
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2016

OR

**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)

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 25, 2016, the registrant had 108,410,279 shares of common stock outstanding.

EXACT SCIENCES CORPORATION

INDEX

	<u>Page Number</u>
<u>Part I - Financial Information</u>	
<u>Item 1. Financial Statements</u>	
<u>Condensed Consolidated Balance Sheets (unaudited) as of September 30, 2016 and December 31, 2015</u>	3
<u>Condensed Consolidated Statements of Operations (unaudited) for the Three and Nine Months Ended September 30, 2016 and 2015</u>	4
<u>Condensed Consolidated Statements of Comprehensive Loss (unaudited) for the Three and Nine Months Ended September 30, 2016 and 2015</u>	5
<u>Condensed Consolidated Statements of Cash Flows (unaudited) for the Nine Months Ended September 30, 2016 and 2015</u>	6
<u>Notes to Condensed Consolidated Financial Statements (unaudited)</u>	7
<u>Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	21
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	32
<u>Item 4. Controls and Procedures</u>	32
<u>Part II - Other Information</u>	
<u>Item 1. Legal Proceedings</u>	33
<u>Item 1A. Risk Factors</u>	33
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	33
<u>Item 3. Defaults Upon Senior Securities</u>	33
<u>Item 4. Mine Safety Disclosures</u>	33
<u>Item 5. Other Information</u>	33
<u>Item 6. Exhibits</u>	33
<u>Signatures</u>	34
<u>Exhibit Index</u>	35

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

	<u>September 30,</u> <u>2016</u>	<u>December 31,</u> <u>2015</u>
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 63,445	\$ 41,135
Marketable securities	274,385	265,744
Accounts receivable, net	7,863	4,933
Inventory, net	7,666	6,677
Prepaid expenses and other current assets	5,673	7,375
Total current assets	<u>359,032</u>	<u>325,864</u>
Property and Equipment, at cost:		
Computer equipment and computer software	19,053	14,025
Laboratory equipment	14,249	12,786
Leasehold improvements	13,308	7,118
Assets under construction	6,536	8,038
Buildings	4,792	4,777
Furniture and fixtures	2,515	1,265
	<u>60,453</u>	<u>48,009</u>
Less—Accumulated depreciation	<u>(21,980)</u>	<u>(13,913)</u>
Net property and equipment	<u>38,473</u>	<u>34,096</u>
Other long-term assets	<u>5,706</u>	<u>4,070</u>
Total assets	<u>\$ 403,211</u>	<u>\$ 364,030</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 2,335	\$ 3,308
Accrued liabilities	26,104	22,253
Debt and capital lease obligation, current portion	172	166
Other short-term liabilities	1,450	996
Total current liabilities	<u>30,061</u>	<u>26,723</u>
Long-term debt	4,673	4,789
Other long-term liabilities	5,308	4,601
Lease incentive obligation, less current portion	840	1,061
Total liabilities	<u>40,882</u>	<u>37,174</u>
Commitments and contingencies		
Stockholders' Equity:		
Preferred stock, \$0.01 par value Authorized—5,000,000 shares issued and outstanding—no shares at September 30, 2016 and December 31, 2015	—	—
Common stock, \$0.01 par value Authorized—200,000,000 shares issued and outstanding—108,410,279 and 96,674,786 shares at September 30, 2016 and December 31, 2015	1,084	967
Additional paid-in capital	1,070,083	904,932
Accumulated other comprehensive loss	(187)	(433)
Accumulated deficit	<u>(708,651)</u>	<u>(578,610)</u>
Total stockholders' equity	<u>362,329</u>	<u>326,856</u>
Total liabilities and stockholders' equity	<u>\$ 403,211</u>	<u>\$ 364,030</u>

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

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

	<u>Three Months Ended</u> <u>September 30,</u>		<u>Nine Months Ended</u> <u>September 30,</u>	
	<u>2016</u>	<u>2015</u>	<u>2016</u>	<u>2015</u>
Laboratory service revenue	\$ 28,115	\$ 12,632	\$ 64,135	\$ 25,017
Cost of sales	12,174	7,528	31,330	16,834
Gross margin	15,941	5,104	32,805	8,183
Operating expenses:				
Research and development	7,625	9,863	26,391	24,549
General and administrative	20,292	15,432	55,400	42,086
Sales and marketing	26,308	23,079	82,320	60,196
Total operating expenses	54,225	48,374	164,111	126,831
Loss from operations	(38,284)	(43,270)	(131,306)	(118,648)
Other income (expense)				
Investment income	535	365	1,426	780
Interest income (expense)	(54)	(40)	(161)	56
Total other income	481	325	1,265	836
Net loss	<u>\$ (37,803)</u>	<u>\$ (42,945)</u>	<u>\$ (130,041)</u>	<u>\$ (117,812)</u>
Net loss per share—basic and diluted	<u>\$ (0.36)</u>	<u>\$ (0.45)</u>	<u>\$ (1.30)</u>	<u>\$ (1.30)</u>
Weighted average common shares outstanding—basic and diluted	<u>104,807</u>	<u>94,444</u>	<u>100,006</u>	<u>90,696</u>

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

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2016	2015	2016	2015
Net loss	\$ (37,803)	\$ (42,945)	\$ (130,041)	\$ (117,812)
Other comprehensive loss, net of tax:				
Unrealized gain (loss) on available-for-sale investments	(145)	75	410	211
Foreign currency translation gain (loss)	(25)	91	(164)	59
Comprehensive loss	<u>\$ (37,973)</u>	<u>\$ (42,779)</u>	<u>\$ (129,795)</u>	<u>\$ (117,542)</u>

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

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

	Nine Months Ended September 30,	
	2016	2015
Cash flows from operating activities:		
Net loss	\$ (130,041)	\$ (117,812)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization of fixed assets	8,237	5,412
Loss on disposal of property and equipment	101	—
Stock-based compensation	16,773	13,148
Amortization of other liabilities	(713)	(399)
Amortization of deferred financing costs	40	33
Forgiveness of long-term debt	—	(1,000)
Amortization of premium on short-term investments	412	1,020
Amortization of intangible assets	150	—
Changes in assets and liabilities:		
Accounts receivable, net	(2,930)	(2,833)
Inventory, net	(989)	(2,015)
Prepaid expenses and other current assets	1,702	(1,907)
Accounts payable	(973)	(1,144)
Accrued liabilities	5,453	4,284
Lease incentive obligation	(159)	(415)
Accrued interest	—	(106)
Net cash used in operating activities	(102,937)	(103,734)
Cash flows from investing activities:		
Purchases of marketable securities	(151,456)	(197,997)
Maturities of marketable securities	142,813	109,826
Purchases of property and equipment	(12,166)	(14,019)
Net cash used in investing activities	(20,809)	(102,190)
Cash flows from financing activities:		
Proceeds from exercise of common stock options	1,049	961
Proceeds from sale of common stock, net of issuance costs	144,247	174,140
Payments on capital lease obligations	—	(360)
Proceeds from mortgage payable	—	3,756
Payments on mortgage payable	(124)	—
Proceeds in connection with the Company's employee stock purchase plan	1,048	759
Net cash provided by financing activities	146,220	179,256
Effects of exchange rate changes on cash and cash equivalents	(164)	59
Net increase (decrease) in cash and cash equivalents	22,310	(26,609)
Cash and cash equivalents, beginning of period	41,135	58,131
Cash and cash equivalents, end of period	<u>\$ 63,445</u>	<u>\$ 31,522</u>
Supplemental disclosure of non-cash investing and financing activities:		
Property and equipment acquired but not paid	\$ 549	\$ 3,521
Unrealized gain on available-for-sale investments	\$ 410	\$ 211
Issuance of 341,507 and 21,826 shares of common stock to fund the Company's 401(k) matching contribution for 2015 and 2014, respectively	\$ 2,151	\$ 835
Interest paid	\$ 157	\$ 9

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

EXACT SCIENCES CORPORATION
Notes to Condensed Consolidated Financial Statements
(Unaudited)

(1) ORGANIZATION AND BASIS OF PRESENTATION

Organization

Exact Sciences Corporation (“Exact” or the “Company”) was incorporated in February 1995. Exact is a molecular diagnostics company currently focused on the early detection and prevention of some of the deadliest forms of cancer. The Company has developed an accurate, non-invasive, patient-friendly screening test called Cologuard for the early detection of colorectal cancer and pre-cancer, and is currently working on the development of tests for other types of cancer.

Basis of Presentation

The accompanying condensed consolidated financial statements, which include the accounts of Exact Sciences Corporation and those of its wholly owned subsidiaries, Exact Sciences Laboratories, LLC, Exact Sciences Finance Corporation, Exact Sciences Europe LTD, Beijing Exact Sciences Medical Technology Company Limited, and variable interest entities 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, 2015 included in the Company’s Annual Report on Form 10-K (the “2015 Form 10-K”). These condensed consolidated financial statements are prepared in conformity with accounting principles generally accepted in the United States of America (“GAAP”) and follow the requirements of the Securities and Exchange Commission (“SEC”) for interim reporting. In the opinion of management, all adjustments (consisting only of adjustments of a normal and recurring nature) considered necessary for a fair presentation of the results of operations have been included. The results of the Company’s operations for any interim period are not necessarily indicative of the results of the Company’s operations for any other interim period or for a full fiscal year. The statements should be read in conjunction with the audited financial statements and related notes included in the 2015 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 subsidiaries, Exact Sciences Laboratories, LLC, Exact Sciences Finance Corporation, Exact Sciences Europe LTD, Beijing Exact Sciences Medical Technology Company Limited, and variable interest entities. All significant intercompany transactions and balances have been eliminated in consolidation.

References to “Exact”, “we”, “us”, “our”, or the “Company” refer to Exact Sciences Corporation and its wholly owned subsidiaries.

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.

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. 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, 2016 and December 31, 2015, the Company's investments were comprised of fixed income investments, and all were deemed available-for-sale. The objectives of the Company's investment strategy are to provide liquidity and safety of principal while striving to achieve the highest rate of return consistent with these two objectives. The Company's investment policy limits investments to certain types of instruments issued by institutions with investment grade credit ratings and places restrictions on maturities and concentration by type and issuer. Investments in which the Company has the ability and intent, if necessary, to liquidate in order to support its current operations (including those with a contractual term greater than one year from the date of purchase) are classified as current. All of the Company's investments are considered current. There were no realized losses for the nine months ended September 30, 2016 and 2015. Realized gains were \$21,000 and \$8,000 for the nine months ended September 30, 2016 and 2015, respectively.

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 nine months ended September 30, 2016, no investments were identified with other-than-temporary declines in value.

Available-for-sale securities at September 30, 2016 consisted of the following:

(In thousands)	September 30, 2016				Estimated Fair Value
	Amortized Cost	Gains in Accumulated Other Comprehensive Income	Losses in Accumulated Other Comprehensive Income		
Corporate bonds	\$ 143,221	\$ 27	\$ (88)	\$ 143,160	
Asset backed securities	56,542	18	(10)	56,550	
U.S. government agency securities	49,596	18	(4)	49,610	
Commercial paper	24,007	7	(1)	24,013	
Certificates of deposit	1,053	—	(1)	1,052	
Total available-for-sale securities	<u>\$ 274,419</u>	<u>\$ 70</u>	<u>\$ (104)</u>	<u>\$ 274,385</u>	

Available-for-sale securities at December 31, 2015 consisted of the following:

(In thousands)	December 31, 2015			
	Amortized Cost	Gains in Accumulated Other Comprehensive Income	Losses in Accumulated Other Comprehensive Income	Estimated Fair Value
Corporate bonds	\$ 179,471	\$ 2	\$ (262)	\$ 179,211
Asset backed securities	77,661	—	(166)	77,495
U.S. government agency securities	7,057	—	(18)	7,039
Certificates of deposit	1,999	—	—	1,999
Total available-for-sale securities	\$ 266,188	\$ 2	\$ (446)	\$ 265,744

Changes in Accumulated Other Comprehensive Income (Loss)

The amounts recognized in accumulated other comprehensive income (loss) (“AOCI”) for the nine months ended September 30, 2016 were as follows:

(In thousands)	Cumulative Translation Adjustment	Unrealized Gain (Loss) on Securities	Accumulated Other Comprehensive Income (Loss)
Balance at December 31, 2015	\$ 11	\$ (444)	\$ (433)
Other comprehensive (loss) income before reclassifications	(164)	346	182
Amounts reclassified from accumulated other comprehensive loss	—	64	64
Net current period change in accumulated other comprehensive (loss) income	(164)	410	246
Balance at September 30, 2016	\$ (153)	\$ (34)	\$ (187)

The amounts recognized in AOCI for the nine months ended September 30, 2015 were as follows:

(In thousands)	Cumulative Translation Adjustment	Unrealized Gain (Loss) on Securities	Accumulated Other Comprehensive Income (Loss)
Balance at December 31, 2014	\$ —	\$ (115)	\$ (115)
Other comprehensive (loss) income before reclassifications	59	224	283
Amounts reclassified from accumulated other comprehensive loss	—	(13)	(13)
Net current period change in accumulated other comprehensive (loss) income	59	211	270
Balance at September 30, 2015	\$ 59	\$ 96	\$ 155

Amounts reclassified from AOCI for the nine months ended September 30, 2016 and 2015 were as follows:

Details about AOCI Components (In thousands)	Affected Line Item in the Statement of Operations	Nine Months Ended September 30,	
		2016	2015
Change in value of available-for-sale investments			
Sales and maturities of available-for-sale investments	Investment income	\$ 64	\$ (13)
Total reclassifications		\$ 64	\$ (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
Computer equipment and computer software	3 years
Leasehold improvements	Lesser of the remaining lease term or useful life
Furniture and fixtures	3 years
Buildings	30 years

At September 30, 2016, the Company had \$6.5 million of assets under construction which consisted of \$0.1 million related to leasehold improvements, \$1.6 million related to computer equipment and computer software projects and \$4.8 million related to machinery and equipment. Depreciation will begin on these assets once they are placed into service. The Company expects to incur an additional \$0.2 million to complete the leasehold improvements, and minimal costs to complete the computer equipment and computer software projects and the machinery and equipment. These projects are expected to be completed in 2016. There were no impairment losses for the periods ended September 30, 2016 and December 31, 2015.

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 incurred during the application development stage that meet the criteria for capitalization are capitalized and amortized, when the software is ready for its intended use, using the straight-line basis over the estimated useful life of the software.

Patent Costs and Intangible Assets

Patent costs, which have historically consisted of related legal fees, are capitalized as incurred, only if the Company determines that there is some probable future economic benefit to be derived from the transaction. A capitalized patent is amortized over its estimated useful life, beginning when such patent is approved. Capitalized patent costs are expensed upon disapproval, upon a decision by the Company to no longer pursue the patent or when the related intellectual property is either sold or deemed to be no longer of value to the Company. The Company determined that all patent costs incurred during the nine months ended September 30, 2016 should be expensed and not capitalized as the future economic benefit to be derived from the transactions cannot be determined.

Under a technology license and royalty agreement entered into with MDx Health, the Company is required to pay MDx Health milestone-based royalties on sales of products or services covered by the licensed intellectual property. Once the achievement of a milestone has occurred or is considered probable, an intangible asset and corresponding liability is reported in other long-term assets and accrued expenses, respectively. The intangible asset is amortized over the estimated ten-year useful life of the licensed intellectual property, and such amortization is reported in cost of sales. The liability is relieved once the milestone has been achieved and payment has been made. As of September 30, 2016, an intangible asset of \$1.6 million and a liability of \$1.0 million were reported in other long-term assets and accrued expenses, respectively. As of December 31, 2015, an intangible asset of \$1.8 million and a liability of \$1.8 million were reported in other long-term assets and accrued expenses, respectively. Amortization expense for the nine months ended September 30, 2016 was \$0.2 million. There was no amortization expense recorded for the nine months ended September 30, 2015.

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)	September 30,	
	2016	2015
Shares issuable upon exercise of stock options	5,080	5,091
Shares issuable upon the release of restricted stock awards	5,989	2,383
	<u>11,069</u>	<u>7,474</u>

Revenue Recognition

Laboratory Service Revenue. The Company's revenues are generated by performing diagnostic services using its Cologuard test, and the service is completed upon delivery of a test result to an ordering physician. The Company recognizes revenue in accordance with the provisions of ASC 954-605, *Health Care Entities – Revenue Recognition*. The Company recognizes revenue related to billings for Medicare and other payors on an accrual basis, net of contractual and other adjustments, when amounts that will ultimately be collected can be reasonably estimated. Contractual and other adjustments represent the difference between the list price (the billing rate) and the estimated reimbursement rate for each payor. Upon ultimate collection, the amount received from Medicare and other payors where reimbursement was estimated is compared to previous collection estimates and, if necessary, the contractual allowance is adjusted.

The estimates of amounts that will ultimately be collected require significant judgment by management. Some patients 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-payments, deductibles and co-insurance in accordance with their insurance carrier and health plans. Some payors may not cover Cologuard as ordered by the prescribing physician under their reimbursement policies. In the absence of the ability to estimate the amount that will ultimately be collected for the Company's services, revenue is recognized upon cash receipt.

The Company uses judgment in determining if it is able to make an estimate of what will ultimately be collected. The Company also uses judgment in estimating the amounts it expects to collect by payor. The Company's judgments will continue to evolve in the future as it continues to gain payment experience with payors and patients.

The components of our revenue, as recognized upon accrual or cash receipt, for the three and nine months ended September 30, 2016 and 2015 were as follows:

(In thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Revenue recognized on an accrual basis	\$ 24,510	\$ 11,854	\$ 57,592	\$ 23,369
Revenue recognized when cash is received	3,605	778	6,543	1,648
Total	<u>\$ 28,115</u>	<u>\$ 12,632</u>	<u>\$ 64,135</u>	<u>\$ 25,017</u>

Inventory

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 net 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 net 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.

Inventory consists of the following:

(In thousands)	September 30, 2016	December 31, 2015
Raw materials	\$ 2,242	\$ 1,772
Semi-finished and finished goods	5,424	4,905
Total inventory	<u>\$ 7,666</u>	<u>\$ 6,677</u>

Foreign Currency Translation

For the Company's international subsidiaries, the local currency is the functional currency. Assets and liabilities of these subsidiaries are translated into United States dollars at the period-end exchange rate or historical rates, as appropriate. Condensed consolidated statements of operations are translated at average exchange rates for the period. The cumulative translation adjustments resulting from changes in exchange rates are included in the condensed consolidated balance sheet as a component of accumulated other comprehensive loss in total Exact Sciences Corporation's stockholders' equity. Transaction gains and losses are included in the condensed consolidated statement of operations.

Reclassifications

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

(3) MAYO LICENSE AGREEMENT

Overview

As more fully described in the 2015 Form 10-K, in June 2009 the Company entered into a patent license agreement with MAYO Foundation for Medical Education and Research ("MAYO"). The Company's license agreement with MAYO was amended and restated in February 2015 and further amended in January 2016. Under the license agreement, MAYO granted the Company an exclusive, worldwide license to certain MAYO patents and patent applications, as well as a non-exclusive, worldwide license with regard to certain MAYO know-how. As expanded by the January 2016 amendment to the license agreement, the scope of the license includes any screening, surveillance or diagnostic tests or tools for use in connection with any type of cancers, pre-cancers, diseases or conditions.

Pursuant to the Company's agreement with MAYO, the Company is required to pay MAYO a low-single-digit royalty on the Company's net sales of products using the licensed MAYO intellectual property, with minimum annual royalty fees of \$25,000 each year through 2033, the year the last patent expires. The January 2016 amendment to the MAYO license agreement established various low-single-digit royalty rates on net sales of current and future products and clarified how net sales will be calculated. As part of the amendment, the royalty rate on the Company's net sales of Cologuard increased and, if in the future, improvements are made to the Cologuard product, the royalty rate may further increase, but, pursuant to the terms of the January 2016 amendment, would remain a low-single-digit percentage of net sales.

In addition to royalties, the Company is required to issue stock or cash to MAYO upon achievement of several milestones. The Company is required to issue MAYO shares of the Company's common stock with a value of \$0.2 million upon commercial launch of our second and third products that use the licensed MAYO intellectual property.

Additionally, for the second and third products that use licensed MAYO intellectual property, the Company is required to pay MAYO cash of \$0.2 million upon commercialization and cash of \$0.2 million, \$0.8 million and \$2.0 million upon such product reaching \$5.0 million, \$20.0 million and \$50.0 million in cumulative net sales, respectively.

As part of the February 2015 amendment and restatement of the license agreement, the Company agreed to pay MAYO an additional \$5.0 million, payable in five annual installments, through 2019. The Company paid MAYO the annual installment of \$1.0 million in the first quarter of each of 2015 and 2016.

In addition, the Company is paying MAYO for research and development efforts. As part of the Company's research collaboration with MAYO, the Company incurred charges of \$0.8 million and \$2.6 million for the three and nine months ended September 30, 2016, respectively. The Company made payments of \$1.0 million and \$3.3 million for the three and nine months ended September 30, 2016, respectively. The Company has recorded an estimated liability of \$0.5 million for research and development efforts as of September 30, 2016. During the three and nine months ended September 30, 2015, the Company incurred charges of \$0.5 million and \$1.6 million, respectively, and made payments of \$0.9 million and \$2.4 million, respectively. The Company recorded an estimated liability of \$0.4 million for research and development efforts as of September 30, 2015.

(4) STOCK-BASED COMPENSATION

Stock-Based Compensation Plans

The Company's stock-based compensation plans include the 2010 Omnibus Long-Term Incentive Plan (As Amended and Restated Effective April 28, 2015), the 2010 Employee Stock Purchase Plan, the 2015 Inducement Award Plan, the 2016 Inducement Award Plan and the 2000 Stock Option and Incentive Plan (collectively, the "Stock Plans").

Stock-Based Compensation Expense

The Company records stock-based compensation expense 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 stock-based compensation expense of \$6.2 million and \$16.8 million, respectively, during the three and nine months ended September 30, 2016. The Company recorded stock-based compensation expense of \$4.9 million and \$13.1 million, respectively, during the three and nine months ended September 30, 2015.

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. The fair value of each market measure-based award is estimated on the date of grant using a Monte Carlo simulation pricing model. The fair value of service-based awards for each restricted stock unit award is determined on the date of grant using the closing stock price on that day. The estimated fair value of these awards is recognized to expense using the straight-line method over the vesting period. The Black-Scholes and Monte Carlo pricing models utilize the following assumptions:

Expected Term – Expected life of an option award is the average length of time over which the Company expects employees will exercise their options, which is based on historical experience with similar grants. Expected life of a market measure-based award is based on the applicable performance period.

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 and Monte Carlo valuation models on the implied yield currently available on U.S. Treasury zero-coupon issues with an equivalent expected term.

Forfeitures - The Company records stock-based compensation expense only for those awards that are expected to vest. A forfeiture rate is estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from initial estimates. The Company's forfeiture rate used in the nine months ended September 30, 2016 and 2015 was 3.48% and 4.99%, respectively.

The fair value of each option and market measure-based award is based on the assumptions in the following table:

	<u>Three Months Ended</u>		<u>Nine Months Ended</u>	
	<u>September 30,</u>		<u>September 30,</u>	
	<u>2016</u>	<u>2015</u>	<u>2016</u>	<u>2015</u>
Option Plan Shares				
Risk-free interest rates	(1)	(1)	1.48% - 1.69%	1.5% - 1.92%
Expected term (in years)	(1)	(1)	6.25 - 6.74	6.25 - 6.6
Expected volatility	(1)	(1)	58.9% - 59.4%	67.1% - 73.2%
Dividend yield	(1)	(1)	0%	0%
Weighted average fair value per share of options granted during the period	(1)	(1)	\$ 3.17	\$15.81
Market Measure-Based Shares				
Risk-free interest rates	0.76%	(2)	0.76% - 0.91%	(2)
Expected term (in years)	2.43	(2)	2.43 - 2.84	(2)
Expected volatility	79.6%	(2)	68.3% - 79.6%	(2)
Dividend yield	0%	(2)	0%	(2)
Weighted average fair value per share of stock purchase rights granted during the period	\$ 13.42	(2)	\$ 3.77	(2)
ESPP Shares				
Risk-free interest rates	(3)	(3)	0.41% - 0.8%	0.25% - 0.6%
Expected term (in years)	(3)	(3)	0.5 - 2	0.5 - 2
Expected volatility	(3)	(3)	70.1% - 92.7%	51.2% - 57.4%
Dividend yield	(3)	(3)	0%	0%
Weighted average fair value per share of stock purchase rights granted during the period	(3)	(3)	\$ 3.08	\$ 7.48

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

(2) The Company did not issue market measure-based shares during the respective period.

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

Stock Option and Restricted Stock Activity

A summary of stock option activity under the Stock Plans during the nine months ended September 30, 2016 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, December 31, 2015	4,936,594	\$ 4.80	4.5	
Granted	883,889	5.48		
Exercised	(681,427)	1.57		
Forfeited	(59,043)	9.75		
Outstanding, September 30, 2016	5,080,013	\$ 5.29	4.8	\$ 69,009
Exercisable, September 30, 2016	3,838,961	\$ 3.81	3.5	\$ 57,076
Vested and expected to vest, September 30, 2016	5,014,789	\$ 5.24	4.8	\$ 68,340

- (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 \$18.57 market price of the Company's common stock at September 30, 2016. The total intrinsic value of options exercised during the nine months ended September 30, 2016 and 2015 was \$5.6 million and \$2.0 million, respectively.

As of September 30, 2016, there was \$49.0 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 forfeitures. The Company expects to recognize that cost over a weighted average period of 2.6 years.

A summary of restricted stock and restricted stock unit activity under the Stock Plans during the nine months ended September 30, 2016 is as follows:

	Restricted Shares	Weighted Average Grant Date Fair Value
Outstanding, January 1, 2016	3,444,694	\$ 14.19
Granted	3,912,879	6.16
Released	(723,808)	17.11
Forfeited	(644,464)	9.78
Outstanding, September 30, 2016	5,989,301	\$ 8.82

(5) FAIR VALUE MEASUREMENTS

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

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

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

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 \$4.7 million and \$4.8 million as of September 30, 2016 and December 31, 2015, respectively, 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, 2016 along with the level within the fair value hierarchy in which the fair value measurements in their entirety fall.

(In thousands)	Fair Value at September 30, 2016	Fair Value Measurement at September 30, 2016 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	\$ 50,347	\$ 50,347	\$ —	\$ —
U.S. government agency securities	7,000	—	7,000	—
Commercial paper	5,498	—	5,498	—
Corporate bonds	600	—	600	—
Available-for-sale				
Marketable securities				
Corporate bonds	143,160	—	143,160	—
Asset backed securities	56,550	—	56,550	—
U.S. government agency securities	49,610	—	49,610	—
Commercial paper	24,013	—	24,013	—
Certificates of deposit	1,052	—	1,052	—
Total	\$ 337,830	\$ 50,347	\$ 287,483	\$ —

[Table of Contents](#)

The following table presents the Company's fair value measurements as of December 31, 2015 along with the level within the fair value hierarchy in which the fair value measurements in their entirety fall.

(In thousands)	Fair Value at December 31, 2015	Fair Value Measurement at December 31, 2015 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	\$ 37,435	\$ 37,435	\$ —	\$ —
Commercial paper	3,700	—	3,700	—
Available-for-sale				
Marketable securities				
Corporate bonds	179,211	—	179,211	—
Asset backed securities	77,495	—	77,495	—
U.S. government agency securities	7,039	—	7,039	—
Certificates of deposit	1,999	—	1,999	—
Total	\$ 306,879	\$ 37,435	\$ 269,444	\$ —

The following table summarizes gross unrealized losses and fair values of our investments in an unrealized loss position as of September 30, 2016, aggregated by investment category and length of time that individual securities have been in a continuous unrealized loss position:

(In thousands)	September 30, 2016					
	Less than 12 months		12 months or greater		Total	
	Fair Value	Gross Unrealized Loss	Fair Value	Gross Unrealized Loss	Fair Value	Gross Unrealized Loss
Marketable securities						
Corporate bonds	\$ 98,190	\$ (88)	\$ —	\$ —	\$ 98,190	\$ (88)
Asset backed securities	18,895	(8)	3,594	(2)	22,489	(10)
U.S. government agency securities	15,033	(4)	—	—	15,033	(4)
Commercial paper	8,444	(1)	—	—	8,444	(1)
Certificates of deposit	1,053	(1)	—	—	1,053	(1)
Total	\$ 141,615	\$ (102)	\$ 3,594	\$ (2)	\$ 145,209	\$ (104)

The following summarizes contractual underlying maturities of the Company's available-for-sale investments in debt securities at September 30, 2016:

(In thousands)	Due after one year through four years			
	Due one year or less		Due after one year through four years	
	Cost	Fair Value	Cost	Fair Value
Marketable securities				
Corporate bonds	\$ 124,796	\$ 124,774	\$ 18,425	\$ 18,386
Certificates of deposit	—	—	1,053	1,052
Commercial paper	24,007	24,013	—	—
U.S. government agency securities	4,559	4,566	45,037	45,044
Asset backed securities	—	—	56,542	56,550
Total	\$ 153,362	\$ 153,353	\$ 121,057	\$ 121,032

(6) NEW MARKET TAX CREDIT

As more fully described in the 2015 Form 10-K, during the fourth quarter of 2014, the Company received approximately \$2.4 million in net proceeds from financing agreements related to working capital and capital improvements at one of its Madison, Wisconsin facilities. This financing arrangement was structured with an unrelated

third party financial institution, an investment fund, and its majority owned community development entity in connection with the Company's participation in transactions qualified under the federal New Markets Tax Credit ("NMTC") program, pursuant to Section 45D of the Internal Revenue Code of 1986, as amended. The \$2.4 million was recorded in Other Long-Term Liabilities on the consolidated balance sheets. The benefit of this net \$2.4 million contribution will be recognized as a decrease in expenses, included in cost of sales, as the Company amortizes the contribution liability over the seven-year compliance period as it is being earned through the Company's on-going compliance with the conditions of the NMTC program. The Company has recorded \$0.1 million and \$0.3 million as a decrease of expenses for the three and nine months ended September 30, 2016. At September 30, 2016, the remaining balance of \$1.8 million is included in Other Long-Term Liabilities. The Company incurred approximately \$0.2 million of debt issuance costs related to the above transactions, which are being amortized over the life of the agreements.

(7) LONG-TERM DEBT

Building Purchase Mortgage

During June 2015, the Company entered into a \$5.1 million credit agreement with an unrelated third-party financial institution to finance the purchase of a facility located in Madison, Wisconsin. The credit agreement is collateralized by the acquired building.

Borrowings under the credit agreement bear interest at 4.15%. The Company made interest-only payments on the outstanding principal balance for the period between July 12, 2015 and September 12, 2015. Beginning on October 12, 2015 and continuing through May 12, 2019, the Company is required to make monthly principal and interest payments of \$31,000. The final principal and interest payment due on the maturity date of June 12, 2019 is \$4.4 million.

Additionally, the Company has recorded \$73,000 in mortgage issuance costs, which are recorded as a direct deduction from the mortgage liability. The issuance costs are being amortized through June 12, 2019. For the three and nine months ended September 30, 2016, the Company has recorded \$4,000 and \$13,000 in amortization of mortgage issuance costs.

(8) WISCONSIN ECONOMIC DEVELOPMENT TAX CREDITS

During the first quarter of 2015, the Company entered into an agreement with the Wisconsin Economic Development Corporation ("WEDC") to earn \$9.0 million in refundable tax credits if the Company expends \$26.3 million in capital investments and establishes and maintains 758 full-time positions in the state of Wisconsin over a seven-year period. The tax credits earned are first applied against the tax liability otherwise due, and if there is no such liability present, the claim for tax credits will be reimbursed in cash to the Company. The maximum amount of the refundable tax credit to be earned for each year is fixed, and the Company earns the credits by meeting certain capital investment and job creation thresholds over the seven-year period. Should the Company earn and receive the job creation tax credits but not maintain those full-time positions through the end of the agreement, the Company may be required to pay those credits back to the WEDC.

The Company records the earned tax credits as job creation and capital investments occur. The amount of tax credits earned is recorded as a liability and amortized as a reduction of operating expenses over the expected period of benefit. The tax credits earned from capital investment are recognized as an offset to depreciation expense over the expected life of the acquired capital assets. The tax credits earned related to job creation are recognized as an offset to operational expenses over the life of the agreement, as the Company is required to maintain the minimum level of full-time positions through the seven-year period.

As of September 30, 2016 the Company has earned \$4.0 million of tax credits and has received payment of \$0.2 million from the WEDC. The unpaid portion is \$3.8 million, of which \$0.9 million is reported in prepaid expenses and other current assets and \$2.9 million is reported in other long-term assets, reflecting when collection of the refundable tax credits is expected to occur. As of September 30, 2016, the Company also has recorded a \$0.8 million liability in other short-term liabilities and a \$2.5 million liability in other long-term liabilities, reflecting when the expected benefit of the tax credit amortization will reduce future operating expenses.

During the three and nine months ended September 30, 2016, the Company amortized \$0.2 million and \$0.5 million, respectively, of the tax credits earned as a reduction of operating expenses.

(9) EQUITY

On August 2, 2016 the Company completed an underwritten public offering of 9.8 million shares of common stock at a price of \$15.50 per share. The Company received approximately \$144.2 million of net proceeds from the offering, after deducting \$7.3 million for the underwriting discount and commissions and other stock issuance costs paid by the Company.

(10) RECENT ACCOUNTING PRONOUNCEMENTS

In August 2015, the Financial Accounting Standards Board issued Accounting Standards Update No. 2015-14, “*Revenue from Contracts with Customers: Deferral of the Effective Date*” (“Update 2015-14”) to defer for one year the effective date of Accounting Standards Update No. 2014-09, “*Revenue from Contracts with Customers*” (“Update 2014-09”) to annual reporting periods beginning after December 15, 2017 and allow early adoption as of the original effective date, which is for annual reports beginning after December 15, 2016. The Company is currently evaluating the impact of this amendment on the Company’s financial position and results of operations .

In February 2016, the Financial Accounting Standards Board issued Accounting Standards Update No. 2016-02, “*Leases (Topic 842)*,” which requires recognition of lease assets and lease liabilities by lessees for those leases classified as operating leases under previous GAAP. The amendments in this update are effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. In transition, lessees and lessors are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. The Company is currently evaluating the impact of this update on its financial position and results of operations .

In March 2016, the Financial Accounting Standards Board issued Accounting Standards Update No. 2016-08, “*Revenue from Contracts with Customers: Principal versus Agent Considerations (Reporting Revenue Gross versus Net)*” (“Update 2016-08”), which intends to improve the operability and understandability of the implementation guidance on principal versus agent considerations. An entity that is a principal recognizes revenue in the gross amount of consideration to which it expects to be entitled in exchange for the specified goods or service transferred. An entity that is an agent recognizes revenue in the amount of any fee of commission to which it expects to be entitled in exchange for arranging for the specified goods or services to be provided by the other party. The effective date and transition requirements for the amendments in Update 2016-08 are the same as the effective date and transition requirements of Update 2015-14. The Company is currently evaluating the impact of Update 2016-08 on its financial position and results of operations .

In March 2016, the Financial Accounting Standards Board issued Accounting Standards Update No. 2016-09, “*Compensation —Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*” as part of its Simplification Initiative. The areas for simplification in this update involve several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification in the statements of cash flows. The amendments in this update are effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. The Company is currently evaluating the impact of this update on its financial position and results of operations .

In April 2016, the Financial Accounting Standards Board issued Accounting Standards Update No. 2016-10, “*Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing*” (“Update 2016-10”), amending Update 2014-09 that was issued jointly with the International Accounting Standards Board in May 2014. The amendments do not change the core principles of the standard, but clarify the accounting for identifying performance obligations, as well as licensing implementation guidance. The effective date for the amendments in Update 2016-10 are the same as the effective date of Update 2015-14. The Company is currently evaluating the impact of Update 2016-10 on its financial position and results of operations.

In May 2016, the Financial Accounting Standards Board issued Accounting Standards Update No. 2016-12, “*Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients*” (“Update 2016-12”), amending Update 2014-09. The amendments do not change the core principles of Update 2014-09, but clarify matters related to assessment of a collectability criterion, presentation of sales and other taxes collected from customers, non-cash consideration, contract modifications at transition and completed contracts at transition. The effective date for the amendments in Update 2016-12 are the same as the effective date of Update 2015-14. The Company is currently evaluating the impact of Update 2016-12 on its financial position and results of operations.

In August 2016, the Financial Accounting Standards Board issued Accounting Standards Update No. 2016-15, “*Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments*” (“Update 2016-15”). Current GAAP either is unclear or does not include specific guidance on the eight cash flow classification issues included in the amendments in Update 2016-15. The amendments are an improvement to GAAP because they provide guidance for each of the eight issues, thereby reducing the current and potential future diversity in practice. The amendments in Update 2016-15 are effective for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. The Company is currently evaluating the impact of Update 2016-15 on its statements of cash flows.

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 subsidiaries, "Exact," "we," "us," "our" or the "Company") should be read in conjunction with the condensed consolidated financial statements and the related notes thereto included elsewhere in this Quarterly Report on Form 10-Q and the audited financial statements and notes thereto and Management's Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K for the year ended December 31, 2015, which has been filed with the SEC (the "2015 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 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. All statements other than statements of historical facts included in this Quarterly Report on Form 10-Q regarding our strategies, prospects, financial condition, operations, costs, plans and objectives are forward-looking statements. Examples of forward-looking statements include, among others, statements we make regarding expected future operating results, anticipated results of our sales and marketing efforts, expectations concerning payor reimbursement and the anticipated results of our product development efforts. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Our actual results and financial condition may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements. Important factors that could cause our actual results and financial condition to differ materially from those indicated in the forward-looking statements include, among others, the following: our ability to successfully and profitably market our products and services; the acceptance of our products and services by patients and healthcare providers; the willingness of health insurance companies and other payors to cover Cologuard and reimburse us for our performance of the Cologuard test; the amount and nature of competition from other cancer screening products and services; the effects of any healthcare reforms, including the Affordable Care Act, or changes in healthcare pricing, coverage and reimbursement; recommendations, guidelines and quality metrics issued by various organizations such as the U.S. Preventive Services Task Force, the American Cancer Society, and the National Committee for Quality Assurance regarding cancer screening or our products and services; our ability to successfully develop new products and services; our success establishing and maintaining collaborative licensing and supplier arrangements; our ability to maintain regulatory approvals and comply with applicable regulations; and the other risks and uncertainties described in the Risk Factors and in Management's Discussion and Analysis of Financial Condition and Results of Operations sections on the 2015 Form 10-K and our subsequently filed Quarterly Reports on Form 10-Q. We undertake no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

Overview

We are a molecular diagnostics company currently focused on the early detection and prevention of some of the deadliest forms of cancer. We have developed an accurate, non-invasive, patient-friendly screening test called Cologuard®, for the early detection of colorectal cancer and pre-cancer, and are currently working on the development of tests for other types of cancer.

Our Cologuard Test

Colorectal cancer is the second leading cause of cancer deaths in the United States and the leading cause of cancer deaths among non-smokers. Each year there are:

- 135,000 new cases in the U.S.
- 50,000 deaths in the U.S.

Colorectal cancer treatment represents a significant and growing healthcare cost. Annually, \$14 billion is spent in the U.S. on colorectal cancer treatment, and the projected annual treatment costs are expected to be \$20 billion in 2020. The incidence of colorectal cancer in Medicare patients is expected to rise from 106,000 cases in 2010 to more than 180,000 cases in 2030.

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 U.S. 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 colorectal cancer diagnosed at stages 3 and 4 are 67 percent and 12 percent, respectively. We believe the large underserved population of unscreened and inadequately screened patients represents a significant opportunity for a patient-friendly screening test.

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

On August 11, 2014 the U.S. Food and Drug Administration (“FDA”) approved Cologuard for use as the first and only sDNA non-invasive colorectal cancer screening test. Our submission to the FDA for Cologuard included the results of our pivotal Deep-C clinical trial that had over 10,000 patients enrolled at 90 enrollment sites in the U.S. and Canada. The results of our Deep-C clinical trial for Cologuard were published in the *New England Journal of Medicine* in April 2014. The peer-reviewed study, “Multi-target Stool DNA Testing for Colorectal-Cancer Screening,” highlighted the performance of Cologuard in the trial population:

- Cancer Sensitivity: 92%
- High-Grade Dysplasia Sensitivity: 69%
- Specificity: 87%

The competitive advantages of sDNA-based screening provide a significant market opportunity. Assuming a 30% test adoption rate and a three-year screening interval, we estimate the potential U.S. market for sDNA screening to be more than \$4 billion, annually.

Our-Cologuard Commercialization Strategy

Our commercialization strategy includes three main elements with a focus on physicians, patients, and payors.

Physicians and Patients

Our sales team actively engages with physicians and their staffs to emphasize the need for colorectal cancer screening, educate them on the benefits of Cologuard, and enroll them in our physician ordering system to enable them to prescribe the test. We are focused on specific physicians based on Cologuard order history. We are also focused on physician groups and larger regional and national health systems.

In June 2016, the US Preventive Services Task Force (“USPSTF”) issued an updated recommendation statement for colorectal cancer screening, and gave an “A” grade to colorectal cancer screening starting at age 50 and continuing until age 75. The statement specifies seven screening methods, including FIT-DNA (which is Cologuard). The updated USPSTF recommendation statement may have certain potentially significant implications. For example, the Affordable Care Act (“ACA”) mandates that certain health insurers cover evidence-based items or services that have in effect a rating of “A” or “B” in the current recommendations of USPSTF without imposing any patient cost-sharing. Similarly, federal regulations require that Medicare Advantage plans cover “A” or “B” graded preventive services without patient cost-sharing. Following the updated USPSTF recommendation statement, the Centers for Medicare & Medicaid Services (“CMS”) issued an updated Evidence of Coverage notice for Medicare Advantage plans that affirms such plans must include coverage of Cologuard every three years without patient cost-sharing. While we believe the ACA mandate will require certain health insurers to cover Cologuard without patient cost-sharing (following an initial phase in period between one and two years), it is possible that certain health insurers will disagree, in which case courts and/or government agencies may need to resolve this matter.

In October 2016, the National Committee for Quality Assurance (“NCQA”) included Cologuard testing on a three-year interval in the final published 2017 Healthcare Effectiveness Data and Information Set (“HEDIS”) measures. More than 90 percent of America’s health plans measure quality based on HEDIS. Because Cologuard is included in the HEDIS measures, we expect that it will also be included in the CMS Star Ratings, which use the HEDIS as the primary data source to guide quality measures for Medicare Advantage plans. The public comment period for the 2018 Star Ratings will be announced in November 2016. The updated Star Ratings are expected to be published in February 2017.

Securing inclusion in guidelines is a key part of our physician engagement strategy since many physicians rely on such guidelines when making screening recommendations. Professional colorectal cancer screening guidelines in the U.S., including those of the ACS, the American College of Gastroenterology (“ACG”), the American Gastroenterological Association (“AGA”) and the National Comprehensive Cancer Network (“NCCN”), recommend regular screening by a variety of methods. Since 2008, joint colorectal cancer screening guidelines endorsed by the ACS and the U.S. Multi-Society Task Force on Colorectal Cancer (“CRC Task Force”) have included sDNA screening technology in national colorectal cancer screening guidelines as a screening option for the detection of colorectal cancer in average risk, asymptomatic individuals age 50 and older. The CRC Task Force is a consortium of several organizations that includes representatives of the ACG, AGA, the American Society for Gastrointestinal Endoscopy and the American College of Physicians/Society of Internal Medicine. In October 2014 the ACS updated its colorectal cancer screening guidelines to specifically include Cologuard as a recommended sDNA screening test. In June 2016, the NCCN updated its Colorectal Cancer Screening Guidelines to add sDNA screening, at a once-every- three-years interval, to its list of recommended screening tests.

A critical part of the value proposition of Cologuard is our compliance program, which involves active engagement with patients and physicians. This activity is focused on enabling patients to complete Cologuard tests that have been ordered for them by their physicians and supporting physicians in their efforts to have their patients screened.

After the launch of Cologuard, we initiated a significant public relations effort to engage patients. We have conducted targeted direct-to-patient advertising campaigns through social media, print and other channels. In early 2016 we began to test television advertising in select markets, and due to the success in the test markets, began a national television advertising campaign in April 2016.

Payors

The cornerstone of our payor-engagement strategy was securing coverage from CMS. Medicare covers 46% of patients in the screening population for Cologuard. On October 9, 2014, CMS issued a final National Coverage Determination (“NCD”) for Cologuard following a parallel review process with FDA. Cologuard was the first screening test approved by FDA and covered by CMS through that process. As outlined in the NCD, Medicare Part B covers Cologuard once every three years for beneficiaries who meet all of the following criteria.

- Age 50 to 85 years,
- Asymptomatic (no signs or symptoms of colorectal disease including but not limited to lower gastrointestinal pain, blood in stool, positive guaiac fecal occult blood test or fecal immunochemical test), and
- At average risk for developing colorectal cancer (no personal history of adenomatous polyps, colorectal cancer, or inflammatory bowel disease, including Crohn’s Disease and ulcerative colitis; no family history of colorectal cancers or adenomatous polyps, familial adenomatous polyposis, or hereditary non-polyposis colorectal cancer).

In the 2016 Clinical Laboratory Fee Schedule, CMS established reimbursement for Cologuard at \$508.87. Payments from CMS are subject to sequestration. Under the Protecting Access to Medicare Act of 2014, effective January 1, 2018, the CMS reimbursement rate for Cologuard will be calculated based on the volume-weighted median of private payor rates for Cologuard. The initial data collection period for that purpose will be the period between January 1, 2016 and June 30, 2016. The CMS reimbursement rate will subsequently be reset every three years, or every year if the Company applies for, and is granted, Advanced Diagnostic Laboratory Test status for Cologuard, based on the volume-weighted median of private payor rates experienced in the applicable six-month data collection period.

In addition to Medicare reimbursement, we believe it is necessary to secure favorable coverage and reimbursement from commercial payors in order for Cologuard to achieve its full commercial potential. Some commercial payors have issued positive coverage decisions for Cologuard and others have agreed to cover Cologuard as an in-network service. We believe that commercial payors’ reimbursement of Cologuard will depend on a number of factors, including payors’ determination that it is: sensitive and specific for colorectal cancer; not experimental or investigational; approved or recommended by major organizations’ guidelines; reliable, safe and effective; medically necessary; appropriate for the specific patient; and cost-effective. Coverage may also depend, in whole or in part, on whether payors determine, or courts and/or governmental agencies determine, coverage is required under the ACA mandate or coverage mandates under the laws of several states. We are pursuing a variety of strategies to increase commercial payor coverage for Cologuard including providing cost effectiveness data to payors to make the case for Cologuard reimbursement. We are focusing our efforts on large national and regional insurers, insurers in states with coverage mandates for colorectal cancer screening and health plans that have affiliated health systems. In certain situations where we believe payors are legally required to cover Cologuard, we have sued to enforce those coverage obligations. We may consider similar litigation in the future.

We believe quality metrics may shape payors’ coverage decisions, as well as physicians’ cancer screening procedures. Some government and private payors are adopting pay-for-performance programs that differentiate payments for healthcare services based on the achievement of documented quality metrics, cost efficiencies or patient outcomes. Payors may look to quality measures such as the HEDIS and CMS Star Ratings measures to assess quality of care. We believe inclusion of Cologuard in the HEDIS measures and Star Ratings measures (if the Star Ratings are revised to include Cologuard, as we expect) may influence some payors’ willingness to reimburse our Cologuard test as well as some physicians’ willingness to prescribe Cologuard.

Our Clinical Lab Facility

As part of our commercialization strategy, we also established a state-of-the-art, highly automated laboratory facility that is certified pursuant to federal Clinical Laboratory Improvement Amendments requirements to process Cologuard tests and provide patient results. Our commercial lab operation is housed in a 32,000 square foot facility in Madison, Wisconsin. At our lab, we currently have the capacity to process approximately one million tests per year, and we have capacity to expand, if needed.

Product Pipeline

We also are focused on developing our pipeline for future products and services. We are continuing to collaborate with MAYO Foundation for Medical Education and Research (“MAYO”) on future tests, including for the detection of lung and other cancers. ACS estimates that lung cancer will be diagnosed in 224,000 Americans and cause 158,000 deaths in the United States this year. Currently, more than half of lung cancer cases are diagnosed at an advanced stage, after symptoms appear, when the five-year survival rate is in the low single digits. If detected at an early stage, lung cancer's five-year survival rate can be as high as 80%. Our current focus for lung cancer is to develop a blood test to aid in the detection of cancer in individuals with lung nodules discovered through a CT or other scan.

We also plan to continue to explore opportunities for improving Cologuard, including improvements that could lower our cost of sales.

How We Recognize Revenue

A portion of our revenue is recognized upon cash receipt, as we are currently unable to estimate the amount that will ultimately be collected from many payors. For tests performed where we have an agreed-upon reimbursement rate or where we can estimate the amount that we will ultimately collect at the time delivery is complete, such as in the case of Medicare and certain other payors, we recognize the related revenue on an accrual basis upon delivery of a test result to an ordering physician. Accrual rates are based on the established billing rates less contractual and other adjustments, which arrive at the amount that we expect to ultimately collect. We determine the amount we expect to ultimately collect based on a per-payor or per-agreement basis. The expected amount is typically lower than, if applicable, the agreed-upon reimbursement amount due to several factors, such as the amount of any patient co-payments, the existence of secondary payors and claim denials. Upon ultimate collection, the amount received from Medicare and other payors where reimbursement was estimated is compared to previous collection estimates and, if necessary, the contractual allowance is adjusted. Finally, should we recognize revenue from payors on an accrual basis and later determine the judgments underlying estimated collections change, our financial results could be negatively impacted in future quarters.

Generally, cash payments are collected within six months of the date the test is billed. Notwithstanding our efforts to obtain payment for these tests, payors may deny our claims, in whole or in part, and if patients fail to pay the balance, we may never receive revenue from previously performed but unpaid tests. Revenue from these tests, if any, may not be equal to the billed amount due to a number of factors, including differences in reimbursement rates, the amounts of patient co-payments and co-insurance, the existence of secondary payors, claims denials and our ability to bill unpaid payor balances to, and collect them from, patients.

Our average reimbursement per test, as further defined below, was approximately \$393 through September 30, 2016. This cumulative average Cologuard reimbursement rate will change over time due to a number of factors, including medical coverage decisions by payors, the effects of contracts signed with payors, changes in allowed amounts by payors, our ability to successfully win appeals for payment, settlements reached with payors regarding previously denied claims and our ability to collect cash payments from payors and individual patients. Historical average reimbursement is not necessarily indicative of future average reimbursement.

We calculate the average Cologuard reimbursement from all payors on a trailing twelve-month basis, whether they are on a cash or an accrual basis, for tests that are at least six months old, since it can take a significant period of time to collect from some payors. Thus, the average reimbursement per test represents the total cash collected to date against tests performed during the relevant period divided by the number of tests performed during that same period.

We incur expense for tests in the period in which the testing activities occur and recognize revenue for tests in the period in which our revenue recognition criteria are met. Accordingly, any revenue that we recognize as a result of cash collection in respect of previously performed but unpaid tests will favorably impact our liquidity and results of operations in future periods.

[Table of Contents](#)

The components of our revenue, as recognized upon accrual or cash receipt, for the three and nine months ended September 30, 2016 and 2015 were as follows:

(In thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Revenue recognized on an accrual basis	\$24,510	\$11,854	\$57,592	\$23,369
Revenue recognized when cash is received	3,605	778	6,543	1,648
Total	\$28,115	\$12,632	\$64,135	\$25,017

Of the revenue recognized in the three and nine months ended September 30, 2016, approximately \$0.9 million and \$2.0 million, respectively, relates to tests processed in the prior year for which our accrual revenue recognition criteria were not met and for which we waited to recognize revenue until cash was received.

2016 Priorities

Our top priorities for 2016 include (1) growing revenue for Cologuard, (2) enhancing our infrastructure to support the growth of Cologuard and future products and (3) improving Cologuard, including reducing its cost.

We will also focus on developing our pipeline for future products as outlined in the Product Pipeline section above.

Results of Operations

We have generated limited operating revenues since inception and, as of September 30, 2016, we had an accumulated deficit of approximately \$708.7 million. We expect to continue to incur losses for the near future, and it is possible we may never achieve profitability.

Laboratory service revenue. Our laboratory service revenue is generated by performing diagnostic services using our Cologuard test. For the three months ended September 30, 2016 and 2015, the Company completed approximately 68,000 and 34,000 Cologuard tests, respectively, and generated laboratory service revenue of \$28.1 million and \$12.6 million, respectively. For the nine months ended September 30, 2016 and 2015, the Company completed approximately 162,000 and 66,000 Cologuard tests, respectively, and generated total laboratory service revenue of \$64.1 million and \$25.0 million, respectively. The increase in revenue was primarily due to an increase in completed Cologuard tests during the current period.

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, shipment of test collection kits, royalties 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 payors and patients.

Cost of Sales. Cost of sales includes costs related to inventory production and usage, shipment of test collection kits, royalties and the cost of laboratory services to process tests and provide results to physicians. Cost of sales increased to \$12.2 million for the three months ended September 30, 2016 compared to \$7.5 million for the three months ended September 30, 2015. Cost of sales increased to \$31.3 million for the nine months ended September 30, 2016 compared to \$16.8 million for the nine months ended September 30, 2015. The increases in cost of sales were primarily due to increases in completed Cologuard tests. The Company completed approximately 68,000 and 34,000 Cologuard tests for the three months ended September 30, 2016 and 2015, respectively. The Company completed approximately 162,000 and 66,000 Cologuard tests for the nine months ended September 30, 2016 and 2015, respectively.

(In millions)	Three Months Ended September 30,		
	2016	2015	Change
Production costs	\$ 8.3	\$ 4.9	\$ 3.4
Facility and support expenses	1.9	1.1	0.8
Personnel expenses	1.7	1.3	0.4
Stock-based compensation	0.3	0.2	0.1
Total cost of sales expenses	\$ 12.2	\$ 7.5	\$ 4.7

(In millions)	Nine Months Ended September 30,		
	2016	2015	Change
Production costs	\$ 20.2	\$ 9.2	\$ 11.0
Facility and support expenses	5.3	2.8	2.5
Personnel expenses	5.0	4.1	0.9
Stock-based compensation	0.8	0.6	0.2
Other cost of sales	—	0.1	(0.1)
Total cost of sales expenses	\$ 31.3	\$ 16.8	\$ 14.5

Research and development expenses . Research and development expenses decreased to \$7.6 million for the three months ended September 30, 2016 compared to \$9.9 million for the three months ended September 30, 2015. The decrease in research and development expenses was primarily due to a reduction in direct research and development expenses as a result of the February 2016 termination of our agreement with MD Anderson which is more fully described in the 2015 Form 10-K. Research and development expenses increased to \$26.4 million for the nine months ended September 30, 2016 compared to \$24.5 million for the nine months ended September 30, 2015. The increase in research and development expenses was primarily due to an increased investment in Cologuard improvements and the development of pipeline products.

(In millions)	Three Months Ended September 30,		
	2016	2015	Change
Direct research and development expenses	\$ 2.9	\$ 4.7	\$ (1.8)
Personnel expenses	2.6	2.5	0.1
Stock-based compensation	1.0	0.9	0.1
Other research and development	0.6	0.9	(0.3)
Legal and professional fees	0.5	0.9	(0.4)
Total research and development expenses	\$ 7.6	\$ 9.9	\$ (2.3)

(In millions)	Nine Months Ended September 30,		
	2016	2015	Change
Direct research and development expenses	\$ 10.8	\$ 8.8	\$ 2.0
Personnel expenses	8.8	7.0	1.8
Stock-based compensation	3.0	2.7	0.3
Other research and development	2.2	1.9	0.3
Legal and professional fees	1.6	4.1	(2.5)
Total research and development expenses	\$ 26.4	\$ 24.5	\$ 1.9

General and administrative expenses . General and administrative expenses increased to \$20.3 million for the three months ended September 30, 2016 compared to \$15.4 million for the three months ended September 30, 2015. General and administrative expenses increased to \$55.4 million for the nine months ended September 30, 2016 compared to \$42.1 million for the nine months ended September 30, 2015. The increase in general and administrative expenses was primarily a result of increased personnel costs and stock-based compensation expense due to increased headcount and additional facility and information technology costs to support the needs of our growing infrastructure and overall growth of the Company.

(In millions)	Three Months Ended September 30,		
	2016	2015	Change
Personnel expenses	\$ 7.4	\$ 5.2	\$ 2.2
Facility and support expenses	4.1	2.7	1.4
Stock-based compensation	3.9	3.0	0.9
Legal and professional fees	3.4	3.1	0.3
Other general and administrative	1.5	1.4	0.1
Total general and administrative expenses	<u>\$ 20.3</u>	<u>\$ 15.4</u>	<u>\$ 4.9</u>

(In millions)	Nine Months Ended September 30,		
	2016	2015	Change
Personnel expenses	\$ 21.4	\$ 13.4	\$ 8.0
Facility and support expenses	11.7	8.3	3.4
Stock-based compensation	10.0	7.0	3.0
Legal and professional fees	8.9	10.0	(1.1)
Other general and administrative	3.4	3.4	—
Total general and administrative expenses	<u>\$ 55.4</u>	<u>\$ 42.1</u>	<u>\$ 13.3</u>

Sales and marketing expenses. Sales and marketing expenses increased to \$26.3 million for the three months ended September 30, 2016 compared to \$23.1 million for the three months ended September 30, 2015. Sales and marketing expenses increased to \$82.3 million for the nine months ended September 30, 2016 compared to \$60.2 million for the nine months ended September 30, 2015. The increase in sales and marketing expenses was a result of hiring additional sales and marketing personnel and increasing our advertising and patient marketing efforts related to the commercialization of our Cologuard test.

(In millions)	Three Months Ended September 30,		
	2016	2015	Change
Personnel expenses	\$ 15.0	\$ 12.8	\$ 2.2
Direct marketing costs and professional fees	10.0	9.0	1.0
Stock-based compensation	1.0	0.8	0.2
Other sales and marketing	0.3	0.5	(0.2)
Total sales and marketing expenses	<u>\$ 26.3</u>	<u>\$ 23.1</u>	<u>\$ 3.2</u>

(In millions)	Nine Months Ended September 30,		
	2016	2015	Change
Personnel expenses	\$ 42.9	\$ 35.1	\$ 7.8
Direct marketing costs and professional fees	35.6	21.4	14.2
Stock-based compensation	3.0	2.7	0.3
Other sales and marketing	0.8	1.0	(0.2)
Total sales and marketing expenses	<u>\$ 82.3</u>	<u>\$ 60.2</u>	<u>\$ 22.1</u>

Investment income . Investment income increased to \$0.5 million for the three months ended September 30, 2016 compared to \$0.4 million for the three months ended September 30, 2015. Investment income increased to \$1.4 million for the nine months ended September 30, 2016 compared to \$0.8 million for the nine months ended September 30, 2015. The increase in investment income was due to a higher return on investments for the three and nine months ended September 30, 2016 when compared to the same period in 2015.

Interest income and expense. Net interest expense of \$54,000 was realized for the three months ended September 30, 2016 compared to net interest expense of \$40,000 for the three months ended September 30, 2015. Net interest expense of \$0.2 million was realized for the nine months ended September 30, 2016 compared to net interest income of \$56,000 for the nine months ended September 30, 2015. The increases in net interest expense were primarily related to interest expense on our building mortgage, which was entered into in June 2015. Additionally, during the nine months ended September 30, 2015 the Company recognized interest income of \$0.1 million due to the forgiveness of accrued interest expense previously recorded. This was triggered by the forgiveness of a \$1.0 million loan with the Wisconsin Department of Commerce based on the terms of the original debt agreement, which is more fully described in the 2015 Form 10-K.

Liquidity and Capital Resources

We have financed our operations since inception primarily through private and public offerings of our common stock and through revenue generated by the sale of Cologuard. As of September 30, 2016, we had approximately \$63.4 million in cash and cash equivalents and approximately \$274.4 million in marketable securities.

All of our investments in marketable securities consist 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. 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 \$102.9 million for the nine months ended September 30, 2016 as compared to \$103.7 million for the nine months ended September 30, 2015. The principal use of cash in operating activities for the nine months ended September 30, 2016 was to fund our net loss. Our net loss increased from the nine months ended September 30, 2015 primarily due to increased sales and marketing efforts and general and administrative costs to support the commercialization of Cologuard and our overall growth.

Net cash used in investing activities was \$20.8 million for the nine months ended September 30, 2016 as compared to \$102.2 million for the nine months ended September 30, 2015. The decrease in cash used in investing activities for the nine months ended September 30, 2016 compared to the same period in 2015 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 \$12.2 million and \$14.0 million for the nine months ended September 30, 2016 and 2015, respectively.

Net cash provided by financing activities was \$146.2 million for the nine months ended September 30, 2016, as compared to \$179.3 million for the nine months ended September 30, 2015. The decrease in cash provided by financing activities for the nine months ended September 30, 2016 compared to the same period in 2015 was primarily the result of lower proceeds from sale of common stock. Excluding the impact of proceeds from the sale of common stock, net cash provided by financing activities was \$2.0 million and \$5.1 million for the nine months ended September 30, 2016 and 2015, respectively. The decrease in cash provided by financing activities, excluding proceeds from the sale of common stock, occurred because there were no new mortgage proceeds during the nine months ended September 30, 2016, as were received in June 2015 when we financed our purchase of a facility located in Madison, Wisconsin.

We expect that cash and cash equivalents and marketable securities on hand at September 30, 2016 will be sufficient to fund our current operations for at least the next twelve months, based on current operating plans. However, we may need to raise additional capital to fully fund our current strategic plan, which includes successfully commercializing Cologuard and developing a pipeline of future products. 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.

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 our 2015 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

Laboratory service revenue. Our laboratory service revenues are generated by performing diagnostic services using our Cologuard test, and the service is completed upon delivery of a test result to an ordering physician. We recognize revenue in accordance with provision of the ASC 954-605, *Health Care Entities – Revenue Recognition*. We recognize revenue related to billings for Medicare and other payors on an accrual basis, net of contractual and other adjustments, when amounts that will ultimately be collected can be reasonably estimated. Contractual and other adjustments represent the difference between the list price (the billing rate) and the estimated reimbursement rate for each payor. Upon ultimate collection, the amount received from Medicare and other payors where reimbursement was estimated is compared to previous collection estimates and, if necessary, the contractual allowance is adjusted.

The estimates of amounts that will ultimately be collected requires significant judgment by management. Some patients 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-payments, deductibles and co-insurance in accordance with their insurance carrier and health plans. Some payors may not cover Cologuard as ordered by the prescribing physician under their reimbursement policies. In the absence of the ability to reasonably estimate the amount that will ultimately be collected for our services, revenue is recognized upon cash receipt.

We use judgment in determining if we are able to make a reasonable estimate of what will ultimately be collected. We also use judgment in estimating the amounts we expect to collect by payor. Our judgments will continue to evolve in the future as we continue to gain payment experience with payors and patients.

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 net 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 net 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.

Stock-Based Compensation. In accordance with GAAP, all stock-based payments, including grants of employee stock options, restricted stock and restricted stock units, market measure-based awards 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, market measure-based awards 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 fair value of each market measure-based award is estimated on the date of grant using a Monte Carlo simulation pricing model. The fair value of service-based awards for each restricted stock unit award is determined on the date of grant using the closing stock price on that day. The

estimated fair value of these awards is recognized to expense using the straight-line method over the vesting period. The Black-Scholes and Monte Carlo pricing models utilize the following assumptions:

- **Expected Term** - Expected life of an option award is the average length of time over which the Company expects employees will exercise their options, which is based on historical experience with similar grants. Expected life of a market measure-based award is based on the applicable performance period.
- **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 and Monte Carlo valuation models on the implied yield currently available on U.S. Treasury zero-coupon issues with an equivalent expected term.
- **Forfeitures** - The Company records stock-based compensation expense only for those awards that are expected to vest. A forfeiture rate is estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from initial estimates. The Company's forfeiture rate used in the nine months ended September 30, 2016 and 2015 was 3.48% and 4.99%, respectively.

The fair value of each award is estimated on the date of grant based on the assumptions noted above and as further described in Note 4 to our condensed consolidated financial statements.

Recent Accounting Pronouncements

In August 2015, the Financial Accounting Standards Board issued Accounting Standards Update No. 2015-14, "*Revenue from Contracts with Customers: Deferral of the Effective Date*" ("Update 2015-14") to defer for one year the effective date of Accounting Standards Update No. 2014-09, "*Revenue from Contracts with Customers*" (Update 2014-09) to annual reporting periods beginning after December 15, 2017 and allow early adoption as of the original effective date, which is for annual reports beginning after December 15, 2016. We are currently evaluating the impact of Update 2015-14 on our financial position and results of operations .

In February 2016, the Financial Accounting Standards Board issued Accounting Standards Update No. 2016-02, "*Leases (Topic 842)*," which requires recognition of lease assets and lease liabilities by lessees for those leases classified as operating leases under previous GAAP. The amendments in this update are effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. In transition, lessees and lessors are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. We are currently evaluating the impact of this update on our financial position and results of operations .

In March 2016, the Financial Accounting Standards Board issued Accounting Standards Update No. 2016-08, "*Revenue from Contracts with Customers: Principal versus Agent Considerations (Reporting Revenue Gross versus Net)*" ("Update 2016-08"), which intends to improve the operability and understandability of the implementation guidance on principal versus agent considerations. An entity that is a principal recognizes revenue in the gross amount of consideration to which it expects to be entitled in exchange for the specified goods or service transferred. An entity that is an agent recognizes revenue in the amount of any fee of commission to which it expects to be entitled in exchange for arranging for the specified goods or services to be provided by the other party. The effective date and transition requirements for the amendments in Update 2016-08 are the same as the effective date and transition requirements of Update 2015-14. We are currently evaluating the impact of Update 2016-08 on our financial position and results of operations .

In March 2016, the Financial Accounting Standards Board issued Accounting Standards Update No. 2016-09, "*Compensation —Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*" as part of its Simplification Initiative. The areas for simplification in this accounting standards update involve several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification in the statements of cash flows. The amendments in this

accounting standards update are effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. We are currently evaluating the impact of this accounting standards update on our financial position and results of operations .

In April 2016, the Financial Accounting Standards Board issued Accounting Standards Update No. 2016-10, “*Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing*” (“Update 2016-10”), amending Update 2014-09 that was issued jointly with the International Accounting Standards Board in May 2014. The amendments do not change the core principles of the standard, but clarify the accounting for identifying performance obligations, as well as licensing implementation guidance. The effective date for the amendments in Update 2016-10 are the same as the effective date of Update 2015-14. We are currently evaluating the impact of Update 2016-10 on our financial position and results of operations.

In May 2016, the Financial Accounting Standards Board issued Accounting Standards Update No. 2016-12, “*Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients*” (“Update 2016-12”), amending Update 2014-09. The amendments do not change the core principles of Update 2014-09, but clarify matters related to assessment of a collectability criterion, presentation of sales and other taxes collected from customers, non-cash consideration, contract modifications at transition and completed contracts at transition. The effective date for the amendments in Update 2016-12 are the same as the effective date of Update 2015-14. We are currently evaluating the impact of Update 2016-12 on our financial position and results of operations.

In August 2016, the Financial Accounting Standards Board issued Accounting Standards Update No. 2016-15, “*Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments*” (“Update 2016-15”). Current GAAP either is unclear or does not include specific guidance on the eight cash flow classification issues included in the amendments in Update 2016-15. The amendments are an improvement to GAAP because they provide guidance for each of the eight issues, thereby reducing the current and potential future diversity in practice. The amendments in Update 2016-15 are effective for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. We are currently evaluating the impact of Update 2016-15 on our statements of cash flows.

Off-Balance Sheet Arrangements

As of September 30, 2016, 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, 2016 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, 2016, 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

We are not currently a party to any pending legal proceedings that we believe will have a material adverse effect on our business, financial condition or results of operations. We may, however, be subject to various claims and legal actions arising in the ordinary course of business from time to time.

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" on the 2015 Form 10-K. There have been no material changes to the risk factors described in the 2015 Form 10-K.

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.

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 26, 2016

By: /s/ Kevin T. Conroy
Kevin T. Conroy
President and Chief Executive Officer
(*Principal Executive Officer*)

Date: October 26, 2016

By: /s/ John K. Bakewell
John K. Bakewell
Chief Financial Officer
(*Principal Financial and Accounting Officer*)

EXHIBIT INDEX

Exhibit Number	Description
3.1	Sixth Amended and Restated Certificate of Incorporation of the Registrant (previously filed as Exhibit 3.3 to the Registrant's Registration Statement on Form S - 1 (File No. 333 - 48812), filed on October 27, 2000, and incorporated herein by reference)
3.2	First Amendment to Sixth Amended and Restated Certificate of Incorporation of the Registrant (previously filed as Appendix B to the Definitive Proxy Statement for the Company's 2014 Annual Meeting of Stockholders, filed on June 20, 2014, and incorporated herein by reference)
3.3	Second Amended and Restated By-Laws of the Registrant, dated October 27, 2015 (previously filed as Exhibit 3.3 to the Registrant's Quarterly Report on Form 10-Q for the period ended September 30, 2015 and incorporated herein by reference)
10.1*	Amendment No. 2 to the 2010 Employee Stock Purchase Plan of the Registrant, dated April 21, 2016 (previously filed as Appendix A to the Definitive Proxy Statement for the Company's 2016 Annual Meeting of the Stockholders, filed on April 29, 2016 and incorporated herein by reference)
10.2*	2016 Inducement Award Plan Form Restricted Stock Unit Award Agreement (previously filed as Exhibit 4.7 to the Registrant's Registration Statement on Form S-8 (File No. 333-211099), filed on May 3, 2016 and 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

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

+ Filed herewith

Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Kevin T. Conroy, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Exact Sciences Corporation (the “registrant”);
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant’s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and
5. The registrant’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: October 26, 2016

By: /s/ Kevin T. Conroy
Kevin T. Conroy
President and Chief Executive Officer
(Principal Executive Officer)

Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, John K. Bakewell, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Exact Sciences Corporation (the “registrant”);
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant’s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and
5. The registrant’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: October 26, 2016

By: /s/ John K. Bakewell
John K. Bakewell
Chief Financial Officer
(Principal Financial and Accounting Officer)

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Exact Sciences Corporation (the "Company") on Form 10-Q for the quarter ended September 30, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), we, Kevin T. Conroy, President and Chief Executive Officer of the Company and John K. Bakewell, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to our knowledge, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Kevin T. Conroy
Kevin T. Conroy
President and Chief Executive Officer

October 26, 2016

/s/ John K. Bakewell
John K. Bakewell
Chief Financial Officer

October 26, 2016
