

EXACT SCIENCES CORP
Form 10-Q
October 26, 2016
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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, 2016

OR

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

Commission File Number: 001-35092

EXACT SCIENCES CORPORATION

(Exact name of registrant as specified in its charter)

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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 25, 2016, the registrant had 108,410,279 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, 2016	December 31, 2015
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 63,445	\$ 41,135
Marketable securities	274,385	265,744
Accounts receivable, net	7,863	4,933
Inventory, net	7,666	6,677
Prepaid expenses and other current assets	5,673	7,375
Total current assets	359,032	325,864
Property and Equipment, at cost:		
Computer equipment and computer software	19,053	14,025
Laboratory equipment	14,249	12,786
Leasehold improvements	13,308	7,118
Assets under construction	6,536	8,038
Buildings	4,792	4,777
Furniture and fixtures	2,515	1,265
	60,453	48,009
Less—Accumulated depreciation	(21,980)	(13,913)
Net property and equipment	38,473	34,096
Other long-term assets	5,706	4,070
Total assets	\$ 403,211	\$ 364,030
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 2,335	\$ 3,308
Accrued liabilities	26,104	22,253
Debt and capital lease obligation, current portion	172	166
Other short-term liabilities	1,450	996
Total current liabilities	30,061	26,723
Long-term debt	4,673	4,789
Other long-term liabilities	5,308	4,601
Lease incentive obligation, less current portion	840	1,061
Total liabilities	40,882	37,174

Commitments and contingencies

Stockholders' Equity:

Preferred stock, \$0.01 par value Authorized—5,000,000 shares issued and outstanding—no shares at September 30, 2016 and December 31, 2015	—	—
Common stock, \$0.01 par value Authorized—200,000,000 shares issued and outstanding—108,410,279 and 96,674,786 shares at September 30, 2016 and December 31, 2015	1,084	967
Additional paid-in capital	1,070,083	904,932
Accumulated other comprehensive loss	(187)	(433)
Accumulated deficit	(708,651)	(578,610)
Total stockholders' equity	362,329	326,856
Total liabilities and stockholders' equity	\$ 403,211	\$ 364,030

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

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

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,	
	2016	2015
Cash flows from operating activities:		
Net loss	\$ (130,041)	\$ (117,812)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization of fixed assets	8,237	5,412
Loss on disposal of property and equipment	101	—
Stock-based compensation	16,773	13,148
Amortization of other liabilities	(713)	(399)
Amortization of deferred financing costs	40	33
Forgiveness of long-term debt	—	(1,000)
Amortization of premium on short-term investments	412	1,020
Amortization of intangible assets	150	—
Changes in assets and liabilities:		
Accounts receivable, net	(2,930)	(2,833)
Inventory, net	(989)	(2,015)
Prepaid expenses and other current assets	1,702	(1,907)
Accounts payable	(973)	(1,144)
Accrued liabilities	5,453	4,284
Lease incentive obligation	(159)	(415)
Accrued interest	—	(106)
Net cash used in operating activities	(102,937)	(103,734)
Cash flows from investing activities:		
Purchases of marketable securities	(151,456)	(197,997)
Maturities of marketable securities	142,813	109,826
Purchases of property and equipment	(12,166)	(14,019)
Net cash used in investing activities	(20,809)	(102,190)
Cash flows from financing activities:		
Proceeds from exercise of common stock options	1,049	961
Proceeds from sale of common stock, net of issuance costs	144,247	174,140
Payments on capital lease obligations	—	(360)
Proceeds from mortgage payable	—	3,756
Payments on mortgage payable	(124)	—
Proceeds in connection with the Company's employee stock purchase plan	1,048	759
Net cash provided by financing activities	146,220	179,256

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Effects of exchange rate changes on cash and cash equivalents	(164)	59
Net increase (decrease) in cash and cash equivalents	22,310	(26,609)
Cash and cash equivalents, beginning of period	41,135	58,131
Cash and cash equivalents, end of period	\$ 63,445	\$ 31,522
Supplemental disclosure of non-cash investing and financing activities:		
Property and equipment acquired but not paid	\$ 549	\$ 3,521
Unrealized gain on available-for-sale investments	\$ 410	\$ 211
Issuance of 341,507 and 21,826 shares of common stock to fund the Company's		
401(k) matching contribution for 2015 and 2014, respectively	\$ 2,151	\$ 835
Interest paid	\$ 157	\$ 9

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

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EXACT SCIENCES CORPORATION

Notes to Condensed Consolidated Financial Statements

(Unaudited)

(1) ORGANIZATION AND BASIS OF PRESENTATION

Organization

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

Basis of Presentation

The accompanying condensed consolidated financial statements, which include the accounts of Exact Sciences Corporation and those of its wholly owned subsidiaries, Exact Sciences Laboratories, LLC, Exact Sciences Finance Corporation, Exact Sciences Europe LTD, Beijing Exact Sciences Medical Technology Company Limited, and variable interest entities are unaudited and have been prepared on a basis substantially consistent with the Company’s audited financial statements and notes as of and for the year ended December 31, 2015 included in the Company’s Annual Report on Form 10-K (the “2015 Form 10-K”). These condensed consolidated financial statements are prepared in conformity with accounting principles generally accepted in the United States of America (“GAAP”) and follow the requirements of the Securities and Exchange Commission (“SEC”) for interim reporting. In the opinion of management, all adjustments (consisting only of adjustments of a normal and recurring nature) considered necessary for a fair presentation of the results of operations have been included. The results of the Company’s operations for any interim period are not necessarily indicative of the results of the Company’s operations for any other interim period or for a full fiscal year. The statements should be read in conjunction with the audited financial statements and related notes included in the 2015 Form 10-K. Management has evaluated subsequent events for disclosure or recognition in the accompanying financial statements up to the filing of this report.

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company's wholly owned subsidiaries, Exact Sciences Laboratories, LLC, Exact Sciences Finance Corporation, Exact Sciences Europe LTD, Beijing Exact Sciences Medical Technology Company Limited, and variable interest entities. All significant intercompany transactions and balances have been eliminated in consolidation.

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

Use of Estimates

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

Cash and Cash Equivalents

The Company considers cash on hand, demand deposits in bank, money market funds, and all highly liquid investments with an original maturity of 90 days or less to be cash and cash equivalents.

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Marketable Securities

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

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

We periodically review our investments in unrealized loss positions for other-than-temporary impairments. This evaluation includes, but is not limited to, significant quantitative and qualitative assessments and estimates regarding credit ratings, collateralized support, the length of time and significance of a security's loss position, our intent not to sell the security, and whether it is more likely than not that we will have to sell the security before recovery of its cost basis. For the nine months ended September 30, 2016, no investments were identified with other-than-temporary declines in value.

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

September 30, 2016

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

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

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

Changes in Accumulated Other Comprehensive Income (Loss)

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

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

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

Accumulated