

EXACT SCIENCES CORP
Form 10-Q
July 25, 2017
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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 June 30, 2017

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 02-0478229
(State or other jurisdiction of (I.R.S. Employer
incorporation or organization) Identification Number)

441 Charmany Drive, Madison WI 53719
(Address of principal executive offices) (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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth 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

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

As of July 24, 2017, the registrant had 119,096,437 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)

	June 30, 2017	December 31, 2016
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 180,407	\$ 48,921
Marketable securities	303,853	262,179
Accounts receivable, net	22,591	8,526
Inventory, net	12,410	6,833
Prepaid expenses and other current assets	6,872	7,114
Total current assets	526,133	333,573
Property and Equipment, at cost:		
Computer equipment and computer software	24,802	20,767
Laboratory equipment	18,258	14,749
Leasehold improvements	13,682	13,549
Assets under construction	9,095	6,711
Buildings	4,792	4,792
Furniture and fixtures	2,897	2,515
	73,526	63,083
Less—Accumulated depreciation	(31,478)	(24,941)
Net property and equipment	42,048	38,142
Other long-term assets	14,420	5,325
Total assets	\$ 582,601	\$ 377,040
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 2,237	\$ 710
Accrued liabilities	26,935	28,106
Debt, current portion	178	174
Other short-term liabilities	1,943	1,702
Total current liabilities	31,293	30,692
Long-term debt	4,552	4,633
Other long-term liabilities	5,684	5,734
Lease incentive obligation, less current portion	378	686
Total liabilities	41,907	41,745
Commitments and contingencies		
Stockholders' Equity:		
	—	—

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Preferred stock, \$0.01 par value Authorized—5,000,000 shares issued and outstanding—no shares at June 30, 2017 and December 31, 2016		
Common stock, \$0.01 par value Authorized—200,000,000 shares issued and outstanding—119,048,783 and 110,236,127 shares at June 30, 2017 and December 31, 2016	1,190	1,102
Additional paid-in capital	1,351,836	1,080,432
Accumulated other comprehensive loss	(379)	(418)
Accumulated deficit	(811,953)	(745,821)
Total stockholders' equity	540,694	335,295
Total liabilities and stockholders' equity	\$ 582,601	\$ 377,040

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		Six Months Ended June 30,	
	June 30, 2017	2016	2017	2016
Laboratory service revenue	\$ 57,646	\$ 21,185	\$ 106,009	\$ 36,020
Cost of sales	17,991	10,097	34,972	19,156
Gross margin	39,655	11,088	71,037	16,864
Operating expenses:				
Research and development	9,737	8,640	17,739	18,766
General and administrative	24,609	17,284	44,679	35,108
Sales and marketing	36,728	30,301	75,529	56,012
Total operating expenses	71,074	56,225	137,947	109,886
Loss from operations	(31,419)	(45,137)	(66,910)	(93,022)
Other income (expense)				
Investment income	683	425	1,278	891
Interest expense	(54)	(53)	(104)	(107)
Total other income	629	372	1,174	784
Net loss	\$ (30,790)	\$ (44,765)	\$ (65,736)	\$ (92,238)
Net loss per share—basic and diluted	\$ (0.27)	\$ (0.46)	\$ (0.59)	\$ (0.95)
Weighted average common shares outstanding—basic and diluted	112,847	97,902	111,721	97,578

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		Six Months Ended June 30,	
	June 30, 2017	2016	2017	2016
Net loss	\$ (30,790)	\$ (44,765)	\$ (65,736)	\$ (92,238)
Other comprehensive loss, net of tax:				
Unrealized gain (loss) on available-for-sale investments	(37)	82	(42)	555
Foreign currency translation gain (loss)	89	(82)	81	(139)
Comprehensive loss	\$ (30,738)	\$ (44,765)	\$ (65,697)	\$ (91,822)

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)

	Six Months Ended June 30,	
	2017	2016
Cash flows from operating activities:		
Net loss	\$ (65,736)	\$ (92,238)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization of fixed assets	6,756	5,289
Loss on disposal of property and equipment	91	44
Stock-based compensation	12,224	10,607
Amortization of other liabilities	(769)	(445)
Amortization of deferred financing costs	26	26
Amortization of premium on short-term investments	57	346
Amortization of intangible assets	290	100
Changes in assets and liabilities:		
Accounts receivable, net	(14,065)	(2,508)
Inventory, net	(5,577)	(1,727)
Prepaid expenses and other current assets	242	80
Accounts payable	1,527	(173)
Accrued liabilities	(268)	2,651
Lease incentive obligation	(308)	(23)
Net cash used in operating activities	(65,510)	(77,971)
Cash flows from investing activities:		
Purchases of marketable securities	(188,248)	(6,118)
Maturities of marketable securities	146,475	97,004
Purchases of property and equipment	(8,648)	(6,415)
Purchases of intangible assets	(8,442)	—
Net cash (used in) provided by investing activities	(58,863)	84,471
Cash flows from financing activities:		
Proceeds from exercise of common stock options	772	549
Proceeds from sale of common stock, net of issuance costs	253,463	—
Payments on mortgage payable	(86)	(82)
Proceeds in connection with the Company's employee stock purchase plan	1,629	1,047
Net cash provided by financing activities	255,778	1,514
Effects of exchange rate changes on cash and cash equivalents	81	(139)
Net increase in cash and cash equivalents	131,486	7,875
Cash and cash equivalents, beginning of period	48,921	41,135
Cash and cash equivalents, end of period	\$ 180,407	\$ 49,010
Supplemental disclosure of non-cash investing and financing activities:		
Property and equipment acquired but not paid	\$ 2,105	\$ 1,055

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Unrealized gain (loss) on available-for-sale investments	\$ (42)	\$ 555
Issuance of 158,717 and 341,507 shares of common stock to fund the Company's 401(k) matching contribution for 2016 and 2015, respectively	\$ 3,008	\$ 2,151
Interest paid	\$ 101	\$ 105

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, 2016 included in the Company’s Annual Report on Form 10-K (the “2016 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 2016 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 condensed 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 June 30, 2017 and December 31, 2016, 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 six months ended June 30, 2017 and 2016. Realized gains were \$10,000 and \$18,000 for the six months ended June 30, 2017 and 2016, 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 six months ended June 30, 2017, no investments were identified with other-than-temporary declines in value.

Available-for-sale securities at June 30, 2017 consisted of the following:

June 30, 2017

Gains in Accumulated Losses in Accumulated

