of common stock, \$1.9 million in connection with the Genzyme strategic transaction and cash inflows from stock option exercises of \$0.3 million. During the nine months ended September 30, 2011, cash inflows were not as significant and consisted of \$0.6 million from stock option exercises.

We expect that cash and cash equivalents on hand at September 30, 2011, will be sufficient to fund 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 expect that we will need to raise additional capital to fully fund our current strategic plan, the primary goal of which is developing and commercializing an FDA-approved non-invasive sDNA colorectal pre-cancer and cancer screening test. 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 our operations. Even if we successfully raise sufficient funds to complete our plan, we cannot assure you that our business will ever generate sufficient cash flow from operations to become profitable.

**Off-Balance Sheet Arrangements**

As of September 30, 2011, 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. governments 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, 2011 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

Table of Contents

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 values or cash flows of risk-sensitive financial instruments would be 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 Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Rule 13a-15e promulgated under the Securities Exchange Act of 1934, as amended. Based upon that evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that, as of September 30, 2011, 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**

In June 2009, we entered into a license agreement with MAYO Foundation for Medical Education and Research ( MAYO ) under which we acquired rights to use certain intellectual property. As part of the license agreement, we granted MAYO a common stock purchase warrant with an exercise price of \$1.90 per share covering 1,000,000 shares.

Prior to June 2011, MAYO had partially exercised the warrant so that at that time it covered a total of 500,000 shares. In June 2011, MAYO partially exercised the warrant by utilizing the cashless exercise provision contained in the warrant 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 2011, MAYO partially exercised the warrant covering the remaining 250,000 shares by utilizing the cashless exercise provision contained in the warrant for a gross amount of 250,000 shares. In lieu of paying a cash

Table of Contents

exercise price, MAYO forfeited its right with respect to 56,641 shares leaving it with a net amount of 193,359 shares. The warrant has now been fully exercised.

We believe that the offer and sale of the securities referenced were exempt from registration under the Securities Act by virtue of Section 4(2) of the Securities Act of 1933 (the Securities Act ) and/or Regulation D promulgated thereunder as transactions not involving any public offering. Use of this exemption is based on the following facts:

- Neither we nor any person acting on our behalf solicited any offer to buy or sell securities by any form of general solicitation or advertising.
- At the time of the purchase, MAYO was an accredited investor, as defined in Rule 501(a) of the Securities Act.
- MAYO has had access to information regarding DARA and is knowledgeable about us and our business affairs.

In addition, we believe the issuance of shares on exercise of the warrants via cashless exercise was exempt from registration under the Securities Act by virtue of Section 3(a)(9) thereof inasmuch as such issuances involved the issuance of shares to an existing security holder in exchange for other securities where no commission or other remuneration was paid or given for soliciting such exchange.

**Item 3. Defaults Upon Senior Securities**

Not applicable.

**Item 4. (Removed and Reserved)**

**Item 5. Other Information**

Not applicable.





Table of Contents

**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 4, 2011

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

President and Chief Executive Officer  
(Authorized Officer)

Date: November 4, 2011

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>
10	Non-Employee Director Compensation Policy
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.