

EXACT SCIENCES CORP
Form 10-Q
October 31, 2014
[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, 2014

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 ☒

Accelerated filer ☐

Non-accelerated filer ☐

Smaller reporting company ☐

(Do not check if a smaller reporting company)

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

As of October 30, 2014, the registrant had 84,250,616 shares of common stock outstanding.

Table of Contents

EXACT SCIENCES CORPORATION

INDEX

**Page
Number**

Part I - Financial Information

Item 1.	Financial Statements	
	<u>Condensed Consolidated Balance Sheets (unaudited) as of September 30, 2014 and December 31, 2013</u>	3
	<u>Condensed Consolidated Statements of Operations (unaudited) for the Three and Nine Months Ended September 30, 2014 and 2013</u>	4
	<u>Condensed Consolidated Statements of Comprehensive Loss (unaudited) for the Three and Nine Months Ended September 30, 2014 and 2013</u>	5
	<u>Condensed Consolidated Statements of Cash Flows (unaudited) for the Nine Months Ended September 30, 2014 and 2013</u>	6
	<u>Notes to Condensed Consolidated Financial Statements (unaudited)</u>	7
<u>Item 2.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	21
<u>Item 3.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	32
<u>Item 4.</u>	<u>Controls and Procedures</u>	32

Part II - Other Information

<u>Item 1.</u>	<u>Legal Proceedings</u>	33
<u>Item 1A.</u>	<u>Risk Factors</u>	33
<u>Item 2.</u>	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	33
<u>Item 3.</u>	<u>Defaults Upon Senior Securities</u>	33
<u>Item 4.</u>	<u>Mine Safety Disclosures</u>	33
<u>Item 5</u>	<u>Other Information</u>	33
<u>Item 6.</u>	<u>Exhibits</u>	33
	<u>Signatures</u>	34
	<u>Exhibit Index</u>	35

Table of Contents

Part I Financial Information

EXACT SCIENCES CORPORATION**Condensed Consolidated Balance Sheets**

(Amounts in thousands, except share data - unaudited)

	September 30, 2014	December 31, 2013
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 27,829	\$ 12,851
Marketable securities	183,315	120,408
Inventory	2,719	
Prepaid expenses and other current assets	2,377	2,199
Total current assets	216,240	135,458
Property and Equipment, at cost:		
Laboratory equipment	10,439	5,087
Assets under construction	1,048	2,592
Computer software and computer equipment	6,866	1,217
Leasehold improvements	5,108	5,043
Furniture and fixtures	268	268
	23,729	14,207
Less Accumulated depreciation	(5,302)	(3,038)
	18,427	11,169
	\$ 234,667	\$ 146,627
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 4,635	\$ 761
Accrued expenses	11,128	5,806
Capital lease obligation, current portion	449	351
Lease incentive obligation, current portion	540	540
Deferred license fees, current portion		294
Total current liabilities	16,752	7,752
Long-term debt	1,000	1,000
Long-term accrued interest	100	84
Capital lease obligation, less current portion		360
Lease incentive obligation, less current portion	1,710	2,115
Commitments and contingencies		
Stockholders' Equity:		
Preferred stock, \$0.01 par value Authorized 5,000,000 shares, Issued and outstanding no shares at September 30, 2014 and December 31, 2013		
Common stock, \$0.01 par value Authorized 100,000,000 shares, Issued and outstanding 83,164,089 and 71,071,838 shares at September 30, 2014 and December 31, 2013	832	711
Additional paid-in capital	602,642	455,239
Accumulated other comprehensive income	(6)	125

Edgar Filing: EXACT SCIENCES CORP - Form 10-Q

Accumulated deficit		(388,363)		(320,759)
Total stockholders' equity		215,105		135,316
	\$	234,667	\$	146,627

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)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
License fees	\$	\$ 1,036	\$ 294	\$ 3,108
Operating expenses:				
Research and development		9,073	23,677	20,965
General and administrative		8,994	19,810	9,962
Sales and marketing		13,217	23,839	6,676
Cost of sales		924	924	
		32,208	68,250	37,603
Loss from operations		(32,208)	(67,956)	(34,495)
Investment income		160	392	220
Interest expense		(12)	(40)	(53)
Net loss	\$	(32,060)	\$ (67,604)	\$ (34,328)
Net loss per share basic and diluted	\$	(0.39)	\$ (0.86)	\$ (0.52)
Weighted average common shares outstanding basic and diluted		82,941	78,702	66,389

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)

	Three Months Ended September 30,		Nine Months September 30,	
	2014	2013	2014	2013
Net loss	\$ (32,060)	\$ (11,160)	\$ (67,604)	\$ (34,328)
Other comprehensive loss, net of tax				
Unrealized holding gain (loss) on available-for-sale investments	(95)	101	(131)	40
Comprehensive loss	\$ (32,155)	\$ (11,059)	\$ (67,735)	\$ (34,288)

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

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

	Nine Months Ended September 30,	
	2014	2013
Cash flows from operating activities:		
Net loss	\$ (67,604)	\$ (34,328)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of property and equipment	2,264	976
Loss on disposal of property and equipment		91
Stock-based compensation	8,643	5,660
Amortization of deferred license fees	(294)	(3,108)
Amortization of premium on short-term investments	628	458
Changes in assets and liabilities:		
Prepaid expenses and other current assets	(178)	(311)
Inventory	(2,719)	
Accounts payable	3,874	(3,047)
Accrued expenses	5,778	2,752
Lease incentive obligation	(405)	871
Accrued interest	16	16
Net cash used in operating activities	(49,997)	(29,970)
Cash flows from investing activities:		
Purchases of marketable securities	(141,355)	(89,261)
Maturities of marketable securities	77,689	45,488
Purchases of property and equipment	(9,522)	(4,413)
Net cash used in investing activities	(73,188)	(48,186)
Cash flows from financing activities:		
Proceeds from sale of common stock, net of issuance costs	137,664	73,296
Proceeds from exercise of common stock options	424	1,212
Payments on capital lease obligations	(262)	(248)
Proceeds in connection with the Company's employee stock purchase plan	337	261
Net cash provided by financing activities	138,163	74,521
Net increase (decrease) in cash and cash equivalents	14,978	(3,635)
Cash and cash equivalents, beginning of period	12,851	13,345
Cash and cash equivalents, end of period	\$ 27,829	\$ 9,710
Supplemental disclosure of non-cash investing and financing activities:		
Unrealized gain on available-for-sale investments	\$ (131)	\$ 40
Issuance of 32,269 and 30,534 shares of common stock to fund the Company's 401(k) matching contribution for 2013 and 2012, respectively	\$ 456	\$ 354

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 (together with its subsidiary, Exact , we , us or the Company) 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, which include the accounts of Exact Sciences Corporation 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, 2013 included in the Company 's Annual Report on Form 10-K (the 2013 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 the 2013 Form 10-K. Management has evaluated subsequent events for disclosure or recognition in the accompanying financial statements up to the filing of this report.

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company 's wholly-owned subsidiary, Exact Sciences Laboratories, LLC. All significant intercompany transactions and balances have been eliminated in consolidation.

Use of Estimates

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

Cash and Cash Equivalents

The Company considers 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, 2014 and December 31, 2013.

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 loss. 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, 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, 2014 and December 31, 2013, 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. Realized gains were \$11.1 thousand and \$5.1 thousand, net of insignificant realized losses, for the nine months ended September 30, 2014 and 2013, respectively. Unrealized gains or losses on investments are recorded in other comprehensive loss.

We periodically review our investments in unrealized loss positions for other-than-temporary impairments. This evaluation includes, but is not limited to, significant quantitative and qualitative assessments and estimates regarding credit ratings, collateralized support, the length of time and significance of a security's loss position, our intent not to sell the security, and whether it is more likely than not that we will have to sell the security before recovery of its cost basis. For the three months ended September 30, 2014, no investments were identified with other-than-temporary declines in value.

Available-for-sale securities at September 30, 2014 consisted of the following:

(In thousands)	Amortized Cost	September 30, 2014		Estimated Fair Value
		Gains in Accumulated Other Comprehensive Income	Losses in Accumulated Other Comprehensive Income	
U.S. government agency securities	\$ 32,690	\$ 7	\$	\$ 32,697
Corporate bonds	112,075		(10)	112,065
Certificates of deposit	300			300
Asset backed securities	38,256		(3)	38,253
Total available-for-sale securities	\$ 183,321	\$ 7	\$ (13)	\$ 183,315

Table of Contents

Available-for-sale securities at December 31, 2013 consisted of the following:

(In thousands)	Amortized Cost	December 31, 2013		Estimated Fair Value
		Gains in Accumulated Other Comprehensive Income	Losses in Accumulated Other Comprehensive Income	
Corporate bonds	\$ 54,487	\$ 67	\$	\$ 54,554
U.S. government agency securities	34,291	47		34,338
Certificates of deposit	6,558	3		6,561
Commercial paper	1,499			1,499
Asset backed securities	23,448	8		23,456
Total available-for-sale securities	\$ 120,283	\$ 125	\$	\$ 120,408

Changes in Accumulated Other Comprehensive Income (Loss)

The amounts recognized in accumulated other comprehensive income (loss) (AOCI) for the three and nine months ended September 30, 2014 were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Beginning balance	\$ 89	\$ 17	\$ 125	\$ 78
Other comprehensive income (loss) before reclassifications	(99)	104	(106)	63
Amounts reclassified from accumulated other comprehensive income (loss)	4	(3)	(25)	(23)
Net current period change in accumulated other comprehensive income (loss)	(95)	101	(131)	40
Ending balance	\$ (6)	\$ 118	\$ (6)	\$ 118

Table of Contents

Amounts reclassified from accumulated other comprehensive income (loss) for the three and nine months ended September 30, 2014 were as follows (in thousands):

Details about AOCI Components	Affected Line Item in the Statement of Operations	Three Months Ended September 30,		Nine Months Ended September 30,	
		2014	2013	2014	2013
Change in value of available-for-sale investments					
Sales and maturities of available-for-sale investments	Investment income	\$ 4	\$ (3)	\$ (25)	\$ (23)
Total reclassifications		\$ 4	\$ (3)	\$ (25)	\$ (23)

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, 2014, the Company had \$1.0 million of assets under construction which consisted of \$0.5 million of capitalized costs related to software projects and \$0.5 million of costs related to leasehold improvement projects. Depreciation will begin on these assets once they are placed into service. We expect that it will cost \$1.7 million to complete the leasehold improvement projects and \$0.2 million to complete the software projects, and these projects are expected to be completed in 2014.

Software Capitalization Policy

Software development costs related to internal use software are incurred in three stages of development: the preliminary project stage, the application development stage, and the post-implementation stage. Costs incurred during the preliminary project and post-implementation stages are expensed as incurred. Costs in the application development stage that meet the criteria for capitalization are capitalized and amortized using the straight-line basis over the estimated economic useful life of the software.

Table of Contents**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.

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)	2014	September 30, 2013
Shares issuable upon exercise of stock options	6,207	6,108
Shares issuable upon exercise of outstanding warrants (1)	75	155
Shares issuable upon the release of restricted stock awards	1,577	1,264
Shares issuable upon the vesting of restricted stock awards related to a licensing agreement	24	49
	7,883	7,576

(1) At September 30, 2014, represents warrants to purchase 75,000 shares of common stock issued under a consulting agreement. 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.

Revenue Recognition

Laboratory Service Revenue. The Company's revenues will be generated primarily by the Cologuard test. Revenues are recognized when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the price is fixed or determinable, and collectability is reasonably assured. The Company assesses whether the fee is fixed or determinable and if the collectability is reasonably assured based on the nature of the fee charged for the laboratory services.

Table of Contents

delivered and whether there are existing contractual arrangements with customers, third-party commercial payors (insurance carriers and health plans) or coverage of the test by Centers for Medicare & Medicaid Services (CMS). In addition, when evaluating collectability, the Company considers factors such as collection experience for the healthcare industry, the financial standing of customers or third-party commercial payors, and whether it has sufficient collection history to reliably estimate a payor's individual payment patterns.

A significant portion of laboratory service revenues earned by the Company will be initially recognized on a cash basis because the above criteria will not have been met at the time the test results are delivered. The Company generally bills third-party payors upon generation and delivery of a test result to the ordering physician following completion of a test. As such, the Company takes assignment of benefits and risk of collection with the third-party payor. Patients may have out-of-pocket costs for amounts not covered by their insurance carrier and the Company bills the patient directly for these amounts in the form of co-pays and deductibles in accordance with their insurance carrier and health plans. Some third-party payors may not cover the Cologuard test as ordered by the physician under their reimbursement policies. Consequently, the Company pursues reimbursement on a case-by-case basis directly from the patient.

For laboratory services performed, where the collectability is not reasonably assured, the Company will continue to recognize revenues upon cash collection until it can reliably estimate the amount that would be ultimately collected for the Cologuard test. In order to begin to record revenue on an accrual basis in these scenarios, the Company expects to use at least several months of payment history, review the number of tests paid against the number of tests billed, and consider the payor's outstanding balance for unpaid tests to determine whether payments are being made for a consistently high percentage of tests billed and at appropriate amounts given the contracted or historical payment amount. Cologuard became available upon FDA approval on August 11, 2014 and no revenue recognition criteria have been met for tests performed as of September 30, 2014. The national coverage decision for Cologuard was released by CMS on October 9, 2014.

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 2013 Form 10-K, in connection with the Company's January 2009 strategic transaction with Genzyme Corporation, the Company deferred the initial \$16.65 million in cash received at closing and amortized that up-front payment on a straight-line basis into revenue over the initial five-year collaboration period which ended in January 2014. In addition, in 2010 the Company received holdback amounts of \$1.85 million, which were deferred at the time of receipt and were amortized on a straight-line basis into revenue over the then remaining term of the collaboration period.

In addition, the Company deferred \$1.53 million premium related to common stock purchased by Genzyme and amortized that amount on a straight-line basis into revenue over the initial five-year collaboration period which ended in January 2014.

The Company did not recognize revenue in connection with the amortization of the up-front payments from Genzyme during the three months ended September 30, 2014. The Company recognized approximately \$1.0 million in license fee revenue in connection with the amortization of the up-front payments from Genzyme during the three months ended September 30, 2013. The Company recognized approximately \$0.3 million and \$3.1 million in license fee revenue in connection with the amortization of up-front payments from Genzyme during each of the nine months ended September 30, 2014 and September 30, 2013, respectively.

Inventory

Edgar Filing: EXACT SCIENCES CORP - Form 10-Q

Inventory is stated at the lower of cost or market value (net realizable value). The Company determines the cost of inventory using the first-in, first out method (FIFO). The Company estimates the recoverability of inventory by reference to internal estimates of future demands and product life cycles, including expiration. The Company periodically analyzes its inventory levels to identify inventory that may expire prior to expected sale or has a cost basis in excess of its estimated realizable value, and records a charge to cost of sales for such inventory as appropriate. In addition, the Company's products are subject to strict quality control and monitoring which the Company performs throughout the manufacturing process. If certain batches or units of product no longer meet quality specifications or become obsolete due to expiration, the Company records a charge to cost of sales to write down such unmarketable inventory to its estimated realizable value.

Table of Contents

Direct and indirect manufacturing costs incurred during process validation and for other research and development activities, which are not permitted to be sold, have been expensed to research and development. Raw material inventory that was purchased in prior periods, and expensed to research and development, may still be on hand and used toward the production of Cologuard, provided it has an appropriate remaining shelf life. This inventory is expected to provide a gross margin benefit to the Company in future periods of \$0.9 million if the entirety of those balances were allocated to inventory produced for resale and not allocated to research and development activities.

The Company has invested in its manufacturing operations to support future demand for Cologuard. Because of this investment in the future, the Company is not currently operating at normal capacity. Charges related to excess capacity are included as current period charges to cost of sales, and are not capitalized into inventory. Total excess capacity charged to cost of sales during the three and nine months ended September 30, 2014 was \$0.6 million.

Inventory consists of the following (amount in thousands):

		September 30,	
	2014	2013	
Raw materials	\$ 1,052	\$	
Semi-finished and finished goods	1,667		
Total inventory	\$ 2,719	\$	

Reclassifications

Certain prior period amounts have been reclassified to conform to the current period presentation in the consolidated financial statements and accompanying notes to the consolidated financial statements.

(3) MAYO LICENSE AGREEMENT**Overview**

As more fully described in the 2013 Form 10-K, on June 11, 2009, the Company entered into a license agreement (the "License Agreement") with MAYO Foundation for Medical Education and Research ("MAYO"). 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 expenses 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.

Table of Contents

MAYO exercised the warrant to purchase 1,000,000 shares through several partial exercises. As of September 2011, the warrant covering 1,000,000 shares was fully exercised.

MAYO exercised the warrant to purchase 250,000 shares through partial exercises, the last of which occurred in June 2014. In June 2014, MAYO exercised the remaining shares of this warrant by utilizing the cashless exercise provision contained in the warrant. As a result of this exercise for a gross amount of 80,000 shares, in lieu of paying a cash exercise price, MAYO forfeited its right with respect to 10,587 shares leaving it with a net amount of 69,413 shares. Following this exercise, all of MAYO's warrants to purchase the Company's common stock were 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. In 2012, minimum royalty payments were \$10,000. For each year from 2013 through 2029 (the year the last patent expires), the minimum royalty payments are \$25,000 per year.

Other Payments

Other payments under the License Agreement include an upfront payment of \$80,000, a milestone payment of \$250,000 on the commencement of patient enrollment in a human cancer screening clinical trial, 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 a human cancer screening clinical trial in June 2011 and the milestone payment of \$250,000 was made and expensed to research and development in June 2011. The Company received FDA approval for its Cologuard test in August 2014, and the milestone payment of \$500,000 was made and expensed to research and development in August 2014.

In addition, the Company is paying MAYO for research and development efforts. During the three and nine months ended September 30, 2014, the Company made payments of \$0.0 million and \$0.7 million, respectively. At September 30, 2014 the Company recorded an estimated liability in the amount of \$1.6 million for MAYO's research and development efforts. During the three and nine months ended September 30, 2013, the Company made research and development payments to MAYO 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.

May 2012 Amendment

As more fully described in the 2013 Form 10-K, 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.

Edgar Filing: EXACT SCIENCES CORP - Form 10-Q

As part of the amendment, the Company will also be responsible for making 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 licensed products. It is uncertain as to when or if 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 and the 2000 Stock Option and Incentive Plan (collectively, as each has been amended, the Stock Plans).

Table of Contents

Stock-Based Compensation Expense

The Company recorded \$4.1 million and \$8.6 million in stock-based compensation expense during the three and nine months ended September 30, 2014 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, and warrants granted to non-employee consultants. 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.

Warrant Expense

Warrants to purchase 75,000 shares of common stock were issued in connection with a consulting agreement in 2009 to provide specific assistance to the Company in attaining FDA approval of Cologuard. The 75,000 warrants vested in the third quarter of 2014 upon successful FDA approval for Cologuard. The Company recorded \$1.3 million, the fair value of the warrant on the vesting date as stock-based compensation expense during the third quarter of 2014 in connection with the vesting of this warrant.

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 model 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

Edgar Filing: EXACT SCIENCES CORP - Form 10-Q

forfeiture rate used in the nine months ended September 30, 2014 was 4.99%. The Company's forfeiture rate used in the nine months ended September 30, 2013 was 2.76%.

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,	
	2014	2013	2014	2013
Option Plan Shares				
Risk-free interest rates	2.01%	1.73%	1.96% - 2.01%	0.94% - 1.73%
Expected term (in years)	6	6	6	6
Expected volatility	77.6%	82.9%	77.6% - 80.8%	82.9% - 84.0%
Dividend yield	0%	0%	0%	0%
Weighted average fair value per share of options granted during the period	\$ 11.37	\$ 10.34	\$ 10.05	\$ 8.12
ESPP Shares				
Risk-free interest rates	(1)	(1)	0.10% - 0.41%	0.11% - 0.20%
Expected term (in years)	(1)	(1)	0.5 - 2	0.5 - 2
Expected volatility	(1)	(1)	42.5% - 49.5%	39.1% - 45.6%
Dividend yield	(1)	(1)	0%	0%
Weighted average fair value per share of stock purchase rights granted during the period	(1)	(1)	\$ 3.76	\$ 2.80

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

Table of Contents**Stock Option and Restricted Stock Activity**

A summary of stock option activity under the Stock Plans during the nine months ended September 30, 2014 is as follows:

Options	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (1)
<i>(Aggregate intrinsic value in thousands)</i>				
Outstanding, January 1, 2014	6,062,587	\$ 2.78	6.6	
Granted	266,477	\$ 14.28		
Exercised	(115,004)	\$ 3.68		
Forfeited	(6,625)	\$ 7.99		
Outstanding, September 30, 2014	6,207,435	\$ 3.25	5.3	100,138
Exercisable, September 30, 2014	5,446,108	\$ 2.14	4.9	93,895
Vested and expected to vest September 30, 2014	6,169,445	\$ 3.20	5.3	99,826

(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 \$19.38 market price of the Company's common stock at September 30, 2014. The total intrinsic value of options exercised during the nine months ended September 30, 2014 and 2013 was \$1.4 million and \$1.6 million, respectively.

Table of Contents

As of September 30, 2014, there was \$20.5 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 2.8 years.

A summary of restricted stock activity under the Stock Plans during the nine months ended September 30, 2014 is as follows:

	Restricted Shares	Weighted Average Grant Date Fair Value
Outstanding, January 1, 2014	1,150,694	\$ 11.24
Granted	833,380	\$ 14.64
Released	(385,825)	\$ 11.38
Forfeited	(21,536)	\$ 12.31
Outstanding, September 30, 2014	1,576,713	\$ 12.99

(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

Table of Contents

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.

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, 2014 and December 31, 2013 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, 2014 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 Measurement at September 30, 2014 Using:			
	Fair Value at September 30, 2014	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	\$ 27,829	\$ 27,829	\$	\$
Available-for-Sale				
Marketable securities				
U.S. government agency securities	32,697		32,697	
Corporate bonds	112,065		112,065	
Certificates of deposit	300		300	
Asset backed securities	38,253		38,253	
Total	\$ 211,144	\$ 27,829	\$ 183,315	\$

Edgar Filing: EXACT SCIENCES CORP - Form 10-Q

Table of Contents

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

Description	Fair Value Measurement at December 31, 2013 Using:			
	Fair Value at December 31, 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	\$ 12,851	\$ 12,851	\$	\$
Available-for-Sale				
Marketable securities				
Corporate bonds	54,554		54,554	
U.S. government agency securities	34,338		34,338	
Certificates of deposit	6,561		6,561	
Commercial paper	1,499		1,499	
Asset backed securities	23,456		23,456	
Total	\$ 133,259	\$ 12,851	\$ 120,408	\$

The following table summarizes the gross unrealized losses and fair values of our investments in an unrealized loss position as of September 30, 2014, aggregated by investment category and length of time that individual securities have been in a continuous unrealized loss position:

(In thousands)	Less than 12 months		September 30, 2014 12 months or greater		Total	
	Fair Value	Gross Unrealized Loss	Fair Value	Gross Unrealized Loss	Fair Value	Gross Unrealized Loss
U.S. government agency securities	\$ 11,875	\$ (22)	\$	\$	\$ 11,875	\$ (22)
Corporate bonds	61,132	(69)			61,132	(69)
Asset backed securities	21,775	(11)			21,775	(11)
Total	\$ 94,782	\$ (102)	\$	\$	\$ 94,782	\$ (102)

The following summarizes contractual underlying maturities of the Company's available-for-sale investments in debt securities at September 30, 2014 (in thousands):

Description	Due in one year or less		Due after one year through two years	
	Cost	Fair Value	Cost	Fair Value
Marketable Securities				
U.S. government agency securities	\$ 20,794	\$ 20,822	\$ 11,897	\$ 11,875
Corporate bonds	52,153	52,202	59,921	59,864
Certificates of deposit	300	300		
Asset backed securities	30,219	30,220	8,038	8,032
Total	\$ 103,466	\$ 103,544	\$ 79,856	\$ 79,771

(6) EQUITY

Edgar Filing: EXACT SCIENCES CORP - Form 10-Q

On April 2, 2014, the Company completed an underwritten public offering of 11.5 million shares of common stock at a price of \$12.75 per share to the public. The Company received approximately \$137.7 million of net proceeds from the offering, after deducting the \$8.9 million for the underwriting discount and other stock issuance costs paid by the Company.

On June 21, 2013, the Company completed an underwritten public offering for 6.3 million shares of common stock at a price of \$12.35 per share to the public. The Company received approximately \$73.3 million of net proceeds from the offering, after deducting \$4.8 million for the underwriting discount and other stock issuance costs paid by the Company.

In February 2011, the Company 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

Table of Contents

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.

(7) RECENT ACCOUNTING PRONOUNCEMENTS

In May 2014, the Financial Accounting Standards Board issued Accounting Standards Update No. 2014-09, *Revenue from Contracts with Customers*. ASU 2014-09 is a comprehensive new revenue recognition model requiring a company to recognize revenue to depict the transfer of goods or services to a customer at an amount reflecting the consideration it expects to receive in exchange for those goods or services. ASU 2014-09 may be applied using either a full retrospective or a modified retrospective approach and is effective for fiscal years, and interim periods within those years, beginning after December 15, 2016, and early adoption is not permitted. We are currently evaluating the impact of this amendment on our financial position and results of operations.

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 (together with its subsidiary, Exact, we, us, our or the Company) 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, 2013, which has been filed with the SEC (the 2013 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, our ability to secure favorable reimbursement rates from Medicare and other third-party payors, our ability to establish a lab facility and secure the required certifications for that facility, 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 2013 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

Table of Contents

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 early detection of colorectal pre-cancer and cancer.

Our strategic roadmap to achieve this goal includes the following key components:

- 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 designed to detect pre-cancerous lesions or polyps, and each of the four stages of colorectal cancer and is expected to be a powerful, preventive tool. Cologuard 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.

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 (ACS) 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.

Physicians and others assessing the effectiveness and value of our Cologuard test, will likely consider, among other things, our Cologuard test's sensitivity and specificity in identifying colorectal cancer and pre-cancerous polyps. Sensitivity (also called the true positive rate) measures the percentage of colorectal cancer or pre-cancerous polyps that our Cologuard test correctly identifies. Specificity (also called the true negative rate) measures the percentage of people who our Cologuard test correctly identifies as not having colorectal cancer or pre-cancerous polyps.

In the first half of 2013 we completed our pivotal 10,000 patient DeeP-C study. All patients provided a sample to be tested with our Cologuard test, and received a FIT test and a colonoscopy.

Table of Contents

Top-line data from the DeeP-C study 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.

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. The FDA approved our PMA on August 11, 2014. The application included data from the DeeP-C study that was published online on March 19, 2014, in the *New England Journal of Medicine*. The peer-reviewed study, "Multi-target Stool DNA Testing for Colorectal-Cancer Screening" also appeared in the journal's April 3, 2014 print issue.

The FDA's Molecular and Clinical Genetics Panel of the Medical Devices Advisory Committee met on March 27, 2014 to review the premarket approval application (PMA) for our Cologuard test and determined by a unanimous vote of 10 to zero that the test has demonstrated safety, effectiveness and a favorable risk benefit profile. The FDA approved our PMA on August 11, 2014.

We obtained a final national coverage decision and a preliminary reimbursement rate from the Centers for Medicare & Medicaid Services (CMS) for our Cologuard test on October 9, 2014. The CMS coverage decision was a necessary element in achieving material commercial success. We worked with CMS to coordinate the CMS coverage review with the FDA pre-market approval through a parallel review process. This program provided a pathway to our CMS national coverage determination shortly after our FDA approval.

CMS also announced on October 9, 2014 its preliminary recommendation for its reimbursement rate for our Cologuard test, but final fee schedule determinations will be made by CMS after a thirty-day public comment period, and there can be no assurance when final determinations will be published or that the final fee schedule will be consistent with the preliminary determination. With over 50% of our target patient population being covered by Medicare, receipt of our positive coverage decision from CMS should help speed adoption of our test. A favorable CMS outcome is also critical to securing positive coverage decisions from major national and regional managed care organizations, insurance carriers, and self-insured employer groups.

We also believe that to achieve commercial success it will be necessary to secure favorable coverage and reimbursement from commercial payors. We believe that third-party payors' reimbursement of our Cologuard test will depend on a number of factors, including payors' determination that it is: sensitive for colorectal cancer, not experimental or investigational; approved by major guidelines organizations; reliable, safe and effective; medically necessary; appropriate for the specific patient; and cost-effective.

We continue to develop and execute our strategy for the commercialization of our Cologuard test. There are two elements to our targeting strategy for early adoption of Cologuard. First, we are focused on large healthcare systems and groups. These networks employ a high percentage of the physicians in the United States and they typically have strong screening programs. Second, we plan to focus on primary care physicians who prescribe a high volume of FOBT and FIT tests since this physician group has displayed a partiality for stool based screening methods.

We have generated limited operating revenues since inception and, as of September 30, 2014, we had an accumulated deficit of approximately \$388.4 million. We expect to continue to incur losses for the next several years, and it is possible we may never achieve profitability.

Table of Contents

2014 Priorities

Our top priorities for 2014 included obtaining FDA approval of our PMA and securing a favorable national coverage decision from CMS for our Cologuard test. The FDA approved our PMA in August of 2014 and CMS provided a national coverage decision in October of 2014. Another 2014 priority is to begin to secure favorable coverage and reimbursement from commercial payors.

In 2014 we also plan to continue implementing our commercialization plan, including building our manufacturing capacity, obtaining CLIA certification for our processing lab, integrating our IT infrastructure for ordering, processing, and billing, and deploying our sales and marketing teams. In July 2014 we successfully completed the FDA inspection of our processing lab without any findings or observations.

We also have identified a new opportunity for our sDNA colorectal cancer screening technology focused on the inflammatory bowel disease (IBD) patient population. We initiated an IBD clinical trial in the first quarter 2013 that will focus on this specific patient group, and plan on enrolling around 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 license fee revenue is comprised of the amortization of up-front license fees for the licensing of certain patent rights to Genzyme. We expect that license fee revenue for 2014 will be less than amounts recorded in 2013 due to the amortization of deferred revenue related to the Genzyme transaction ending in January 2014. Our laboratory service revenues will be generated primarily by the Cologuard test. Cologuard became available upon FDA approval on August 11, 2014 and no revenue recognition criteria have been met for tests performed as of September 30, 2014.

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.

Cost of sales includes costs related to inventory production and usage and the cost of laboratory services to process tests and provide results to physicians. Gross margin as a percentage of laboratory service revenue is also affected by our current revenue recognition policy, which may result in costs being incurred in one period that relate to revenues recognized in a later period.

We expect that gross margin for our laboratory services will continue to fluctuate and be affected by the adoption rates of the Cologuard test, our revenue recognition policy, the levels of reimbursement, and payment patterns of third-party payors and patients.

Critical Accounting Policies and Estimates

Management's discussion and analysis of our financial condition and results of operations is based on our condensed consolidated 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 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.

Table of Contents

While our significant accounting policies are more fully described in Note 2 of our financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2013, 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.

Laboratory service revenue. Our revenues will be generated primarily by the Cologuard test. Revenues are recognized when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the price is fixed or determinable, and collectability is reasonably assured. We assess whether the fee is fixed or determinable based on the nature of the fee charged for the laboratory services delivered and whether there are existing contractual arrangements with customers, third-party commercial payors (insurance carriers and health plans) or coverage of the test by CMS. When evaluating collectability, we consider factors such as collection experience for the healthcare industry, the financial standing of customers or third-party commercial payors, and whether we have sufficient collection history to reliably estimate a payor's individual payment patterns.

A significant portion of laboratory service revenues earned by us will initially be recognized on a cash basis because the above criteria will not have been met at the time the test results are delivered. We generally bill third-party payors upon generation and delivery of a test result to the ordering physician following completion of a test. As such, we take assignment of benefits and risk of collection with the third-party payor. Patients may have out-of-pocket costs for amounts not covered by their insurance carrier and we bill the patient directly for these amounts in the form of co-pays and deductibles in accordance with their insurance carrier and health plans. Some third-party payors may not cover the Cologuard test as ordered by the physician under their reimbursement policies. Consequently, we pursue reimbursement on a case-by-case basis directly from the patient.

For laboratory services performed, where the collectability is not reasonably assured, we will continue to recognize revenues upon cash collection until it can reliably estimate the amount that would be ultimately collected for the Cologuard test. In order to begin to record revenue on an accrual basis in these scenarios, we expect to use at least several months of payment history, review the number of tests paid against the number of tests billed, and consider the payor's outstanding balance for unpaid tests to determine whether payments are being made for a consistently high percentage of tests billed and at appropriate amounts given the contracted or historical payment amount. Our Cologuard test became available upon FDA approval on August 11, 2014 and no revenue recognition criteria have been met for tests performed as of September 30, 2014. The national coverage decision was released by CMS on October 9, 2014.

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.

As more fully described in our 2013 Form 10-K, in connection with our January 2009 strategic transaction with Genzyme Corporation, we deferred the initial \$16.65 million in cash received at closing and amortized that up-front payment on a straight-line basis into revenue over the initial five-year collaboration period which ended in January 2014. In addition, in 2010 we received holdback amounts of \$1.85 million, which were deferred at the time of receipt and were amortized on a straight-line basis into revenue over the then remaining term of the collaboration period.

Edgar Filing: EXACT SCIENCES CORP - Form 10-Q

In addition, we deferred a \$1.53 million premium related to common stock purchased by Genzyme and amortized that amount on a straight-line basis into revenue over the initial five-year collaboration period which ended in January 2014.

We did not recognize revenue in connection with the amortization of the up-front payments from Genzyme during the three months ended September 30, 2014. We recognized approximately \$1.0 million in license fee revenue in connection with the amortization of the up-front payments from Genzyme during the three months ended September 30, 2013. We recognized approximately \$0.3 million and \$3.1 million in license fee revenue in connection with the amortization of up-front payments from Genzyme during each of the nine months ended September 30, 2014 and September 30, 2013, respectively.

Table of Contents

Inventory. Inventory is stated at the lower of cost or market value (net realizable value). We determine the cost of inventory using the first-in, first out method (FIFO). We estimate the recoverability of inventory by reference to internal estimates of future demands and product life cycles, including expiration. We periodically analyze our inventory levels to identify inventory that may expire prior to expected sale or has a cost basis in excess of its estimated realizable value, and record a charge to cost of sales for such inventory as appropriate. In addition, our products are subject to strict quality control and monitoring which we perform throughout the manufacturing process. If certain batches or units of product no longer meet quality specifications or become obsolete due to expiration, we record a charge to cost of sales to write down such unmarketable inventory to its estimated realizable value.

Direct and indirect manufacturing costs incurred during process validation and for other research and development activities, which are not permitted to be sold, have been expensed to research and development. Raw material inventory that was purchased in prior periods, and expensed to research and development, may still be on hand and used toward the production of commercial Cologuard, provided it has an appropriate remaining shelf life.

In connection with the launch of Cologuard, we have invested in its manufacturing operations to support future demand for Cologuard. Because of this investment in the future, we are not currently operating at normal capacity. Charges related to excess capacity are included as current period charges to cost of sales, and are not capitalized into inventory.

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 model on the implied yield currently available on U.S. Treasury zero-coupon issues with an equivalent remaining expected term.

Edgar Filing: EXACT SCIENCES CORP - Form 10-Q

- **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, 2014 was 4.99%. The Company's forfeiture rate used in the nine months ended September 30, 2013 was 2.76%.

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.

Table of Contents**Results of Operations**

Laboratory service revenue. Our laboratory service revenues will be generated primarily by the Cologuard test. Our Cologuard test became available upon FDA approval on August 11, 2014 and no revenue recognition criteria have been met for tests performed as of September 30, 2014.

License fee revenue. Total license fee revenue was \$0.0 million and \$1.0 million for the three month periods ended September 30, 2014 and September 30, 2013, respectively. License fee revenue was \$0.3 million and \$3.1 for the nine month period ended September 30, 2014 and September 30, 2013. License fee revenue is composed of the amortization of up-front technology license fee payments associated with our collaboration, license and purchase agreement with Genzyme. The previously unamortized Genzyme up-front payment and holdback amounts were amortized on a straight-line basis over the initial Genzyme collaboration period, which ended in January 2014 therefore leading to a decline in revenue when compared to the prior year.

Research and development expenses. Research and development expenses increased to \$9.1 million for the three months ended September 30, 2014 from \$7.0 million for the three months ended September 30, 2013. Research and development expenses increased to \$23.7 million for the nine months ended September 30, 2014 from \$21.0 million for the nine months ended September 30, 2013. This was primarily due to an increase in personnel expenses, lab expenses, professional fees, clinical trial expenses, license and royalty fees, and stock-based compensation expenses due to increased headcount. The increase to stock-based compensation is primarily attributable to our recognition of \$1.3 million of expense related to the vesting of a 2009 warrant grant to a consultant to purchase 75,000 shares of common stock. The vesting was triggered by FDA approval of our Cologuard test.

	Three Months Ended September 30,				
	2014		2013		Change
Stock-based compensation	\$	2.1	\$	0.7	\$ 1.4
Personnel expenses		2.0		2.2	(0.2)
Lab expenses		1.7		0.9	0.8
Clinical trial expenses		0.8		1.0	(0.2)
Professional fees		0.7		0.3	0.4
Other research and development		0.6		1.4	(0.8)
Research collaborations		0.6		0.4	0.2
License and royalty fees		0.6		0.1	0.5
Total research and development expenses	\$	9.1	\$	7.0	\$ 2.1

	Nine Months Ended September 30,				
	2014		2013		Change
Personnel expenses	\$	7.1	\$	6.9	\$ 0.2
Lab expenses		3.5		2.0	1.5
Stock-based compensation		3.5		1.8	1.7
Other research and development		3.3		3.4	(0.1)
Clinical trial expenses		2.6		4.2	(1.6)
Research collaborations		1.7		1.4	0.3
Professional fees		1.3		1.0	0.3
License and royalty fees		0.7		0.3	0.4
	\$	23.7	\$	21.0	\$ 2.7

Total research and development
expenses

Table of Contents

General and administrative expenses. General and administrative expenses increased to \$9.0 million for the three months ended September 30, 2014 compared to \$3.7 million for the three months ended September 30, 2013. General and administrative expenses increased to \$19.8 million for the nine months ended September 30, 2014 compared to \$10.0 million for the nine months ended September 30, 2013. The increase in general and administrative expenses was primarily a result of increased legal and professional fees, increased personnel costs and stock-based compensation expense due to increased headcount, additional information technology costs, and other general and administrative expenses to support the overall growth of the Company.

		Three Months Ended September 30,		
	2014	2013	Change	
Legal and professional fees	\$ 2.2	\$ 0.9	\$	1.3
Other general and administrative	2.2	0.9		1.3
Personnel expenses	2.0	0.6		1.4
Stock-based compensation	1.2	1.0		0.2
Information technology costs	1.2	0.1		1.1
Facility costs	0.2	0.2		
Total general and administrative expenses	\$ 9.0	\$ 3.7	\$	5.3

		Nine Months Ended September 30,		
	2014	2013	Change	
Legal and professional fees	\$ 5.2	\$ 3.1	\$	2.1
Personnel expenses	4.4	2.0		2.4
Stock-based compensation	3.8	2.0		1.8
Other general and administrative	3.6	2.2		1.4
Information technology costs	2.2	0.3		1.9
Facility costs	0.6	0.4		0.2
Total general and administrative expenses	\$ 19.8	\$ 10.0	\$	9.8

Table of Contents

Sales and marketing expenses. Sales and marketing expenses increased to \$13.2 million for the three months ended September 30, 2014, from \$1.6 million for the three months ended September 30, 2013. Sales and marketing expenses increased to \$23.8 million for the nine months ended September 30, 2014 from \$6.7 million for the nine months ended September 30, 2013. The increase in sales and marketing expense was a result of hiring additional sales and marketing personnel and increasing our advertising and patient marketing efforts to prepare for the commercialization of our Cologuard test. These increases were partially offset by a decrease in stock-based compensation for the nine months ended September 30, 2014 as compared to the same period in 2013 when we incurred one-time severance costs related to the resignation of Laura Stoltenberg, the Company's former Chief Commercial Officer.

	Three Months Ended September 30,		
	2014	2013	Change
Professional fees	\$ 7.1	\$ 0.7	\$ 6.4
Personnel expenses	5.0	0.6	4.4
Other sales and marketing	0.8	0.2	0.6
Stock-based compensation	0.3	0.1	0.2
Total sales and marketing expenses	\$ 13.2	\$ 1.6	\$ 11.6

Table of Contents

	Nine Months Ended September 30,		
	2014	2013	Change
Professional fees	\$ 13.0	\$ 1.9	\$ 11.1
Personnel expenses	8.3	2.4	5.9
Other sales and marketing	1.6	0.7	0.9
Stock-based compensation	0.9	1.7	(0.8)
Total sales and marketing expenses	\$ 23.8	\$ 6.7	\$ 17.1

Cost of Sales. Cost of sales includes costs related to inventory production and usage and the cost of laboratory services to process tests and provide results to physicians. Gross margin as a percentage of laboratory service revenue is also affected by our current revenue recognition policy, which may result in costs being incurred in one period that relate to revenues recognized in a later period. Cost of sales was \$0.9 million for the three and nine months ended September 30, 2014 compared to none in the comparable prior year periods. The increase in cost of sales is related to the production of our Cologuard test which obtained FDA approval during the third quarter of 2014. Cost of sales includes \$0.6 million related to excess capacity and \$0.3 million related to inventory production and lab services costs.

Investment income. Investment income increased to \$160.0 thousand for the three months ended September 30, 2014 compared to \$103.0 thousand for the three months ended September 30, 2013. Investment income increased to \$392.0 thousand for the nine months ended September 30, 2014 compared to \$220.0 thousand for the nine months ended September 30, 2013. This is 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 2013.

Table of Contents

Interest expense. Interest expense decreased to \$12.0 thousand for the three months ended September 30, 2014 from \$16.0 thousand for the three months ended September 30, 2013. Interest expense decreased to \$40.0 thousand for the nine months ended September 30, 2014 from \$53.0 thousand for the nine months ended September 30, 2013. This decrease is primarily due to less interest expense recognized for our capital lease during the three and nine months ended September 30, 2014 when compared to the same period in 2013.

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, 2014, we had approximately \$27.8 million in unrestricted cash and cash equivalents and approximately \$183.3 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 \$50.0 million for the nine months ended September 30, 2014 as compared to \$30.0 million for the nine months ended September 30, 2013. The principal use of cash in operating activities for the nine months ended September 30, 2014 was to fund our net loss which increased from the nine months ended September 30, 2013 primarily due to increased sales and marketing efforts and general and administrative costs to prepare for the commercial launch of Cologuard and to support the overall growth of the Company.

Net cash used in investing activities was \$73.2 million for the nine months ended September 30, 2014 as compared to \$48.2 million of cash used in investing activities for the nine months ended September 30, 2013. The increase in cash used in investing activities for the nine months ended September 30, 2014 compared to the same period in 2013 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 \$9.5 million for the nine months ended September 30, 2014 and \$4.4 million for the same period in 2013. The increase in property and equipment purchases during the nine months ended September 30, 2014 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 \$138.2 million for the nine months ended September 30, 2014, as compared to net cash provided by financing activities of \$74.5 million for the nine months ended September 30, 2013. The increase in cash provided by financing activities for the nine months ended September 30, 2014 was due to the receipt of \$137.7 million of cash from our April 2014 common stock offering, the receipt of \$0.4 million from stock option exercises, and the receipt of \$0.3 million from proceeds in connection with the Company's employee stock purchase plan, slightly offset by capital lease payments of \$0.3 million compared to the receipt of \$73.3 million of cash from our June 2013 common stock offering, the receipt of \$1.2 million from stock option exercises, and the receipt of \$0.3 million from proceeds in connection with the Company's employee stock purchase plan, slightly offset by capital lease payments of \$0.2 million for the same period in 2013.

Edgar Filing: EXACT SCIENCES CORP - Form 10-Q

We expect that cash and cash equivalents and marketable securities on hand at September 30, 2014, will be sufficient to fund our current operations for at least the next twelve months, based on current operating plans. However, since payments for our Cologuard test will be our only material revenue source and we have not yet begun to collect such payments and do not know the timing or amount of any such payments, it is possible that we may need to raise additional capital to fully fund our current strategic plan. If we are unable to obtain sufficient additional funds to enable us to fund our operations through the completion of such plan, our results of operations and financial condition would be materially adversely affected and we may be required to delay the implementation of our plan and otherwise scale back our operations. Even if we successfully raise sufficient funds to complete our plan, we cannot assure that our business will ever generate sufficient cash flow from operations to become profitable.

Table of Contents

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board issued Accounting Standards Update No. 2014-09, *Revenue from Contracts with Customers*. ASU 2014-09 is a comprehensive new revenue recognition model requiring a company to recognize revenue to depict the transfer of goods or services to a customer at an amount reflecting the consideration it expects to receive in exchange for those goods or services. ASU 2014-09 may be applied using either a full retrospective or a modified retrospective approach and is effective for fiscal years, and interim periods within those years, beginning after December 15, 2016, and early adoption is not permitted. We are currently evaluating the impact of this amendment on our financial position and results of operations.

Off-Balance Sheet Arrangements

As of September 30, 2014, 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, asset backed securities and corporate bonds, which, as of September 30, 2014 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.

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 principal 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 (the Exchange Act). Based upon that evaluation, our principal executive officer and our principal financial officer concluded that, as of September 30, 2014, 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 Exchange Act 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 quarter ended September 30, 2014 and in connection with the launch of our Cologuard test, we designed and implemented inventory and revenue recognition internal controls and policies. Other than the implementation of these new internal controls and policies, there have been no significant changes in internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

Part II - Other Information

Item 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: October 31, 2014

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

President and Chief Executive Officer
(Principal Executive Officer)

Date: October 31, 2014

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

Principal Financial Officer

Table of Contents

EXHIBIT INDEX

Exhibit Number	Description
3.1	First Amendment to our Sixth Amended and Restated Certificate of Incorporation of the Registrant (previously filed as Appendix A to the Definitive Proxy Statement for the Company's 2014 Annual Meeting of Stockholders filed on June 20, 2014, which is incorporated herein by reference).
10.1	First Amendment to the Company's 2010 Employee Stock Purchase Plan (previously filed as Appendix B to the Definitive Proxy Statement for the Company's 2014 Annual Meeting of Stockholders filed on June 20, 2014, which is incorporated herein by reference).
31.1	Certification Pursuant to Rule 13(a)-14(a) or Rule 15d-14(a) of Securities Exchange Act of 1934.
31.2	Certification Pursuant to Rule 13(a)-14(a) or Rule 15d-14(a) of Securities Exchange Act of 1934.
32.1	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	Interactive Data Files