EXACT SCIENCES CORP
Form 10-Q
October 30, 2015
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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, 2015

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 (Do not check if a smaller reporting company)	Smaller reporting company

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

As of October 28, 2015, the registrant had 96,338,000 shares of common stock outstanding.

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Part I — Financial Information

EXACT SCIENCES CORPORATION

Condensed Consolidated Balance Sheets

(Amounts in thousands, except share data - unaudited)

	September 30, 2015	December 31, 2014
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 31,522	$ 58,131
Marketable securities	311,987	224,625
Accounts receivable, net	4,209	1,376
Inventory, net	6,032	4,017
Prepaid expenses and other current assets	5,602	3,528
Total current assets	359,352	291,677
Property and Equipment, at cost:		
Laboratory equipment	11,929	10,381
Computer equipment and computer software	12,662	7,577
Assets under construction	7,066	1,552
Leasehold improvements	6,454	5,937
Buildings	4,777	—
Furniture and fixtures	1,038	939
	43,926	26,386
Less—Accumulated depreciation	(11,851)	(6,439)
Net property and equipment	32,075	19,947
Other long-term assets	2,562	1,200
Total assets	$ 393,989	$ 312,824
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 1,503	$ 2,647
Accrued liabilities	20,929	13,960
Debt and capital lease obligation, current portion	221	360
Other short-term liabilities	861	554
Total current liabilities	23,514	17,521
Long-term debt	3,535	1,000
Long-term accrued interest	—	106
Other long-term liabilities	4,455	3,599
Lease incentive obligation, less current portion	1,199	1,614
Total liabilities	32,703	23,840

Commitments and contingencies		
Stockholders' Equity:		
Preferred stock, $0.01 par value Authorized—5,000,000 shares issued and outstanding—no shares at September 30, 2015 and December 31, 2014	—	—
Common stock, $0.01 par value Authorized—200,000,000 shares issued and outstanding—96,311,415 and 88,626,042 shares at September 30, 2015 and December 31, 2014	964	887
Additional paid-in capital	898,786	709,019
Accumulated other comprehensive income (loss)	155	(115)
Accumulated deficit	(538,619)	(420,807)
Total stockholders' equity	361,286	288,984
Total liabilities and stockholders' equity	$ 393,989	$ 312,824

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

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EXACT SCIENCES CORPORATION

Condensed Consolidated Statements of Operations

(Amounts in thousands, except per share data - unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Laboratory service revenue	$ 12,632	$ —	$ 25,017	$ —
License fees	—	—	—	294
Total revenue	12,632	—	25,017	294
Cost of sales	7,528	924	16,834	924
Gross margin	5,104	(924)	8,183	(630)
Operating expenses:				
Research and development	9,863	9,073	24,549	23,677
General and administrative	15,432	8,994	42,086	19,810
Sales and marketing	23,079	13,217	60,196	23,839
Total operating expenses	48,374	31,284	126,831	67,326
Loss from operations	(43,270)	(32,208)	(118,648)	(67,956)
Other income (expense)				
Investment income	365	160	780	392
Interest income (expense)	(40)	(12)	56	(40)
Total other income	325	148	836	352
Net loss	$ (42,945)	$ (32,060)	$ (117,812)	$ (67,604)
Net loss per share—basic and diluted	$ (0.45)	$ (0.39)	$ (1.30)	$ (0.86)
Weighted average common shares outstanding—basic and diluted	94,444	82,941	90,696	78,702

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

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EXACT SCIENCES CORPORATION

Condensed Consolidated Statements of Comprehensive Loss

(Amounts in thousands - unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Net loss	$ (42,945)	$ (32,060)	$ (117,812)	$ (67,604)
Other comprehensive loss, net of tax:				
Unrealized gain (loss) on available-for-sale investments	75	(95)	211	(131)
Foreign currency translation gain	91	—	59	—
Comprehensive loss	$ (42,779)	$ (32,155)	$ (117,542)	$ (67,735)

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

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EXACT SCIENCES CORPORATION

Condensed Consolidated Statements of Cash Flows

(Amounts in thousands, except share data - unaudited)

	Nine Months Ended September 30,	
	2015	2014
Cash flows from operating activities:		
Net loss	$ (117,812)	$ (67,604)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization of fixed assets	5,412	2,264
Stock-based compensation	13,148	8,643
Amortization of deferred license fees	—	(294)
Amortization of other liabilities	(399)	—
Amortization of deferred financing costs	33	—
Forgiveness of long-term debt	(1,000)	—
Amortization of premium on short-term investments	1,020	628
Changes in assets and liabilities:		
Accounts receivable	(2,833)	—
Inventory, net	(2,015)	(2,719)
Prepaid expenses and other current assets	(1,907)	(178)
Accounts payable	(1,144)	3,874
Accrued liabilities	7,805	5,778
Lease incentive obligation	(415)	(405)
Accrued interest	(106)	16
Net cash used in operating activities	(100,213)	(49,997)
Cash flows from investing activities:		
Purchases of marketable securities	(197,997)	(141,355)
Maturities of marketable securities	109,826	77,689
Purchases of property and equipment	(17,540)	(9,522)
Net cash used in investing activities	(105,711)	(73,188)
Cash flows from financing activities:		
Proceeds from exercise of common stock options	961	424
Proceeds from sale of common stock, net of issuance costs	174,140	137,664
Payments on capital lease obligations	(360)	(262)
Proceeds from mortgage payable	3,756	—
Proceeds in connection with the Company's employee stock purchase plan	759	337
Net cash provided by financing activities	179,256	138,163
Effects of exchange rate on cash and cash equivalents	59	—

Net (decrease) increase in cash and cash equivalents	(26,609)	14,978
Cash and cash equivalents, beginning of period	58,131	12,851
Cash and cash equivalents, end of period	$ 31,522	$ 27,829
Supplemental disclosure of non-cash investing and financing activities:		
Unrealized gain on available-for-sale investments	$ 211	$ (131)
Issuance of 21,826 and 32,669 shares of common stock to fund the Company's 401(k) matching contribution for 2014 and 2013, respectively	$ 835	$ 456

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

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EXACT SCIENCES CORPORATION

Notes to Condensed Consolidated Financial Statements

(Unaudited)

(Amounts in thousands, except share and per share data, unless otherwise noted or instances where expressed in millions)

(1) ORGANIZATION AND BASIS OF PRESENTATION

Organization

Exact Sciences Corporation (together with its subsidiaries, “Exact”, “we”, “us” or the “Company”) was incorporated in February 1995. Exact is a molecular diagnostics company focused on the early detection and prevention of some of the deadliest forms of cancer. The Company has developed an accurate, non-invasive, patient-friendly screening test for the early detection of colorectal cancer and pre-cancer, and is currently working on the development of tests for lung cancer, pancreatic cancer and esophageal 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, 2014 included in the Company’s Annual Report on Form 10-K (the “2014 Form 10-K”). These condensed financial statements are prepared in conformity with accounting principles generally accepted in the United States of America (“GAAP”) and follow the requirements of the Securities and Exchange Commission (“SEC”) for interim reporting. In the opinion of management, all adjustments (consisting only of adjustments of a normal and recurring nature) considered necessary for a fair presentation of the results of operations have been included. The results of the Company’s operations for any interim period are not necessarily indicative of the results of the Company’s operations for any other interim period or for a full fiscal year. The statements should be read in conjunction with the audited financial statements and related notes included in the 2014 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.

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Cash and Cash Equivalents

The Company considers cash on hand, demand deposits in bank, money market funds, and all highly liquid investments with an original maturity of 90 days or less to be cash and cash equivalents. The Company had no restricted cash at September 30, 2015 and December 31, 2014.

Marketable Securities

Management determines the appropriate classification of debt securities at the time of purchase and re-evaluates such designation as of each balance sheet date. Debt securities carried at amortized cost are classified as held-to-maturity when the Company has the positive intent and ability to hold the securities to maturity. Marketable equity securities and debt securities not classified as held-to-maturity are classified as available-for-sale. Available-for-sale securities are carried at fair value, with the unrealized gains and losses, net of tax, reported in other comprehensive loss. The amortized cost of debt securities in this category is adjusted for amortization of premiums and accretion of discounts to maturity computed under the straight-line method, which approximates the effective interest method. Such amortization is included in investment income. Realized gains and losses and declines in value judged to be other-than-temporary on available-for-sale securities are included in investment income. The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in investment income.

At September 30, 2015 and December 31, 2014, 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, 2015 and 2014. Realized gains were $7.7 thousand and $11.1 thousand for the nine months ended September 30, 2015 and 2014, 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, 2015, no investments were identified with other-than-temporary declines in value.

Available-for-sale securities at September 30, 2015 consisted of the following:

	September 30, 2015			
(In thousands)	Amortized Cost	Gains in Accumulated Other Comprehensive Income	Losses in Accumulated Other Comprehensive Income	Estimated Fair Value
Corporate bonds	$ 209,953	$ 113	$ (39)	$ 210,027
U.S. government agency securities	7,056	7	(1)	7,062
Asset backed securities	89,306	45	(30)	89,321
Certificates of deposit	1,999	—	—	1,999
Commercial paper	3,577	1	—	3,578
Total available-for-sale securities	$ 311,891	$ 166	$ (70)	$ 311,987

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Available-for-sale securities at December 31, 2014 consisted of the following:

	December 31, 2014			
(In thousands)	Amortized Cost	Gains in Accumulated Other Comprehensive Income	Losses in Accumulated Other Comprehensive Income	Estimated Fair Value
Corporate bonds	$ 141,239	$ 21	$ (136)	$ 141,124
U.S. government agency securities	18,687	8	(7)	18,688
Asset backed securities	60,821	17	(18)	60,820
Commercial paper	3,993	—	—	3,993
Total available-for-sale securities	$ 224,740	$ 46	$ (161)	$ 224,625

Changes in Accumulated Other Comprehensive Income (Loss)

The amounts recognized in accumulated other comprehensive income (loss) (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 income (loss)	59	211	270
Balance at September 30, 2015	$ 59	$ 96	$ 155

The amounts recognized in AOCI for the nine months ended September 30, 2014 were as follows (in thousands):

	Cumulative Translation	Unrealized Gain (Loss)	Accumulated Other Comprehensive

	Adjustment	on Securities	Income (Loss)
Balance at December 31, 2013	$ —	$ 125	$ 125
Other comprehensive loss before reclassifications	—	(106)	(106)
Amounts reclassified from accumulated other comprehensive loss	—	(25)	(25)
Net current period change in accumulated other comprehensive loss	—	(131)	(131)
Balance at September 30, 2014	$ —	$ (6)	$ (6)

Amounts reclassified from AOCI for the nine months ended September 30, 2015 were as follows (in thousands):

Details about AOCI Components	Affected Line Item in the Statement of Operations	Nine Months Ended September 30, 2015	2014
Change in value of available-for-sale investments			
Sales and maturities of available-for-sale investments	Investment income	$ (13)	$ (25)
Total reclassifications		$ (13)	$ (25)

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:

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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, 2015, the Company had $7.1 million of assets under construction which consisted of $4.6 million related to building and leasehold improvements, $1.6 million of capitalized costs related to software projects and $0.9 million of costs related to machinery and equipment. Depreciation will begin on these assets once they are placed into service. At September 30, 2015, the Company has incurred $2.2 million in building improvement costs, of which, $0.1 million has been paid through financing at the period end and an additional $1.3 million will be financed in October 2015. The Company expects to incur minimal costs to complete the leasehold improvements, machinery and equipment, and the software projects, and these projects are expected to be completed in 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 in 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 economic useful life of the software.

Net Loss Per Share

Basic net loss per common share was determined by dividing net loss applicable to common stockholders by the weighted average common shares outstanding during the period. Basic and diluted net loss per share are the same because all outstanding common stock equivalents have been excluded, as they are anti-dilutive due to the Company’s losses.

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:

	September 30,	
	2015	2014
Shares issuable upon exercise of stock options	5,091	6,207
Shares issuable upon exercise of outstanding warrants(1)	—	75
Shares issuable upon the release of restricted stock awards	2,383	1,577
Shares issuable upon the vesting of restricted stock awards related to licensing agreement	—	24
	7,474	7,883

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

Revenue Recognition

Laboratory Service Revenue. The Company's revenues are generated by the Cologuard® test. Revenues are recognized when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the price is fixed and determinable, and collectability is reasonably assured. The Company assesses whether the fee is fixed or determinable and if the collectability is reasonably assured based on the nature of the fee charged for the laboratory services delivered and whether there are existing contractual arrangements with customers, third-party

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

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

For laboratory services performed, where the collectability is not reasonably assured, the Company will continue to recognize revenues upon cash collection until it can reliably estimate the amount that will be ultimately collected for the Cologuard test. In order to begin to record revenue on an accrual basis in these scenarios, the Company expects to use at least several months of payment history, review the number of tests paid against the number of tests billed, and consider the payor's outstanding balance for unpaid tests to determine whether payments are being made for a consistently high percentage of tests billed and at appropriate amounts given the contracted or historical payment amount. With regard to Cologuard tests covered by Medicare, the national coverage determination for Cologuard was released by CMS on October 9, 2014 and for these tests, revenue is recognized on an accrual basis once the services have been performed as the price is fixed or determinable, and collectability is reasonably assured.

The Company recognized approximately $12.6 million and $25.0 million in laboratory service revenue for the three and nine months ended September 30, 2015.

License fees. License fees for the licensing of product rights are recorded as deferred revenue upon receipt of cash and recognized as revenue on a straight-line basis over the license period. As more fully described in the 2014 Form 10-K, in connection with the Company’s January 2009 strategic transaction with Genzyme Corporation, the Company deferred the initial $16.65 million in cash received at closing and amortized that up-front payment on a straight-line basis into revenue over the initial five-year collaboration period which ended in January 2014. In addition, in 2010 the Company received holdback amounts of $1.85 million, which were deferred at the time of receipt and were amortized on a straight-line basis into revenue over the then remaining term of the collaboration period.

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

The Company did not recognize revenue in connection with the amortization of the up-front payments from Genzyme during the three and nine months ended September 30, 2015. The Company recognized approximately $0.3 million in license fee revenue in connection with the amortization of the up-front payments from Genzyme during the nine months ended September 30, 2014. There was no license fee revenue recognized during the three months ended September 30, 2014.

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 realizable value, and records a charge to cost of sales for such inventory as appropriate. In addition, the Company's products are subject to strict quality control and monitoring which the Company performs throughout the manufacturing process. If certain batches or units of product no longer meet quality specifications or become obsolete due to expiration, the Company records a charge to cost of sales to write down such unmarketable inventory to its estimated realizable value.

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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 consist of the following (amount in thousands):

	September 30, 2015	December 31, 2014
Raw materials	$ 1,746	$ 1,019
Semi-finished and finished goods	4,286	2,998
Total inventory	$ 6,032	$ 4,017

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. Consolidated statements of operations amounts are translated at average exchange rates for the period. The cumulative translation adjustments resulting from changes in exchange rates are included in the consolidated balance sheet as a component of accumulated other comprehensive income in total Exact Sciences Corporation’s shareholders’ equity. Transaction gains and losses are included in the consolidated statement of operations in 2015.

Reclassifications

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

(3) MAYO LICENSE AGREEMENT

Overview

As more fully described in the 2014 Form 10-K, in June 2009 the Company entered into a license agreement (the "MAYO Agreement") with MAYO Foundation for Medical Education and Research ("MAYO"). Pursuant to the MAYO Agreement, the Company granted MAYO two common stock purchase warrants with an exercise price of $1.90 per share covering 1,000,000 and 250,000 shares of common stock, respectively. The MAYO Agreement required the Company to make payments to MAYO for up-front fees, fees upon the achievement of certain milestones, and certain other payments. In addition to the license to intellectual property owned by MAYO, MAYO agreed to make available personnel to provide the Company product development and research and development assistance. The Company agreed to make royalty payments to MAYO on potential future net sales of any products developed from the licensed technology. The Company sought rights to the MAYO intellectual property for the specific purpose of developing a non-invasive, stool-based DNA screening test for colorectal cancer. At the time the MAYO Agreement was executed, the Company's sole focus was the development of such a test. Accordingly, the Company recognized the initial payments and expenses related to the warrants at the time of the transaction and the amounts were expensed to research and development as there were no anticipated alternative future uses associated with the intellectual property.

Warrants

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

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

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MAYO exercised the warrant to purchase 250,000 shares through partial exercises, the last of which occurred in June 2014. In June 2014, MAYO exercised the remaining shares of this warrant by utilizing the cashless exercise provision contained in the warrant. As a result of this exercise for a gross amount of 80,000 shares, in lieu of paying a cash exercise price, MAYO forfeited its right with respect to 10,587 shares leaving it with a net amount of 69,413 shares. Following this exercise, all of MAYO's warrants to purchase the Company's common stock were fully exercised.

Royalty Payments

Under the MAYO Agreement, the Company agreed to make royalty payments to MAYO based on a percentage of net sales of products developed from the licensed technology starting in the third year of the agreement. Starting in 2012, minimum royalty payments were $10,000 per year. For each year from 2015 through 2033 (the year the last patent expires), the minimum royalty payments are $25,000 per year.

Other Payments

Other payments under the MAYO Agreement include an upfront payment of $80,000, a milestone payment of $250,000 on the commencement of patient enrollment in a human cancer screening clinical trial, and a $500,000 payment upon FDA approval of the Company's Cologuard test. The upfront payment of $80,000 was made in the third quarter of 2009 and expensed to research and development in the second quarter of 2009. The Company began enrollment in human cancer screening clinical trial in June 2011 and the milestone payment of $250,000 was made and expensed to research and development in June 2011. The Company received FDA approval for its Cologuard test in August 2014, and the milestone payment of $500,000 was made and expensed to research and development in August 2014.

In addition, the Company pays MAYO for research and development efforts. During the three and nine months ended September 30, 2015, the Company made payments of $0.9 million and $2.4 million, respectively. At September 30, 2015 the Company recorded an estimated liability in the amount of $0.4 million for MAYO's research and development efforts. During the three months ended September 30, 2014, the Company did not make research and development payments to MAYO. During the nine months ended September 30, 2014, the Company made research and development payments to MAYO of $0.7 million. At September 30, 2014 the Company recorded an estimated liability in the amount of $1.6 million for research and development efforts.

May 2012 Amendment

In May 2012 the Company expanded the relationship with MAYO through an amendment to the MAYO Agreement. As part of the amendment, MAYO expanded the Company's license to include all gastrointestinal cancers and diseases, and new cancer screening applications of stool- and blood-based testing.

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

February 2015 Amendment

In February 2015 the Company amended and restated the MAYO Agreement to extend the Company's arrangement with MAYO for an additional five years and to broaden the Company's and MAYO's collaboration efforts to develop screening, surveillance and diagnostic tests and tools for use in connection with gastrointestinal cancers, precancers, diseases and conditions. Under the amended and restated agreement (the "Restated MAYO Agreement"), MAYO agreed to continue to make personnel available during the additional five year period to provide the Company product development and research and development assistance. The Restated MAYO Agreement defines "gastrointestinal" to include certain airway organs (including the pharynx, larynx, trachea, bronchi and lungs) and

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certain head and neck organs (including nasal passages, mouth and throat). The Restated MAYO Agreement also reflects an expanded list of patent rights that MAYO licenses to the Company.

Pursuant to the Restated MAYO Agreement, the Company agreed to pay MAYO an additional $5.0 million, payable in five annual $1.0 million installments, the first of which was due February 10, 2015. The first $1.0 million payment was made to MAYO in February 2015 and was capitalized to pre-paid assets and will be amortized to research and development expenses straight-line over the initial 12 month research period. Additionally, the Company will make milestone payments once certain sales levels are reached on licensed products. It is uncertain as to when or if these milestones will be met; therefore, the milestone payments have not been recorded as a liability. The Company evaluates the status of the milestone payments at each reporting date to determine if a liability should be recorded for the milestone payment.

(4) MD ANDERSON LICENSE AGREEMENT

Overview

On April 10, 2015, the Company entered into a Joint Development and License Agreement ("MD Anderson Agreement") with the University of Texas M.D. Anderson Cancer Center ("MD Anderson") to jointly develop, clinically validate and obtain FDA approval and CMS coverage and reimbursement for in-vitro diagnostic and screening tools for the early detection of lung cancer (the "IVD Assays"). Under the MD Anderson Agreement, MD Anderson assigned certain patent rights to the Company and granted the Company an exclusive license to certain intellectual property rights for the purpose of developing, manufacturing and marketing IVD Assays. In addition, MD Anderson agreed to make personnel available to provide the Company product development and research and development assistance. Pursuant to the MD Anderson Agreement, the Company is obligated to reimburse IVD Assay development expenses incurred by the staff at MD Anderson, up to a maximum of $1.0 million per year for the first two years of the MD Anderson Agreement. At September 30, 2015 the Company recorded an estimated liability in the amount of $0.5 million for IVD Assay development efforts. During the three and nine months ended September 30, 2015, the Company made payments for IVD Assay development costs to MD Anderson of $0.3 million. Beginning on April 30, 2015 and continuing through December 31, 2016, the Company is required to pay a quarterly fee of $0.3 million for the use of samples already collected prior to the effective date of the agreement which will be utilized in the continued research and development of IVD Assays. Further, the Company has agreed to pay MD Anderson a low single digit royalty on the Company's net sales of licensed products covered by specified patent rights. As of September 30, 2015 there have been no commercial sales of such product.

(5) 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 Grant Plan and the 2000 Stock Option and Incentive Plan (collectively, the "Stock Plans").

Stock-Based Compensation Expense

The Company recorded $4.9 million and $13.1 million in stock-based compensation expense during the three and nine months ended September 30, 2015 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 $4.1 million and $8.6 million in stock-based compensation expense during the three and nine months ended September 30, 2014, respectively, 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.

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Determining Fair Value

Valuation and Recognition – The fair value of each option award is estimated on the date of grant using the Black-Scholes option pricing model based on the assumptions in the table below. The estimated fair value of employee stock options is recognized to expense using the straight-line method over the vesting period.

Expected Term – Expected term is based on the Company's historical life data and is determined using the average of the vesting period and the contractual life of the stock options granted.

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

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

Forfeitures - The Company records stock-based compensation expense only for those awards that are expected to vest. A forfeiture rate is estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from initial estimates. The Company's forfeiture rate used in the nine months ended September 30, 2015 and 2014 was 4.99%.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
Option Plan Shares	2015	2014	2015	2014
Risk-free interest rates	(1)	2.01%	1.5% - 1.92%	1.96% - 2.01%
Expected term (in years)	(1)	6	6.25 - 6.6	6
Expected volatility	(1)	77.6%		

			67.1% - 73.2%	77.6% - 80.8%
Dividend yield	(1)	0%	0 %	0%
Weighted average fair value per share of options granted during the period	(1)	$ 11.37	$ 15.81	$ 10.05
ESPP Shares				
			0.25% - 0.6%	0.1% - 0.41%
Risk-free interest rates	(2)	(2)		
Expected term (in years)	(2)	(2)	0.5 - 2	0.5 - 2
			51.2% - 57.4%	42.5% - 49.5%
Expected volatility	(2)	(2)		
Dividend yield	(2)	(2)	0 %	0%
Weighted average fair value per share of stock purchase rights granted during the period	(2)	(2)	$ 7.48	$ 3.76

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

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Stock Option and Restricted Stock Activity

A summary of stock option activity under the Stock Plans during the nine months ended September 30, 2015 is as follows:

Options (Aggregate intrinsic value in thousands)	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value(1)
Outstanding, December 31, 2014	4,934,317	$ 3.63	5.2	
Granted	340,978	23.51		
Exercised	(141,615)	7.79		
Forfeited	(42,236)	16.78		
Outstanding, September 30, 2015	5,091,444	$ 4.77	6.0	$ 69,314
Exercisable, September 30, 2015	4,354,302	$ 2.63	4.1	$ 66,868
Vested and expected to vest, September 30, 2015	5,054,661	$ 4.77	5.2	$ 67,495

(1) The aggregate intrinsic value of options outstanding, exercisable and vested and expected to vest is calculated as the difference between the exercise price of the underlying options and the market price of the Company's common stock for options that had exercise prices that were lower than the $17.99 market price of the Company's common stock at September 30, 2015. The total intrinsic value of options exercised during the nine months ended September 30, 2015 and 2014 was $2.0 million and $1.4 million, respectively.

As of September 30, 2015, there was $39.5 million of total unrecognized compensation cost related to non-vested share-based compensation arrangements granted under all Stock Plans. Total unrecognized compensation cost will be adjusted for future changes in forfeitures. The Company expects to recognize that cost over a weighted average period of 2.9 years.

A summary of restricted stock activity under the Stock Plans during the nine months ended September 30, 2015 is as follows:

	Restricted Shares	Weighted Average Grant Date Fair Value
Outstanding, January 1, 2015	1,541,114	$ 13.86
Granted	1,424,114	23.93
Released	(478,249)	13.16

Forfeited	(104,397)		16.01
Outstanding, September 30, 2015	2,382,582	$	19.93

(6) FAIR VALUE MEASUREMENTS

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

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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 $3.5 million and $1.0 million as of September 30, 2015 and December 31, 2014, 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, 2015 along with the level within the fair value hierarchy in which the fair value measurements in their entirety fall. Amounts in the table are in thousands.

		Fair Value Measurement at September 30, 2015 Using:		
Description	Fair Value at September 30, 2015	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	$ 31,522	$ 31,522	$ —	$ —
Available-for-Sale Marketable securities				
Corporate bonds	210,027	—	210,027	—
Asset backed securities	89,321	—	89,321	—
U.S. government agency securities	7,062	—	7,062	—

Commercial paper	3,578	—	3,578	—
Certificates of deposit	1,999	—	1,999	—
Total	$ 343,509	$ 31,522	$ 311,987	$ —

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The following table presents the Company's fair value measurements as of December 31, 2014 along with the level within the fair value hierarchy in which the fair value measurements in their entirety fall. Amounts in the table are in thousands.

		Fair Value Measurement at December 31, 2014 Using:		
Description	Fair Value at December 31, 2014	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash and cash equivalents				
Cash and money market	$ 53,569	$ 53,569	$ —	$ —
Corporate bonds	4,562	—	4,562	—
Available-for-Sale Marketable securities				
Corporate bonds	141,124	—	141,124	—
U.S. government agency securities	18,688	—	18,688	—
Asset backed securities	60,820	—	60,820	—
Commercial paper	3,993	—	3,993	—
Total	$ 282,756	$ 53,569	$ 229,187	$ —

The following table summarizes gross unrealized losses and fair values of our investments in an unrealized loss position as of September 30, 2015, aggregated by investment category and length of time that individual securities have been in a continuous unrealized loss position:

	September 30, 2015					
	Less than 12 months		12 months or greater		Total	
(In thousands)	Fair Value	Gross Unrealized Loss	Fair Value	Gross Unrealized Loss	Fair Value	Gross Unrealized Loss
Marketable Securities						
Corporate bonds	$ 84,960	$ (39)	$ —	$ —	$ 84,960	$ (39)
U.S. government agency securities	2,499	(1)	—	—	2,499	(1)
Asset backed securities	30,431	(30)	4,736	(3)	35,167	(33)
Total	$ 117,890	$ (70)	$ 4,736	$ (3)	$ 122,626	$ (73)

The following summarizes contractual underlying maturities of the Company's available-for-sale investments in debt securities at September 30, 2015 (in thousands):

	Due one year or less		Due after one year through two years	
Description	Cost	Fair Value	Cost	Fair Value
Marketable Securities				
U.S. government agency securities	$ 2,499	$ 2,499	$ 4,557	$ 4,563
Corporate bonds	122,579	122,601	87,374	87,426
Commercial paper	3,577	3,578	—	—
Certificates of deposit	1,999	1,999	—	—
Asset backed securities	1,654	1,654	87,652	87,667
Total	$ 132,308	$ 132,331	$ 179,583	$ 179,656

(7) NEW MARKET TAX CREDIT

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

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facilities. This financing arrangement was structured with an unrelated third party financial institution (the "Investor"), 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. Through its participation in this program, the Company has secured low interest financing and the potential for future debt forgiveness related to the Madison, Wisconsin facility. Upon closing of this transaction, the Company provided an aggregate of approximately $5.1 million to the Investor, in the form of a loan receivable, with a term of seven years, bearing an interest rate of 2.74% per annum. This $5.1 million in proceeds plus capital from the Investor was used to make an aggregate $7.5 million loan to a subsidiary of the Company. This financing arrangement is not secured by any assets of the Company. On December 1, 2021, the Company would receive a repayment of its approximately $5.1 million loan. The $5.1 million is eliminated in the consolidation of the financial statements. This transaction also includes a put/call feature that becomes enforceable at the end of the seven-year compliance period. The Investor may exercise its put option or the Company can exercise the call, both of which will serve to trigger forgiveness of the net debt. The value attributable to the put/call is nominal. 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 our 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, 2015. At September 30, 2015, the remaining balance is $2.1 million. 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.

The Investor is subject to 100% recapture of the NMTC it receives for a period of seven years as provided in the Internal Revenue Code and applicable U.S. Treasury regulations. The Company is required to be in compliance with various regulations and contractual provisions that apply to the NMTC arrangement. Noncompliance with applicable requirements could result in the Investor's projected tax benefits not being realized and, therefore, require the Company to indemnify the Investor for any loss or recapture of NMTC related to the financing until such time as the recapture provisions have expired under the applicable statute of limitations. The Company does not anticipate any credit recapture will be required in connection with this financing arrangement.

The Investor and its majority owned community development entity are considered Variable Interest Entities (VIEs) and the Company is the primary beneficiary of the VIEs. This conclusion was reached based on the following:

- The ongoing activities of the VIEs—collecting and remitting interest and fees and NMTC compliance—were all considered in the initial design and are not expected to significantly affect performance throughout the life of the VIE;
- Contractual arrangements obligate the Company to comply with NMTC rules and regulations and provide various other guarantees to the Investor and community development entity;
- The Investor lacks a material interest in the underling economics of the project; and
- The Company is obligated to absorb losses of the VIEs.

Because the Company is the primary beneficiary of the VIEs, they have been included in the consolidated financial statements. There are no other assets, liabilities or transactions in these VIEs outside of the financing transactions executed as part of the NMTC arrangement. The $5.1 million loan is eliminated in consolidation of the financial statements.

Also in December 2014, in connection with the NMTC transaction, the Company entered into a land purchase option agreement with the owner of certain real property (land) adjacent to certain of the Company's current Madison, Wisconsin facilities. The option is renewable annually in exchange for a fee. If the Company exercises its land purchase option, it will pay a fixed amount for the land. That fixed amount approximates the then-current fair value of the land. If the Company decides not to exercise its option, then on December 31, 2021 (which is after the seven year compliance period of the NMTC program) the Company must pay $1.2 million to the community development entity. As discussed below, the community development entity is a variable interest entity consolidated into the Company. The community development entity would then distribute this money to its members. The majority member of the community development entity is also the owner of the land subject to the land purchase option. The Company has recorded the obligation and the land purchase option asset for $1.2 million to reflect the Company's assessment that it is probable that

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at least $1.2 million will be paid in the future based on resolution of the land purchase option. The asset is included in Other Long-Term Assets and the liability is included in Other Long-Term Liabilities on the consolidated balance sheet.

(8) LONG-TERM DEBT

Building Purchase Mortgage

During June 2015, the Company entered into a credit agreement with an unrelated third party financial institution to finance the purchase of the facility and contemplated improvements located at 501 Charmany Drive in Madison, WI for $5.1 million. Of the $5.1 million in funds available pursuant to the credit agreement, $3.7 million was directly applied towards the purchase price of the building in June 2015 and the remaining $1.4 million is a construction loan available to finance future improvements. The credit agreement is secured by the acquired building.

Borrowings under the credit agreement bear interest at 4.15% per annum which is calculated on the outstanding principal balance. The Company made interest only payments on the outstanding principal balance for the period between July 12, 2015 and September 12, 2015 which is the period the Company anticipates completing all building related improvements. Beginning on October 12, 2015 and continuing through the maturity date, May 12, 2019, the Company is required to make monthly principal and interest payments of $31.2 thousand. The final principal and interest payment due on June 12, 2019 is $4.4 million.

As of September 30, 2015, the building improvements were nearly complete and the Company had drawn $0.1 million of the total available construction funds. The Company expects the financial institution to fund the remaining $1.3 million in October 2015. The financial institution did not fund the $1.3 million on or prior to September 30, 2015, as such the liability is included in our financial statements under other current liabilities. There is an outstanding principal balance of $3.8 million, and the current portion is $0.2 million. Additionally, the Company has recorded $70.4 thousand in deferred financing costs which are being amortized through June 12, 2019. For the three and nine months ended September 30, 2015, the Company has recorded $5.7 thousand in amortization of deferred financing costs.

Wisconsin Department of Commerce Loan

During November 2009, the Company entered into a loan agreement with the Wisconsin Department of Commerce pursuant to which the Wisconsin Department of Commerce agreed to lend up to $1.0 million to the Company subject to the Company’s satisfaction of certain conditions. The Company received the $1.0 million in December 2009. The terms of the loan are such that portions of the loan become forgivable if the Company meets certain job creation requirements at a specified wage rate. After the Company creates 100 full time positions, the principal shall be reduced at the rate of $5,405 for each new position created thereafter during the measurement period. The loan bears an interest rate of 2%, which is subject to an increase to 4% if the Company does not meet certain job creation

requirements. Both principal and interest payments under the loan agreement are deferred for five years. The loan's terms also contain a milestone that if the Company has created 185 new full time positions as of June 30, 2015, the full amount of principal shall be forgiven. The Company met this job creation milestone and the $1.0 million benefit associated with the loan forgiveness has been recorded as an offset to the operating expenses during the nine months ended September 30, 2015.

(9) 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 should first be 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 will record the earned tax credits as job creation and capital investments occur. The amount of tax credits earned will be 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 will be recognized as an offset to depreciation expense over

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the expected life of the acquired capital assets. The tax credits earned related to job creation will be 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, 2015 the Company has earned $1.6 million of tax credits. $0.2 million is classified as a current asset and $1.4 million is classified as a long term asset, reflecting when collection of the refundable tax credits is expected to occur.

During the three and nine month periods ending September 30, 2015, the Company has amortized $72.6 thousand and $112.8 thousand of the credits earned as a reduction of operating expenses, respectively. At September 30, 2015, the Company also has a $0.3 million current liability and a $1.1 million long term liability, reflecting when the expected benefit of the tax credit amortization will reduce future operating expenses.

(10) EQUITY

On July 24, 2015 the Company completed an underwritten public offering of 7.0 million shares of common stock at a price of $25.50 per share to the public. The Company received approximately $174.1 million of net proceeds from the offering, after deducting $4.4 million for the underwriting discount and commissions and other stock issuance costs paid by the Company.

(11) RECENT ACCOUNTING PRONOUNCEMENTS

In July 2015, the Financial Accounting Standards Board issued Accounting Standards Update No. 2015-11, “Simplifying the Measurement of Inventory (Topic 330).” The new guidance requires most inventory to be measured at the lower of cost and net realizable value, thereby simplifying the previous guidance under which an entity must measure inventory at the lower of cost or market. Market is defined as replacement cost, net realizable value (“NRV”), or NRV less a normal profit margin. The Accounting Standards Update will not apply to inventory that is measured using either the last-in, first-out method or the retail inventory method. The standard will be effective prospectively for the first interim period within annual reporting periods beginning after December 15, 2016. Early adoption is permitted. The Company does not expect to early adopt this guidance and is currently assessing the provisions of the guidance and has not determined the impact of the adoption of this guidance on its consolidated financial statements.

In April 2015, the Financial Accounting Standards Board issued Accounting Standards Update No. 2015-05, “Customer’s Accounting for Fees Paid in a Cloud Computing Arrangement”, which provides guidance that requires management to evaluate each cloud computing arrangement in order to determine whether it includes a software license that must be accounted for separately from hosted services. The new guidance clarifies that if a cloud computing arrangement includes a software license, the Company should account for the software license consistent

with its accounting for other software licenses. If the arrangement does not include a software license, the Company should account for the arrangement as a service contract. The standard is effective for the Company's financial statements issued for fiscal years beginning after December 15, 2015, and interim periods within those fiscal years. Early adoption is permitted for financial statements that have not previously been issued. The adoption of this standard is not expected to have a material impact on the Company's consolidated financial statements.

In April 2015, the Financial Accounting Standards Board issued Accounting Standards Update No. 2015-03, "Simplifying the Presentation of Debt Issuance Costs", which requires debt issuance costs to be presented in the balance sheet as a direct deduction from the associated debt liability. This guidance simplifies presentation of debt issuance costs but does not address presentation or subsequent measurement of debt issue costs related to line of credit arrangements. In August 2015, the Financial Accounting Standards Board issued Accounting Standards Update No. 2015-15 "Interest-Imputation of Interest (Subtopic 835-30) Presentation and Subsequent Measurement of Debt Issuance Costs Associated with Line-of-Credit Arrangements" which indicates the SEC staff would not object to an entity deferring and presenting debt issuance costs related to line-of-credit arrangements as an asset and subsequently amortizing the deferred debt issuance costs ratably over the term of the line-of-credit arrangement, regardless of whether there are any outstanding borrowings on the line-of-credit arrangement. Accounting Standards Update No. 2015-03 will be effective for the first interim period within annual reporting periods beginning after December 15, 2015. Early adoption is permitted. The adoption of this standard is not expected to have a material impact on the Company's financial statements.

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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” to defer for one year the effective date of the new revenue standard 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 its financial position and results of operations.

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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 financia 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, 2014, which has been filed with the SEC (the "2014 Form 10-K").

Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities and Exchange Act of 1934, as amended, that are intended to be covered by the "safe harbor" created by those sections. Forward-looking statements, which are based on certain assumptions and describe our future plans, strategies and expectations, can generally be identified by the use of forward-looking terms such as "believe," "expect," "may," "will," "should," "could," "seek," "intend," "plan," "estimate 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; the acceptance of our products by patients and health care providers; the willingness of health insurance companies and other payors to reimburse us for our performance of the Cologuard test; the amount and nature of competition from other cancer screening products and procedures; our ability to maintain regulatory approvals and comply with applicable regulations; our success establishing and maintaining collaborative and licensing arrangements; recommendations and/or guidelines issued by the U.S. Preventive Services Task Force, the American Cancer Society, or other organizations regarding cancer screening or our products and services; our ability to successfully develop new products; 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 of our most recent Annual Report on 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. Exact has developed an accurate, non-invasive, patient-friendly screening test, Cologuard®, for the early detection of colorectal cancer and pre-cancer, and is currently working on the development of tests for lung cancer, pancreatic cancer and esophageal cancer.

Cologuard

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:

- 137,000 new cases in the U.S.
- 50,000 deaths in the U.S.

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- 1,200,000 new cases worldwide
- 600,000 deaths worldwide

Colorectal cancer treatment represents a significant 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 rapidly 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 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%

Professional colorectal cancer screening guidelines in the U.S., including those of the ACS, the American College of Gastroenterology, and the American Gastroenterological Association, recommend regular screening by a variety of methods. Historically, these recommendations consisted of colonoscopy, flexible sigmoidoscopy and fecal occult

blood testing (FOBT) as well as combinations of some of these methods. On March 4, 2008, the ACS and the U.S. Multi-Society Task Force on Colorectal Cancer included sDNA screening technology in updated 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 U.S. Multi-Society Task Force on Colorectal Cancer is a consortium of several organizations that includes representatives of the American College of Gastroenterology, American Gastroenterological Association, American Society for Gastrointestinal Endoscopy and the American College of Physicians/Society of Internal Medicine. In November 2014 the ACS updated the colorectal cancer screening guidelines to specifically include Cologuard as a recommended sDNA screening test.

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

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On October 9, 2014, the CMS issued a final National Coverage Detrmination (NCD) for Cologuard. As outlined in the NCD, Medicare Part B will cover 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 2015 Clinical Laboratory Fee Schedule, CMS established reimbursement for Cologuard (HCPCS code G0464) at $492.72. Cologuard has been assigned a new American Medical Association CPT code (81528), and CMS has issued a preliminary determination that, effective January 1, 2016, code 81528 will be reimbursed on the same basis as the G0464 code, which it is replacing. The preliminary CMS determination regarding 2016 reimbursement rates is presently subject to public comment, and is expected to be finalized in November, 2015. Payments from CMS are subject to sequestration. Under the Protecting Access to Medicare Act of 2014 ("PAMA"), the basis for Cologuard's CMS reimbursement rate is expected to change, beginning in January, 2017. Under PAMA, the CMS reimbursement rate for Cologuard is expected to be calculated based on the weighted median of private payor rates during the prior calendar year (for the initial rates calculated under PAMA, taking effect January 1, 2017, the calculation is expected to be based on the weighted median of private payor rates during the period July 1 through December 31, 2015). Medicare covers 43% of patients in the screening population for Cologuard.

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

In October 2015, the US Preventive Services Task Force (USPSTF) issued a draft recommendation statement for colorectal cancer screening, which recommends an "A" grade for colorectal cancer screening starting at age 50 and continuing until age 75. Screening for individuals age 75 through 85 is graded a "C." The draft recommends certain screening tests and includes Cologuard as an alternative screening test, along with CT colonography. This approach, if adopted in the final recommendation statement, would represent a change from the 2008 USPSTF recommendations, which assigned specific grades for different tests, including an "I" rating for stool-based DNA. The draft statement is currently open for public comment, and USPSTF is expected to issue final recommendations during the first half of 2016. If the final USPSTF colorectal cancer screening recommendations continue to designate Cologuard as an "alternative" test, or otherwise fail to designate Cologuard as either a "recommended" test or as having an "A" or "B" grade, market acceptance of Cologuard could be adversely affected. For example, without a clear USPSTF "recommendation" or "A" or "B" grade, private health insurance plans may take the position that they are not required to cover Cologuard under the screening mandate provisions of the Patient Protection and Affordable Care Act (which will require most private insurance plans to cover screening tests that receive an "A" or "B" grade from USPSTF without

charging the patient any co-pay or deductible) and may decline to provide coverage. Also, the lack of a clear USPSTF endorsement may result in Cologuard not being credited under certain quality measures such as the National Committee for Quality Assurance (NCQA), Healthcare Effectiveness Data and Information Set (HEDIS) and the CMS Star ratings. If physicians do not earn quality credit for prescribing Cologuard, they may be less inclined to do so, which could adversely affect our business.

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

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

We are engaging physicians with several strategies. We have a 260 person sales team, including approximately 210 in a direct field sales force, actively engaging with physicians and their staffs to emphasize the need for colorectal cancer screening, educate them on the value 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 specialty and propensity to prescribe colorectal cancer screening tests. We are also focused on physician groups and larger regional and national health systems. We have entered into a co-promotion agreement with Ironwood Pharmaceuticals under which its 160 clinical sales specialists promote Cologuard in a second position to physicians across the United States. Further, to build awareness, we have launched a medical education program that includes on-line training and peer-to-peer presentations.

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.

One of the key components to engaging with payors was securing coverage from CMS, which we did in October of 2014. Additionally, we are 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 that require health insurers to cover colorectal cancer screening consistent with the ACS guidelines and health plans that have affiliated health systems.

As part of our commercialization strategy, we also established a state of the art, highly automated lab facility that is certified pursuant to applicable CLIA regulations 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 have the capacity to process approximately one million tests per year.

Product Pipeline

We also are focused on developing our pipeline for future products. We are continuing to collaborate with MAYO on future products related to early detection of gastrointestinal (GI) cancers specifically in the areas of esophageal and pancreatic cancers. GI cancers account for 145,000 or 25% of all U.S. cancer deaths annually and represent a significant market opportunity for future products. In February 2015, we amended and restated our license agreement

with MAYO to extend our working relationship for an additional five years and broaden our collaboration efforts to develop screening, surveillance and diagnostic tests and tools for use in connection with gastrointestinal cancers, pre-cancers, diseases and conditions.

In April 2015, we entered into a joint development and license agreement with The University of Texas MD Anderson Cancer Center to establish a collaboration aimed at developing in vitro diagnostic and screening tools for the early detection of lung cancer. The American Cancer Society estimates that lung cancer will be diagnosed in 221,200 Americans and cause 158,040 deaths in the United States this year and that, world-wide, lung cancer will be diagnosed in 1,825,000 people and cause 1,590,000 deaths. 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 percent.

Additionally, we will continue to explore opportunities for expanding the indications of Cologuard such as for patients between the ages of 40-49 or for high risk patients.

2015 Priorities

Our top priorities for 2015 include growing revenue for Cologuard, continuing to provide world class service as order volume grows, and developing our product pipeline for future products.

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We plan to grow Cologuard revenue through the continued efforts of our sales force working with physicians and systems to adopt Cologuard for colorectal cancer screening. In addition, we are working with payors to secure favorable reimbursement for Cologuard which will be a key component to growing revenue for 2015.

Another key priority for 2015 is to achieve and maintain at least a 70% compliance rate for patients who are prescribed Cologuard and to whom we ship a Cologuard test kit. As of September 30, 2015, our patient compliance rate for Cologuard was approximately 73%. The patient compliance rate is derived from the number of valid test results reported divided by the number of collection kits shipped to patients 60 or more days prior to September 30, 2015.

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

Financial Overview

We have generated limiting operating revenues since inception and, as of September 30, 2015, we had an accumulated deficit of approximately $538.6 million. We expect to continue to incur losses for the next several years, and it is possible we may never achieve profitability.

Laboratory service revenue. Total laboratory service revenue was $12.6 million and $25.0 million for the three and nine months ended September 30, 2015, respectively. Our laboratory service revenue is generated by performance of the Cologuard test. Cologuard became available to be marketed and sold upon FDA approval on August 11, 2014.

License fee revenue. There was no license fee revenue for the three and nine months ended September 30, 2015 and $0.3 million for the nine months ended September 30, 2014. There was no license fee revenue for the three months ended September 30, 2014. License fee revenue is composed of the amortization of up-front technology license fee payments associated with our collaboration, license and purchase agreement with Genzyme. The previously unamortized Genzyme up-front payment and holdback amounts were amortized on a straight-line basis over the initial Genzyme collaboration period, which ended in January 2014 therefore leading to a decline in revenue when compared to the prior year. Due to completion of the collaboration period in January 2014, we do not expect to recognize further significant revenues under this agreement.

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

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

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

Critical Accounting Policies and Estimates

Management’s discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States (GAAP). The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments, including those related to revenue recognition, tax positions and stock-based compensation. We base our estimates on historical experience and on various other factors that are believed to be appropriate under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

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While our significant accounting policies are more fully described in Note 2 of our financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2014, we believe that the following accounting policies and judgments are most critical to aid in fully understanding and evaluating our reported financial results.

Revenue Recognition.

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

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

For laboratory services performed, where the collectability is not reasonably assured, we will continue to recognize revenues upon cash collection until we can reliably estimate the amount that would be ultimately collected for the Cologuard test. In order to begin to record revenue on an accrual basis in these scenarios, we expect to use at least several months of payment history, review the number of tests paid against the number of tests billed, and consider the payor's outstanding balance for unpaid tests to determine whether payments are being made for a consistently high percentage of tests billed and at appropriate amounts given the contracted or historical payment amount. Our Cologuard test became available upon FDA approval on August 11, 2014. The national coverage decision was released by CMS on October 9, 2014 and for these tests, revenue is recognized on an accrual basis once the services have been performed as the price is fixed or determinable, and collectability is reasonably assured.

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

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

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

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

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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 and shares purchased under an employee stock purchase plan (ESPP) (if certain parameters are not met), are recognized in the financial statements based on their fair values. The following assumptions are used in determining fair value for stock options, restricted stock and ESPP shares:

- Valuation and Recognition — The fair value of each option award is estimated on the date of grant using the Black-Scholes option pricing model. The estimated fair value of employee stock options is recognized to expense using the straight-line method over the vesting period.

- Expected Term - Expected term is based on the Company's historical life data and is determined using the average of the vesting period and the contractual life of the stock options granted.

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

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

- Forfeitures - The Company records stock-based compensation expense only for those awards that are expected to vest. A forfeiture rate is estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from initial estimates. The Company's forfeiture rate used in the nine months ended September 30, 2015 and 2014 was 4.99%.

The fair value of each restricted stock award and restricted stock unit is determined on the date of grant using the closing stock price on that day. The fair value of each option award is estimated on the date of grant using the Black-Scholes option pricing model based on the assumptions in Note 5 to our condensed financial statements.

Results of Operations

Laboratory service revenue. Our laboratory service revenues are generated primarily by our performance of the Cologuard test. Our Cologuard test became available upon FDA approval on August 11, 2014. Total laboratory service revenue for the three and nine months ended September 30, 2015 was $12.6 million and $25.0 million,

respectively.

License fee revenue. There was no license fee revenue for the three and nine months ended September 30, 2015. Total license fee revenue was $0.3 million for the nine month periods ended September 30, 2014. There was no license fee revenue for the three months ended September 30, 2014. License fee revenue is composed of the amortization of up-front technology license fee payments associated with our collaboration, license and purchase agreement with Genzyme. The previously unamortized Genzyme up-front payment and holdback amounts were amortized on a straight-line basis over the initial Genzyme collaboration period, which ended in January 2014 therefore leading to a decline in revenue when compared to the prior year.

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Cost of Sales. Cost of sales includes costs related to inventory production and usage and the cost of laboratory services to process tests and provide results to physicians. Gross margin as a percentage of laboratory service revenue is also affected by our current revenue recognition policy, which may result in costs being incurred in one period that relate to revenues recognized in a later period. Cost of sales was $7.5 million and $16.8 million for the three and nine months ended September 30, 2015 compared to $0.9 million for the three and nine months ended September 30, 2014. The increase in cost of sales is related to the increase in production and testing services of our Cologuard test, which obtained FDA approval during the third quarter of 2014.

	Three Months Ended September 30,		
	2015	2014	Change
Direct production costs	$ 2.4	$ 0.2	$ 2.2
Indirect production costs	2.4	—	2.4
Personnel expenses	1.3	0.6	0.7
Depreciation expense	0.7	—	0.7
Facility costs	0.4	—	0.4
Stock-based compensation	0.2	0.1	0.1
Other cost of sales	0.1	—	0.1
Total cost of sales expenses	$ 7.5	$ 0.9	$ 6.6

	Nine Months Ended September 30,		
	2015	2014	Change
Indirect production costs	$ 4.8	$ —	$ 4.8
Direct production costs	4.3	0.2	4.1
Personnel expenses	4.1	0.6	3.5
Depreciation expense	2.0	—	2.0
Facility costs	0.9	—	0.9
Stock-based compensation	0.6	0.1	0.5
Other cost of sales	0.1	—	0.1
Total cost of sales expenses	$ 16.8	$ 0.9	$ 15.9

Research and development expenses. Research and development expenses increased to $9.9 million for the three months ended September 30, 2015 from $9.1 million for the three months ended September 30, 2014. Research and development expense increased to $24.5 million for the nine months ended September 30, 2015, from $23.7 million for the nine months ended September 30, 2014. The increase in research and development expenses was primarily due to an increase in research collaboration expenses, clinical trial expenses, and professional fees related to product

pipeline development.

	Three Months Ended September 30,		
	2015	2014	Change
Personnel expenses	$ 2.5	$ 2.1	$ 0.4
Clinical trial expenses	2.1	0.9	1.2
Research collaborations	1.6	0.6	1.0
Legal and professional fees	1.0	0.7	0.3
Other research and development	0.9	1.2	(0.3)
Stock-based compensation	0.9	2.0	(1.1)
Lab expenses	0.9	1.6	(0.7)
Total research and development expenses	$ 9.9	$ 9.1	$ 0.8

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	Nine Months Ended September 30,		
	2015	2014	Change
Personnel expenses	$ 7.0	$ 7.1	$ (0.1)
Legal and professional fees	4.3	1.3	3.0
Research collaborations	3.4	1.6	1.8
Clinical trial expenses	3.3	3.6	(0.3)
Stock-based compensation	2.7	3.5	(0.8)
Lab expenses	1.9	3.5	(1.6)
Other research and development	1.1	2.5	(1.4)
Facility costs	0.8	0.6	0.2
Total research and development expenses	$ 24.5	$ 23.7	$ 0.8

General and administrative expenses. General and administrative expenses increased to $15.4 million for the three months ended September 30, 2015 compared to $9.0 million for the three months ended September 30, 2014. General and administrative expenses increased to $42.1 million for the nine months ended September 30, 2015, from $19.8 million for the nine months ended September 30, 2014. The increase in general and administrative expenses was primarily a result of increased legal and professional fees, increased personnel costs and stock-based compensation expense due to increased headcount, additional information technology costs, increased depreciation expense, and other general and administrative expenses to support the needs of our growing infrastructure and overall growth of the Company.

	Three Months Ended September 30,		
	2015	2014	Change
Personnel expenses	$ 5.1	$ 1.9	$ 3.2
Legal and professional fees	3.1	2.1	1.0
Stock-based compensation	3.0	1.6	1.4
Information technology costs	1.4	1.2	0.2
Other general and administrative	1.4	1.7	(0.3)
Depreciation expense	1.1	0.3	0.8
Facility costs	0.3	0.2	0.1
Total general and administrative expenses	$ 15.4	$ 9.0	$ 6.4

	Nine Months Ended September 30,

	2015	2014	Change
Personnel expenses	$ 13.4	$ 4.5	$ 8.9
Legal and professional fees	10.0	5.0	5.0
Stock-based compensation	7.0	4.1	2.9
Information technology costs	4.8	2.2	2.6
Other general and administrative	3.3	2.5	0.8
Depreciation expense	2.8	0.9	1.9
Facility costs	0.8	0.6	0.2
Total general and administrative expenses	$ 42.1	$ 19.8	$ 22.3

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Sales and marketing expenses. Sales and marketing expenses increased to $23.1 million for the three months ended September 30, 2015, compared to $13.2 million for the three months ended September 30, 2014. Sales and marketing expenses increased to $60.2 million for the nine months ended September 30, 2015, compared to $23.8 million for the nine months ended September 30, 2014. The increase in sales and marketing expense was a result of hiring additional sales and marketing personnel and increasing our advertising and patient marketing efforts related to the commercialization of our Cologuard test.

	Three Months Ended September 30,		
	2015	2014	Change
Personnel expenses	$ 12.8	$ 5.0	$ 7.8
Professional fees	9.1	7.1	2.0
Stock-based compensation	0.8	0.3	0.5
Other sales and marketing	0.4	0.8	(0.4)
Total sales and marketing expenses	$ 23.1	$ 13.2	$ 9.9

	Nine Months Ended September 30,		
	2015	2014	Change
Personnel expenses	$ 35.1	$ 9.7	$ 25.4
Professional fees	21.4	12.9	8.5
Stock-based compensation	2.7	1.0	1.7
Other sales and marketing	1.0	0.2	0.8
Total sales and marketing expenses	$ 60.2	$ 23.8	$ 36.4

Investment income. Investment income increased to $365.0 thousand for the three months ended September 30, 2015 compared to $160.0 thousand for the three months ended September 30, 2014. Investment income increased to $780.0 thousand for the nine months ended September 30, 2015 compared to $392.0 thousand for the nine months ended September 30, 2014. The increase in investment income was primarily due to an increase in the average investment balance for the three months ended September 30, 2015 when compared to the same period in 2014.

Interest income and expense. Interest expense increased to $40.0 thousand for the three months ended September 30, 2015 from $12.0 thousand of interest expense for the three months ended September 30, 2014. This increase was primarily related to interest expense on our mortgage payable. Interest income increased to $56.0 thousand for the nine months ended September 30, 2015 from $40.0 thousand of interest expense for the nine months ended September

30, 2014. This change was primarily due to the forgiveness of the accrued interest expense previously recorded on the Wisconsin Department of Commerce loan.

Liquidity and Capital Resources

We have financed our operations since inception primarily through private and public offerings of our common stock. As of September 30, 2015, we had approximately $31.5 million in unrestricted cash and cash equivalents and approximately $312.0 million in marketable securities.

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

Net cash used in operating activities was $100.2 million for the nine months ended September 30, 2015 as compared to $50.0 million for the nine months ended September 30, 2014. The principal use of cash in operating activities for the nine months ended September 30, 2015 was to fund our net loss which increased from the nine months ended September 30, 2014 primarily due to increased sales and marketing efforts and general and administrative costs due to the commercial launch of Cologuard and to support the overall growth of the Company.

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Net cash used in investing activities was $105.7 million for the nine months ended September 30, 2015 as compared to $73.2 million of cash used in investing activities for the nine months ended September 30, 2014. The increase in cash used by investing activities for the nine months ended September 30, 2015 compared to the same period in 2014 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 was $17.5 million which consisted of purchases of property and equipment for the nine months ended September 30, 2015 and $9.5 million for the same period in 2014. The increase in property and equipment purchases during the nine months ended September 30, 2015 was primarily the result of increased laboratory equipment purchases, computer equipment and software purchases, building purchases, and leasehold improvement purchases.

Net cash provided by financing activities was $179.3 million for the nine months ended September 30, 2015, as compared to net cash provided by financing activities of $138.2 million for the nine months ended September 30, 2014. The increase in cash provided by financing activities for the nine months ended September 30, 2015 was due to the receipt of $174.1 million of cash from our July 2015 common stock offering, $3.8 million of cash proceeds from mortgage payable, $961.0 thousand from stock option exercises and $759.0 thousand from proceeds in connection with the Company's employee stock purchase plan slightly offset by capital lease payments of $360.0 thousand compared to the receipt of $137.7 million of cash from our April 2014 common stock offering, the receipt of $337.0 thousand from proceeds in connection with the Company's employee stock purchase plan, $424.0 thousand from stock option exercises slightly offset by capital lease payments of $262.0 thousand for the same period in 2014.

We expect that cash and cash equivalents and marketable securities on hand at September 30, 2015, will be sufficient to fund our current operations for at least the next twelve months, based on current operating plans. However, since payments for our Cologuard test will be our only material revenue source and we have just begun to collect such payments and do not know the timing or amount of any such payments, it is possible that we may need to raise additional capital to fully fund our current strategic plan. If we are unable to obtain sufficient additional funds to enable us to fund our operations through the completion of such plan, our results of operations and financial condition would be materially adversely affected and we may be required to delay the implementation of our plan and otherwise scale back our operations. Even if we successfully raise sufficient funds to complete our plan, we cannot assure that our business will ever generate sufficient cash flow from operations to become profitable.

Recent Accounting Pronouncements

In July 2015, the Financial Accounting Standards Board issued Accounting Standards Update No. 2015-11, "Simplifying the Measurement of Inventory (Topic 330)." The new guidance requires most inventory to be measured at the lower of cost and net realizable value, thereby simplifying the previous guidance under which an entity must measure inventory at the lower of cost or market. Market is defined as replacement cost, net realizable value ("NRV"), or NRV less a normal profit margin. The Accounting Standards Update will not apply to inventory that is measured using either the last-in, first-out method or the retail inventory method. The standard will be effective prospectively for the first interim period within annual reporting periods beginning after December 15, 2016. Early adoption is permitted. We do not expect to early adopt this guidance and are currently assessing the provisions of the guidance and have not determined the impact of the adoption of this guidance on our consolidated financial statements.

In April 2015, the Financial Accounting Standards Board issued Accounting Standards Update No. 2015-05, “Customer’s Accounting for Fees Paid in a Cloud Computing Arrangement”, which provides guidance that requires management to evaluate each cloud computing arrangement in order to determine whether it includes a software license that must be accounted for separately from hosted services. The new guidance clarifies that if a cloud computing arrangement includes a software license, we should account for the software license consistent with our accounting for other software licenses. If the arrangement does not include a software license, we should account for the arrangement as a service contract. The standard is effective for our financial statements issued for fiscal years beginning after December 15, 2015, and interim periods within those fiscal years. Early adoption is permitted for financial statements that have not previously been issued. The adoption of this standard is not expected to have a material impact on our consolidated financial statements.

In April 2015, the Financial Accounting Standards Board issued Accounting Standards Update No. 2015-03, “Simplifying the Presentation of Debt Issuance Costs”, which requires debt issuance costs to be presented in the balance sheet as a direct deduction from the associated debt liability. This guidance simplifies presentation of debt issuance costs

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but does not address presentation or subsequent measurement of debt issue costs related to line of credit arrangements. In August 2015, the Financial Accounting Standards Board issued Accounting Standards Update No. 2015-15 “Interest-Imputation of Interest (Subtopic 835-30) Presentation and Subsequent Measurement of Debt Issuance Costs Associated with Line-of-Credit Arrangements” which indicates the SEC staff would not object to an entity deferring and presenting debt issuance costs related to line-of-credit arrangements as an asset and subsequently amortizing the deferred debt issuance costs ratably over the term of the line-of-credit arrangement, regardless of whether there are any outstanding borrowings on the line-of-credit arrangement. Accounting Standards Update No. 2015-03 will be effective for the first interim period within annual reporting periods beginning after December 15, 2015. Early adoption is permitted. The adoption of this standard is not expected to have a material impact on our financial statements.

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” to defer for one year the effective date of the new revenue standard 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 this amendment on our financial position and results of operations.

Off-Balance Sheet Arrangements

As of September 30, 2015, 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, 2015 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, 2015, 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.

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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" in our most recent Annual Report on Form 10-K and our subsequent Quarterly Reports on Form 10-Q. Other than the factors set forth below, there have been no material changes to the risk factors described in those reports.

If the Draft USPSTF colorectal cancer screening recommendations become final as currently drafted, they could adversely impact our business.

On October 5, 2015, the US Preventive Services Task Force ("USPSTF") issued a draft recommendation statement on colorectal cancer screening (the "Draft Statement"). In the Draft Statement, USPSTF assigns an "A" grade to colorectal cancer screening for individuals starting at age 50 and continuing until age 75. Unlike prior USPSTF recommendations, the Draft Statement does not assign individual letter grades to individual screening tests. The Draft Statement designates certain screening modalities as "recommended" and others (including multi-target stool DNA testing, which is Cologuard) as "alternative tests." The Draft Statement indicates that the alternative tests "may be useful in select clinical circumstances" but are supported by "less mature evidence." The Draft Statement is open for public comment through November 2, 2015. We expect that a final version of the USPSTF colorectal cancer screening recommendations will be published in the first half of 2016.

If the final USPSTF colorectal cancer screening recommendations continue to designate Cologuard as an "alternative" test, or otherwise fail to designate Cologuard as either a "recommended" test or as having an "A" or "B" grade, market acceptance of Cologuard could be adversely affected, potentially materially so. For example, without a clear USPSTF "recommendation" or "A" or "B" grade, private health insurance plans may take the position that they are not required to cover Cologuard under the screening mandate provisions of the Patient Protection and Affordable Care Act (which

will require most private insurance plans to cover screening tests that receive an “A” or “B” grade from USPSTF without charging the patient any co-pay or deductible) and may decline to provide coverage. Also, the lack of a clear USPSTF endorsement may result in Cologuard not being credited under certain quality measures such as the National Committee for Quality Assurance (NCQA), Healthcare Effectiveness Data and Information Set (HEDIS) and the CMS Star ratings. If physicians do not earn quality credit for prescribing Cologuard, they may be less inclined to do so, which could adversely affect our business.

We face uncertainty related to healthcare reform, pricing, coverage and reimbursement, which could reduce our revenue.

Recent healthcare reform laws, including the Patient Protection and Affordable Care Act and the Protecting Access to Medicare Act of 2014 (“PAMA”), are significantly affecting the U.S. healthcare and medical services industry. Existing legislation, and possible future legal and regulatory changes, could substantially change the structure and finances of the health insurance system and the methodology for reimbursing medical services, drugs and devices, including our current and future products and services. Any change in reimbursement policy could result in a change in patient co-payments, which could adversely affect patient willingness and ability to use our Cologuard test and any other product or service we may develop. Healthcare reforms, which may intend to reduce healthcare costs, may have the effect of discouraging third-party payors from covering certain kinds of medical products and services, particularly newly developed technologies, such as our Cologuard test.

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Even without further legislative reform, there can be no assurance that CMS will maintain its current reimbursement rate for our Cologuard test. If the CMS reimbursement rate for Cologuard is reduced, our revenues could be adversely affected. There can be no assurance that CMS and third party payors who initially decide to cover Cologuard will continue to cover Cologuard. A hedge fund has submitted a request that CMS reconsider its reimbursement rate for Cologuard, which was presented at a CMS public meeting on July 16, 2015. CMS has issued a preliminary determination maintaining the current reimbursement rate. After a public comment period, CMS will issue a final determination in November, 2015. We can provide no assurance that CMS will not negatively alter its coverage or reimbursement rate based on this request or otherwise.

Under PAMA, the basis for Cologuard's CMS reimbursement rate is expected to change, beginning in January, 2017. CMS issued proposed regulations for the implementation of PAMA on September 25, 2015, which are open for public comment through November 25, 2015 (the "Proposed Regulations"). Under PAMA and the Proposed Regulations, the CMS reimbursement rate for Cologuard will be tied to the volume-weighted median reimbursement for Cologuard from commercial payors. Therefore, if Cologuard's volume-weighted median commercial reimbursement rate falls below the current CMS reimbursement rate (or the adjusted rate, if CMS determines to adjust the reimbursement rate as a result of the above-referenced request for reconsideration or otherwise) in 2016, we anticipate that the CMS reimbursement rate for Cologuard would decline in 2017.

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

On October 27, 2015, the Company's Board of Directors approved the Company's Second Amended and Restated Bylaws (the "Second Amended and Restated Bylaws"), effective immediately. The Second Amended and Restated Bylaws amend and restate in their entirety the Company's bylaws to, among other things:

- amend Article 2, Section 11 to allow for special meetings of the Company's Board of Directors (the "Board") in the event of an emergency with at least six (6) hours' notice, and to set quorum requirements for such meetings;
- amend Article 2, Section 17 to allow the Board to designate a committee by the vote of the majority of directors present at a duly convened meeting;
- include a new Article 7, which, unless the Company consents in writing, establishes certain Delaware courts as the exclusive forum for certain types of claims involving the Company; and
- make other non-substantive technical amendments, including to conform to developments in Delaware law.

The foregoing summary is subject to, and qualified in its entirety by, the full text of the Second Amended and Restated Bylaws, a copy of which is filed as Exhibit 3.3 to this Quarterly Report on Form 10-Q and is incorporated herein by reference.

Item 6. Exhibits

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

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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 30, 2015 By: /s/ Kevin T. Conroy
Kevin T. Conroy

President and Chief Executive Officer
(Principal Executive Officer)

Date: October 30, 2015 By: /s/ William J. Megan
William J. Megan
Senior Vice President, Finance
(Principal Financial Officer)

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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 A 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
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