

EXACT SCIENCES CORP  
Form 10-Q  
August 01, 2018  
Table of Contents

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, 2018

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)

Edgar Filing: EXACT SCIENCES CORP - Form 10-Q

DELAWARE  
(State or other jurisdiction of  
incorporation or organization)

02-0478229  
(I.R.S. Employer  
Identification Number)

441 Charmany Drive, Madison WI  
(Address of principal executive offices)

53719  
(Zip Code)

(608) 284-5700 (Registrant's telephone number, including area code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically, if any, every Interactive Data File required to be submitted 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 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	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 31, 2018, the registrant had 122,753,839 shares of common stock outstanding.



Table of Contents

EXACT SCIENCES CORPORATION

INDEX

	Page Number
<u>Part I - Financial Information</u>	
<u>Item 1. Financial Statements</u>	
<u>Condensed Consolidated Balance Sheets (unaudited) as of June 30, 2018 and December 31, 2017</u>	3
<u>Condensed Consolidated Statements of Operations (unaudited) for the Three and Six Months Ended June 30, 2018 and 2017</u>	4
<u>Condensed Consolidated Statements of Comprehensive Loss (unaudited) for the Three and Six Months Ended June 30, 2018 and 2017</u>	5
<u>Condensed Consolidated Statements of Cash Flows (unaudited) for the Six Months Ended June 30, 2018 and 2017</u>	6
<u>Notes to Condensed Consolidated Financial Statements (unaudited)</u>	7
<u>Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	29
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	44
<u>Item 4. Controls and Procedures</u>	44
<u>Part II - Other Information</u>	
<u>Item 1. Legal Proceedings</u>	45
<u>Item 1A. Risk Factors</u>	45
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	45
<u>Item 3. Defaults Upon Senior Securities</u>	45
<u>Item 4. Mine Safety Disclosures</u>	45
<u>Item 5. Other Information</u>	45

<u>Item 6. Exhibits</u>	45
<u>Signatures</u>	47

Table of Contents

## Part I — Financial Information

## EXACT SCIENCES CORPORATION

## Condensed Consolidated Balance Sheets

(Amounts in thousands, except share data - unaudited)

	June 30, 2018	December 31, 2017
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 225,662	\$ 77,491
Marketable securities	996,500	347,224
Accounts receivable, net	36,268	26,419
Inventory, net	35,409	26,027
Prepaid expenses and other current assets	16,465	10,055
Total current assets	1,310,304	487,216
Long-term Assets:		
Property, plant and equipment, net	140,467	79,986
Intangibles, net	23,108	24,205
Other long-term assets, net	8,773	7,153
Total assets	\$ 1,482,652	\$ 598,560
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts payable	\$ 10,992	\$ 16,135
Accrued liabilities	60,046	49,126
Accrued interest	4,154	—
Debt, current portion	4,588	182
Other short-term liabilities	3,182	2,681
Total current liabilities	82,962	68,124
Convertible notes, net	647,923	—
Long-term debt, less current portion	878	4,269
Other long-term liabilities	6,501	5,749
Total liabilities	738,264	78,142
Commitments and contingencies		
Stockholders' Equity:		
Preferred stock, \$0.01 par value Authorized—5,000,000 shares issued and outstanding—no shares at June 30, 2018 and December 31, 2017	—	—
Common stock, \$0.01 par value Authorized—200,000,000 shares issued and outstanding—122,604,714 and 120,497,426 shares at June 30, 2018 and December 31, 2017	1,226	1,205
Additional paid-in capital	1,681,465	1,380,577
Accumulated other comprehensive loss	(1,878)	(750)

Edgar Filing: EXACT SCIENCES CORP - Form 10-Q

Accumulated deficit	(936,425)	(860,614)
Total stockholders' equity	744,388	520,418
Total liabilities and stockholders' equity	\$ 1,482,652	\$ 598,560

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

3

---

Table of Contents

## 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, 2018	2017	2018	2017
Laboratory service revenue	\$ 102,894	\$ 57,646	\$ 193,190	\$ 106,009
Cost of sales	26,888	17,991	49,802	34,972
Gross margin	76,006	39,655	143,388	71,037
Operating expenses:				
Research and development	14,712	9,737	29,647	17,739
General and administrative	39,565	24,609	75,132	44,679
Sales and marketing	54,431	36,728	107,839	75,529
Total operating expenses	108,708	71,074	212,618	137,947
Loss from operations	(32,702)	(31,419)	(69,230)	(66,910)
Other income (expense)				
Investment income	4,917	683	8,590	1,278
Interest expense	(8,603)	(54)	(15,113)	(104)
Total other income (expense)	(3,686)	629	(6,523)	1,174
Net loss before tax	(36,388)	(30,790)	(75,753)	(65,736)
Income tax benefit (expense)	1	—	(58)	—
Net loss	\$ (36,387)	\$ (30,790)	\$ (75,811)	\$ (65,736)
Net loss per share—basic and diluted	\$ (0.30)	\$ (0.27)	\$ (0.62)	\$ (0.59)
Weighted average common shares outstanding—basic and diluted	122,129	112,847	121,578	111,721

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



Table of Contents

## EXACT SCIENCES CORPORATION

## Condensed Consolidated Statements of Comprehensive Loss

(Amounts in thousands - unaudited)

	Three Months Ended		Six Months Ended June 30,	
	June 30, 2018	2017	2018	2017
Net loss	\$ (36,387)	\$ (30,790)	\$ (75,811)	\$ (65,736)
Other comprehensive loss, net of tax:				
Unrealized gain (loss) on available-for-sale investments	476	(37)	(1,130)	(42)
Foreign currency translation gain (loss)	(18)	89	2	81
Comprehensive loss	\$ (35,929)	\$ (30,738)	\$ (76,939)	\$ (65,697)

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

Table of Contents

## EXACT SCIENCES CORPORATION

## Condensed Consolidated Statements of Cash Flows

(Amounts in thousands, except share data - unaudited)

	Six Months Ended June 30,	
	2018	2017
Cash flows from operating activities:		
Net loss	\$ (75,811)	\$ (65,736)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization of property and equipment	8,808	6,756
Loss on disposal of property and equipment	96	91
Stock-based compensation	28,056	12,224
Amortization of debt discount	10,822	—
Amortization of debt issuance costs	920	—
Amortization of other liabilities	(1,136)	(769)
Amortization of deferred financing costs	49	26
Amortization of premium on short-term investments	(1,392)	57
Amortization of intangible assets	1,228	290
Changes in assets and liabilities, net of effects of acquisition:		
Accrued interest	4,154	—
Accounts receivable, net	(9,849)	(14,065)
Inventory, net	(9,382)	(5,577)
Prepaid expenses and other current assets	(6,410)	242
Accounts payable	(5,143)	1,527
Accrued liabilities	(9,798)	(268)
Other short-term liabilities	69	—
Lease incentive obligation	683	(308)
Net cash used in operating activities	(64,036)	(65,510)
Cash flows from investing activities:		
Purchases of marketable securities	(894,856)	(188,248)
Maturities of marketable securities	245,842	146,475
Purchases of property and equipment	(44,364)	(8,648)
Purchases of intangible assets	—	(8,442)
Internally developed software	(131)	—
Net cash used in investing activities	(693,509)	(58,863)
Cash flows from financing activities:		
Proceeds from issuance of convertible notes, net	896,425	—
Proceeds from exercise of common stock options	5,645	772
Proceeds from sale of common stock, net of issuance costs	—	253,463
Proceeds in connection with the Company's employee stock purchase plan	2,661	1,629
Payments of deferred financing costs	(24)	—
Proceeds from construction loan	1,097	—
Payments on mortgage payable	(90)	(86)
Net cash provided by financing activities	905,714	255,778

Edgar Filing: EXACT SCIENCES CORP - Form 10-Q

Effects of exchange rate changes on cash and cash equivalents	2	81
Net increase in cash and cash equivalents	148,171	131,486
Cash and cash equivalents, beginning of period	77,491	48,921
Cash and cash equivalents, end of period	\$ 225,662	\$ 180,407
Supplemental disclosure of non-cash investing and financing activities:		
Property and equipment acquired but not paid	\$ 25,021	\$ 2,105
Unrealized loss on available-for-sale investments	\$ (1,130)	\$ (42)
Issuance of 86,882 and 158,717 shares of common stock to fund the Company's		
401(k) matching contribution for 2017 and 2016, respectively	\$ 4,303	\$ 3,008
Interest paid	\$ 97	\$ 101

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

Table of Contents

EXACT SCIENCES CORPORATION

Notes to Condensed Consolidated Financial Statements

(Unaudited)

(1) ORGANIZATION AND BASIS OF PRESENTATION

Organization

Exact Sciences Corporation (“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, with the goal of becoming a leader in cancer diagnostics.

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, CG Growth, LLC, Exact Sciences Development Company, LLC, Sampleminded, Inc., 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, 2017 included in the Company’s Annual Report on Form 10-K (the “2017 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 2017 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, CG Growth, LLC, Exact Sciences Development Company, LLC, Sampleminded, Inc., 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.

## Table of Contents

### Cash and Cash Equivalents

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

### Marketable Securities

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

At June 30, 2018 and December 31, 2017, 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, 2018 and 2017. Realized gains were \$0.1 million and \$10,000 for the six months ended June 30, 2018 and 2017, 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, 2018, no investments were identified with other-than-temporary declines in value.

Available-for-sale securities at June 30, 2018 consisted of the following:

(In thousands)	June 30, 2018		Losses in Accumulated Other Comprehensive Income (Loss)	Estimated Fair Value
	Amortized Cost	Gains in Accumulated Other Comprehensive Income (Loss)		
Corporate bonds	\$ 408,569	53	(845)	\$ 407,777
Asset backed securities	284,134	10	(749)	283,395
U.S. government agency securities	248,730	10	(258)	248,482
Commercial paper	6,118	—	(3)	6,115
Certificates of deposit	50,768	5	(42)	50,731
Total available-for-sale securities	\$ 998,319	\$ 78	\$ (1,897)	\$ 996,500

Table of Contents

Available-for-sale securities at December 31, 2017 consisted of the following:

(In thousands)	December 31, 2017		Losses in Accumulated Other Comprehensive Income (Loss)	Estimated Fair Value
	Amortized Cost	Gains in Accumulated Other Comprehensive Income (Loss)		
Corporate bonds	\$ 181,639	\$ 10	\$ (344)	\$ 181,305
Asset backed securities	94,700	—	(185)	94,515
U.S. government agency securities	54,974	—	(162)	54,812
Commercial paper	9,953	—	(7)	9,946
Certificates of deposit	6,647	1	(2)	6,646
Total available-for-sale securities	\$ 347,913	\$ 11	\$ (700)	\$ 347,224

## Changes in Accumulated Other Comprehensive Income (Loss)

The amounts recognized in accumulated other comprehensive income (loss) ("AOCI") for the six months ended June 30, 2018 were as follows:

(In thousands)	Cumulative Translation Adjustment	Unrealized Gain (Loss) on Securities	Accumulated Other Comprehensive Income (Loss)
Balance at December 31, 2017	\$ (61)	\$ (689)	\$ (750)
Other comprehensive loss before reclassifications	2	(1,244)	(1,242)
Amounts reclassified from accumulated other comprehensive loss	—	114	114
Net current period change in accumulated other comprehensive loss	2	(1,130)	(1,128)
Balance at June 30, 2018	\$ (59)	\$ (1,819)	\$ (1,878)

The amounts recognized in AOCI for the six months ended June 30, 2017 were as follows:

Cumulative Translation	Unrealized Gain (Loss)	Accumulated Other Comprehensive
---------------------------	---------------------------	---------------------------------------



Edgar Filing: EXACT SCIENCES CORP - Form 10-Q

(In thousands)	Adjustment	on Securities	Income (Loss)
Balance at December 31, 2016	\$ (204)	\$ (214)	\$ (418)
Other comprehensive loss before reclassifications	81	(38)	43
Amounts reclassified from accumulated other comprehensive loss	—	(4)	(4)
Net current period change in accumulated other comprehensive loss	81	(42)	39
Balance at June 30, 2017	\$ (123)	\$ (256)	\$ (379)

Amounts reclassified from AOCI for the six months ended June 30, 2018 and 2017 were as follows:

Details about AOCI Components (In thousands)	Affected Line Item in the Statement of Operations	Six Months Ended June 30,	
		2018	2017
Change in value of available-for-sale investments			
Sales and maturities of available-for-sale investments	Investment income	\$ 114	\$ (4)
Total reclassifications		\$ 114	\$ (4)

Table of Contents

## 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. Property and equipment consisted of the following as of June 30, 2018 and December 31, 2017:

(In thousands)	Estimated Useful Life	June 30, 2018	December 31, 2017
Property, plant and equipment			
Land	(1)	\$ 4,466	\$ 4,466
Leasehold and building improvements	(2)	23,301	17,629
Land improvements	15 years	1,530	1,419
Buildings	30 - 40 years	7,928	7,928
Computer equipment and computer software	3 years	33,455	30,148
Laboratory equipment	3 - 5 years	30,345	23,296
Furniture and fixtures	3 years	5,693	4,531
Assets under construction	(3)	80,518	28,655
Property, plant and equipment, at cost		187,236	118,072
Accumulated depreciation		(46,769)	(38,086)
Property, plant and equipment, net		\$ 140,467	\$ 79,986

(1) Not depreciated.

(2) Lesser of the remaining lease term, building life, or useful life.

(3) Not depreciated until placed into service.

At June 30, 2018, the Company had \$80.5 million of assets under construction which consisted of \$22.7 million related to laboratory equipment, \$55.4 million related to leasehold and building improvements, and \$2.4 million related to computer equipment and computer software projects. Depreciation will begin on these assets once they are placed into service. The Company expects to incur an additional \$9.7 million to complete the laboratory equipment, \$231.9 million to complete the building projects, and \$1.6 million to complete the computer equipment and computer software projects. These projects are expected to be completed throughout 2018, 2019 and 2020. The Company assesses its long-lived assets, consisting primarily of property and equipment, for impairment when material events and changes in circumstances indicate that the carrying value may not be recoverable. There were no impairment losses for the periods ended June 30, 2018 and December 31, 2017.

## Software Capitalization Policy

Software development costs related to internal use software are incurred in three stages of development: the preliminary project stage, the application development stage, and the post-implementation stage. Costs incurred during the preliminary project and post-implementation stages are expensed as incurred. Costs incurred during the application development stage that meet the criteria for capitalization are capitalized and amortized, when the software

is ready for its intended use, using the straight-line basis over the estimated useful life of the software.

Table of Contents

## Intangible Assets

## Intangible Assets

Intangible assets consisted of the following:

(In thousands)	June 30, 2018	December 31, 2017
Finite-lived intangible assets		
Finite-lived intangible assets	\$ 23,862	\$ 23,731
Less: Accumulated amortization	(2,733)	(1,505)
Finite-lived intangible assets, net	21,129	22,226
Indefinite-lived intangible assets		
Goodwill	1,979	1,979
Net carrying value	\$ 23,108	\$ 24,205

## Finite-Lived Intangible Assets

The following table summarizes the net-book-value and estimated remaining life of the Company's finite-lived intangible assets as of June 30, 2018:

(In thousands)	Net Balance at June 30, 2018	Weighted Average Remaining Life (Years)
Licensed intellectual property and patents	\$ 20,110	10.0
Developed technology	1,019	6.4
Total	\$ 21,129	

The table below represents estimated future amortization expense associated with the Company's finite-lived intangible assets as of June 30, 2018:

(In thousands)

2018	\$ 1,237
2019	2,474
2020	2,469
2021	2,383
2022	2,370
Thereafter	10,196
	\$ 21,129

The Company reviews long-lived assets and certain identifiable intangibles for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. Assets to be disposed of are reported at the lower of the carrying amount or fair value less costs to sell. There were no impairment losses for periods ended June 30, 2018 and December 31, 2017.

Patent costs, which have historically consisted of related legal fees, are capitalized as incurred, only if the Company determines that there is some probable future economic benefit to be derived from the transaction. A capitalized patent is amortized over its estimated useful life, beginning when such patent is approved. Capitalized patent costs are expensed upon disapproval, upon a decision by the Company to no longer pursue the patent or when the related intellectual property is either sold or deemed to be no longer of value to the Company. Other than the transactions discussed below,

Table of Contents

the Company determined that all patent costs incurred during the six months ended June 30, 2018 and 2017 should be expensed and not capitalized as the future economic benefit to be derived from the transactions cannot be determined.

Direct and indirect manufacturing costs incurred during the process validation and for other research and development activities, which are not permitted to be sold, have been expensed to research and development.

Under a technology license and royalty agreement entered into with MDxHealth (“MDx”), dated July 26, 2010 (as subsequently amended, the “MDx License Agreement”), the Company was required to pay MDx milestone-based royalties on sales of products or services covered by the licensed intellectual property. Once the achievement of a milestone occurred or was considered probable, an intangible asset and corresponding liability was reported in other long-term assets and accrued liabilities, respectively. The liability was relieved once the milestone was achieved and payment made. The intangible asset is being amortized over the estimated ten-year useful life of the licensed intellectual property through 2024, and such amortization is reported in cost of sales. Payment for all remaining milestones under the MDx License Agreement was made as part of the Royalty Buy-Out agreement outlined below.

Effective April 25, 2017, the Company and MDx entered into a Royalty Buy-Out Agreement (“Royalty Buy-Out Agreement”), which terminated the MDx License Agreement. Pursuant to the Royalty Buy-Out Agreement, the Company paid MDx a one-time fee of \$8.0 million in exchange for an assignment of certain patents covered by the MDx License Agreement and the elimination of all ongoing royalties and other payments by the Company to MDx under the MDx License Agreement. Also included in the Royalty Buy-Out Agreement is a mutual release of liabilities, which includes all amounts previously accrued under the MDx License Agreement. Concurrently with entering into the Royalty Buy-Out Agreement, the Company entered into a Patent Purchase Agreement (“Patent Purchase Agreement”) with MDx under which it paid MDx an additional \$7.0 million in exchange for the assignment of certain other patent rights that were not covered by the MDx License Agreement. The total \$15.0 million paid by the Company pursuant to the Royalty Buy-Out Agreement and Patent Purchase Agreement, net of liabilities relieved of \$6.6 million, was recorded as an intangible asset and is being amortized over the estimated useful life of the licensed intellectual property through 2024, and such amortization is reported in cost of sales. The \$6.6 million of liabilities relieved were related to historical milestones and accrued royalties under the MDx License Agreement.

As of June 30, 2018, and December 31, 2017, an intangible asset of \$8.4 million and \$9.0 million, respectively, related to historical milestone payments made under the MDx License Agreement and intangible assets acquired as part of the Royalty Buy-Out Agreement and Patent Purchase Agreement is reported in intangible assets in the Company’s condensed consolidated balance sheets. Amortization expense was \$0.3 million and \$0.2 million for the three months ended June 30, 2018 and 2017, respectively. Amortization expense was \$0.7 million and \$0.3 million for the six months ended June 30, 2018 and 2017, respectively.

On December 15, 2017, the Company entered into an asset purchase agreement (the “Armune Purchase Agreement”) with Armune BioScience, Inc. (“Armune”), pursuant to which the Company acquired intellectual property and certain other assets underlying Armune’s APIFINY®, APIFINY® PRO and APIFINY® ACTIVE SURVEILLANCE prostate

cancer diagnostic tests. The portfolio of Armune assets the Company acquired is expected to complement its product pipeline. The total consideration was comprised of an up-front cash payment of \$12.0 million and \$17.5 million in contingent payment obligations that will become payable upon the Company's achievement of development and commercial milestones using the acquired intellectual property. The ability to meet these events is subject to many risks and is therefore uncertain. The Company will not record the contingent consideration until it is probable that the milestones will be met. There is no other consideration due to Armune beyond the milestone payments and the Company is not subject to future royalty obligations should a product be developed and commercialized. In connection with the Armune Purchase Agreement, Armune terminated a license agreement pursuant to which it licensed certain patent rights and know-how from the Regents of the University of Michigan ("University of Michigan"), and the Company entered into a license agreement with the University of Michigan with respect to such patent rights and know-how, as well as certain additional intellectual property rights. Pursuant to the Company's agreement with the University of Michigan, it is required to pay the University of Michigan a low single-digit royalty on its net sales of products using the licensed intellectual property.

## Table of Contents

The Company accounted for the transaction as an asset acquisition under GAAP. The asset is comprised of a portfolio of biomarkers and related technology and know-how, which is a group of complementary assets concentrated in a single identifiable asset. The transaction costs directly related to the asset acquisition were added to the asset in accordance with GAAP. As such, the collective asset value from the acquisition resulted in an intangible asset of \$12.2 million. The intellectual property asset, which includes related transaction costs, is being amortized on a straight-line basis over the period the Company expects to be benefited, which is in line with the legal life of the patents acquired. The Company capitalized these costs as there is a reasonable expectation that the assets acquired will be used in an alternative manner in the future, that is not contingent on future development subsequent to acquisition, and the Company anticipates there to be economic benefit from these alternative uses. For the three and six months ended June 30, 2018, the Company recorded amortization expense of \$0.2 million and \$0.5 million, respectively. At June 30, 2018 and December 31, 2017, the net balance of \$11.7 million and \$12.2 million, respectively, is reported in net intangible assets in the Company's condensed consolidated balance sheets.

As a result of the Sampleminded acquisition during the third quarter of 2017, the Company recorded an intangible asset of \$1.0 million, which was comprised of developed technology acquired of \$0.9 million, customer relationships of \$0.1 million, and non-compete agreements of \$32,000. The intangible assets acquired are being amortized over the remaining useful life, which was determined to be eight years for developed technology acquired, three years for customer relationships, and five years for non-compete agreements. For the three months ended June 30, 2018 and 2017, the Company recorded amortization expense of \$36,000 and \$0, respectively. For the six months ended June 30, 2018, and 2017 the Company recorded amortization expense of \$0.1 million and \$0, respectively. At June 30, 2018 and December 31, 2017 the net balance of \$0.8 million and \$0.9 million, respectively, is reported in net intangible assets in the Company's condensed consolidated balance sheets.

## Goodwill

During the third quarter of 2017, the Company recognized goodwill of \$2.0 million from the acquisition of Sampleminded, Inc. Goodwill is reported in net intangible assets in the Company's condensed consolidated balance sheets. The Company evaluates goodwill impairment on an annual basis, or more frequently should an event or change in circumstance occur that indicate the carrying amount is in excess of the fair value. There were no impairment losses for the periods ended June 30, 2018 and December 31, 2017.

## Investment in Privately-Held Company

On November 30, 2017, the Company made a 10 percent investment in a supplier. The investment does not constitute a variable interest entity, as the Company does not have control over the supplier's business. Additionally, as the ownership percentage is below 20 percent, the equity method is not being used to account for the investment. The supplier is privately-held, and there are no quoted prices or observable pricing inputs available. Therefore, the Company has accounted for this investment at cost, less any impairments, plus or minus changes resulting from observable price changes in orderly transactions for an identical or similar investment. The investment will be evaluated annually for impairment and adjusted to fair value whenever there is an observable price change in the identical or alike investment. There was no impairment recorded during the period ended June 30, 2018. The total cash paid related to the investment was \$3.0 million, which agrees to the carrying value as of June 30, 2018 and is reported in other long-term assets in the Company's condensed consolidated balance sheets. There were no



adjustments to the carrying value, upward or downward, during the three and six months ended June 30, 2018.

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.

Table of Contents

The following potentially issuable common shares were not included in the computation of diluted net loss per share because they would have an anti-dilutive effect due to net losses for each period:

(In thousands)	June 30,	
	2018	2017
Shares issuable upon exercise of stock options	2,918	3,513
Shares issuable upon the release of restricted stock awards	6,312	5,424
Shares issuable upon conversion of convertible notes	12,044	—
	21,274	8,937

## Revenue Recognition

The Company's laboratory service revenues are generated by performing diagnostic services using its Cologuard test, and the service is completed upon delivery of a patient's test result to the ordering physician. The Company accounts for revenue in accordance with ASC Topic 606, Revenue from Contracts with Customers ("ASC 606"), which it adopted on January 1, 2018, using the modified retrospective method, which it elected to apply to all contracts. Application of the modified retrospective method did not impact amounts previously reported by the Company, nor did it require a cumulative effect adjustment upon adoption, as the Company's method of recognizing revenue under ASC 606 was analogous to the method utilized immediately prior to adoption. Accordingly, there is no need for the Company to disclose the amount by which each financial statement line item was affected as a result of applying the new standard and an explanation of significant changes.

The core principle of ASC 606 is that the Company recognizes revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services. The Company recognizes revenue in accordance with that core principle, and key aspects considered by the Company include the following:

## Contracts

The Company's customer is the patient. However, the Company does not enter into a formal reimbursement contract with a patient, as formal reimbursement contracts, including national coverage determination for Cologuard, are established with payers. Accordingly, the Company establishes a contract with a patient in accordance with other customary business practices.

- Approval of a contract is established via the order submitted by the patient's physician and the return of a sample by the patient.
- The Company is obligated to perform its diagnostic services upon receipt of a sample from a patient, and the patient and/or applicable payer are obligated to reimburse the Company for services rendered based on the patient's insurance benefits.
- Payment terms are a function of a patient's existing insurance benefits, including the impact of coverage decisions with CMS and applicable reimbursement contracts established between the Company and payers, unless the patient is a self-pay patient, whereby the Company requires payment from the patient prior to the Company shipping a collection kit to the patient.
- Once the Company delivers a patient's test result to the ordering physician the contract with a patient has commercial substance, as the Company is legally able to collect payment and bill an insurer and/or patient, depending on payer contract status or patient insurance benefit status.
- The Company's consideration is deemed to be variable, and the Company considers collection of such consideration to be probable to the extent that it is unconstrained.

#### Performance obligations

A performance obligation is a promise in a contract to transfer a distinct good or service (or a bundle of goods or services) to the customer. Our contracts have a single performance obligation, which is satisfied upon rendering of services, which culminates in the delivery of a patient's Cologuard test result to the ordering physician. The duration of time between sample receipt and delivery of a valid test result to the ordering physician is typically less than two weeks.

## Table of Contents

Accordingly, the Company elects the practical expedient and therefore, does not disclose the value of unsatisfied performance obligations.

### Transaction price

The transaction price is the amount of consideration to which the Company expects to collect in exchange for transferring promised goods or services to a customer, excluding amounts collected on behalf of third parties (for example, some sales taxes). The consideration expected from a contract with a customer may include fixed amounts, variable amounts, or both.

The consideration derived from the Company's contracts is deemed to be variable, though the variability is not explicitly stated in any contract. Rather, the implied variability is due to several factors, such as the amount of contractual adjustments, any patient co-payments, deductibles or compliance incentives, the existence of secondary payers and claim denials.

The Company estimates the amount of variable consideration using the expected value method, which represents the sum of probability-weighted amounts in a range of possible consideration amounts. When estimating the amount of variable consideration, the Company considers several factors, such as historical collections experience, patient insurance eligibility and payer reimbursement contracts.

The Company limits the amount of variable consideration included in the transaction price to the unconstrained portion of such consideration. In other words, the Company recognizes revenue up to the amount of variable consideration that is not subject to a significant reversal until additional information is obtained or the uncertainty associated with the additional payments or refunds is subsequently resolved. Differences between original estimates and subsequent revisions, including final settlements, represent changes in the estimate of variable consideration and are included in the period in which such revisions are made. Revenue recognized from changes in transaction prices was \$3.4 million and \$11.9 million for the three and six months ended June 30, 2018.

The Company monitors its estimates of transaction price to depict conditions that exist at each reporting date. If the Company subsequently determines that it will collect more consideration than it originally estimated for a contract with a patient, it will account for the change as an increase in the estimate of the transaction price (i.e., an upward revenue adjustment) in the period identified. Similarly, if the Company subsequently determines that the amount it expects to collect from a patient is less than it originally estimated, it will generally account for the change as a decrease in the estimate of the transaction price (i.e., a downward revenue adjustment), provided that such downward adjustment does not result in a significant reversal of cumulative revenue recognized.

When the Company does not have significant historical experience or that experience has limited predictive value, the constraint over estimates of variable consideration may result in no revenue being recognized upon delivery of a patient's Cologuard test result to the ordering physician, with recognition, generally occurring at the date of cash receipt. Since the first quarter of 2017, the Company has determined that its historical experience has sufficient predictive value, such that there are no longer any contracts for which no revenue is recognized upon delivery of a Cologuard test result to an ordering physician. Of the revenue recognized in the twelve months ended December 31, 2017, approximately \$4.3 million relates to the one-time impact of certain payers meeting the Company's revenue recognition criteria for accrual-basis revenue recognition beginning with the period ended March 31, 2017.

Approximately \$1.0 million of this one-time impact relates to tests completed in the prior year and for which the Company's accrual revenue recognition criteria were not met until 2017.

#### Allocate transaction price

The entire transaction price is allocated to the single performance obligation contained in a contract with a patient.

Table of Contents

## Point in time recognition

The Company's single performance obligation is satisfied at a point in time, and that point in time is defined as the date a patient's successful test result is delivered to the patient's ordering physician. The Company considers this date to be the time at which the patient obtains control of the promised Cologuard test service.

## Disaggregation of Revenue

The following tables present our revenues disaggregated by revenue source for the three and six months ended June 30, 2018 and 2017, respectively:

(In thousands)	Three Months Ended	
	June 30,	
	2018	2017
Medicare Parts B & C	\$ 59,706	\$ 40,893
Commercial	39,589	14,713
Other	3,599	2,040
Total	\$ 102,894	\$ 57,646

(In thousands)	Six Months Ended June 30,	
	2018	2017
Medicare Parts B & C	\$ 112,181	\$ 72,705
Commercial	74,423	29,849
Other	6,586	3,455
Total	\$ 193,190	\$ 106,009

## Contract Balances

The timing of revenue recognition, billings and cash collections results in billed accounts receivable and deferred revenue on the condensed consolidated balance sheets. Generally, billing occurs subsequent to delivery of a patient's test result to the ordering physician, resulting in an account receivable. However, the Company sometimes receives advance payment from a patient, particularly a self-pay patient, before a Cologuard test result is completed, resulting in deferred revenue. The deferred revenue balance is relieved upon delivery of the applicable patient's test result to the ordering physician. Changes in accounts receivable and deferred revenue were not materially impacted by any other factors.

Deferred revenue balances are reported in other short-term liabilities in the Company's condensed consolidated balance sheets and were \$0.3 million and \$0.2 million as of June 30, 2018 and December 31, 2017, respectively.

Revenue recognized for the three months ended June 30, 2018 and 2017, that was included in the deferred revenue balance at the beginning of each period was \$0.1 million and \$44,000, respectively. Revenue recognized for the six months ended June 30, 2018 and 2017, that was included in the deferred revenue balance at the beginning of each period was \$0.1 million and \$44,000, respectively.

#### Practical expedients

The Company does not adjust the transaction price for the effects of a significant financing component, as at contract inception, the Company expects the collection cycle to be one year or less.

The Company expenses sales commissions when incurred because the amortization period would have been one year or less. These costs are recorded within sales and marketing expenses in the Company's condensed consolidated statements of operations.

The Company incurs certain other costs that are incurred regardless of whether a contract is obtained. Such costs are primarily related to legal services and patient communications (e.g. compliance reminder letters). These costs are expensed as incurred and recorded within general and administrative expenses in the Company's condensed consolidated statements of operations.

Table of Contents

## Inventory

Inventory is stated at the lower of cost or market value (net realizable value). The Company determines the cost of inventory using the first-in, first out method (“FIFO”). The Company estimates the recoverability of inventory by reference to internal estimates of future demands and product life cycles, including expiration. The Company periodically analyzes its inventory levels to identify inventory that may expire prior to expected sale or has a cost basis in excess of its estimated net realizable value, and records a charge to cost of sales for such inventory, as appropriate. In addition, the materials used in performing Cologuard tests are subject to strict quality control and monitoring which the Company performs throughout the manufacturing process. If certain batches or units of product no longer meet quality specifications or become obsolete due to expiration, the Company records a charge to cost of sales to write down such unmarketable inventory to its estimated net realizable value.

Direct and indirect manufacturing costs incurred during process validation and for other research and development activities, which are not permitted to be sold, have been expensed to research and development in the Company’s condensed consolidated statements of operations.

Inventory consisted of the following:

(In thousands)	June 30, 2018	December 31, 2017
Raw materials	\$ 11,797	\$ 10,344
Semi-finished and finished goods	23,612	15,683
Total inventory	\$ 35,409	\$ 26,027

## Foreign Currency Translation

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



## Reclassifications

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

### (3) MAYO LICENSE AGREEMENT

#### Overview

As more fully described in the 2017 Form 10-K, in June 2009 the Company entered into a patent license agreement with MAYO Foundation for Medical Education and Research ("MAYO"). The Company's license agreement with MAYO was amended and restated in February 2015 and further amended in January 2016 and October 2017. Under the license agreement, MAYO granted the Company an exclusive, worldwide license to certain MAYO patents and patent applications, as well as a non-exclusive, worldwide license with regard to certain MAYO know-how. As expanded by the January 2016 amendment to the license agreement, the scope of the license includes any screening, surveillance or diagnostic tests or tools for use in connection with any type of cancers, pre-cancers, diseases or conditions.

## Table of Contents

Pursuant to the Company's agreement with MAYO, the Company is required to pay MAYO a low-single-digit royalty on the Company's net sales of products using the licensed MAYO intellectual property, with minimum annual royalty fees of \$25,000 each year through 2033, the year the last patent expires. The January 2016 amendment to the MAYO license agreement established various low-single-digit royalty rates on net sales of current and future products and clarified how net sales will be calculated. The October 2017 amendment further modified royalty rates. As part of these amendments, the royalty rate on the Company's net sales of Cologuard increased and, if in the future, improvements are made to the Cologuard product, the royalty rate may further increase, but would remain a low-single-digit percentage of net sales.

In addition to royalties, the Company is required to pay MAYO cash of \$0.2 million, \$0.8 million and \$2.0 million upon each product using the licensed MAYO intellectual property reaching \$5.0 million, \$20.0 million and \$50.0 million in cumulative net sales, respectively.

As part of the February 2015 amendment and restatement of the license agreement, the Company agreed to pay MAYO an additional \$5.0 million, payable in five annual installments, through 2019. The Company paid MAYO the annual installment of \$1.0 million in the first quarter of each of 2015, 2016 and 2018. The Company paid MAYO the 2017 installment in December 2016. The Company records the \$1.0 million installments to prepaid expenses and other current assets and amortizes each installment over a twelve-month period commencing on February 1 of each year. For the three and six months ended June 30, 2018 and 2017 the Company has recorded \$0.3 million and \$0.5 million in amortization of the installments, respectively.

In addition, the Company is paying MAYO for research and development efforts. As part of the Company's research collaboration with MAYO, the Company incurred charges of \$1.4 million and \$2.6 million for the three and six months ended June 30, 2018. The Company made payments of \$0.8 million and \$2.6 million for the three and six months ended June 30, 2018. The Company recorded an estimated liability of \$1.8 million for research and development efforts as of June 30, 2018. The Company incurred charges of \$1.1 million and \$2.2 million for the three and six months ended June 30, 2017. The Company made payments of \$0.5 million and \$1.8 million for the three and six months ended June 30, 2017. The Company recorded an estimated liability of \$1.2 million for research and development efforts as of June 30, 2017.

## (4) STOCK-BASED COMPENSATION

### Stock-Based Compensation Plans

The Company maintains the 2010 Omnibus Long-Term Incentive Plan (As Amended and Restated Effective July 27, 2017), the 2010 Employee Stock Purchase Plan, the 2015 Inducement Award Plan, the 2016 Inducement Award Plan and the 2000 Stock Option and Incentive Plan (collectively, the "Stock Plans").

## Stock-Based Compensation Expense

The Company records stock-based compensation expense in connection with the amortization of restricted stock and restricted stock unit awards, stock purchase rights granted under the Company's employee stock purchase plan and stock options granted to employees, non-employee consultants and non-employee directors. The Company recorded \$15.6 million and \$28.1 million in stock-based compensation expense during the three and six months ended June 30, 2018. The Company recorded \$6.1 million and \$12.2 million in stock-based compensation expense during the three and six months ended June 30, 2017.

In connection with the April 25, 2018 transition of the Company's Chief Operating Officer, the Company accelerated the vesting of 69,950 shares under his previously unvested stock options and 54,350 shares under his previously unvested restricted stock units whereby such unvested stock options and unvested restricted stock units vest on December 31, 2018. It was determined that the continuing service to be provided by the Company's former Chief Operating Officer to the Company through December 31, 2018 is substantive and, as a result, the Company will recognize the additional non-cash stock-based compensation expense for the modified awards evenly over the transition term of April 25, 2018 through December 31, 2018. During the three and six months ended June 30, 2018, the Company recorded \$1.0 million of non-cash stock-based compensation expense for the modified awards.

Table of Contents

Determining Fair Value

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

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

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

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

Forfeitures – Beginning in 2017, the Company adopted Accounting Standards Update (“ASU”) No. 2016-09, Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting (“Update 2016-09”). With the adoption of Update 2016-09, forfeiture estimates are no longer required, and the effects of actual forfeitures are recorded at the time they occur. The impact on the Company’s condensed consolidated balance sheet as of March 31, 2017 was a cumulative-effect adjustment of \$0.4 million, increasing opening accumulated deficit and additional paid-in capital.

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

Six Months Ended

Edgar Filing: EXACT SCIENCES CORP - Form 10-Q

	June 30, 2018	2017
Option Plan Shares		
Risk-free interest rates	2.73% - 2.79%	2.13%
Expected term (in years)	5.45 - 6.44	6.59
Expected volatility	61.8% - 66.2%	62.9%
Dividend yield	0%	0%
Weighted average fair value per share of options granted during the period	\$24.55	\$13.20
ESPP Shares		
		0.98 -
Risk-free interest rates	2.05% - 2.5%	1.28%
Expected term (in years)	0.5 - 2	0.5 - 2
		66.4% -
Expected volatility	51.7% - 65.4%	85.5%
Dividend yield	0 %	0 %
Weighted average fair value per share of stock purchase rights granted during the period	\$ 18.68	\$ 13.05

Table of Contents

## Stock Option and Restricted Stock Activity

A summary of stock option activity under the Stock Plans during the six months ended June 30, 2018 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, January 1, 2018	3,360,461	\$ 11.89	6.4	
Granted	343,566	44.37		
Exercised	(785,695)	7.18		
Forfeited	—	—		
Outstanding, June 30, 2018	2,918,332	\$ 16.98	6.9	\$ 124,921
Exercisable, June 30, 2018	1,391,818	\$ 10.58	5.1	\$ 68,497

(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 \$59.79 market price of the Company's common stock at June 30, 2018. The total intrinsic value of options exercised during the six months ended June 30, 2018 and 2017 was \$36.3 million and \$2.6 million, respectively.

As of June 30, 2018, there was \$127.7 million of total unrecognized compensation cost related to non-vested share-based compensation arrangements granted under all Stock Plans. Total unrecognized compensation cost will be adjusted for future forfeitures. The Company expects to recognize that cost over a weighted average period of 3.0 years.

A summary of restricted stock and restricted stock unit activity under the Stock Plans during the six months ended June 30, 2018 is as follows:

	Restricted Shares	Weighted Average Grant Date Fair Value
Outstanding, January 1, 2018	6,148,778	\$ 15.76
Granted	1,221,130	43.86
Released	(943,948)	17.75
Forfeited	(113,924)	30.04
Outstanding, June 30, 2018	6,312,036	\$ 20.51

#### (5) FAIR VALUE MEASUREMENTS

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

Table of Contents

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 \$0.9 million and \$4.5 million as of June 30, 2018 and December 31, 2017, 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 June 30, 2018 along with the level within the fair value hierarchy in which the fair value measurements in their entirety fall.

(In thousands)	Fair Value at June 30, 2018	Fair Value Measurement at June 30, 2018 Using:		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash and cash equivalents				
Cash and money market	\$ 69,911	\$ 69,911	\$ —	\$ —
Certificates of deposit	3,900	—	3,900	—
Commercial paper	19,088	—	19,088	—
U.S. government agency securities Available-for-sale	132,763	—	132,763	—
Marketable securities				
Corporate bonds	407,777	—	407,777	—
Asset backed securities	283,395	—	283,395	—
U.S. government agency securities	248,482	—	248,482	—
Commercial paper	6,115	—	6,115	—



Edgar Filing: EXACT SCIENCES CORP - Form 10-Q

Certificates of deposit	50,731	—	50,731	—
Total	\$ 1,222,162	\$ 69,911	\$ 1,152,251	\$ —

Table of Contents

The following table presents the Company's fair value measurements as of December 31, 2017 along with the level within the fair value hierarchy in which the fair value measurements in their entirety fall.

(In thousands)	Fair Value at December 31, 2017	Fair Value Measurement at December 31, 2017 Using:		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash and cash equivalents				
Cash and money market	\$ 61,297	\$ 61,297	\$ —	\$ —
Commercial paper	10,995		10,995	—
Certificates of deposit	1,499		1,499	—
U.S. government agency securities	3,700		3,700	—
Available-for-sale				
Marketable securities				
Corporate bonds	181,305	—	181,305	—
Asset backed securities	94,515	—	94,515	—
U.S. government agency securities	54,812	—	54,812	—
Commercial paper	9,946	—	9,946	—
Certificates of deposit	6,646	—	6,646	—
Total	\$ 424,715	\$ 61,297	\$ 363,418	\$ —

The Company monitors investments for other-than-temporary impairment. It was determined that unrealized gains and losses as of June 30, 2018 and December 31, 2017 are temporary in nature because the change in market value for those securities has resulted from fluctuating interest rates rather than a deterioration of the credit worthiness of the issuers. So long as the Company holds these securities to maturity, it is unlikely to experience gains or losses. In the event that the Company disposes of these securities before maturity, it is expected that realized gains or losses, if any, will be immaterial.

The following table summarizes gross unrealized losses and fair values of our investments in an unrealized loss position as of June 30, 2018, aggregated by investment category and length of time that individual securities have been in a continuous unrealized loss position:

(In thousands)	June 30, 2018				Total	
	Less than 12 months	12 months or greater				
	Fair Value	Gross Unrealized Loss	Fair Value	Gross Unrealized Loss	Fair Value	Gross Unrealized Loss
Marketable securities						
Corporate bonds	\$ 351,069	\$ (845)	\$ —	\$ —	\$ 351,069	\$ (845)
	248,598	(736)	3,454	(13)	252,052	(749)

Asset backed securities						
U.S. government agency securities	179,202	(249)	9,990	(9)	189,192	(258)
Commercial paper	25,203	(3)	—	—	25,203	(3)
Certificates of deposit	20,331	(42)	—	—	20,331	(42)
Total	\$ 824,403	\$ (1,875)	\$ 13,444	\$ (22)	\$ 837,847	\$ (1,897)

Table of Contents

The following summarizes contractual underlying maturities of the Company's available-for-sale investments in debt securities at June 30, 2018:

(In thousands)	Due one year or less		Due after one year through four years	
	Cost	Fair Value	Cost	Fair Value
Marketable securities				
Corporate bonds	\$ 274,864	\$ 274,238	\$ 133,705	\$ 133,539
U.S. government agency securities	199,377	199,119	49,353	49,363
Commercial paper	6,118	6,115	—	—
Certificates of deposit	45,329	45,307	5,439	5,424
Asset backed securities	42,855	42,749	241,279	240,646
Total	\$ 568,543	\$ 567,528	\$ 429,776	\$ 428,972

**(6) NEW MARKET TAX CREDIT**

As more fully described in the 2017 Form 10-K, during the fourth quarter of 2014, the Company received approximately \$2.4 million in net proceeds from financing agreements related to working capital and capital improvements at one of its Madison, Wisconsin facilities. This financing arrangement was structured with an unrelated third party financial institution, an investment fund, and its majority owned community development entity in connection with the Company's participation in transactions qualified under the federal New Markets Tax Credit ("NMTC") program, pursuant to Section 45D of the Internal Revenue Code of 1986, as amended. The \$2.4 million was recorded in Other Long-Term Liabilities on the condensed consolidated balance sheets. The benefit of this net \$2.4 million contribution will be recognized as a decrease in expenses, included in cost of sales, as the Company amortizes the contribution liability over the seven-year compliance period as it is being earned through the Company's on-going compliance with the conditions of the NMTC program. The Company has recorded \$0.1 million and \$0.2 million as a decrease of expenses for the three and six months ended June 30, 2018. At June 30, 2018, the remaining balance of \$1.2 million is included in other long-term liabilities in the Company's condensed consolidated balance sheets. The Company recorded \$0.1 million and \$0.2 million as a decrease of expenses for the three and six months ended June 30, 2017. At June 30, 2017, the remaining balance of \$1.5 million was included in other long-term liabilities in the Company's condensed consolidated balance sheets. The Company incurred approximately \$0.2 million of debt issuance costs related to the above transactions, which are recorded as a direct deduction from the liability. The debt issuance costs are being amortized over the life of the agreements.

**(7) LONG-TERM DEBT****Building Purchase Mortgage**

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

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

Additionally, the Company has recorded \$73,000 in mortgage issuance costs, which are recorded as a direct deduction from the mortgage liability. The issuance costs are being amortized through June 12, 2019. The Company has recorded \$4,000 and \$9,000 in amortization of mortgage issuance costs for each of the three and six months ended June 30, 2018 and 2017.

## Table of Contents

### Revolving Loan Agreement

During December 2017, the Company entered into a revolving loan agreement with MB Financial Bank, N.A. (“MB Bank”). The revolving loan agreement provides the Company with a 24-month secured revolving credit facility of up to \$15.0 million. The credit facility is collateralized by the Company’s accounts receivable and inventory. The credit facility is available for general working capital purposes and all other lawful corporate purposes, provided that the Company may not use the credit facility to purchase or carry margin stock.

Borrowings under the revolving loan agreement accrue interest at one of the following per annum rates, as elected by the Company (i) the sum of the 1-month LIBOR rate plus 2.00 percent, (ii) the sum of the 3-month LIBOR rate plus 2.00 percent, or (iii) the MB Bank Reference Rate minus 0.5 percent. Loans under the credit facility may be prepaid at any time without penalty. The maturity date of the loan under the revolving credit agreement is December 10, 2019.

The Company has agreed to various financial covenants including minimum liquidity and minimum tangible net worth. At June 30, 2018, the Company is in compliance with all covenants.

As of June 30, 2018, the Company has not drawn any funds from the revolving credit agreement, and no amounts are outstanding under the loan agreement.

### Construction Loan Agreement

During December 2017, the Company entered into a loan agreement with MB Bank, which provides the Company with a non-revolving construction loan of \$25.6 million. The Company will use the loan proceeds to finance the construction of an additional clinical laboratory and related facilities in Madison, Wisconsin. The non-revolving construction loan is collateralized by the additional clinical laboratory and related facilities.

Pursuant to the construction loan agreement, funds drawn will bear interest at a rate equal to the sum of the 1-month LIBOR rate plus 2.25 percent. Regular monthly payments are interest-only for the first 24 months, with further payments based on a 20-year amortization schedule. Amounts borrowed pursuant to this loan agreement may be prepaid at any time without penalty. The maturity date of this loan agreement is December 10, 2022.

MB Bank, on behalf of the Company, previously issued an Irrevocable Standby Letter of Credit in the amount of \$0.6 million in favor of the City of Madison, Wisconsin, which is deemed to have been issued pursuant to the construction

loan agreement (the “City Letter of Credit”). The amount of the City Letter of Credit will reduce, dollar for dollar, the amount available for borrowing under the construction loan agreement.

As a condition to MB Bank’s initial advance of loan proceeds under the loan agreement, the Company is required to first invest at least \$16.4 million of its own cash into the construction project. The Company fulfilled its required initial investment and made its first draw on the non-revolving construction loan in June 2018. In accordance with the construction loan agreement, the Company will make monthly interest-only payments through November 2019. Starting in December 2019, the Company will make monthly payments toward the outstanding principal balance due plus accrued interest. As of June 30, 2018, the Company has invested \$17.5 million into the construction project, and has drawn \$1.1 million from the non-revolving construction loan. For the three and six months ended June 30, 2018, the Company incurred interest of \$3,000. The Company capitalized the \$3,000 to the construction project.

Additionally, the Company has recorded deferred financing costs of \$0.2 million. These deferred financing costs are recorded as a reduction to long-term debt in the Company’s condensed consolidated balance sheets. The deferred financing costs are being amortized through December 10, 2022. The Company has recorded \$11,000 and \$23,000 in amortization of deferred financing costs for the three and six months ended June 30, 2018. There was no amortization expense recorded for the three and six months ended June 30, 2017.

The Company has agreed to various financial covenants including minimum liquidity and minimum tangible net worth. As of June 30, 2018, the Company is in compliance with all covenants.

Table of Contents

(8) WISCONSIN ECONOMIC DEVELOPMENT TAX CREDITS

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

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

As of June 30, 2018, the Company has earned \$8.8 million of tax credits and has received payment of \$2.4 million from the WEDC. The unpaid portion is \$6.4 million, of which \$1.9 million is reported in prepaid expenses and other current assets and \$4.5 million is reported in other long-term assets, reflecting when collection of the refundable tax credits is expected to occur. As of June 30, 2018, the Company also has recorded a \$2.3 million liability in other short-term liabilities and a \$3.3 million liability in other long-term liabilities, reflecting when the expected benefit of the tax credit amortization will reduce future operating expenses.

During the three and six months ended June 30, 2018, the Company amortized \$0.4 million and \$1.0 million, respectively, of the tax credits earned as a reduction of operating expenses. During the three and six months ended June 30, 2017, the Company amortized \$0.3 million and \$0.6 million, respectively, of the tax credits earned as a reduction of operating expenses.

(9) CONVERTIBLE NOTES

On January 17, 2018, the Company issued and sold \$690.0 million in aggregate principal amount of 1.0% Convertible Notes (the “Notes”) with a maturity date of January 15, 2025 (the “Maturity Date”). The Notes accrue interest at a fixed rate of 1.0% per year, payable semi-annually in arrears on January 15 and July 15 of each year, beginning on July 15, 2018. The net proceeds from the issuance of the Notes were approximately \$671.1 million, after deducting underwriting discounts and commissions and the offering expenses payable by the Company.



Prior to July 15, 2024, the Notes are convertible only upon the occurrence of certain events and during certain periods, as set forth in the indenture governing the Notes (the “Indenture”), and thereafter, until the close of business on the second scheduled trading day immediately preceding the Maturity Date. The Notes will be convertible into cash, shares of the Company’s common stock (plus, if applicable, cash in lieu of any fractional share), or a combination of cash and shares of the Company’s common stock, at the Company’s election. On or after July 15, 2024, until the close of business on the second scheduled trading day immediately preceding the maturity date, holders may convert their Notes at any time.

It is the Company’s intent and policy to settle all conversions through combination settlement. The initial conversion rate for the Notes is 13.2569 shares of common stock per \$1,000 principal amount, which is equivalent to an initial conversion price of approximately \$75.43 per share of the Company’s common stock. The conversion rate is subject to adjustment upon the occurrence of certain specified events but will not be adjusted for accrued and unpaid interest. In addition, holders of the Notes who convert their Notes in connection with a “make-whole fundamental change” (as defined in the Indenture), will, under certain circumstances, be entitled to an increase in the conversion rate.

Table of Contents

If the Company undergoes a “fundamental change” (as defined in the Indenture), holders of the Notes may require the Company to repurchase for cash all or part of their Notes at a repurchase price equal to 100% of the principal amount of the Notes to be repurchased, plus accrued and unpaid interest.

The Notes are the Company’s senior unsecured obligations and (i) rank senior in right of payment to all of its future indebtedness that is expressly subordinated in right of payment to the Notes; equal in right of payment to all of the Company’s future liabilities that are not so subordinated, unsecured indebtedness; (ii) are effectively junior to all of our existing and future secured indebtedness and other secured obligations, to the extent of the value of the assets securing that indebtedness and other secured obligations; and (iii) are structurally subordinated to all indebtedness and other liabilities of the Company’s subsidiaries.

While the Notes are currently classified on the Company’s condensed consolidated balance sheets at June 30, 2018 as long-term, the future convertibility and resulting balance sheet classification of this liability will be monitored at each quarterly reporting date and will be analyzed dependent upon market prices of the Company’s common stock during the prescribed measurement periods. In the event that the holders of the Notes have the election to convert the Notes at any time during the prescribed measurement period, the Notes would then be considered a current obligation and classified as such.

Under current accounting guidance, an entity must separately account for the liability and equity components of convertible debt instruments (such as the Notes) that may be settled entirely or partially in cash upon conversion in a manner that reflects the issuer’s economic interest cost. The liability component of the instrument was valued in a manner that reflects the market interest rate for a similar nonconvertible instrument at the date of issuance. The initial carrying value of the liability component of \$495.1 million was calculated using a 6.0% assumed borrowing rate. The equity component of \$194.9 million, representing the conversion option, was determined by deducting the fair value of the liability component from the par value of the Notes and is recorded in additional paid-in capital on the Company’s condensed consolidated balance sheet at the issuance date. That equity component is treated as a discount on the liability component of the Notes, which is amortized over the seven-year term of the Notes using the effective interest rate method. The equity component is not re-measured as long as it continues to meet the conditions for equity classification.

The Company allocated the total transaction costs of approximately \$18.8 million related to the issuance of the Notes to the liability and equity components of the Notes based on their relative values, with \$13.1 million being allocated to the liability component of the Notes. Transaction costs attributable to the liability component are amortized to interest expense over the seven-year term of the Notes, and transaction costs attributable to the equity component are netted with the equity component in stockholders’ equity.

On June 12, 2018, the Company issued and sold an additional \$218.5 million in aggregate principal amount of 1.0% Convertible Notes. These Convertible Notes were issued under the Indenture pursuant to which the Company previously issued \$690.0 million of Notes in January 2018. The notes have identical terms and will be treated as a

single series of securities. The net proceeds from the issuance of these Convertible Notes were approximately \$225.3 million, after deducting underwriting discounts and commissions and the offering expenses payable by the Company.

Following the same accounting guidance as above, the Company must separately account for the liability and equity components of convertible debt instruments (such as the Notes) that may be settled entirely or partially in cash upon conversion in a manner that reflects the issuer's economic interest cost. The liability component of the instrument was valued in a manner that reflects the market interest rate for a similar nonconvertible instrument at the date of issuance. The initial carrying value of the liability component of \$159.7 million was calculated using a 6.0% assumed borrowing rate. The equity component of \$73.0 million, representing the conversion option, was determined by deducting the fair value of the liability component from the par value of the notes and adding in the premium which the notes were sold at. This is recorded in additional paid-in capital on the condensed consolidated balance sheet at the issuance date. That equity component, prior to adding in the premium, is treated as a discount on the liability component of the notes, which is amortized over the remaining term of six and a half years of the notes using the effective interest rate method. The equity component is not re-measured as long as it continues to meet the conditions for equity classification.

Table of Contents

The Company allocated the total transaction costs of approximately \$7.4 million related to the issuance of the notes to the liability and equity components of the notes based on their relative values, with \$5.1 million being allocated to the liability component of the Notes. Transaction costs attributable to the liability component are amortized to interest expense over the remaining six-and-a-half year term of the notes, and transaction costs attributable to the equity component are netted with the equity component in stockholders' equity.

The Notes do not contain any financial or operating covenants or any restrictions on the payment of dividends, the issuance of other indebtedness or the issuance or repurchase of securities by the Company.

Debt, net of discounts and deferred financing costs at June 30, 2018, consisted of the following:

(In thousands)	
Principal	\$ 908,500
Debt discount, net	(242,872)
Deferred financing costs	(17,705)
Net carrying amount	\$ 647,923

**(10) RELATED PARTY TRANSACTION**

In May 2017, the Company entered into a professional services agreement for recruiting and related services with a firm whose principal is a non-employee director. In accordance with the agreement, the Company is expected to make cash payments totaling up to an aggregate of \$0.4 million under the agreement during 2017 and 2018. The Company incurred charges of \$50,000 and \$0.2 million for the three and six months ended June 30, 2018. The Company made payments of \$20,000 and \$0.1 million for the three and six months ended June 30, 2018. The Company incurred charges of \$50,000 for the three and six months ended June 30, 2017. The Company made payments of \$50,000 for the three and six months ended June 30, 2017.

In November 2017, the Company made a 10 percent investment in a supplier, as further described in Note 2. The Company incurred \$0.1 million and \$0.1 million in purchases from the supplier for the three and six months ended June 30, 2018. In June 2018, the Company entered into a short-term \$1.0 million Senior Secured Promissory Note and Security Agreement with the same supplier, which is reported in prepaid expenses and other current assets on the Company's condensed consolidated balance sheets.

**(11) RECENT ACCOUNTING PRONOUNCEMENTS**

In May 2014, the Financial Accounting Standards Board issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606). The Company adopted this guidance on January 1, 2018. See Note 2 for additional discussion.

In January 2016, the Financial Accounting Standards Board issued ASU No. 2016-01, “Financial Instruments – Overall: Recognition and Measurement of Financial Assets and Financial Liabilities (“Update 2016-01”). Update 2016-01 modifies how entities measure equity investments and present changes in the fair value of financial liabilities. Under the new guidance, entities will have to measure equity investments that do not result in consolidation and are not accounted for under the equity method at fair value and recognize any changes in fair value in net income unless the investments qualify for the new practicality exception. A practicality exception will apply to those equity investments that do not have readily determinable fair value and do not qualify for the practical expedient to estimate fair value under ASC 820, “Fair Value Measurements,” and as such these investments may be measured at cost. Update 2016-01 will be effective for the Company’s fiscal year beginning January 1, 2018, and subsequent interim periods. Update 2016-01 was further amended in February 2018 by ASU No. 2018-03, Technical Corrections and Improvements to Financial Instruments – Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities, (“Update 2018-03”). Update 2018-03 clarifies certain aspects of the guidance issued in Update 2016-01. Public business entities with fiscal years beginning between December 15, 2017 and June 15, 2018, are not required to adopt these amendments until the interim period beginning after June 15, 2018. Early adoption is allowed as long as Update 2016-01 has been adopted. The Company adopted Update 2016-01 on January 1, 2018, and it did not have an impact on the Company’s condensed consolidated financial statements.

Table of Contents

In February 2016, the Financial Accounting Standards Board issued ASU No. 2016-02, Leases (Topic 842), (“Update 2016-02”) which requires recognition of lease assets and lease liabilities by lessees for those leases classified as operating leases under previous GAAP. The amendments in this update are effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. In transition, lessees and lessors are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. The Company expects to adopt the guidance in 2019. The Company is currently evaluating the effects that the adoption of Update 2016-02 will have on the Company’s condensed consolidated financial statements; however, as the Company has several leases, assets and liabilities are expected to increase upon adoption for right-of-use assets and lease liabilities.

In August 2016, the Financial Accounting Standards Board issued ASU No. 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments, (“Update 2016-15”). Current GAAP either is unclear or does not include specific guidance on the eight cash flow classification issues included in the amendments in Update 2016-15. The amendments are an improvement to GAAP because they provide guidance for each of the eight issues, thereby reducing the current and potential future diversity in practice. The Company adopted this guidance January 1, 2018, and it did not have an impact on the Company’s condensed consolidated financial statements.

In October 2016, the Financial Accounting Standards Board issued ASU No. 2016-16, Income Taxes (Topic 740): Intra-Entity Transfers of Assets Other Than Inventory, (“Update 2016-16”). This amendment improves the accounting for the income tax consequences of intra-entity transfers of assets other than inventory. The Company adopted this guidance on January 1, 2018, and it did not have an impact on the Company’s condensed consolidated financial statements.

In November 2016, the Financial Accounting Standards Board issued ASU No. 2016-18, Statement of Cash Flows; Restricted Cash, (“Update 2016-18”). Update 2016-18 provides guidance on the classification of restricted cash in the statement of cash flows. The Company adopted this guidance on January 1, 2018, and it did not have an impact on the Company’s condensed consolidated financial statements, as the Company does not have restricted cash.

In May 2017, the Financial Accounting Standards Board issued ASU No. 2017-09, Compensation – Stock Compensation (Topic 718): Scope of Modification Accounting, (“Update 2017-09”). Update 2017-09 provides guidance on determining which changes to the terms and conditions of share-based payment awards require an entity to apply modification accounting under Topic 718. The Company adopted this guidance on January 1, 2018, and it did not have an impact on the Company’s condensed consolidated financial statements.

In June 2018, the Financial Accounting Standards Board issued ASU No. 2018-07 (Topic 718), Improvements to Nonemployee Share-Based Payment Accounting, (“Update 2018-07”). Update 2018-07 expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. An entity should

apply the requirements to Topic 718 to nonemployee awards except for certain exemptions specified in the amendment. The guidance is effective for fiscal years beginning after December 15, 2018, including interim reporting periods within that fiscal year. Early adoption is permitted, but no earlier than an entity's adoption of Topic 606. The Company is currently evaluating the impact of the guidance on its condensed consolidated financial statements.

Table of Contents

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following Discussion and Analysis of Financial Condition and Results of Operations of Exact Sciences Corporation (together with its subsidiaries, "Exact," "we," "us," "our" or the "Company") should be read in conjunction with the condensed consolidated financial statements and the related notes thereto included elsewhere in this Quarterly Report on Form 10-Q and the audited financial statements and notes thereto and Management's Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K for the year ended December 31, 2017, which has been filed with the SEC (the "2017 Form 10-K").

Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, that are intended to be covered by the "safe harbor" created by those sections. Forward-looking statements, which are based on certain assumptions and describe our future plans, strategies and expectations, can generally be identified by the use of forward-looking terms such as "believe," "expect," "may," "will," "should," "would," "could," "seek," "intend," "plan," "goal," "estimate," "anticipate" or other comparable terms. All statements other than statements of historical facts included in this Quarterly Report on Form 10-Q regarding our strategies, prospects, financial condition, operations, costs, plans and objectives are forward-looking statements. Examples of forward-looking statements include, among others, statements we make regarding expected future operating results, anticipated results of our sales and marketing efforts, expectations concerning payer reimbursement and the anticipated results of our product development efforts. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Our actual results and financial condition may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements. Important factors that could cause our actual results and financial condition to differ materially from those indicated in the forward-looking statements include, among others, the following: our ability to successfully and profitably market our products and services; the acceptance of our products and services by patients and healthcare providers; our ability to meet demand for our products and services; the willingness of health insurance companies and other payers to cover Cologuard and adequately reimburse us for our performance of the Cologuard test; the amount and nature of competition from other cancer screening and diagnostic products and services; the effects of the adoption, modification or repeal of any healthcare reform law, rule, order, interpretation or policy; the effects of changes in the pricing, coverage and reimbursement for our products and services, including without limitation as a result of the Protecting Access to Medicare Act of 2014; recommendations, guidelines and quality metrics issued by various organizations such as the U.S. Preventive Services Task Force, the American Cancer Society and the National Committee for Quality Assurance regarding cancer screening or our products and services; our ability to successfully develop new products and services; our success establishing and maintaining collaborative, licensing and supplier arrangements; our ability to maintain regulatory approvals and comply with applicable regulations; and the other risks and uncertainties described in the Risk Factors and in Management's Discussion and Analysis of Financial Condition and Results of Operations sections of the 2017 Form 10-K and subsequently filed Quarterly Report(s) on Form 10-Q. We undertake no obligation to publicly update any



forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

## Overview

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

## Table of Contents

### Our Cologuard Test

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

- 140,000 new cases of colorectal cancer
- 51,000 deaths from colorectal cancer

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

It is widely accepted that colorectal cancer is among the most preventable, yet least prevented cancers. Colorectal cancer can take up to 10-15 years to progress from a pre-cancerous lesion to metastatic cancer and death. Patients who are diagnosed early in the progression of the disease—with pre-cancerous lesions or polyps or early-stage cancer—are more likely to have a complete recovery and to be treated less expensively. Of the more than 85 million people who are at average-risk for colorectal cancer in the U.S., 38 percent have not been screened according to current guidelines. Poor compliance with screening guidelines 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 70 percent and 13 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 that utilizes a multi-target approach to detect DNA and hemoglobin biomarkers associated with colorectal cancer and pre-cancer. Eleven biomarkers are targeted that have been shown to be strongly associated with colorectal cancer and pre-cancer. Methylation, mutation, and hemoglobin results are combined in the laboratory analysis through a proprietary algorithm to provide a single positive or negative reportable result.

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 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%
- Stage I and II Cancer Sensitivity: 94%
- High-Grade Dysplasia Sensitivity: 69%
- Specificity: 87%

The competitive advantages of sDNA screening may provide a significant market opportunity. If the test were used by 40-percent of the 85 million people that we estimate to be eligible for screening in the U.S. between the ages of 50-85, at a three-year interval, and if average revenue per test was \$500, we estimate that our annual Cologuard revenue would be more than \$5.5 billion.

### Our Cologuard Commercialization Strategy

Our commercialization strategy includes three main elements focusing on physicians, patients, and payers.

#### Physicians and Patients

Our sales team actively engages with physicians and their staff 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 focus on specific physicians based on a combination of their Cologuard order history and ordering potential and also on physician groups and larger regional and national health systems.

Table of Contents

Securing inclusion in guidelines and quality measures is a key part of our physician engagement strategy since many physicians rely on such guidelines and quality measures when making screening recommendations. In June 2016, the US Preventive Services Task Force (“USPSTF”) issued an updated recommendation statement for colorectal cancer screening and gave an “A” grade to colorectal cancer screening starting at age 50 and continuing until age 75. The statement specifies seven screening methods, including FIT-DNA (which is Cologuard).

Many professional colorectal cancer screening guidelines in the U.S., including those of the ACS and the National Comprehensive Cancer Network (“NCCN”), recommend regular screening using any of a variety of methods. Since 2008, joint colorectal cancer screening guidelines endorsed by the ACS have included sDNA screening technology as a screening option for the detection of colorectal cancer in average risk, asymptomatic individuals starting at age 50. In October 2014, the ACS updated its colorectal cancer screening guidelines to specifically include Cologuard as a recommended screening test. In June 2016, the NCCN updated its Colorectal Cancer Screening Guidelines to add sDNA screening, at a once-every-three-years interval, to its list of recommended screening tests. In May 2018, the ACS updated its colorectal cancer screening guidelines to recommend colorectal cancer screening begin at age 45 for people at average risk of the disease due to the rising incidence rate in that population. There are 21 million people who are between the ages of 45-49, and we estimate approximately 18 million of them are at average risk for colorectal cancer and eligible for screening. Cologuard is currently indicated for average risk individuals age 50 years or older. We intend to seek FDA approval to expand Cologuard’s indication to people age 45 and older who are at average risk for colorectal cancer to align with the ASC updated guideline. The timing of such approval is unknown and subject to clinical evidence requirements that are not yet defined.

In October 2016, the National Committee for Quality Assurance (“NCQA”) included stool DNA testing (which is Cologuard) on a three-year interval as one of the methods permitted for colorectal cancer screening in the 2017 Healthcare Effectiveness Data and Information Set (“HEDIS”) quality measures. More than 90 percent of America’s health plans measure quality based on HEDIS. In April 2017, the Centers for Medicare & Medicaid Services (“CMS”) included Cologuard in its updated 2018 Medicare Advantage Star Ratings program.

A critical part of the value proposition of Cologuard is our compliance program, which involves active engagement with patients and providers. This customer-service-oriented activity is focused on encouraging and helping patients to complete Cologuard tests that have been ordered for them by their providers. We may undertake several activities to promote patient compliance including letters, text messages, emails, phone calls, and incentives such as gift cards.

After the launch of Cologuard, we initiated a significant public relations effort to engage patients in the U.S., and launched demographically-targeted direct-to-patient advertising campaigns in digital, social, print, and other channels. In 2016, we began a national television advertising campaign, with a majority of placements in national cable and syndicated programming widely viewed by our target patient demographic. In the second quarter of 2018, we extended our television advertising campaign to highlight the accuracy, ease of use, and commercial coverage of Cologuard. In the remainder of 2018, we plan to increase our television advertising efforts, accelerate our investment in digital and social media, and embark upon strategic branded partnerships designed to increase awareness for

Cologuard.

## Payers

The cornerstone of our payer-engagement strategy was securing coverage from CMS. Medicare covers approximately 47 percent of patients in the current screening population for Cologuard. On October 9, 2014, CMS issued a National Coverage Determination (“NCD”) for Cologuard following a parallel review process with the FDA. Cologuard was the first screening test approved by the FDA and covered by CMS through that process. As outlined in the NCD, Medicare Part B covers Cologuard once every three years for beneficiaries who meet all of the following criteria:

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

Table of Contents

colorectal cancers or adenomatous polyps, familial adenomatous polyposis, or hereditary non-polyposis colorectal cancer).

Pursuant to the 2017 Clinical Laboratory Fee Schedule, CMS reimbursed Cologuard at the rate of \$512.43 per test. Under the Protecting Access to Medicare Act of 2014, effective January 1, 2018, the CMS reimbursement rate for Cologuard was set at \$508.87, which was the volume-weighted median of private payer rates for Cologuard for the period from January 1, 2016 to June 30, 2016. We expect that the CMS reimbursement rate established for 2018 will remain in place for three years and then be reset based on the volume-weighted median of private payer rates for Cologuard during the data collection period from January 1, 2019 to June 30, 2019. Payments from CMS are currently subject to sequestration.

In addition to Medicare reimbursement, we seek to secure favorable coverage and in-network reimbursement agreements from commercial payers. Most commercial payers have issued positive coverage decisions for Cologuard, and we have entered into contracts with several payers to include Cologuard as an in-network service. In-network agreements with payers have varying terms and conditions, including reimbursement rate, term and termination. From time to time in the ordinary course of our business, we may enter into new agreements, certain existing agreements may expire without renewal and certain other existing agreements may be terminated early by us or the third-party payer. We believe that commercial payers' reimbursement of Cologuard will depend on a number of factors, including payers' determination that it is: sensitive and specific for colorectal cancer; not experimental or investigational; approved or recommended by major organizations' guidelines; reliable, safe and effective; medically necessary; appropriate for the specific patient; and cost-effective. Reimbursement may also be affected by whether Cologuard is in-network for a given payer. Also, some payers may apply various medical management requirements, including a requirement that they give prior authorization for a Cologuard test before they are willing to pay for it. Other payers may perform post-payment reviews or audits, which could lead to payment recoupments. Medical management, such as prior authorizations and post-payment review or audits, may require that we, patients, or physicians provide the payer with extensive medical records and other information.

Coverage of Cologuard may also depend, in whole or in part, on whether payers determine, or courts and/or regulatory authorities determine, coverage is required under applicable federal or state laws mandating coverage of certain colorectal cancer screening services. For example, Section 2713 of the Patient Protection and Affordable Care Act ("ACA") mandates that certain health insurers cover evidence-based items or services that have in effect a rating of "A" or "B" in the current recommendations of USPSTF without imposing any patient cost-sharing ("ACA Mandate"). Similarly, federal regulations require that Medicare Advantage plans cover "A" or "B" rated preventive services without patient cost-sharing. Following the June 2016 update to the USPSTF colorectal cancer screening recommendation statement, CMS issued an updated Evidence of Coverage notice for Medicare Advantage plans that affirms such plans must include coverage of Cologuard every three years without patient cost-sharing. While we believe the ACA Mandate requires most health insurers to cover Cologuard without patient cost-sharing, it is possible that certain health insurers will disagree and determine not to cover Cologuard. It may be difficult for us or patients to enforce the ACA Mandate directly, and we may need to rely on states to take enforcement action, which they may choose not to do. It is also possible that the ACA Mandate will be repealed or significantly modified in the future.

We believe quality metrics may influence payers' coverage and contracting decisions, as well as physicians' cancer screening procedures. Some government and private payers are adopting pay-for-performance programs that differentiate payments for healthcare services based on the achievement of documented quality metrics, cost efficiencies or patient outcomes. Payers may look to quality measures such as HEDIS and CMS Star Ratings, to assess quality of care. We believe inclusion in the HEDIS measures and Star Ratings measures may have a positive impact on payers' willingness to reimburse Cologuard, as well as on physicians' willingness to prescribe the test.

## Table of Contents

### Our Clinical Lab Facilities

As part of our commercialization strategy, we established a state-of-the-art, highly automated lab facility that is certified pursuant to federal Clinical Laboratory Improvement Amendments (“CLIA”) requirements to process Cologuard tests and provide patient results. Our commercial lab operation is housed in a 50,000 square foot facility in Madison, Wisconsin. At our lab, we currently have the capacity to process over two million tests per year. We are expanding our current facility to increase our lab processing capacity to approximately three million tests per year by the end of 2018.

During the fourth quarter of 2017, we began construction of a new clinical lab facility in Madison, Wisconsin that is expected to be completed mid-2019. We expect our total lab capacity at both facilities will be approximately five million tests per year by the end of 2019.

### Product Pipeline

The ACS updated its colorectal cancer screening guidelines in May 2018, moving the recommended screening age from 50 to 45 for people at average risk of the disease. There are more than 21 million people who are between the ages of 45-49, and we estimate approximately 18 million of them are at average risk for colorectal cancer and eligible for screening. As indicated above, we plan to seek FDA approval to expand Cologuard’s indication to people age 45 and older who are at average risk for colorectal cancer and to undertake the clinical work necessary to support such approval, so that we can promote Cologuard to that population.

We also are developing a pipeline of potential future products and services. We are continuing to collaborate with MAYO Foundation for Medical Education and Research (“MAYO”), our development partner for Cologuard, on developing new tests, with the goal of becoming a leader in the early detection of cancer. We believe our proprietary technology platform provides a strong foundation for the development of additional cancer diagnostic tests. Through our collaboration with MAYO, we have identified proprietary biomarkers for several major cancers, including liver cancer and lung cancer. We have successfully performed validation studies on tissue samples for seven major cancers and on blood samples for four major cancers.

The ACS estimates that liver cancer will be diagnosed in 42,000 Americans and cause 30,000 deaths in 2018, three-fourths of which will be hepatocellular carcinoma (“HCC”). Incidence and mortality rates are both increasing at approximately 3 percent per year. People who have been diagnosed with cirrhosis of the liver or Hepatitis B are at high risk of developing HCC. Evidence shows that HCC testing in these high-risk groups leads to earlier detection and improved outcomes. The NCCN and American Association for the Study of Liver Diseases (“AASLD”) guidelines recommend that these two groups be tested for HCC every six months using ultrasound and the blood-based biomarker alpha-fetoprotein (“AFP”). However, ultrasound and AFP are documented to have poor sensitivity for early



stage cancer, which is the primary target of testing. We are currently seeking to develop a blood-based biomarker test to serve as an alternative to ultrasound and AFP for use in HCC testing. We published a small case-control study in 2016 showing high accuracy for detecting HCC using a blood-based panel of methylation markers. In June 2018, we announced significant progress toward developing a panel of blood-based, DNA biomarkers that could accurately detect HCC. The biomarker panel was shown to be 95 percent sensitive for detecting HCC across all stages. Sensitivity among patients with curable-stage disease was 91 percent, and the panel has overall specificity of 93 percent. These results came from using DNA extracted from blood samples of 244 people, including 95 diagnosed across all stages of HCC, 51 with cirrhosis, and 98 healthy volunteers. Researchers tested the samples against 15 biomarkers to identify the combination of six biomarkers that yielded the most accurate detection of HCC.

The ACS estimates that, in the U.S. in 2018, lung cancer will be diagnosed in 234,000 people and cause 154,000 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. We are currently seeking to develop a blood-based biomarker test to aid in the early detection of lung cancer in individuals with lung nodules discovered through a computerized tomography (“CT”) or other scan. Such a test may help reduce the number of unnecessary biopsies and other follow-up procedures, and thereby reduce costs and improve health outcomes.

## Table of Contents

We also continue to explore opportunities for improving Cologuard, including improvements that could lower our cost of goods or expand the usage of Cologuard to different patient populations.

### How We Recognize Revenue

For tests performed where we have an agreed-upon reimbursement rate or where we can estimate the amount that we will ultimately collect at the time delivery is complete, we recognize the related revenue on an accrual basis upon delivery of a test result to an ordering healthcare provider. Accrual rates are based on the established billing rates less contractual and other adjustments, which yields the amount that we expect to ultimately collect. We determine the amount we expect to ultimately collect on a per-payer or per-agreement basis. The expected amount is typically lower than, if applicable, the agreed-upon reimbursement amount due to several factors, such as the amount of any patient co-payments, the existence of secondary payers and claim denials. Upon ultimate collection, the aggregate amount received from payers and patients where reimbursement was estimated is compared to previous collection estimates and, if necessary, the contractual allowance is adjusted. Finally, should we recognize revenue from claims on an accrual basis and later determine the judgments underlying estimated collections change, our financial results could be negatively impacted in future quarters. Historically, a portion of our revenue was recognized upon cash receipt when we were unable to reasonably estimate the amount that would ultimately be collected from a payer. Effective during the first quarter of 2017, we determined that we had the ability to reasonably estimate the amount that will ultimately be collected from all payers, including the impact of patient cost-share collections. Accordingly, we now recognize revenue on an accrual basis for all billed claims.

Our average reimbursement per test, as further defined below, was approximately \$462 and \$423 through June 30, 2018 and 2017, respectively. This cumulative average Cologuard reimbursement rate will change over time due to a number of factors, such as medical coverage decisions by payers, changes in the payer mix, the effects of contracts signed with payers, changes in allowed amounts by payers, our ability to successfully win appeals for payment, settlements reached with payers regarding previously denied claims and our ability to collect cash payments from payers and individual patients. Historical average reimbursement is not necessarily indicative of future average reimbursement.

We calculate the average Cologuard reimbursement per test on a trailing twelve-month basis for all tests that are at least six months old, since it can take that long, or in some cases longer, to collect from some payers and patients. Thus, the average reimbursement per test at June 30, 2018 and June 30, 2017, respectively, represents the total cash collected through such dates for tests performed during the twelve-month periods ended December 31, 2017 and December 31, 2016, respectively, divided by the number of tests performed during those same periods.

### 2018 Priorities

Our top priorities for 2018 are to (1) continue to strengthen our core Cologuard business including by increasing the size of our nationwide sales force by approximately 200 representatives, which would bring our total number of sales personnel to approximately 550, (2) prepare for future demand including by continuing to invest in people, processes, technology and systems to build capacity, and (3) expand our product pipeline by developing additional cancer diagnostic tests, which may include liver and lung cancer tests, which we expect will result in a material increase to our research and development expenditures.

## Results of Operations

We have generated significant losses since inception and, as of June 30, 2018, we had an accumulated deficit of approximately \$936.4 million. We expect to continue to incur losses for the near future, and it is possible we may never achieve profitability.

Laboratory service revenue. Our laboratory service revenue is generated by performing screening services using our Cologuard test. For the three months ended June 30, 2018 and 2017, we completed approximately 215,000 and 135,000 Cologuard tests, respectively, and generated laboratory service revenue of \$102.9 million and \$57.6 million, respectively. For the six months ended June 30, 2018 and 2017, we completed approximately 401,000 and 235,000 Cologuard tests, respectively, and generated laboratory service revenue of \$193.2 million and \$106.0 million,

Table of Contents

respectively. The increase in revenue was primarily due to an increase in completed Cologuard tests and an increase in average revenue recognized per test during the current period.

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

Cost of sales includes costs related to inventory production and usage, shipment of test collection kits, royalties and the cost of laboratory services to process tests and provide results to physicians. We incur expense for tests in the period in which the activities occur, therefore, gross margin as a percentage of laboratory service revenue may vary due to 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 Cologuard test volume, operating efficiencies, patient compliance rates, payer mix, the levels of reimbursement, and payment patterns of payers and patients.

**Cost of Sales.** Cost of sales increased to \$26.9 million for the three months ended June 30, 2018 compared to \$18.0 million for the three months ended June 30, 2017. Cost of sales increased to \$49.8 million for the six months ended June 30, 2018 compared to \$35.0 million for the six months ended June 30, 2017. The increase in cost of sales is primarily due to the increase in completed Cologuard tests. The Company completed approximately 215,000 and 135,000 Cologuard tests for the three months ended June 30, 2018 and 2017, respectively. The Company completed approximately 401,000 and 235,000 Cologuard tests for the six months ended June 30, 2018 and 2017, respectively.

(In millions)	Three Months Ended June 30,		
	2018	2017	Change
Production costs	\$ 18.9	\$ 13.0	\$ 5.9
Personnel expenses	4.6	2.7	1.9
Facility and support expenses	2.4	1.8	0.6
Stock-based compensation	0.9	0.4	0.5
Other cost of sales	0.1	0.1	—
Total cost of sales expenses	\$ 26.9	\$ 18.0	\$ 8.9

(In millions)	Six Months Ended June 30,		
	2018	2017	Change
Production costs	\$ 34.5	\$ 25.2	\$ 9.3
Personnel expenses	8.9	5.1	3.8

Edgar Filing: EXACT SCIENCES CORP - Form 10-Q

Facility and support expenses	4.7	3.9	0.8
Stock-based compensation	1.6	0.7	0.9
Other cost of sales	0.1	0.1	—
Total cost of sales expenses	\$ 49.8	\$ 35.0	\$ 14.8

Research and development expenses. Research and development expenses increased to \$14.7 million for the three months ended June 30, 2018 compared to \$9.7 million for the three months ended June 30, 2017. Research and development expenses increased to \$29.6 million for the six months ended June 30, 2018 compared to \$17.7 million for the six months ended June 30, 2017. The increase in research and development expenses was primarily due to an increase in personnel costs and stock-based compensation due to an increased headcount and an increase in direct research and development expenses for our pipeline.

Table of Contents

(In millions)	Three Months Ended June 30,		
	2018	2017	Change
Direct research and development expenses	\$ 5.9	\$ 4.0	\$ 1.9
Personnel expenses	4.2	3.3	0.9
Stock-based compensation	2.8	1.3	1.5
Other research and development	1.1	0.6	0.5
Legal and professional fees	0.7	0.5	0.2
Total research and development expenses	\$ 14.7	\$ 9.7	\$ 5.0

(In millions)	Six Months Ended June 30,		
	2018	2017	Change
Direct research and development expenses	\$ 12.3	\$ 7.1	\$ 5.2
Personnel expenses	8.9	6.4	2.5
Stock-based compensation	4.8	2.3	2.5
Other research and development	2.2	1.0	1.2
Legal and professional fees	1.4	0.9	0.5
Total research and development expenses	\$ 29.6	\$ 17.7	\$ 11.9

General and administrative expenses. General and administrative expenses increased to \$39.6 million for the three months ended June 30, 2018 compared to \$24.6 million for the three months ended June 30, 2017. General and administrative expenses increased to \$75.1 million for the six months ended June 30, 2018 compared to \$44.7 million for the six months ended June 30, 2017. The increase in general and administrative expenses was primarily a result of increased personnel costs, facility and support costs, and stock-based compensation to support the overall growth of the Company.

(In millions)	Three Months Ended June 30,		
	2018	2017	Change
Personnel expenses	\$ 14.8	\$ 9.0	\$ 5.8
Facility and support expenses	9.1	4.7	4.4
Stock-based compensation	8.7	3.1	5.6
Professional and legal fees	5.0	5.8	(0.8)
Other general and administrative	2.0	2.0	—
Total general and administrative expenses	\$ 39.6	\$ 24.6	\$ 15.0

(In millions)	Six Months Ended June 30,		
	2018	2017	Change
Personnel expenses	\$ 28.7	\$ 16.8	\$ 11.9
Professional and legal fees	9.6	9.9	(0.3)
Facility and support expenses	17.0	8.5	8.5
Stock-based compensation	16.0	6.3	9.7

Edgar Filing: EXACT SCIENCES CORP - Form 10-Q

Other general and administrative	3.8	3.2	0.6
Total general and administrative expenses	\$ 75.1	\$ 44.7	\$ 30.4

Sales and marketing expenses. Sales and marketing expenses increased to \$54.4 million for the three months ended June 30, 2018 compared to \$36.7 million for the three months ended June 30, 2017. Sales and marketing expenses increased to \$107.8 million for the six months ended June 30, 2018 compared to \$75.5 million for the six months ended June 30, 2017. The increase in sales and marketing expenses was a result of hiring additional sales and marketing personnel and increasing our advertising and patient marketing efforts as part of the ongoing commercialization of our Cologuard test.

Table of Contents

(In millions)	Three Months Ended June 30,		
	2018	2017	Change
Direct marketing costs and professional fees	\$ 28.7	\$ 19.0	\$ 9.7
Personnel expenses	21.6	16.1	5.5
Stock-based compensation	3.2	1.3	1.9
Other sales and marketing	0.9	0.3	0.6
Total sales and marketing expenses	\$ 54.4	\$ 36.7	\$ 17.7

(In millions)	Six Months Ended June 30,		
	2018	2017	Change
Direct marketing costs and professional fees	\$ 55.2	\$ 39.9	\$ 15.3
Personnel expenses	45.6	32.1	13.5
Stock-based compensation	5.7	2.9	2.8
Other sales and marketing	1.3	0.6	0.7
Total sales and marketing expenses	\$ 107.8	\$ 75.5	\$ 32.3

Investment income. Investment income increased to \$4.9 million for the three months ended June 30, 2018 compared to \$0.7 million for the three months ended June 30, 2017. Investment income increased to \$8.6 million for the six months ended June 30, 2018 compared to \$1.3 million for the six months ended June 30, 2017. The increase in investment income was due to an increase in the average cash and marketable securities balance and an increase in the average rate of return on investments for the three and six months ended June 30, 2018 when compared to the same periods in 2017.

Interest expense. Net interest expense of \$8.6 million was realized for the three months ended June 30, 2018 compared to net interest expense of \$0.1 million for the three months ended June 30, 2017. Net interest expense of \$15.1 million was realized for the six months ended June 30, 2018 compared to net interest expense of \$0.1 million for the six months ended June 30, 2017. During January 2018, we issued \$690.0 million of convertible debt and in June 2018 we issued \$218.5 million of convertible debt, which resulted in \$8.6 million and \$15.0 million in interest expense during the three and six months ended June 30, 2018, respectively, \$6.7 million and \$11.7 million of which relates to amortization of debt discount and debt issuance costs for the three and six months ended June 30, 2018, respectively. The remaining \$1.9 million and \$3.3 million for the three and six months ended June 30, 2018, respectively, relates to the stated interest which will be paid in cash during the year. The interest expense for the three and six months ended June 30, 2017 is related to the mortgage on one of our facilities in Madison, WI which was entered into in June 2015.

## Liquidity and Capital Resources



We have financed our operations since inception primarily through public offerings of our common stock and convertible debt and through revenue generated by the sale of Cologuard. As of June 30, 2018, we had approximately \$225.7 million in cash and cash equivalents and approximately \$996.5 million in marketable securities.

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

Net cash used in operating activities was \$64.0 million for the six months ended June 30, 2018 as compared to \$65.5 million for the six months ended June 30, 2017. The principal use of cash in operating activities for the six months ended June 30, 2018 was to fund our net loss.

Net cash used in investing activities was \$693.5 million for the six months ended June 30, 2018 as compared to \$58.9 million for the six months ended June 30, 2017. The increase in cash used in investing activities for the six months ended June 30, 2018 compared to the same period in 2017 was primarily the result of the timing of purchases and maturities of marketable securities following our convertible debt offerings. Excluding the impact of purchases and maturities of marketable securities, net cash used in investing activities was \$44.5 million for the six months ended June 30, 2018. Cash use consisted of purchases of property and equipment of \$44.4 million, and \$0.1 of internally developed

## Table of Contents

software. For the same period in 2017, there were purchases of property and equipment of \$8.6 million and purchases of intangible assets of \$8.4 million. The increase in purchases of property and equipment during the six months ended June 30, 2018 was primarily the result of increased laboratory equipment purchases, computer equipment and computer software purchases, and assets under construction in order to continue to scale-up our operations for future expected growth of our Cologuard business.

Net cash provided by financing activities was \$905.7 million for the six months ended June 30, 2018, as compared to \$255.8 million for the six months ended June 30, 2017. The increase in cash provided by financing activities for the six months ended June 30, 2018 compared to the same period in 2017 was primarily the result of proceeds from our offerings of convertible debt in January 2018 and June 2018.

We expect that cash and cash equivalents and marketable securities on hand at June 30, 2018 will be sufficient to fund our current operations for at least the next twelve months, based on current operating plans. However, we may need to raise additional capital to fully fund our current strategic plan, which includes successfully commercializing Cologuard and developing a pipeline of future products. If we are unable to obtain sufficient additional funds to enable us to fund our operations through the completion of such plan, our results of operations and financial condition would be materially adversely affected, and we may be required to delay the implementation of our plan and otherwise scale back our operations. Even if we successfully raise additional funds, we cannot assure that our business will ever generate sufficient cash flow from operations to become profitable.

A table of our specified contractual obligations as of December 31, 2017 was provided in the Management's Discussion and Analysis of Financial Condition and Results of Operation of our 2017 Form 10-K. During January 2018 and June 2018, we issued \$690.0 million and \$218.5 million, respectively, in aggregate principal amount of 1.0% Convertible Notes (the "Notes") that will mature on January 15, 2025, unless earlier converted. We may not redeem the Notes prior to January 15, 2025. The holders of the Notes may convert prior to July 15, 2024, only under certain circumstances. On or after July 15, 2024, holders may convert their Notes at any time. As further discussed in Note 9 of the condensed consolidated financial statements of this Quarterly Report, the Notes accrue interest at a fixed rate of 1.0% per year, payable semi-annually in arrears on January 15 and July 15 of each year, beginning on July 15, 2018. With the exception of the Notes discussed above, there were no material changes outside the ordinary course of our business in the specified contractual obligations during the six months ended June 30, 2018.

## Critical Accounting Policies and Estimates

Management's discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP"). The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments, including those related to revenue

recognition, tax positions and stock-based compensation. We base our estimates on historical experience and on various other factors that are believed to be appropriate under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 2 of our financial statements included in our 2017 Form 10-K, we believe that the following accounting policies and judgments are most critical to aid in fully understanding and evaluating our reported financial results.

### Revenue Recognition

Laboratory service revenue. Our laboratory service revenues are generated by performing diagnostic services using our Cologuard test, and the service is completed upon delivery of a patient's test result to the ordering physician. We account for revenue in accordance with ASC Topic 606, Revenue from Contracts with Customers ("ASC 606"), which we adopted on January 1, 2018, using the modified retrospective method, which we elected to apply to all contracts. Application of the modified retrospective method did not impact amounts previously reported by us, nor did it require a cumulative effect adjustment upon adoption, as our method of recognizing revenue under ASC 606 was

## Table of Contents

analogous to the method utilized immediately prior to adoption. Accordingly, there is no need for us to disclose the amount by which each financial statement line item was affected as a result of applying the new standard and an explanation of significant changes.

The core principle of ASC 606 is that we recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which we expect to be entitled in exchange for those goods or services. We recognize revenue in accordance with that core principle, and key aspects considered include the following:

### Contracts

Our customer is the patient. However, we do not enter into a formal reimbursement contract with a patient, as formal reimbursement contracts, including national coverage determination, are established with payers. Accordingly, we establish a contract with a patient in accordance with other customary business practices.

- Approval of a contract is established via the order submitted by the patient's physician and the return of a sample by the patient.
- We are obligated to perform its diagnostic services upon receipt of a sample from a patient, and the patient and/or applicable payer are obligated to reimburse us for services rendered based on the patient's insurance benefits.
- Payment terms are a function of a patient's existing insurance benefits, including the impact of coverage decisions with CMS and applicable reimbursement contracts established between us and payers, unless the patient is a self-pay patient, whereby we require payment from the patient prior to us shipping a collection kit to the patient.
- Once we deliver a patient's test result to the ordering physician the contract with a patient has commercial substance, as we are legally able to collect payment and bill an insurer and/or patient, depending on payer contract status or patient insurance benefit status.
- Our consideration is deemed to be variable, and we consider collection of such consideration to be probable to the extent that it is unconstrained.

### Performance obligations

A performance obligation is a promise in a contract to transfer a distinct good or service (or a bundle of goods or services) to the customer. Our contracts have a single performance obligation, which is satisfied upon rendering of services, which culminates in the delivery of a patient's Cologuard test result to the ordering physician. The duration of time between sample receipt and delivery of a valid test result to the ordering physician is typically less than two weeks. Accordingly, we elect the practical expedient and therefore, we do not disclose the value of unsatisfied performance obligations.

### Transaction price

The transaction price is the amount of consideration to which we expect to collect in exchange for transferring promised goods or services to a customer, excluding amounts collected on behalf of third parties (for example, some sales taxes). The consideration expected from a contract with a customer may include fixed amounts, variable amounts, or both.

The consideration derived from our contracts is deemed to be variable, though the variability is not explicitly stated in any contract. Rather, the implied variability is due to several factors, such as the amount of contractual adjustments, any patient co-payments, deductibles or compliance incentives, the existence of secondary payers and claim denials.

We estimate the amount of variable consideration using the expected value method, which represents the sum of probability-weighted amounts in a range of possible consideration amounts. When estimating the amount of variable consideration, the company considers several factors, such as historical collections experience, patient insurance eligibility and payer reimbursement contracts.

## Table of Contents

We limit the amount of variable consideration included in the transaction price to the unconstrained portion of such consideration. In other words, we recognize revenue up to the amount of variable consideration that is not subject to a significant reversal until additional information is obtained or the uncertainty associated with the additional payments or refunds is subsequently resolved. Differences between original estimates and subsequent revisions, including final settlements, represent changes in the estimate of variable consideration and are included in the period in which such revisions are made. Revenue recognized from changes in transaction prices was \$3.4 million and \$11.9 million for the three and six months ended June 30, 2018.

We monitor our estimates of transaction price to depict conditions that exist at each reporting date. If we subsequently determine that we will collect more consideration than we originally estimated for a contract with a patient, we will account for the change as an increase in the estimate of the transaction price (i.e., an upward revenue adjustment) in the period identified. Similarly, if we subsequently determine that the amount we expect to collect from a patient is less than we originally estimated, we will generally account for the change as a decrease in the estimate of the transaction price (i.e., a downward revenue adjustment), provided that such downward adjustment does not result in a significant reversal of cumulative revenue recognized.

When we do not have significant historical experience or that experience has limited predictive value, the constraint over estimates of variable consideration may result in no revenue being recognized upon delivery of a patient's Cologuard test result to the ordering physician, with recognition generally occurring at the date of cash receipt. Since the first quarter of 2017, we determined that our historical experience has sufficient predictive value, such that there are no longer any contracts for which no revenue is recognized upon delivery of a Cologuard test result to an ordering physician. Of the revenue recognized in the twelve months ended December 31, 2017, approximately \$4.3 million relates to the one-time impact of certain payers meeting our revenue recognition criteria for accrual-basis revenue recognition beginning with the period ended March 31, 2017. Approximately \$1.0 million of this one-time impact relates to tests completed in the prior year and for which our accrual revenue recognition criteria were not met until 2017.

### Allocate transaction price

The entire transaction price is allocated to the single performance obligation contained in a contract with a patient.

### Point in time recognition

Our single performance obligation is satisfied at a point in time, and that point in time is defined as the date a patient's successful test result is delivered to the patient's ordering physician. We consider this date to be the time at which the patient obtains control of the promised Cologuard test service.

## Contract Balances

The timing of revenue recognition, billings and cash collections results in billed accounts receivable and deferred revenue on the condensed consolidated balance sheets. Generally, billing occurs subsequent to delivery of a patient's test result to the ordering physician, resulting in an account receivable. However, we sometimes receive advance payment from a patient, particularly a self-pay patient, before a Cologuard test result is completed, resulting in deferred revenue. The deferred revenue balance is relieved upon delivery of the applicable patient's test result to the ordering physician. Changes in accounts receivable and deferred revenue were not materially impacted by any other factors.

Deferred revenue balances are included in other short-term liabilities on our condensed consolidated balance sheets and were \$0.3 million and \$0.2 million as of June 30, 2018 and December 31, 2017, respectively.

Revenue recognized for the three months ended June 30, 2018 and 2017, that was included in the deferred revenue balance at the beginning of each period was \$0.1 million and \$44,000, respectively. Revenue recognized for the six months ended June 30, 2018 and 2017, that was included in the deferred revenue balance at the beginning of each period was \$0.1 million and \$44,000, respectively.

Table of Contents

Practical expedients

We do not adjust the transaction price for the effects of a significant financing component, as at contract inception, we expect the collection cycle to be one year or less.

We expense sales commissions when incurred because the amortization period would have been one year or less. These costs are recorded within sales and marketing expenses on our condensed consolidated statements of operations.

We incur certain other costs that are incurred regardless of whether a contract is obtained. Such costs are primarily related to legal services and patient communications (e.g. compliance reminder letters). These costs are expensed as incurred and recorded within general and administrative expenses on our condensed consolidated statements of operations.

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

Direct and indirect manufacturing costs incurred during process validation and for other research and development activities, which are not permitted to be sold, have been expensed to research and development on our condensed consolidated statements of operations.

Stock-Based Compensation. In accordance with GAAP, all stock-based payments, including grants of employee stock options, restricted stock and restricted stock units, market measure-based awards and shares purchased under an employee stock purchase plan ("ESPP") (if certain parameters are not met), are recognized in the financial statements based on their fair values. The grant date fair value of market measure-based share-based compensation plans are calculated using a Monte Carlo simulation pricing model. 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 fair value of each market measure-based award is estimated on the date of grant using a Monte Carlo simulation pricing model. The fair value of service-based awards for each restricted stock unit award is determined on the date of grant using the closing stock price on that day. The estimated fair value of these awards is recognized to expense using the straight-line method over the vesting period. For awards issued to non-employees, the measurement date is the date when the performance is complete or when the award vests, whichever is the earliest. Accordingly, non-employee awards are re-measured at each reporting period until the final measurement date. The fair value of the award is recognized as stock-based compensation expense over the requisite service period, generally the vesting period. The Black-Scholes and Monte Carlo pricing models utilize the following assumptions:
  - Expected Term - Expected term is based on our historical life data and is determined using the average of the vesting period and the contractual life of the stock options granted. Expected life of a market measure-based award is based on the applicable performance period.
  - Expected Volatility - Expected volatility is based on our historical stock volatility data over the expected term of the awards.
  - Risk-Free Interest Rate – We base the risk-free interest rate used in the Black-Scholes and Monte Carlo valuation models on the implied yield currently available on U.S. Treasury zero-coupon issues with an equivalent expected term.

## Table of Contents

· Forfeitures – Beginning in 2017, we adopted Accounting Standards Update (“ASU”) No. 2016-09, Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting (“Update 2016-09”). With the adoption of Update 2016-09, forfeiture estimates are no longer required, and the effects of actual forfeitures are recorded at the time they occur. The impact on our condensed consolidated balance sheet as of March 31, 2017 was a cumulative-effect adjustment of \$0.4 million, increasing opening accumulated deficit and additional paid-in capital.

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

**Convertible Debt.** We account for convertible debt instruments that may be settled in cash or equity upon conversion by separating the liability and equity components of the instruments in a manner that reflects our nonconvertible debt borrowing rate. In January 2018 and June 2018, we issued \$690.0 million and \$218.5 million, respectively, in aggregate principal amount of 1.0% Convertible Notes with a maturity date of January 15, 2025 (the “Notes”). We determined the carrying amount of the liability component of the Notes by using assumptions that market participants would use in pricing a debt instrument, including market interest rates, credit standing, yield curves and volatilities. Determining the fair value of the debt component requires the use of accounting estimate and assumptions. These estimates and assumptions are judgmental in nature and could have a significant impact on the determination of the debt component, and the associated non-cash interest expense.

For the January 2018 offering, we allocated \$194.9 million to the equity component of the convertible debt instrument. That equity component is treated as a discount on the liability component of the Notes, which is amortized over the seven-year term of the Notes using the effective interest rate method. For the June 2018 offering, we allocated \$73.0 million to the equity component of the convertible debt instrument. That equity component, less the \$14.2 million premium, is treated as a discount on the liability component of the Notes, which is amortized over the remaining six-and-a-half-year term of the Notes using the effective interest rate method. In addition, debt issuance costs related to the Notes were \$18.8 million and \$7.4 million for the January 2018 and June 2018 offerings, respectively. We allocated the costs to the liability and equity components of the Notes based on their relative values. The debt issuance costs allocated to the liability component are being amortized over the life of the Notes as additional non-cash interest expense. The transaction costs allocated to the equity component are netted with the equity component of the convertible debt instrument in stockholders’ equity.

## Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606). We adopted this guidance on January 1, 2018. See Note 2 for additional discussion.

In January 2016, the Financial Accounting Standards Board issued ASU No. 2016-01, “Financial Instruments – Overall: Recognition and Measurement of Financial Assets and Financial Liabilities (“Update 2016-01”). Update 2016-01 modifies how entities measure equity investments and present changes in the fair value of financial liabilities. Under the new guidance, entities will have to measure equity investments that do not result in consolidation and are not accounted for under the equity method at fair value and recognize any changes in fair value in net income unless the investments qualify for the new practicality exception. A practicality exception will apply to those equity investments that do not have readily determinable fair value and do not qualify for the practical expedient to estimate fair value under ASC 820, “Fair Value Measurements,” and as such these investments may be measured at cost. Update 2016-01 will be effective for the fiscal year beginning January 1, 2018, and subsequent interim periods. Update 2016-01 was further amended in February 2018 by ASU No. 2018-03, Technical Corrections and Improvements to Financial Instruments – Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities, (“Update 2018-03”). Update 2018-03 clarifies certain aspects of the guidance issued in Update 2016-01. Public business entities with fiscal years beginning between December 15, 2017 and June 15, 2018, are not required to adopt these amendments until the interim period beginning after June 15, 2018. Early adoption is allowed as long as Update 2016-01 has been adopted. We adopted Update 2016-01 on January 1, 2018, and it did not have an impact on our condensed consolidated financial statements.

Table of Contents

In February 2016, the Financial Accounting Standards Board issued ASU No. 2016-02, Leases (Topic 842), (“Update 2016-02”) which requires recognition of lease assets and lease liabilities by lessees for those leases classified as operating leases under previous GAAP. The amendments in this update are effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. In transition, lessees and lessors are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. We expect to adopt the guidance in 2019. We are currently evaluating the effects that the adoption of Update 2016-02 will have on our condensed consolidated financial statements; however, as we have several leases, assets and liabilities are expected to increase upon adoption for right-of-use assets and lease liabilities.

In August 2016, the Financial Accounting Standards Board issued ASU No. 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments, (“Update 2016-15”). Current GAAP either is unclear or does not include specific guidance on the eight cash flow classification issues included in the amendments in Update 2016-15. The amendments are an improvement to GAAP because they provide guidance for each of the eight issues, thereby reducing the current and potential future diversity in practice. We adopted this guidance on January 1, 2018, and it did not have an impact on our statements of cash flows.

In October 2016, the Financial Accounting Standards Board issued ASU No. 2016-16, Income Taxes (Topic 740): Intra-Entity Transfers of Assets Other Than Inventory, (“Update 2016-16”). This amendment improves the accounting for the income tax consequences of intra-entity transfers of assets other than inventory. We adopted this guidance on January 1, 2018, and it did not have an impact on our condensed consolidated financial statements.

In November 2016, the Financial Accounting Standards Board issued ASU No. 2016-18, Statement of Cash Flows: Restricted Cash, (“Update 2016-18”). Update 2016-18 provides guidance on the classification of restricted cash in the statement of cash flows. We adopted this guidance on January 1, 2018, and it did not have an impact on our condensed consolidated financial statements, as we do not have restricted cash.

In May 2017, the Financial Accounting Standards Board issued ASU No. 2017-09, Compensation – Stock Compensation (Topic 718): Scope of Modification Accounting, (“Update 2017-09”). Update 2017-09 provides guidance on determining which changes to the terms and conditions of share-based payment awards require an entity to apply modification accounting under Topic 718. We adopted this guidance on January 1, 2018, and it did not have an impact on our condensed consolidated financial statements.

In June 2018, the Financial Accounting Standards Board issued ASU No. 2018-07 (Topic 718), Improvements to Nonemployee Share-Based Payment Accounting, (“Update 2018-07”). Update 2018-07 expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. An entity should apply the requirements to Topic 718 to nonemployee awards except for certain exemptions specified in the amendment. The guidance is effective for fiscal years beginning after December 15, 2018, including interim reporting periods within that fiscal year. Early adoption is permitted, but no earlier than an entity’s adoption of Topic 606. We are currently evaluating the impact of the guidance on our condensed consolidated financial statements.

Off-Balance Sheet Arrangements

As of June 30, 2018, we had no off-balance sheet arrangements.

43

---

Table of Contents

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Market risk represents the risk of loss that may result from the change in value of financial instruments due to fluctuations in their market price. Market risk is inherent in all financial instruments. Our exposure to market risk is principally confined to our cash, cash equivalents and marketable securities. We invest our cash, cash equivalents and marketable securities in securities of the U.S. government and its agencies and in investment-grade, highly liquid investments consisting of commercial paper, bank certificates of deposit, asset backed securities and corporate bonds, which, as of June 30, 2018 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.

The primary quantifiable market risk associated with our financial instruments is sensitivity to changes in interest rates. Interest rate risk represents the potential loss from adverse changes in market interest rates. Due to the nature of the financial instruments we hold, we believe there is no material exposure to interest rate risk arising from our portfolio of financial instruments.

Our assets and liabilities are denominated in U.S. dollars. Consequently, we have not considered it necessary to use foreign currency contracts or other derivative instruments to manage changes in currency rates. We do not now, nor do we plan to, use derivative financial instruments for speculative or trading purposes. However, these circumstances might change.

Item 4. Controls and Procedures

As of the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and our principal financial officer, of the effectiveness of our disclosure controls and procedures, as defined in Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Based upon that evaluation, our principal executive officer and our principal financial officer concluded that, as of June 30, 2018, 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.

44

---

Table of Contents

Part II - Other Information

Item 1. Legal Proceedings

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

Item 1A. Risk Factors

We operate in a rapidly changing environment that involves a number of risks that could materially affect our business, financial condition or future results, some of which are beyond our control. In addition to the other information set forth in this report, the risks and uncertainties that we believe are most important for you to consider are discussed in Part I, “Item 1A. Risk Factors” on the 2017 Form 10-K. There have been no material changes to the risk factors described in the 2017 Form 10-K.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Not applicable.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.



Item 5. Other Information

Not applicable.

Item 6. Exhibits

The following documents are filed as part of this Form 10-Q.

Exhibit Number	Description
3.1	<u>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)</u>
3.2	<u>First Amendment to Sixth Amended and Restated Certificate of Incorporation of the Registrant (previously filed as Appendix B to the Definitive Proxy Statement for the Company's 2014 Annual Meeting of Stockholders, filed on June 20, 2014, and incorporated herein by reference)</u>
3.3	<u>Third Amended and Restated By-Laws of the Registrant (previously filed as Exhibit 3.3 to the Registrant's Quarterly Report on Form 10-Q for the period ended September 30, 2017, and incorporated herein by reference)</u>
10.1*	<u>Employee Transition Agreement, between Maneesh Arora and the Registrant, dated April 25, 2018 (previously filed as Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q for the period ended March 31, 2018, and incorporated herein by reference)</u>
31.1+	<u>Certification Pursuant to Rule 13(a)-14(a) or Rule 15d-14(a) of Securities Exchange Act of 1934</u>

45

---

Table of Contents

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

---

+Filed herewith

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

Table of Contents

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

EXACT SCIENCES CORPORATION

Date: August 1, 2018 By: /s/ Kevin T. Conroy  
Kevin T. Conroy  
President and Chief Executive Officer  
(Principal Executive Officer)

Date: August 1, 2018 By: /s/ Jeffrey T. Elliott  
Jeffrey T. Elliott  
Chief Financial Officer  
(Principal Financial and Accounting Officer)