

EXACT SCIENCES CORP
Form 10-Q
August 01, 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 June 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 July 30, 2014, the registrant had 82,934,536 shares of common stock outstanding.

Table of Contents

EXACT SCIENCES CORPORATION

INDEX

	Page Number
<u>Part I - Financial Information</u>	
Item 1. Financial Statements	
<u>Condensed Consolidated Balance Sheets (Unaudited) as of June 30, 2014 and December 31, 2013</u>	3
<u>Condensed Consolidated Statements of Operations (Unaudited) for the Three and Six Months Ended June 30, 2014 and 2013</u>	4
<u>Condensed Consolidated Statements of Comprehensive Loss (Unaudited) for the Three and Six Months Ended June 30, 2014 and 2013</u>	5
<u>Condensed Consolidated Statements of Cash Flows (Unaudited) for the Six Months Ended June 30, 2014 and 2013</u>	6
<u>Notes to Condensed Consolidated Financial Statements (Unaudited)</u>	7
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	21
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	30
Item 4. <u>Controls and Procedures</u>	30
<u>Part II - Other Information</u>	
Item 1. <u>Legal Proceedings</u>	30
Item 1A. <u>Risk Factors</u>	30
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	31
Item 3. <u>Defaults Upon Senior Securities</u>	31
Item 4. <u>Mine Safety Disclosures</u>	31
Item 5. <u>Other Information</u>	31
Item 6. <u>Exhibits</u>	31
<u>Signatures</u>	32
<u>Exhibit Index</u>	33

Table of Contents

Part I Financial Information

EXACT SCIENCES CORPORATION**Condensed Consolidated Balance Sheets**

(Amounts in thousands, except share data - unaudited)

	June 30, 2014	December 31, 2013
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 20,708	\$ 12,851
Marketable securities	214,089	120,408
Prepaid expenses and other current assets	3,987	2,199
Total current assets	238,784	135,458
Property and Equipment, at cost:		
Laboratory equipment	8,127	5,087
Assets under construction	6,694	2,592
Office and computer equipment	1,260	1,217
Leasehold improvements	5,055	5,043
Furniture and fixtures	268	268
	21,404	14,207
Less Accumulated depreciation	(4,383)	(3,038)
	17,021	11,169
	\$ 255,805	\$ 146,627
LIABILITIES AND STOCKHOLDERS EQUITY		
Current Liabilities:		
Accounts payable	\$ 357	\$ 761
Accrued expenses	8,560	5,806
Capital lease obligation, current portion	361	351
Lease incentive obligation, current portion	540	540
Deferred license fees, current portion		294
Total current liabilities	9,818	7,752
Long-term debt	1,000	1,000
Long-term accrued interest	95	84
Capital lease obligation, less current portion	177	360
Lease incentive obligation, less current portion	1,845	2,115
Commitments and contingencies		
Stockholders Equity:		
Preferred stock, \$0.01 par value Authorized 5,000,000 shares, Issued and outstanding no shares at June 30, 2014 and December 31, 2013		
Common stock, \$0.01 par value Authorized 100,000,000 shares, Issued and outstanding 82,920,004 and 71,071,838 shares at June 30, 2014 and December 31, 2013	829	711
Additional paid-in capital	598,255	455,239
Accumulated other comprehensive income	89	125
Accumulated deficit	(356,303)	(320,759)

Edgar Filing: EXACT SCIENCES CORP - Form 10-Q

Total stockholders' equity		242,870		135,316
	\$	255,805	\$	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 - unaudited)**

	Three Months Ended June 30,		Six Months Ended June 30,			
	2014	2013	2014	2013		
License fees	\$	\$	1,036	\$	2,072	
Operating expenses:						
Research and development		7,174	6,457	14,604	13,983	
General and administrative		6,230	3,628	10,816	6,276	
Sales and marketing		6,166	3,302	10,622	5,061	
		19,570	13,387	36,042	25,320	
Loss from operations		(19,570)	(12,351)	(35,748)	(23,248)	
Investment income		146	55	232	117	
Interest expense		(13)	(18)	(28)	(37)	
Net loss	\$	(19,437)	\$	(12,314)	\$	(23,168)
Net loss per share basic and diluted	\$	(0.24)	\$	(0.19)	\$	(0.46)
Weighted average common shares outstanding basic and diluted		82,048	64,699	76,548	64,270	

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 June 30,		Six Months June 30,	
	2014	2013	2014	2013
Net loss	\$ (19,437)	\$ (12,314)	\$ (35,544)	\$ (23,168)
Other comprehensive loss, net of tax				
Unrealized holding loss on available-for-sale investments	(44)	(54)	(36)	(61)
Comprehensive loss	\$ (19,481)	\$ (12,368)	\$ (35,580)	\$ (23,229)

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)**

	Six Months Ended June 30,	
	2014	2013
Cash flows from operating activities:		
Net loss	\$ (35,544)	\$ (23,168)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of fixed assets	1,344	646
Loss on disposal of fixed asset		91
Stock-based compensation	4,478	3,811
Amortization of deferred license fees	(294)	(2,072)
Amortization of premium on short-term investments	370	270
Changes in assets and liabilities:		
Prepaid expenses and other current assets	(1,788)	(494)
Accounts payable	(404)	(2,568)
Accrued expenses	3,210	1,254
Lease incentive obligation	(270)	
Accrued interest	11	10
Net cash used in operating activities	(28,887)	(22,220)
Cash flows from investing activities:		
Purchases of marketable securities	(138,855)	(71,833)
Maturities of marketable securities	44,768	30,067
Purchases of property and equipment	(7,196)	(1,726)
Net cash used in investing activities	(101,283)	(43,492)
Cash flows from financing activities:		
Proceeds from sale of common stock, net of issuance costs	137,670	73,302
Proceeds from exercise of common stock options	193	486
Payments on capital lease obligations	(173)	(164)
Proceeds in connection with the Company's employee stock purchase plan	337	261
Net cash provided by financing activities	138,027	73,885
Net increase in cash and cash equivalents	7,857	8,173
Cash and cash equivalents, beginning of period	12,851	13,345
Cash and cash equivalents, end of period	\$ 20,708	\$ 21,518
Supplemental disclosure of non-cash investing and financing activities:		
Unrealized loss on available-for-sale investments	\$ 36	\$ 61
Issuance of 32,266 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 June 30, 2014 and December 31, 2013.

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

Table of Contents

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 June 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 \$7.6 thousand and \$2.8 thousand, net of insignificant realized losses, for the six months ended June 30, 2014 and 2013, respectively. Unrealized gains or losses on investments are recorded in other comprehensive loss.

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

(In thousands)	Amortized Cost	June 30, 2014		Estimated Fair Value
		Gains in Accumulated Other Comprehensive Income	Losses in Accumulated Other Comprehensive Income	
U.S. government agency securities	\$ 48,550	\$ 27	\$	\$ 48,577
Corporate bonds	118,696	41		118,737
Certificates of deposit	3,550	1		3,551
Asset backed securities	43,204	20		43,224
Total available-for-sale securities	\$ 214,000	\$ 89	\$	\$ 214,089

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

The amounts recognized in accumulated other comprehensive income (AOCI) were as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Beginning balance	\$ 133	\$ 71	\$ 125	\$ 78
Other comprehensive loss before reclassifications	(39)	(52)	(24)	(48)
Amounts reclassified from accumulated other comprehensive income	(5)	(2)	(12)	(13)
Net current period change in accumulated other comprehensive income	(44)	(54)	(36)	(61)
Ending balance	\$ 89	\$ 17	\$ 89	\$ 17

Amounts reclassified from accumulated other comprehensive income were as follows (in thousands):

Table of Contents

Details about AOCI Components	Affected Line Item in the Statement of Operations	Three Months Ended June 30,		Six Months Ended June 30,	
		2014	2013	2014	2013
Change in value of available-for-sale investments					
Sales and maturities of available-for-sale investments	Investment income	\$ (5)	\$ (2)	\$ (12)	\$ (13)
Total reclassifications		\$ (5)	\$ (2)	\$ (12)	\$ (13)

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 June 30, 2014, the Company had \$6.7 million of assets under construction which consisted of \$4.4 million of capitalized costs related to software projects and \$2.3 million of costs related to equipment projects. Depreciation will begin on these assets once they are placed into service. We expect that it will cost \$1.0 million to complete the equipment projects and \$2.2 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.

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.

Edgar Filing: EXACT SCIENCES CORP - Form 10-Q

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:

Table of Contents

(In thousands)	2014	June 30,	2013
Shares issuable upon exercise of stock options	6,221		6,249
Shares issuable upon exercise of outstanding warrants (1)	75		155
Shares issuable upon the release of restricted stock awards	1,546		875
Shares issuable upon the vesting of restricted stock awards related to a licensing agreement	24		49
	7,866		7,328

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

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, Genzyme agreed to pay the Company a total of \$18.5 million, of which \$16.65 million was paid on January 27, 2009 and \$1.85 million was subject to a holdback by Genzyme to satisfy certain potential indemnification obligations in exchange for the assignment and licensing of certain intellectual property to Genzyme. The Company's on-going performance obligations to Genzyme under the Collaboration, License and Purchase Agreement (the "CLP Agreement"), as described below, including its obligation to deliver through licenses certain intellectual property improvements to Genzyme, if improvements are made during the initial five-year collaboration period, were deemed to be undelivered elements of the CLP Agreement on the date of closing. Accordingly, the Company deferred the initial \$16.65 million in cash received at closing and amortized that up-front payment on a straight-line basis into revenue over the initial five-year collaboration period which ended in January 2014. The Company received the first holdback amount of \$1.0 million, which included accrued interest due, from Genzyme during the first quarter of 2010. The Company received the second holdback amount of \$0.9 million, which included accrued interest due, from Genzyme during the third quarter of 2010. The amounts were deferred 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, Genzyme purchased 3,000,000 shares of common stock on January 27, 2009 for \$2.00 per share, representing a premium of \$0.51 per share above the closing price of the Company's common stock on that date of \$1.49 per share. The aggregate premium paid by Genzyme over the closing price of the Company's common stock on the date of the transaction of \$1.53 million is deemed to be a part of the total consideration for the CLP Agreement. Accordingly, the Company deferred the aggregate \$1.53 million premium and 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 June 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 June 30, 2013. The

Table of Contents

Company recognized approximately \$0.3 million and \$2.1 million in license fee revenue in connection with the amortization of up-front payments from Genzyme during each of the six months ended June 30, 2014 and June 30, 2013, respectively.

Reclassifications

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

(3) MAYO LICENSE AGREEMENT

Overview

On June 11, 2009, the Company entered into a license agreement (the License Agreement) with MAYO Foundation for Medical Education and Research (MAYO). Under the License Agreement, MAYO granted the Company an exclusive, worldwide license within the field (the Field) of stool or blood based cancer diagnostics and screening (excluding a specified proteomic target) with regard to certain MAYO patents, and a non-exclusive worldwide license within the Field with regard to certain MAYO know-how. The licensed patents cover advances in sample processing, analytical testing and data analysis associated with non-invasive, stool-based DNA screening for colorectal cancer. Under the License Agreement, the Company assumes the obligation and expense of prosecuting and maintaining the licensed patents and is obligated to make commercially reasonable efforts to bring products covered by the license to market. Pursuant to the License Agreement, the Company granted MAYO two common stock purchase warrants with an exercise price of \$1.90 per share covering 1,000,000 and 250,000 shares of common stock, respectively. The Company is also required to make payments to MAYO for up-front fees, fees once certain milestones are reached by the Company, and other payments as outlined in the License Agreement. In addition to the license to intellectual property owned by MAYO, the Company receives product development and research and development efforts from MAYO personnel. The Company is also obligated to make royalty payments to MAYO on potential future net sales of any products developed from the licensed technology. The Company sought rights to the MAYO intellectual property for the specific purpose of developing a non-invasive, stool-based DNA screening test for colorectal cancer. At the time the license agreement was executed, the sole focus of the Company was the development of such a test. Accordingly, the Company recognized the initial payments and 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.

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.

Edgar Filing: EXACT SCIENCES CORP - Form 10-Q

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

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

In June of 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.

Table of Contents

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. It is uncertain as to when or if the FDA will approve the Company's Cologuard test; therefore the \$500,000 milestone payment has not been recorded as a liability. The Company evaluates the status of the FDA trial at each reporting date to determine if a liability should be recorded for the milestone payment.

In addition, the Company is paying MAYO for research and development efforts. During the three and six months ended June 30, 2014, the Company made payments of \$0.2 million and \$0.7 million, respectively. At June 30, 2014 the Company recorded an estimated liability in the amount of \$1.0 million for research and development efforts. During the three and six months ended June 30, 2013, the Company made payments of \$0.3 million and \$0.5 million, respectively. At June 30, 2013 the Company recorded an estimated liability in the amount of \$0.5 million for research and development efforts.

May 2012 Amendment

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

As part of the amendment, the Company will also be responsible for making additional restricted stock grants to MAYO as certain milestones are met with respect to commercial launch of the Company's second and third licensed products. Additionally, the Company will make milestone

Edgar Filing: EXACT SCIENCES CORP - Form 10-Q

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.

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 and the 2000 Stock Option and Incentive Plan (collectively, as each has been amended, the "Stock Plans").

Stock-Based Compensation Expense

The Company recorded \$2.5 million and \$4.5 million in stock-based compensation expense during the three and six months ended June 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. The Company recorded \$2.8 million and \$3.8 million in stock-based compensation expense during the three and six months ended June 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.

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.

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 six months ended June 30, 2014 was 4.99%. The Company's forfeiture rate used in the six months ended June 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 June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Option Plan Shares				
Risk-free interest rates	(1)	0.94%	1.96%	0.94% - 1.15%
Expected term (in years)	(1)	6	6	6
Expected volatility	(1)	82.9%	80.8%	82.9% - 84.0%
Dividend yield	(1)	0%	0%	0%
Weighted average fair value per share of options granted during the period	(1)	\$ 6.55	\$ 9.86	\$ 7.66
ESPP Shares				
Risk-free interest rates	0.10% - 0.41%	0.11% - 0.20%	0.10% - 0.41%	0.11% - 0.20%
Expected term (in years)	0.5 - 2	0.5 - 2	0.5 - 2	0.5 - 2
Expected volatility	42.5% - 49.5%	39.1% - 45.6%	42.5% - 49.5%	39.1% - 45.6%
Dividend yield	0%	0%	0%	0%
Weighted average fair value per share of stock purchase rights granted during the period	\$ 3.76	\$ 2.80	\$ 3.76	\$ 2.80

(1) The Company did not grant options under its 2010 Option Plan during the period indicated.

Stock Option and Restricted Stock Activity

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

Table of Contents

Options (Aggregate intrinsic value in thousands)	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (1)
Outstanding, January 1, 2014	6,062,587	\$ 2.78	6.6	
Granted	233,000	\$ 13.96		
Exercised	(69,064)	\$ 2.79		
Forfeited	(5,125)	\$ 7.80		
Outstanding, June 30, 2014	6,221,398	\$ 3.19	5.5	\$ 86,097
Exercisable, June 30, 2014	5,374,375	\$ 2.06	5.1	\$ 80,441
Vested and expected to vest, June 30, 2014	6,179,132	\$ 3.14	5.5	\$ 85,815

(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 \$17.03 market price of the Company's common stock at June 30, 2014. The total intrinsic value of options exercised during the six months ended June 30, 2014 and 2013 was \$0.7 million and \$0.5 million, respectively.

As of June 30, 2014, there was \$18.9 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 2.92 years.

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

Table of Contents

	Restricted Shares	Weighted Average Grant Date Fair Value
Outstanding, January 1, 2014	1,150,694	\$ 11.24
Granted	576,794	\$ 13.81
Released	(166,756)	\$ 8.99
Forfeited	(14,599)	\$ 12.05
Outstanding, June 30, 2014	1,546,133	\$ 12.43

(5) FAIR VALUE MEASUREMENTS

The FASB has issued authoritative guidance which requires that fair value should be based on the assumptions market participants would use when pricing an asset or liability and establishes a fair value hierarchy that prioritizes the information used to develop those assumptions. Under the standard, fair value measurements are separately disclosed by level within the fair value hierarchy. The fair value hierarchy establishes and prioritizes the inputs used to measure fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs. Observable inputs are inputs that reflect the assumptions that market participants would use in pricing the asset or liability developed based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the assumptions market participants would use in pricing the asset or liability developed based on the best information available in the circumstances.

The three levels of the fair value hierarchy established are as follows:

- Level 1** Quoted prices (unadjusted) in active markets for identical assets or liabilities that the Company has the ability to access as of the reporting date. Active markets are those in which transactions for the asset or liability occur in sufficient frequency and volume to provide pricing information on an ongoing basis.
- Level 2** Pricing inputs other than quoted prices in active markets included in Level 1, which are either directly or indirectly observable as of the reporting date. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active.

Table of Contents

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 June 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 June 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 at June 30, 2014	Fair Value Measurement at June 30, 2014 Using:		
		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	\$ 20,708	\$ 20,708	\$	\$
Available-for-Sale				
Marketable securities				
U.S. government agency securities	48,577		48,577	
Corporate bonds	118,737		118,737	
Certificates of deposit	3,551		3,551	
Asset backed securities	43,224		43,224	
Total	\$ 234,797	\$ 20,708	\$ 214,089	\$

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	\$

As of June 30, 2014 and December 31, 2013 the Company held available-for-sale securities which had been in a continuous unrealized loss position for less than twelve months, the total unrealized losses of which were \$51.4 thousand, as of June 30, 2014, and \$7.2 thousand, as of December 31, 2013. The total fair value of the securities in a continuous unrealized loss position were \$83.5 million, as of June 30, 2014 and \$13.9 million as of December 31, 2013. At June 30, 2014 and December 31, 2013 there were no available-for-sale securities in a continuous loss position for greater than twelve months.

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

Table of Contents

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	\$ 32,906	\$ 32,932	\$ 15,644	\$ 15,645
Corporate bonds	29,096	29,134	89,600	89,603
Certificates of deposit	3,550	3,551		
Asset backed securities	33,932	33,947	9,272	9,277
Total	\$ 99,484	\$ 99,564	\$ 114,516	\$ 114,525

(6) EQUITY

On April 2, 2014, the Company completed an underwritten public offering of 11,500,000 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.

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

Table of Contents

(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, intend, plan, estimate, anticipate or other comparable terms. Forward-looking statements in this Quarterly Report on Form 10-Q may address the following subjects among others: statements regarding the sufficiency of our capital resources, expected operating losses, timing and anticipated results of the FDA's review of our pivotal clinical trial and our related FDA submissions, 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, timing of our launch of a commercial product, 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 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

Edgar Filing: EXACT SCIENCES CORP - Form 10-Q

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.

Table of Contents

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

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

Our Cologuard® test is 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.

Our current focus is on seeking FDA approval for our Cologuard test. We believe obtaining FDA approval is important to building broad demand and successfully commercializing our sDNA colorectal cancer screening technology.

The FDA, as well as 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.

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.

Table of Contents

We submitted the results of our clinical trial to the FDA through a three part submission of a manufacturing module, analytical module, and clinical module. The manufacturing module was submitted to the FDA in December 2012, the analytical module was submitted to the FDA in February 2013, and the clinical module was submitted to the FDA in June 2013. Our submission is currently under review by the FDA. The application includes 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 is not bound by the recommendation of its advisory committee, but will consider the committee's guidance as it evaluates the Cologuard PMA.

We believe that obtaining a favorable national coverage decision and a favorable reimbursement rate from the Centers for Medicare & Medicaid Services (CMS) for our Cologuard test will be a necessary element in achieving material commercial success. With the goal of expediting receipt of a favorable coverage decision, we are working with CMS to coordinate the CMS coverage review with the FDA pre-market approval through a parallel review process. This program provides a pathway to a potential CMS national coverage determination shortly after an FDA approval, should it occur. With over 50% of our target patient population being covered by Medicare, receipt of a positive coverage decision from CMS would help speed adoption of our test after commercial launch. A favorable CMS outcome will also be 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 June 30, 2014, we had an accumulated deficit of approximately \$356.3 million. We expect to continue to incur losses for the next several years, and it is possible we may never achieve profitability.

2014 Priorities

Our top priorities for 2014 include securing FDA approval and a favorable national coverage decision from CMS for our Cologuard test. If for any reason the FDA does not approve our PMA or such approval is substantially delayed, our business and prospects would likely be materially adversely impacted. Likewise it would be a material adverse event for our business if we do not receive a positive national coverage decision and favorable reimbursement rate from CMS or if for any other reason we are unable to successfully commercialize our Cologuard test.

Another priority is 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.

Table of Contents

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 revenue is comprised of the amortization of up-front license fees for the licensing of certain patent rights to Genzyme. We expect that license fees for 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 Cost Structure. Our selling, general and administrative expenses consist primarily of non-research personnel salaries, office expenses, professional fees, sales and marketing expenses incurred in support of our commercialization efforts and non-cash stock-based compensation.

Critical Accounting Policies and Estimates

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

While our significant accounting policies are more fully described in Note 2 of our financial statements included in the 2013 Form 10-K, we believe that the following accounting policies and judgments are most critical to aid in fully understanding and evaluating our reported financial results.

Revenue Recognition.

License fees. License fees for the licensing of product rights on initiation of strategic agreements are recorded as deferred revenue upon receipt of cash and recognized as revenue on a straight-line basis over the license period.

Edgar Filing: EXACT SCIENCES CORP - Form 10-Q

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

Table of Contents

aggregate \$1.53 million premium and are amortizing 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 June 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 June 30, 2013. The Company recognized approximately \$0.3 million and \$2.1 million in license fee revenue in connection with the amortization of up-front payments from Genzyme during each of the six months ended June 30, 2014 and June 30, 2013, respectively.

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.

- **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 six months ended June 30, 2014 was 4.99%. The Company's forfeiture rate used in the six months ended June 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.

Results of Operations

Revenue. Total revenue was \$0.0 million and \$1.0 million for the three month periods ended June 30, 2014 and June 30, 2013, respectively. Total revenue was \$0.3 million and \$2.1 for the six month period ended June 30, 2014 and June 30, 2013. Total revenue is composed of the amortization of up-front technology license fee payments associated with our collaboration, license and purchase agreement with Genzyme. The 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 \$7.2 million for the three months ended June 30, 2014 from \$6.5 million for the three months ended June 30, 2013. Research and development expenses increased to \$14.6 million for the six months ended June 30, 2014 from \$14.0 million for the six months ended June 30, 2013. This was primarily due to an increase in personnel expenses, lab expenses, and stock-based compensation expenses due to increased headcount. This increase was slightly offset by a decrease in clinical trial expenses due to the completion of the FDA clinical trial for our Cologuard test in April 2013.

Table of Contents

	Three Months Ended June 30,				
	2014		2013		Change
Personnel expenses	\$	2.6	\$	2.3	\$ 0.3
Other research and development		1.0		0.8	0.2
Lab expenses		0.9		0.5	0.4
Clinical trial expenses		0.9		1.1	(0.2)
Stock-based compensation		0.8		0.6	0.2
Research collaborations		0.6		0.5	0.1
Professional fees		0.3		0.5	(0.2)
License and royalty fees		0.1		0.2	(0.1)
Total research and development expenses	\$	7.2	\$	6.5	\$ 0.7

	Six Months Ended June 30,				
	2014		2013		Change
Personnel expenses	\$	5.1	\$	4.6	\$ 0.5
Other research and development		2.5		2.0	0.5
Lab expenses		1.9		1.1	0.8
Clinical trial expenses		1.8		3.2	(1.4)
Stock-based compensation		1.5		1.1	0.4
Research collaborations		1.1		1.0	0.1
Professional fees		0.6		0.7	(0.1)
License and royalty fees		0.1		0.3	(0.2)
Total research and development expenses	\$	14.6	\$	14.0	\$ 0.6

General and administrative expenses. General and administrative expenses increased to \$6.2 million for the three months ended June 30, 2014 compared to \$3.6 million for the three months ended June 30, 2013. General and administrative expenses increased to \$10.8 million for the six months ended June 30, 2014 compared to \$6.3 million for the six months ended June 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 IT costs, and other general and administrative expenses to support the overall growth of the Company.

Table of Contents

	Three Months Ended June 30,				
	2014		2013		Change
Other general and administrative	\$	1.9	\$	0.9	\$ 1.0
Legal and professional fees		1.6		1.3	0.3
Personnel expenses		1.3		0.5	0.8
Stock-based compensation		1.2		0.8	0.4
Facility costs		0.2		0.1	0.1
Total general and administrative expenses	\$	6.2	\$	3.6	\$ 2.6

	Six Months Ended June 30,				
	2014		2013		Change
Legal and professional fees	\$	2.9	\$	2.2	\$ 0.7
Other general and administrative		2.8		1.8	1.0
Personnel expenses		2.5		1.0	1.5
Stock-based compensation		2.2		1.0	1.2
Facility costs		0.4		0.3	0.1
Total general and administrative expenses	\$	10.8	\$	6.3	\$ 4.5

Sales and marketing expenses. Sales and marketing expenses increased to \$6.2 million for the three months ended June 30, 2014, from \$3.3 million for the three months ended June 30, 2013. Sales and marketing expenses increased to \$10.6 million for the six months ended June 30, 2014 from \$5.1 million for the six months ended June 30, 2013. The increase in sales and marketing expense was a result of hiring additional sales and marketing personnel and increasing our efforts to prepare for the commercialization of our Cologuard test. These increases were partially offset by a decrease in stock-based compensation 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.

Table of Contents

	Three Months Ended June 30,		
	2014	2013	Change
Professional fees	\$ 3.3	\$ 0.6	\$ 2.7
Personnel expenses	2.1	1.1	1.0
Other sales and marketing	0.6	0.2	0.4
Stock-based compensation	0.2	1.4	(1.2)
Total sales and marketing expenses	\$ 6.2	\$ 3.3	\$ 2.9

	Six Months Ended June 30,		
	2014	2013	Change
Professional fees	\$ 5.9	\$ 1.2	\$ 4.7
Personnel expenses	3.6	1.9	1.7
Other sales and marketing	0.8	0.6	0.2
Stock-based compensation	0.3	1.4	(1.1)
Total sales and marketing expenses	\$ 10.6	\$ 5.1	\$ 5.5

Investment income. Investment income increased to \$146.0 thousand for the three months ended June 30, 2014 compared to \$55.0 thousand for the three months ended June 30, 2013. Investment income increased to \$232.0 thousand for the six months ended June 30, 2014 compared to \$117.0 thousand for the six months ended June 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.

Interest expense. Interest expense decreased to \$13.0 thousand for the three months ended June 30, 2014 from \$18.0 thousand for the three months ended June 30, 2013. Interest expense decreased to \$28.0 thousand for the six months ended June 30, 2014 from \$37.0 thousand for the six months ended June 30, 2013. This decrease is primarily due

Table of Contents

to less interest expense recognized for our capital lease during the three and six months ended June 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 June 30, 2014, we had approximately \$20.7 million in unrestricted cash and cash equivalents and approximately \$214.1 million in marketable securities.

All of our investments in marketable securities are comprised of fixed income investments and all are deemed available-for-sale. The objectives of this portfolio are to provide liquidity and safety of principal while striving to achieve the highest rate of return, consistent with these two objectives. Our investment policy limits investments to certain types of instruments issued by institutions with investment grade credit ratings and places restrictions on maturities and concentration by type and issuer.

Net cash used in operating activities was \$28.9 million for the six months ended June 30, 2014 as compared to \$22.2 million for the six months ended June 30, 2013. The principal use of cash in operating activities for the six months ended June 30, 2014 was to fund our net loss which increased from the six months ended June 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 \$101.3 million for the six months ended June 30, 2014 as compared to \$43.5 million of cash used in investing activities for the six months ended June 30, 2013. The increase in cash used in investing activities for the six months ended June 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 \$7.2 million for the six months ended June 30, 2014 and \$1.7 million for the same period in 2013. The increase in property and equipment purchases during the six months ended June 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 \$138.0 million for the six months ended June 30, 2014, as compared to net cash provided by financing activities of \$73.9 million for the six months ended June 30, 2013. The increase in cash provided by financing activities for the six months ended June 30, 2014 was due to the receipt of \$137.7 million of cash from our April 2014 common stock offering, the receipt of \$0.5 million from stock option exercises and from the employee stock purchase plan slightly offset by capital lease payments of \$0.2 million compared to the receipt of \$73.3 million of cash from our June 2013 common stock offering, the receipt of \$0.7 million from stock option exercises and from the employee stock purchase plan slightly offset by capital lease payments of \$0.2 million for the same period in 2013.

We expect that cash and cash equivalents and marketable securities on hand at June 30, 2014, 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, it is possible that we may need to raise additional capital to fully fund our current strategic plan, the primary goal of which is commercializing our 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 that our business will ever generate sufficient cash flow from operations to become profitable.

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.

Table of Contents

Off-Balance Sheet Arrangements

As of June 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 June 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 June 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 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.

Table of Contents

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 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.

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 also exercised the warrant to purchase 250,000 shares through several partial exercises. As of June 2013, the warrant had been exercised with respect to all but 80,000 shares.

In June of 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.

We believe that the offer and sale of the securities referenced were exempt from registration under the Securities Act of 1933 (the Securities Act) by virtue of Section 4(2) of 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 Exact 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. 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: August 1, 2014

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

President and Chief Executive Officer
(Principal Executive Officer)

Date: August 1, 2014

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

Principal Financial Officer

Table of Contents

EXHIBIT INDEX

Exhibit Number	Description
10	Exact Sciences Corporation Non-employee Director Compensation Policy dated April 28, 2014
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