

---

**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 March 31, 2019

OR

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

Commission File Number: 001-35092

**EXACT SCIENCES CORPORATION**

(Exact name of registrant as specified in its charter)

**DELAWARE**

(State or other jurisdiction of  
incorporation or organization)

**02-0478229**

(I.R.S. Employer  
Identification Number)

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

**53719**  
(Zip Code)

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

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

Indicate by check mark whether the registrant has submitted electronically, 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 April 29, 2019, the registrant had 129,138,838 shares of common stock outstanding.

---

---

EXACT SCIENCES CORPORATION

INDEX

	<u>Page Number</u>
<b><u>Part I - Financial Information</u></b>	
<b><u>Item 1. Financial Statements</u></b>	
<u>Condensed Consolidated Balance Sheets (unaudited) as of March 31, 2019 and December 31, 2018</u>	3
<u>Condensed Consolidated Statements of Operations (unaudited) for the Three Months Ended March 31, 2019 and 2018</u>	4
<u>Condensed Consolidated Statements of Comprehensive Loss (unaudited) for the Three Months Ended March 31, 2019 and 2018</u>	5
<u>Condensed Consolidated Statements of Stockholders' Equity (unaudited) for the Three Months Ended March 31, 2019 and 2018</u>	6
<u>Condensed Consolidated Statements of Cash Flows (unaudited) for the Three Months Ended March 31, 2019 and 2018</u>	7
<u>Notes to Condensed Consolidated Financial Statements (unaudited)</u>	8
<b><u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u></b>	31
<b><u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u></b>	43
<b><u>Item 4. Controls and Procedures</u></b>	43
<b><u>Part II - Other Information</u></b>	
<b><u>Item 1. Legal Proceedings</u></b>	44
<b><u>Item 1A. Risk Factors</u></b>	44
<b><u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u></b>	45
<b><u>Item 3. Defaults Upon Senior Securities</u></b>	45
<b><u>Item 4. Mine Safety Disclosures</u></b>	45
<b><u>Item 5. Other Information</u></b>	45
<b><u>Item 6. Exhibits</u></b>	46
<u>Signatures</u>	47

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

	March 31, 2019	December 31, 2018
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 285,200	\$ 160,430
Marketable securities	997,506	963,752
Accounts receivable, net	56,095	44,239
Inventory, net	44,269	39,148
Prepaid expenses and other current assets	24,050	20,498
Total current assets	1,407,120	1,228,067
Long-term Assets:		
Property, plant and equipment, net	291,629	245,259
Goodwill and intangibles, net	45,610	46,281
Other long-term assets, net	26,189	4,415
Total assets	<u>\$ 1,770,548</u>	<u>\$ 1,524,022</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts payable	\$ 17,552	\$ 28,141
Accrued liabilities	143,129	100,644
Accrued interest	1,066	4,172
Debt, current portion	21	8
Other short-term liabilities	5,889	3,204
Total current liabilities	167,657	136,169
Convertible notes, net	770,510	664,749
Long-term debt, less current portion	24,787	24,494
Other long-term liabilities	6,821	9,475
Long-term obligations	23,833	8,194
Total liabilities	993,608	843,081
Commitments and contingencies		
Stockholders' Equity:		
Preferred stock, \$0.01 par value Authorized—5,000,000 shares issued and outstanding—no shares at March 31, 2019 and December 31, 2018	—	—
Common stock, \$0.01 par value Authorized—200,000,000 shares issued and outstanding—129,083,822 and 123,192,540 shares at March 31, 2019 and December 31, 2018	1,292	1,232
Additional paid-in capital	1,894,116	1,716,894
Accumulated other comprehensive income (loss)	354	(1,422)
Accumulated deficit	(1,118,822)	(1,035,763)
Total stockholders' equity	776,940	680,941
Total liabilities and stockholders' equity	<u>\$ 1,770,548</u>	<u>\$ 1,524,022</u>

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

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

	Three Months Ended March 31,	
	2019	2018
Revenue	\$ 162,043	\$ 90,296
Cost of sales	43,252	22,914
Gross margin	118,791	67,382
Operating expenses:		
Research and development	32,016	14,935
General and administrative	64,030	35,567
Sales and marketing	90,939	53,408
Total operating expenses	186,985	103,910
Loss from operations	(68,194)	(36,528)
Other income (expense)		
Investment income	6,655	3,673
Interest expense	(21,990)	(6,510)
Total other expense	(15,335)	(2,837)
Net loss before tax	(83,529)	(39,365)
Income tax benefit (expense)	470	(59)
Net loss	\$ (83,059)	\$ (39,424)
Net loss per share—basic and diluted	\$ (0.66)	\$ (0.33)
Weighted average common shares outstanding—basic and diluted	126,248	121,016

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

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

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2019</b>	<b>2018</b>
Net loss	\$ (83,059)	\$ (39,424)
Other comprehensive loss, before tax:		
Unrealized gain (loss) on available-for-sale investments	2,176	(1,606)
Foreign currency translation gain	120	20
Comprehensive loss, before tax	(80,763)	(41,010)
Income tax expense related to items of other comprehensive loss	(520)	—
Comprehensive loss, net of tax	\$ (81,283)	\$ (41,010)

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

**EXACT SCIENCES CORPORATION**  
**Condensed Consolidated Statements of Stockholders' Equity**  
**(Amounts in thousands, except share data - unaudited)**

	Common Stock		Additional Paid In Capital	Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Number of Shares	\$0.01 Par Value				
Balance, January 1, 2019	123,192,540	\$ 1,232	\$ 1,716,894	\$ (1,422)	\$ (1,035,763)	\$ 680,941
Equity component of convertible notes, net of issuance costs	—	—	268,390	—	—	268,390
Shares issued to settle convertible notes	2,158,991	22	182,413	—	—	182,435
Settlement of convertible notes	—	—	(300,768)	—	—	(300,768)
Exercise of common stock options	235,278	2	3,648	—	—	3,650
Issuance of common stock to fund the Company's 2018 401(k) match	86,532	1	7,408	—	—	7,409
Compensation expense related to issuance of stock options and restricted stock awards	3,410,481	35	16,131	—	—	16,166
Net loss	—	—	—	—	(83,059)	(83,059)
Accumulated other comprehensive loss	—	—	—	1,776	—	1,776
Balance, March 31, 2019	<u>129,083,822</u>	<u>\$ 1,292</u>	<u>\$ 1,894,116</u>	<u>\$ 354</u>	<u>\$ (1,118,822)</u>	<u>\$ 776,940</u>
Balance, January 1, 2018	<u>120,497,426</u>	<u>\$ 1,205</u>	<u>\$ 1,380,577</u>	<u>\$ (750)</u>	<u>\$ (860,614)</u>	<u>\$ 520,418</u>
Equity component of convertible notes, net of issuance costs	—	—	189,456	—	—	189,456
Exercise of common stock options	420,129	4	1,387	—	—	1,391
Issuance of common stock to fund the Company's 2017 401(k) match	86,828	1	4,299	—	—	4,300
Compensation expense related to issuance of stock options and restricted stock awards	862,376	9	12,454	—	—	12,463
Net loss	—	—	—	—	(39,424)	(39,424)
Accumulated other comprehensive loss	—	—	—	(1,586)	—	(1,586)
Balance, March 31, 2018	<u>121,866,759</u>	<u>\$ 1,219</u>	<u>\$ 1,588,173</u>	<u>\$ (2,336)</u>	<u>\$ (900,038)</u>	<u>\$ 687,018</u>

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

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

	<b>Three Months Ended March 31,</b>	
	<b>2019</b>	<b>2018</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (83,059)	\$ (39,424)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization of property, plant and equipment	6,324	4,281
Loss on disposal of property, plant and equipment	82	98
Deferred tax benefit	(520)	—
Stock-based compensation	16,166	12,463
Loss on settlement of convertible notes	10,558	—
Non-cash lease expense	845	—
Amortization of liabilities	8,420	4,543
Amortization of premium on short-term investments	(1,306)	(515)
Amortization of intangible assets	810	612
Changes in assets and liabilities:		
Accrued interest	(3,106)	1,407
Accounts receivable, net	(11,856)	(8,156)
Inventory, net	(5,121)	(6,353)
Prepaid expenses and other current assets	(3,552)	(2,812)
Accounts payable	(10,589)	(3,861)
Accrued liabilities	7,891	(623)
Other short-term liabilities	(60)	(29)
Other long-term liabilities	(2,092)	—
Long-term obligations	18,492	(153)
Other long-term assets	(22,734)	—
Net cash used in operating activities	(74,407)	(38,522)
<b>Cash flows from investing activities:</b>		
Purchases of marketable securities	(262,887)	(628,502)
Maturities of marketable securities	232,615	81,161
Purchases of property, plant and equipment	(10,657)	(15,328)
Internally developed software	(140)	(62)
Net cash used in investing activities	(41,069)	(562,731)
<b>Cash flows from financing activities:</b>		
Proceeds from issuance of convertible notes, net	729,536	671,091
Proceeds from exercise of common stock options	3,650	1,391
Payments on settlement of convertible notes	(493,355)	—
Proceeds from construction loan	295	—
Payments on mortgage payable	—	(45)
Net cash provided by financing activities	240,126	672,437
Effects of exchange rate changes on cash and cash equivalents	120	20
Net increase in cash and cash equivalents	124,770	71,204
Cash and cash equivalents, beginning of period	160,430	77,491
Cash and cash equivalents, end of period	<u>\$ 285,200</u>	<u>\$ 148,695</u>
<b>Supplemental disclosure of non-cash investing and financing activities:</b>		
Property, plant and equipment acquired but not paid	<u>\$ 42,119</u>	<u>\$ 12,513</u>
Unrealized gain (loss) on available-for-sale investments, before tax	<u>\$ 2,176</u>	<u>\$ (1,606)</u>
Issuance of 86,532 and 86,828 shares of common stock to fund the Company's 401(k) matching contribution for 2018 and 2017, respectively	<u>\$ 7,409</u>	<u>\$ 4,300</u>
Issuance of 2,158,991 shares of common stock upon settlement of convertible notes	<u>\$ 182,435</u>	<u>\$ —</u>
Retirement of equity component of convertible notes settled	<u>\$ (300,768)</u>	<u>\$ —</u>
Interest paid	<u>\$ 5,214</u>	<u>\$ 48</u>

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

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

**(1) ORGANIZATION AND BASIS OF PRESENTATION**

**Organization**

Exact Sciences Corporation (together with its subsidiaries, “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 additional tests for other types of cancer, with the goal of becoming a leader in cancer screening and 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 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, 2018 included in the Company’s Annual Report on Form 10-K (the “2018 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 2018 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 and variable interest entities. See Note 7 for the discussion of financing arrangements involving certain entities that are variable interest entities that are included in the Company’s condensed consolidated financial statements. All significant intercompany transactions and balances have been eliminated in consolidation.

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

**Use of Estimates**

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

**Cash and Cash Equivalents**

The Company considers cash on hand, demand deposits in bank, money market funds, and all highly liquid investments with an original maturity of 90 days or less to be cash and cash equivalents. The Company had no restricted cash at March 31, 2019 or December 31, 2018.



**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 income. 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 March 31, 2019 and December 31, 2018, the Company's marketable securities 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. Realized gains were \$0.1 million and \$30,000, net of insignificant realized losses, for the three months ended March 31, 2019 and 2018, respectively, and are included in investment income.

The Company periodically reviews 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, the Company's intent not to sell the security, and whether it is more likely than not that the Company will have to sell the security before recovery of its cost basis. For the three months ended March 31, 2019, no investments were identified with other-than-temporary declines in value.

Available-for-sale securities at March 31, 2019 consisted of the following:

(In thousands)	March 31, 2019			
	Amortized Cost	Gains in Accumulated Other Comprehensive Income (Loss) (1)	Losses in Accumulated Other Comprehensive Income (Loss) (1)	Estimated Fair Value
Corporate bonds	\$ 445,236	\$ 516	\$ (83)	\$ 445,669
Asset backed securities	308,764	325	(122)	308,967
U.S. government agency securities	198,943	141	(32)	199,052
Commercial paper	6,000	—	(1)	5,999
Certificates of deposit	37,784	36	(1)	37,819
Total available-for-sale securities	<u>\$ 996,727</u>	<u>\$ 1,018</u>	<u>\$ (239)</u>	<u>\$ 997,506</u>

(1) Gains and losses in accumulated other comprehensive income (loss) are reported before tax impact.

Available-for-sale securities at December 31, 2018 consisted of the following:

(In thousands)	December 31, 2018			
	Amortized Cost	Gains in Accumulated Other Comprehensive Income (Loss) (1)	Losses in Accumulated Other Comprehensive Income (Loss) (1)	Estimated Fair Value
Corporate bonds	\$ 392,973	\$ 33	\$ (719)	\$ 392,287
Asset backed securities	277,537	30	(568)	276,999
U.S. government agency securities	250,606	43	(178)	250,471
Commercial paper	12,158	—	(7)	12,151
Certificates of deposit	31,875	—	(31)	31,844
Total available-for-sale securities	<u>\$ 965,149</u>	<u>\$ 106</u>	<u>\$ (1,503)</u>	<u>\$ 963,752</u>

(1) Gains and losses in accumulated other comprehensive income (loss) are reported before tax impact.

#### Changes in Accumulated Other Comprehensive Income (Loss)

The amount recognized in accumulated other comprehensive income (loss) (“AOCI”) for the three months ended March 31, 2019 were as follows:

(In thousands)	Cumulative Translation Adjustment	Unrealized Gain (Loss) on Securities	Accumulated Other Comprehensive Income (Loss)
Balance at December 31, 2018	\$ (25)	\$ (1,397)	\$ (1,422)
Other comprehensive income (loss) before reclassifications	120	2,051	2,171
Amounts reclassified from accumulated other comprehensive loss	—	125	125
Net current period change in accumulated other comprehensive loss, before tax	120	2,176	2,296
Income tax expense related to items of other comprehensive income	—	(520)	(520)
Balance at March 31, 2019	<u>\$ 95</u>	<u>\$ 259</u>	<u>\$ 354</u>

The amounts recognized in AOCI for the three months ended March 31, 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	20	(1,630)	(1,610)
Amounts reclassified from accumulated other comprehensive loss	—	24	24
Net current period change in accumulated other comprehensive loss	20	(1,606)	(1,586)
Balance at March 31, 2018	<u>\$ (41)</u>	<u>\$ (2,295)</u>	<u>\$ (2,336)</u>

Amounts reclassified from AOCI for the three months ended March 31, 2019 and 2018 were as follows:

Details about AOCI Components (In thousands)	Affected Line Item in the Statements of Operations	Three Months Ended March 31,	
		2019	2018
Change in value of available-for-sale investments			
Sales and maturities of available-for-sale investments	Investment income	\$ 125	\$ 24
Total reclassifications		<u>\$ 125</u>	<u>\$ 24</u>

## Property, Plant and Equipment

Property and equipment are stated at cost and depreciated using the straight-line method over the assets' estimated useful lives. Land is stated at cost and does not depreciate. Maintenance and repairs are expensed when incurred; additions and improvements are capitalized. The estimated useful lives of property and equipment are as follows:

(In thousands)	Estimated Useful Life	March 31, 2019	December 31, 2018
Property, plant and equipment			
Land	(1)	\$ 4,466	\$ 4,466
Leasehold and building improvements	(2)	59,759	38,895
Land improvements	15 years	1,766	1,530
Buildings	30 years	7,928	7,928
Computer equipment and computer software	3 years	37,658	36,969
Laboratory equipment	3 - 10 years	45,111	37,518
Furniture and fixtures	3 years	8,481	8,353
Assets under construction	(3)	190,143	167,462
Property, plant and equipment, at cost		355,312	303,121
Accumulated depreciation		(63,683)	(57,862)
Property, plant and equipment, net		<u>\$ 291,629</u>	<u>\$ 245,259</u>

- (1) Not depreciated.
- (2) Lesser of remaining lease term, building life, or useful life.
- (3) Not depreciated until placed into service.

Depreciation expense for the three months ended March 31, 2019 and 2018 was \$6.3 million and \$4.3 million, respectively.

At March 31, 2019, the Company had \$190.1 million of assets under construction which consisted of \$35.7 million related to laboratory equipment, \$143.5 million related to leasehold and building improvements, and \$10.9 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 \$14.7 million to complete the laboratory equipment, \$105.2 million to complete the building projects, and \$2.8 million to complete the computer equipment and computer software projects. These projects are expected to be completed throughout 2019, 2020 and 2021. The Company assesses its long-lived assets, consisting primarily of property, plant 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 March 31, 2019 and December 31, 2018.

## Software Capitalization Policy

Software development costs related to internal use software are incurred in three stages of development: the preliminary project stage, the application development stage, and the post-implementation stage. Costs incurred during the preliminary project and post-implementation stages are expensed as incurred. Costs incurred during the application development stage that meet the criteria for capitalization are capitalized and amortized, when the software is ready for its intended use, using the straight-line basis over the estimated useful life of the software.

**Patent Costs, Intangible Assets and Goodwill**

Goodwill and Intangible assets consisted of the following:

<b>(In thousands)</b>	<b>March 31, 2019</b>	<b>December 31, 2018</b>
Finite-lived intangible assets		
Finite-lived intangible assets	\$ 33,083	\$ 33,058
Less: Accumulated amortization	(4,917)	(4,107)
Finite-lived intangible assets, net	28,166	28,951
Internally developed technology in process	165	51
Total finite-lived intangible assets, net	28,331	29,002
Goodwill	17,279	17,279
Goodwill and intangible assets, net	<u>\$ 45,610</u>	<u>\$ 46,281</u>

*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 March 31, 2019:

<b>(In thousands)</b>	<b>Net Balance at March 31, 2019</b>	<b>Weighted Average Remaining Life (Years)</b>
Trade name	\$ 677	14.6
Customer relationships	2,611	14.6
Patents	18,413	9.4
Acquired developed technology	5,960	13.6
Internally developed technology	505	2.4
Total	<u>\$ 28,166</u>	

As of March 31, 2019, the estimated future amortization expense associated with the Company's finite-lived intangible assets for each of the five succeeding fiscal years is as follows:

<b>(In thousands)</b>	
2019	\$ 2,401
2020	3,201
2021	3,100
2022	2,956
2023	2,953
Thereafter	13,555
	<u>\$ 28,166</u>

The Company reviews long-lived assets, including property and equipment and 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 March 31, 2019 and December 31, 2018.

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 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, the Company determined that all patent costs incurred during the three months ended March 31, 2019 and 2018 should be expensed and not capitalized as the future economic benefit derived from the transactions cannot be determined.

Under a technology license and royalty agreement entered into with MDx Health (“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 goodwill and intangible 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 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 remaining 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 March 31, 2019, and December 31, 2018, an intangible asset of \$7.4 million and \$7.7 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 net goodwill and intangible assets on the Company’s condensed consolidated financial statements. Amortization expense was \$0.3 million and \$0.3 million for the three months ended March 31, 2019 and 2018, respectively.

In December 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 Company has utilized the Armune assets in its research and development program. 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 satisfaction of these milestones 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.

The Company accounted for the transaction as an asset acquisition under GAAP. The asset is comprised of a portfolio of biomarkers, 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 months ended March 31, 2019 and 2018, the Company recorded amortization expense of \$0.2 million and \$0.2 million, respectively. At March 31, 2019 and December 31, 2018, the net balance of \$11.1 million and \$11.3 million, respectively, is reported in net goodwill and intangible assets in the Company's condensed consolidated balance sheet.

In 2017, the Company acquired all of the equity interests of Sampleminded, Inc. ("Sampleminded"). As a result of the acquisition, 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 March 31, 2019 and 2018, the Company recorded amortization expense of \$36,000 and \$36,000, respectively. At March 31, 2019 and December 31, 2018 the net balance of \$0.7 million and \$0.8 million, respectively, is reported in net intangible assets in the Company's condensed consolidated balance sheets.

As more fully described in the 2018 Form 10-K, during the fourth quarter of 2018, the Company completed a full acquisition of Biomatrix, Inc. ("Biomatrix", and the "Biomatrix Acquisition"). As a result of the Biomatrix Acquisition, the Company recorded an intangible asset of \$8.8 million which was comprised of acquired developed technology of \$5.4 million, customer relationships of \$2.7 million, and trade names of \$0.7 million. The intangible assets acquired are being amortized over the remaining useful life, which was determined to be fifteen years for the acquired developed technology, fifteen years for the customer relationships, and fifteen years for the trade names. For the three months ended March 31, 2019, the Company recorded amortization expense of \$0.1 million. At March 31, 2019 and December 31, 2018, the net balance of \$8.5 million and \$8.7 million, respectively, is reported in net goodwill and intangible assets in the Company's condensed consolidated balance sheets.

#### *Goodwill*

In 2018, the Company recognized goodwill of \$15.3 million from the acquisition of Biomatrix. Goodwill is reported in net goodwill and intangible assets in the Company's condensed consolidated balance sheet. 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 March 31, 2019 and December 31, 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 is the same because all outstanding common stock equivalents have been excluded, as they are anti-dilutive as a result of the Company's losses.

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

<b>(In thousands)</b>	<b>March 31,</b>	
	<b>2019</b>	<b>2018</b>
Shares issuable upon exercise of stock options	2,482	3,284
Shares issuable upon the release of restricted stock awards	4,216	6,315
Shares issuable upon conversion of convertible notes	12,197	9,148
	<u>18,895</u>	<u>18,747</u>

## Revenue Recognition

The Company's revenue is primarily generated by screening 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 Accounting Standards Codification ("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 from its Cologuard test 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 laboratory 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. The Company's 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, the Company elects the practical expedient and therefore, the Company does not disclose the value of unsatisfied performance obligations.

### *Transaction price*

The transaction price is the amount of consideration that 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.

## [Table of Contents](#)

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 patient 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 \$1.5 million and \$8.5 million for the three months ended March 31, 2019 and 2018, respectively.

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.

### *Allocate transaction price*

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

### *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 table presents the Company's revenues disaggregated by revenue source for the three months ended March 31, 2019 and 2018, respectively:

<b>(In thousands)</b>	<b>Three Months Ended March 31,</b>	
	<b>2019</b>	<b>2018</b>
Medicare Parts B & C	\$ 82,917	\$ 52,475
Commercial	73,351	34,834
Other	5,775	2,987
Total	\$ 162,043	\$ 90,296



### *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 \$0.4 million and \$0.5 million as of March 31, 2019 and December 31, 2018, respectively.

Revenue recognized for the three months ended March 31, 2019 and 2018, which was included in the deferred revenue balance at the beginning of each period was \$0.1 million and \$0.1 million, 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.

### **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:

<b>(In thousands)</b>	<b>March 31, 2019</b>	<b>December 31, 2018</b>
Raw materials	\$ 15,266	\$ 12,761
Semi-finished and finished goods	29,003	26,387
Total inventory	\$ 44,269	\$ 39,148

## **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 2018 Form 10-K, in June 2009 the Company entered into a 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, October 2017, and January 2019. 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. The scope of the license, as amended, covers any screening, surveillance or diagnostic test or tool for use in connection with any type of cancer, pre-cancer, disease or condition.

Pursuant to the Company's agreement with Mayo, the Company is required to pay Mayo a low-single-digit royalty on the Company's net sales of products using the licensed Mayo intellectual property, with minimum annual royalty fees of \$25,000 each year through 2033, the year the last patent expires. The January 2016 amendment to the Mayo license agreement established various low-single-digit royalty rates on net sales of current and future products and clarified how net sales will be calculated. As part of the October 2017 amendment, the royalty rate on the Company's net sales of Cologuard increased and, if in the future, improvements are made to the Cologuard product, the royalty rate may further increase, but pursuant to the terms of the January 2016 and October 2017 amendment, the rate remains 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, 2018, and 2019. 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 months ended March 31, 2019 and 2018 the Company has recorded \$0.3 million and \$0.3 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 \$1.1 million for the three months ended March 31, 2019. The Company made payments of \$1.8 million for the three months ended March 31, 2019. The Company recorded an estimated liability of \$1.2 million for research and development efforts as of March 31, 2019. The Company incurred charges of \$1.3 million for the three months ended March 31, 2018. The Company made payments of \$1.8 million for the three months ended March 31, 2018. The Company recorded an estimated liability of \$1.3 million for research and development efforts as of March 31, 2018.

#### **(4) PFIZER PROMOTION AGREEMENT**

In August 2018, the Company entered into a Promotion Agreement (“Promotion Agreement”) with Pfizer Inc. (“Pfizer”). Under the terms of the Promotion Agreement, Pfizer will promote Cologuard and provide certain sales, marketing, analytical and other commercial operations support services. The Company and Pfizer committed in the Promotion Agreement to invest specified amounts in the advertising and promotion of Cologuard.

The Company agreed to pay Pfizer for promotion, sales and marketing costs incurred on behalf of the Company. The Company incurred charges of \$17.6 million for promotion, sales and marketing services performed by Pfizer on behalf of the Company during the three months ended March 31, 2019. The Company recorded a liability of \$17.6 million and \$0.5 million for promotion, sales and marketing services performed by Pfizer on behalf of the Company in accrued liabilities in the Company’s condensed consolidated balance sheets as of March 31, 2019 and December 31, 2018, respectively. These costs are recorded in sales and marketing in the Company’s condensed consolidated statements of operations.

The Company also agreed to pay Pfizer a service fee based on incremental gross profits over specified baselines during the term and royalties for Cologuard related revenues for a specified period after the expiration or termination of the Promotion Agreement. The initial term of the Promotion Agreement runs through December 31, 2021. The Company incurred charges of \$19.2 million for this service fee during the three months ended March 31, 2019. The Company recorded a liability of \$24.0 million and \$4.8 million for the service fee earned by Pfizer as of March 31, 2019 and December 31, 2018, respectively, in accrued liabilities in the Company’s condensed consolidated balance sheets. These costs are recorded in sales and marketing in the Company’s condensed consolidated statements of operations.

#### **(5) 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 (“RSUs”), 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 \$16.2 million in stock-based compensation expense during the three months ended March 31, 2019. The Company recorded \$12.5 million in stock-based compensation expense during the three months ended March 31, 2018.

In connection with the April 2018 transition of the Company’s former 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 vested on December 31, 2018. It was determined that the continuing service to be provided by the Company’s Chief Operating Officer to the Company through December 31, 2018 was substantive and, as a result, the Company recognized 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 transition period in 2018, the Company recorded \$3.9 million of non-cash stock-based compensation expense for the modified awards.

In February 2019, the Company issued performance-based equity awards to certain employees which vest upon the achievement of certain performance goals, including financial performance targets and operational milestones. Determining the appropriate amount to expense based on the anticipated achievement of the stated goals requires judgment, including forecasting future financial results. The estimate of the timing of the expense recognition is revised periodically based on the probability of achieving the goals and adjustments are made as appropriate. The cumulative impact of any revision is reflected in the period of the change. If the financial performance targets or operational milestones are not achieved, the award does not vest, so no compensation cost is recognized and any previously recognized stock-based compensation expense is reversed.

**Determining Fair Value**

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

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

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

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

**Forfeitures** - The Company records the effects of actual forfeitures at the time they occur.

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

	Three Months Ended March 31,	
	2019	2018
<b>Option Plan Shares</b>		
Risk-free interest rates	2.54%	2.79%
Expected term (in years)	6.28	6.44
Expected volatility	64.95%	61.82%
Dividend yield	0 %	0 %
Weighted average fair value per share of options granted during the period	\$ 57.11	\$ 26.84

**Stock Option, Restricted Stock, and Restricted Stock Unit Activity**

A summary of stock option activity under the Stock Plans during the three months ended March 31, 2019 is as follows:

Options	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value(1)
<i>(Aggregate intrinsic value in thousands)</i>				
Outstanding, January 1, 2019	2,531,561	\$ 17.86	6.3	
Granted	186,044	92.61		
Exercised	(235,278)	15.51		
Forfeited	(184)	44.37		
Outstanding, March 31, 2019	<u>2,482,143</u>	<u>\$ 23.68</u>	<u>6.9</u>	<u>\$ 157,328</u>
Exercisable, March 31, 2019	<u>1,509,808</u>	<u>\$ 14.49</u>	<u>5.9</u>	<u>\$ 108,900</u>

(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 \$86.62 market price of the Company’s common stock at March 29, 2019. The total intrinsic value of options exercised during the three months ended March 31, 2019 and 2018 was \$16.1 million and \$19.1 million, respectively.

As of March 31, 2019, there was \$209.2 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 3.2 years.

A summary of restricted stock and restricted stock unit activity under the Stock Plans during the three months ended March 31, 2019 is as follows:

	Restricted Shares and RSUs	Weighted Average Grant Date Fair Value
Outstanding, January 1, 2019	6,246,174	\$ 23.16
Granted	1,431,635	91.09
Released	(3,401,278)	10.77
Forfeited	(60,163)	50.16
Outstanding, March 31, 2019	4,216,368	\$ 56.17

#### (6) FAIR VALUE MEASUREMENTS

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

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

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

Fixed-income securities 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 pricing change from period to period. The estimated fair value of the Company’s long-term debt represents a Level 2 measurement. When determining the estimated fair value of the Company’s long-term debt, the Company used market-based risk measurements, such as credit risk. See Note 8 for further detail on the Company’s long-term debt. The fair value of contingent consideration related to the Biomatrix Acquisition was categorized as a Level 3 liability, as the measurement amount is based primarily on significant inputs not observable in the market. The Company assesses the fair value of expected contingent consideration and the corresponding liability each annual reporting period using the Monte Carlo Method, which is consistent with the initial measurement of the expected Biomatrix Acquisition earn-out liability. This fair value measurement is considered a Level 3 measurement because the Company estimates projections during the earn-out period utilizing various potential pay-out scenarios. Probabilities were applied to each potential scenario and the resulting values were discounted using a rate that considers weighted average cost of capital as well as a specific risk

[Table of Contents](#)

premium associated with the riskiness of the earn out itself, the related projections, and the overall business. The contingent earn-out liability is classified as a component of other long-term liabilities in the Company's condensed consolidated balance sheet. There were no changes in the fair value assessed between the acquisition date and March 31, 2019.

The following table presents the Company's fair value measurements as of March 31, 2019 along with the level within the fair value hierarchy in which the fair value measurements in their entirety fall.

(In thousands)	Fair Value at March 31, 2019	Fair Value Measurement at March 31, 2019 Using:		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>Cash and cash equivalents</b>				
Cash and money market	\$ 104,890	\$ 104,890	\$ —	\$ —
U.S. government agency securities	180,310	—	180,310	—
Commercial paper	—	—	—	—
<b>Available-for-sale</b>				
<b>Marketable securities</b>				
Corporate bonds	445,669	—	445,669	—
Asset backed securities	308,967	—	308,967	—
U.S. government agency securities	199,052	—	199,052	—
Certificates of deposit	37,819	—	37,819	—
Commercial paper	5,999	—	5,999	—
Contingent consideration	(3,060)	—	—	(3,060)
<b>Total</b>	<b>\$ 1,279,646</b>	<b>\$ 104,890</b>	<b>\$ 1,177,816</b>	<b>\$ (3,060)</b>

The following table presents the Company's fair value measurements as of December 31, 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 December 31, 2018	Fair Value Measurement at December 31, 2018 Using:		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>Cash and cash equivalents</b>				
Cash and money market	\$ 86,375	\$ 86,375	\$ —	\$ —
U.S. government agency securities	49,985	—	49,985	—
Commercial paper	24,070	—	24,070	—
<b>Available-for-sale</b>				
<b>Marketable securities</b>				
Corporate bonds	392,287	—	392,287	—
Asset backed securities	276,999	—	276,999	—
U.S. government agency securities	250,471	—	250,471	—
Certificates of deposit	31,844	—	31,844	—
Commercial paper	12,151	—	12,151	—
Contingent consideration	(3,060)	—	—	(3,060)
<b>Total</b>	<b>\$ 1,121,122</b>	<b>\$ 86,375</b>	<b>\$ 1,037,807</b>	<b>\$ (3,060)</b>

The Company monitors investments for other-than-temporary impairment. It was determined that unrealized gains and losses as of March 31, 2019 and December 31, 2018 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.

[Table of Contents](#)

The following table summarizes the gross unrealized losses and fair values of investments in an unrealized loss position as of March 31, 2019, aggregated by investment category and length of time that individual securities have been in a continuous unrealized loss position:

(In thousands)	March 31, 2019					
	Less than 12 months		12 months or greater		Total	
	Fair Value	Gross Unrealized Loss	Fair Value	Gross Unrealized Loss	Fair Value	Gross Unrealized Loss
Marketable securities						
Corporate bonds	\$ 93,381	\$ (41)	\$ 48,405	\$ (42)	\$ 141,786	\$ (83)
U.S. government agency securities	133,361	(25)	19,979	(7)	153,340	(32)
Asset backed securities	15,381	(8)	80,638	(114)	96,019	(122)
Certificates of deposit	499	—	1,993	(1)	2,492	(1)
Commercial paper	5,999	(1)	—	—	5,999	(1)
Total	\$ 248,621	\$ (75)	\$ 151,015	\$ (164)	\$ 399,636	\$ (239)

The following table summarizes contractual underlying maturities of the Company's available-for-sale investments at March 31, 2019:

(In thousands)	Due after one year through four years			
	Due one year or less		Due after one year through four years	
	Cost	Fair Value	Cost	Fair Value
Marketable securities				
Corporate bonds	\$ 240,925	240,927	204,311	204,742
U.S. government agency securities	178,982	179,078	19,961	19,974
Asset backed securities	82,085	82,082	226,679	226,885
Certificates of deposit	22,072	22,076	15,712	15,743
Commercial paper	6,000	5,999	—	—
Total	\$ 530,064	\$ 530,162	\$ 466,663	\$ 467,344

**(7) NEW MARKET TAX CREDIT**

As more fully described in the 2018 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 Company's 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 as a decrease of expenses for the three months ended March 31, 2019. At March 31, 2019, the remaining balance of \$0.9 million is included in other long-term liabilities in the Company's condensed consolidated balance sheets. The Company recorded \$0.1 million as a decrease of expenses for the three months ended March 31, 2018. At March 31, 2018, the remaining balance of \$1.3 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.

## **(8) LONG-TERM DEBT**

### **Building Purchase Mortgage**

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

In September 2018, the Company entered into a Purchase and Sale Agreement with a third-party to sell its research and development facility. The Company also simultaneously entered into a Master Lease Agreement with the third-party to lease the facility back. The sale-leaseback arrangement is recorded under the financing method of accounting as the Company has continuing involvement in planned expansions of the facility and construction of the adjacent corporate headquarters facility. Under the financing method, the Company does not recognize the proceeds received from the third party as a sale of the facility. The facility remains in property, plant and equipment on the Company's condensed consolidated balance sheet, and the consideration of \$6.8 million received in the sale is recorded as a financing obligation in other long-term liabilities on the Company's condensed consolidated balance sheet as of March 31, 2019. A portion of the proceeds received from the sale were used to repay the mortgage on the facility, and as of September 2018, the \$4.5 million outstanding balance of the mortgage had been fully repaid in connection with the termination of the credit agreement. The remaining proceeds were utilized to fund the initial construction of the Company's corporate headquarters discussed in more detail in Note 9.

Prior to the repayment in September 2018, borrowings under the credit agreement bore interest at 4.15 percent. The Company made interest-only payments on the outstanding principal balance for the period between July 12, 2015 and September 12, 2015. The credit agreement required the Company to make, beginning on October 12, 2015 and continuing through May 12, 2019, monthly principal and interest payments of \$31,000, and a final principal and interest payment of \$4.4 million would have been due on the maturity date of June 12, 2019.

Additionally, the Company previously recorded \$0.1 million in deferred financing costs, which were recorded as a direct deduction from the mortgage liability. The issuance costs were being amortized through June 12, 2019. The Company recorded \$4,000 in amortization of mortgage issuance costs for the three months ended March 31, 2018. As a result of the sale of the research and development facility, the outstanding balance of the mortgage issuance costs was written down to \$0 during the third quarter of 2018. As such there is no outstanding balance as of March 31, 2019.

### **Revolving Loan Agreement**

During December 2017, the Company entered into a revolving loan agreement (the "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 "Revolver"). The Revolver is collateralized by the Company's accounts receivable and inventory. The Revolver is available for general working capital purposes and all other lawful corporate purposes, provided that the Company may not use the Revolver 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 Revolving Loan Agreement may be prepaid at any time without penalty. The Revolver's maturity date is December 10, 2019.

The Company has agreed in the Revolving Loan Agreement to various financial covenants including minimum liquidity and minimum tangible net worth. As of March 31, 2019, the Company is in compliance with all covenants.

As of March 31, 2019, the Company has not drawn funds from, nor are any amounts outstanding under, the Revolving Loan Agreement.



## Construction Loan Agreement

During December 2017, the Company entered into a loan agreement with MB Bank (the “Construction Loan Agreement”), which provides the Company with a non-revolving construction loan (the “Construction Loan”) of \$25.6 million. The Company will use the Construction Loan proceeds to finance the construction of an additional clinical laboratory and related facilities in Madison, Wisconsin. The 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 the Construction Loan Agreement may be prepaid at any time without penalty. The maturity date of the Construction Loan Agreement is December 10, 2022.

In November 2017, MB Bank, on behalf of the Company, issued an Irrevocable Standby Letter of Credit in the amount of \$0.6 million in favor of the City of Madison, Wisconsin (the “City Letter of Credit”). The City Letter of Credit is deemed to have been issued pursuant to the Construction Loan Agreement. 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 Construction Loan Agreement, the Company was 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 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 towards the outstanding principal balance due plus accrued interest. As of March 31, 2019, the Company has drawn \$25.0 million from the Construction Loan, including \$0.7 million of interest incurred, which is accrued for as an interest reserve and represents a portion of the \$25.0 million loan balance as of March 31, 2019. The Company capitalized the \$0.7 million to the construction project. As of December 31, 2018, the Company had drawn \$24.7 million from the Construction Loan.

Additionally, the Company has recorded deferred financing costs of \$0.2 million related to the Construction Loan. 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 in amortization of deferred financing costs related to the Construction Loan for the three months ended March 31, 2019. There was no amortization expense recorded for the three months ended March 31, 2018.

The Company has agreed in the Construction Loan Agreement to various financial covenants including minimum liquidity and minimum tangible net worth. As of March 31, 2019, the Company is in compliance with all covenants.

## (9) COMMITMENTS AND CONTINGENCIES

The Company acts as lessee under all its lease agreements, which includes operating leases for corporate offices, lab space, warehouse space, vehicles and certain lab and office equipment. As of March 31, 2019, the Company is not party to any finance leases. The leases have remaining lease terms of 1 year to 6 years, some of which include options to extend the lease for up to 10 years, and some of which include options to terminate the lease within 1 year. The Company includes any renewal or termination option in its lease payment calculations if it is reasonably certain to exercise the option. Reasonably certain is assessed internally based on economic, industry, company, strategic and contractual factors. The components of lease expense for the three months ended March 31, 2019 were as follows:

<b>(In thousands)</b>	
Operating lease cost (cost resulting from lease payments)	\$ 1,086
Short-term lease cost	60
Variable lease cost (cost excluded from lease payments)	1
	<u>\$ 1,147</u>

Certain vehicle leases include variable lease payments that depend on an index or rate. Those lease payments are initially measured using the index or rate at the lease commencement date.

The Company calculates its incremental borrowing rates for specific lease terms, used to discount future lease payments, as a function of the U.S. Treasury rate and an indicative Moody's rating for operating leases. The Company's weighted average discount rate and weighted average lease term remaining on lease liabilities is approximately 7.82% and 6.36 years, respectively. The Company had operating cash flows from operating leases of \$1.1 million related to leases for the three months ended March 31, 2019.

As of March 31, 2019, the Company's right-of-use assets are \$21.8 million, which are reported in other long-term assets in the Company's condensed consolidated balance sheets. As of March 31, 2019, the Company has outstanding lease obligations of \$20.0 million, of which \$3.0 million is reported in other short-term liabilities and \$17.0 million is reported in long-term obligations in the Company's condensed consolidated balance sheets.

The Company has taken advantage of certain practical expedients offered to registrants at adoption of ASC 842. The Company does not apply the recognition requirements of ASC 842 to short-term leases and sub leases. Instead, those lease payments are recognized in profit or loss on a straight-line basis over the lease term. Further, as a practical expedient, all lease contracts are accounted for as one single lease component, as opposed to separating lease and non-lease components to allocate the consideration within a single lease contract.

Maturities of operating lease liabilities as of March 31, 2019 were as follows:

<b>(In thousands)</b>	
2019	\$ 4,445
2020	3,989
2021	3,813
2022	3,669
2023	3,679
Thereafter	7,051
Total minimum lease payments	26,646
Imputed interest	(6,618)
Total	<u>\$ 20,028</u>

The Company evaluates whether it is the accounting owner of leased assets during the construction period when it is involved in the construction of the leased asset. Due to the funding provided by the Company for costs related to the construction of its new headquarters, as of December 31, 2018, the Company was considered, for accounting purposes only, the owner of the construction project in accordance with build-to-suit accounting under the accounting guidance that was superseded by ASC 842 on January 1, 2019. As of December 31, 2018, the Company had contributed \$2.7 million towards the project. All project construction costs paid by the landlord were accounted for as assets under construction. As of December 31, 2018, the landlord funded \$3.9 million towards construction costs related to this project, of which \$2.1 million was included as a financing obligation and recorded in other long-term liabilities and \$1.8 million was included as a financing obligation and recorded in accrued expenses in the Company's condensed consolidated balance sheets. Upon transition to ASC 842 on January 1, 2019, the Company is no longer considered to be the owner of the construction project under build-to-suit accounting. As such, the amounts funded by the landlord, previously recognized as an asset under construction and corresponding financing obligation, have been de-recognized.

The Company's new headquarters building is expected to be completed in 2020. Upon completion, the Company will lease the building for an initial term of 15 years with an option to extend for an additional 10 years. Construction of the facility is the responsibility of the landlord; however, the Company has funded \$4.0 million towards construction costs as of March 31, 2019. This contribution is accounted for as prepaid rent and will be included in the beginning right-of-use asset balance of the leased facility. The Company anticipates an additional \$32.2 million to be recognized at lease commencement for the right-of-use asset and lease liability, respectively.

#### **(10) 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 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 March 31, 2019, the Company has earned \$9.0 million of tax credits and has received payment of \$4.3 million from the WEDC. The unpaid portion is \$4.7 million, of which \$1.6 million is reported in prepaid expenses and other current assets and \$3.1 million is reported in other long-term assets, reflecting when collection of the refundable tax credits is expected to occur. As of March 31, 2019, the Company also has recorded a \$2.4 million liability in other short-term liabilities and a \$1.6 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 months ended March 31, 2019, the Company amortized \$0.6 million of the tax credits earned as a reduction of operating expenses. During the three months ended March 31, 2018, the Company amortized \$0.4 million of the tax credits earned as a reduction of operating expenses.

## **(11) CONVERTIBLE NOTES**

### **Issuances and Settlements**

In January 2018, the Company issued and sold \$690.0 million in aggregate principal amount of 1.0% Convertible Notes (the "January 2018 Notes") with a maturity date of January 15, 2025 (the "Maturity Date"). The January 2018 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 January 2018 Notes were approximately \$671.1 million, after deducting underwriting discounts and commissions and the offering expenses payable by the Company.

In June 2018, the Company issued and sold an additional \$218.5 million in aggregate principal amount of 1.0% Convertible Notes (the "June 2018 Notes"). The June 2018 Notes were issued under the same indenture pursuant to which the Company previously issued the January 2018 Notes (the "Indenture"). The January 2018 Notes and the June 2018 Notes (collectively, the "2025 Notes") have identical terms and will be treated as a single series of securities. The net proceeds from the issuance of the June 2018 Notes were approximately \$225.3 million, after deducting underwriting discounts and commissions and the offering expenses payable by the Company.

In March 2019, the Company issued and sold \$747.5 million in aggregate principal amount of 0.375% Convertible Notes (the "2027 Notes" and, collectively with the 2025 Notes, the "Notes") with a maturity date of March 15, 2027 (the "Maturity Date"). The 2027 Notes accrue interest at a fixed rate of 0.375% per year, payable semi-annually in arrears on March 15 and September 15 of each year, beginning on September 15, 2019. The net proceeds from the issuance of the 2027 Notes were approximately \$729.5 million, after deducting underwriting discounts and commissions and the offering expenses payable by the Company.

The Company utilized a portion of the proceeds from the issuance of the 2027 Notes to settle a portion of the 2025 Notes in privately negotiated transactions. In March 2019, the Company used cash of \$494.0 million and an aggregate of 2.2 million shares of the Company's common stock valued at \$182.4 million for total consideration of \$676.5 million to settle \$493.4 million of the 2025 Notes, of which \$375.1 million was allocated to the liability component, \$300.8 million was allocated to the equity component, and \$0.6 million was used to pay off interest accrued on the 2025 Notes. The

consideration transferred was allocated to the liability and equity components of the 2025 Notes using the equivalent rate that reflected the borrowing rate for a similar non-convertible debt instrument immediately prior to settlement. The transaction resulted in a loss on settlement of convertible notes of \$10.6 million, which is recorded in interest income (expense) in the Company's condensed consolidated statement of operations. The loss represents the difference between (i) the fair value of the liability component and (ii) the sum of the carrying value of the debt component and any unamortized debt issuance costs at the time of repurchase.

### **Summary of Conversion Features**

Until the six-months immediately preceding the maturity date of the applicable series of Notes, each series of Notes is convertible only upon the occurrence of certain events and during certain periods, as set forth in the Indenture. 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 the date that is six-months immediately preceding the maturity date of the applicable series of Notes until the close of business on the second scheduled trading day immediately preceding the maturity date, holders may convert such Notes at any time.

It is the Company's intent and policy to settle all conversions through combination settlement. The initial conversion rate is 13.2569 and 8.9554 shares of common stock per \$1,000 principal amount for the 2025 Notes and 2027 Notes, respectively, which is equivalent to an initial conversion price of approximately \$75.43 and \$111.66 per share of the Company's common stock for the 2025 Notes and 2027 Notes, respectively. 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.

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.

### **Ranking of Convertible Notes**

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 March 31, 2019 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 2025 Notes and the 2027 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. On the January 2018 Notes, 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 January 2018 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 January 2018 Notes, which is amortized over the seven-year term of the January 2018 Notes using the effective interest rate method. On the

June 2018 Notes, 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 June 2018 Notes and adding in the premium at which the June 2018 Notes were sold. This is recorded in additional paid-in capital on the Company's 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 June 2018 Notes, which is amortized over the remaining term of six-and-a-half years of the June 2018 Notes using the effective interest rate method. On the 2027 Notes, the initial carrying value of the liability component of \$472.5 million was calculated using a 6.3% assumed borrowing rate. The equity component of \$275.0 million, representing the conversion option, was determined by deducting the fair value of the liability component from the par value of the 2027 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 2027 Notes, which is amortized over the eight-year term of the 2027 Notes using the effective interest rate method. The equity component of each series of convertible notes 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 January 2018 Notes to the liability and equity components of the January 2018 Notes based on their relative values, with \$13.6 million being allocated to the liability component of the January 2018 Notes. Transaction costs attributable to the liability component are amortized to interest expense over the seven-year term of the January 2018 Notes, and transaction costs attributable to the equity component are netted with the equity component in stockholders' equity.

The Company allocated the total transaction costs of approximately \$7.4 million related to the issuance of the June 2018 Notes to the liability and equity components of the June 2018 Notes based on their relative values, with \$5.1 million being allocated to the liability component of the June 2018 Notes. Transaction costs attributable to the liability component are amortized to interest expense over the remaining six-and-a-half-year term of the June 2018 Notes, and transaction costs attributable to the equity component are netted with the equity component in stockholders' equity.

The Company allocated the total transaction costs of approximately \$18.0 million related to the issuance of the 2027 Notes to the liability and equity components of the 2027 Notes based on their relative values, with \$11.4 million being allocated to the liability component of the 2027 Notes. Transaction costs attributable to the liability component are amortized to interest expense over the eight-year term of the 2027 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.

Convertible notes, net of discounts and deferred financing costs at March 31, 2019, consisted of the following:

<b>(In thousands)</b>	<b>2025 Notes</b>	<b>2027 Notes</b>
Principal	\$ 415,104	\$ 747,500
Debt discount, net	(100,304)	(273,375)
Deferred financing costs	(7,147)	(11,268)
Net carrying amount	<u>\$ 307,653</u>	<u>\$ 462,857</u>

## **(12) INCOME TAXES**

The Company recorded an income tax benefit of \$0.5 million for the three months ended March 31, 2019 and income tax expense of \$0.1 million for the three months ended March 31, 2018 in continuing operations. The Company's income tax benefit recorded during the three months ended March 31, 2019, is primarily related to the intraperiod tax allocation rules that require the Company to allocate the provision for income taxes between continuing operations and other categories of earnings. The Company continues to maintain a full valuation allowance against its deferred tax assets based on management's determination that it is more likely than not the benefit will not be realized.

### **(13) 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. The Company did not incur charges or make any payments during the three months ended March 31, 2019. The Company incurred charges of \$0.1 million for the three months ended March 31, 2018. The Company made payments of \$0.1 million for the three months ended March 31, 2018.

### **(14) RECENT ACCOUNTING PRONOUNCEMENTS**

In February 2016, the Financial Accounting Standards Board issued ASU No. 2016-02, *Leases (Topic 842)* and subsequent amendments to the initial guidance: ASU 2017-13, ASU 2018-10, ASU 2018-11, ASU 2018-20 and ASU 2019-01, (collectively, "Update 2016-02"). Update 2016-02 requires recognition of right-of-use assets and lease liabilities on the balance sheet, including those leases classified as operating leases under previous GAAP. Update 2016-02 provides an option of recognizing a cumulative-effect adjustment to the opening balance of retained earnings upon adoption. The amendments in this update are effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. The Company adopted Update 2016-02 on January 1, 2019 using the modified retrospective method of adoption. As a result of the adoption, the Company recorded an opening right-of-use asset balance of \$20.6 million, which is included in other long-term assets in the Company's condensed consolidated financial statements. The Company also recorded an opening lease liability of \$20.1 million, of which \$3.0 million was classified in other short-term liabilities and \$17.1 million was classified in long-term obligations in the Company's condensed consolidated financial statements. See Note 9 for more detail.

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. The Company adopted this guidance on January 1, 2019, and it did not have an impact on the Company's condensed consolidated financial statements.

In July 2018, the Financial Accounting Standards Board issued ASU 2018-09, *Codification Improvements*, ("Update 2018-09"). Update 2018-09 provided various minor codification updates and improvements to address comments that the FASB had received regarding unclear or vague accounting guidance. The guidance is effective for fiscal years beginning after December 15, 2018, including interim reporting periods within that fiscal year. The Company adopted this guidance on January 1, 2019, and it did not have an impact on the Company's condensed consolidated financial statements.

In August 2018, the Financial Accounting Standards Board issued ASU 2018-13, *Fair Value Measurement (Topic 820); Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement*, ("Update 2018-13"). Update 2018-13 provided an update to the disclosure requirements for fair value measurements under the scope of ASC 820. The guidance is effective for fiscal years beginning after December 15, 2019. The Company is currently evaluating the impact of the guidance on its condensed consolidated financial statements.

## 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, 2018, which has been filed with the SEC (the "2018 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," "project," "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 our products and services and adequately reimburse us for such products and services; 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 law, rule, order, interpretation or policy relating to the healthcare system, including without limitation as a result of any judicial, executive or legislative action; the effects of changes in 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 ability to effectively utilize strategic partnerships, such as our Promotion Agreement with Pfizer, Inc., and acquisitions; 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 this Quarterly Report on Form 10-Q and the 2018 Form 10-K. 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 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 screening and diagnostics.

### ***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:

- 146,000 new cases of colorectal cancer
- 51,000 deaths from colorectal cancer

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 87 million people between the ages of 50 and 85, who are at average-risk for colorectal cancer in the U.S., 38 percent have not been screened according to current guidelines. Internal studies have shown that approximately 50% of Cologuard users were previously unscreened for colorectal cancer. 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.

Changes in DNA methylation, and the occurrence of mutations, alter gene expression and other mechanisms for cell cycle regulation and differentiation. As a result, the affected cells continue to proliferate, often resulting in malignancies associated with colorectal cancer and pre-cancer. Hemoglobin is the protein complex responsible for transporting oxygen in red blood cells. During the progression of cancer, the probability of bleeding into the colon increases. The presence of hemoglobin, released from red blood cells, can be detected in the stool. Using sDNA Cologuard purifies, amplifies and detects increased levels of methylation, and presence of mutations, in specific genes. By combining these DNA indicators with a test for hemoglobin, Cologuard produces a multi-marker result effective for the detection of colorectal cancer and pre-cancerous adenomas.

In August 2014, the U.S. Food and Drug Administration (“FDA”) granted premarket approval (“PMA”) to Cologuard for use as a colorectal cancer screening test in adults 50 years of age and older who are at a typical average-risk for colorectal cancer. Upon approval, Cologuard became the first and only FDA-approved sDNA non-invasive colorectal cancer screening test. Our original PMA 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%

We believe the competitive advantages of sDNA screening provide a significant market opportunity. There are 87 million people in the U.S. between the ages of 50-85 who are at average risk for colorectal cancer. At a three-year screening interval and an average revenue per test of \$500 this represents a potential \$15 billion market for Cologuard, of which our current share is approximately 4.6 percent.

The Centers for Medicare & Medicaid Services has issued a National Coverage Determination (“NCD”) for Cologuard. Medicare covers approximately half of patients in the current screening population for Cologuard. 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 colorectal cancers or adenomatous polyps, familial adenomatous polyposis or hereditary non-polyposis colorectal cancer).

In addition to Medicare reimbursement, we seek to secure favorable coverage and in-network reimbursement agreements from commercial payers. Most major 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.

#### ***Our Clinical Laboratory and Manufacturing 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 clinical lab operation is housed in a 55,000 square foot facility in Madison, Wisconsin. At our lab, we currently have the capacity to process approximately three million tests per year.

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. After the new clinical laboratory is operational, we expect our total lab capacity at both facilities will be approximately seven million tests per year by the end of 2019.

We currently manufacture our Cologuard test kit in a facility in Madison, Wisconsin. As we expand the commercialization of Cologuard, we believe it will be necessary to expand our manufacturing capacity. Accordingly, we are in the process of building an additional manufacturing facility which we expect to complete in 2019. We are committed to manufacturing and providing medical devices and related products that meet customer expectations and applicable regulatory requirements. We adhere to manufacturing and safety standards required by federal, state, and local laws and regulations and operate our manufacturing facilities under a quality management system. We purchase certain components for our Cologuard test from third-party suppliers and manufacturers.

#### ***How We Recognize Revenue***

We recognize revenue on the delivery of a test result to an ordering healthcare provider for tests performed. The amount recognized is based on our estimate of what we will ultimately collect at the time delivery is complete. The amount of revenue we recognize is based on the established billing rates less contractual and other adjustments, which yields the constrained amount that we expect to ultimately collect. We determine the amount we expect to ultimately collect on a per-payer or per-agreement basis, using historical collections, established reimbursement rates and other adjustments. To the extent we have agreed on a reimbursement amount with a payer, the expected amount is typically lower, 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, because we were unable to reasonably estimate the amount that would ultimately be collected from certain payers. 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, as noted above, we now recognize revenue for all billed claims at the time the test results are delivered to the customer.

Our average reimbursement per test, as further defined below, was approximately \$480 and \$452 through March 31, 2019 and 2018, 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, non-renewal or termination of payer contracts, 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 March 31, 2019 and 2018, respectively, represents the total cash collected through such dates for tests performed during the twelve-month periods ended September 30, 2018 and September 30, 2017, respectively, divided by the number of tests performed during those same periods.

### ***2019 Priorities***

Our top priorities for 2019 are to (1) power our partnership with Pfizer, (2) enhance Cologuard through label expansion and product improvements, and (3) advance liquid biopsy.

#### *Power the Partnership*

In August 2018, we entered into a Promotion Agreement with Pfizer. Under the terms of the Promotion Agreement, Pfizer agreed to promote Cologuard and provide certain other sales and marketing services. We and Pfizer committed in the Promotion Agreement to invest specified amounts in the advertising and promotion of Cologuard. Pfizer has a large primary care sales team that has extensive experience with large health system organizations and enhances our physician and consumer marketing capabilities. A priority for 2019 is executing on the Pfizer partnership in order to grow the Cologuard brand and get more patients screened with Cologuard.

#### *Enhance Cologuard*

In May 2018, the ACS updated its guidelines to recommend colorectal cancer screening begin at age 45, rather than 50, for people at average risk of the disease, due to the rising incidence rate within the 45-49 year-old population. There are nearly 21 million people who are between the ages of 45-49, and we estimate approximately 19 million of them are at average risk for colorectal cancer and would be eligible for screening under the ACS guidelines. We plan to conduct clinical and other necessary work to gain FDA approval to expand Cologuard's indication to people between the ages of 45 and 49 who are at average risk for colorectal cancer.

In addition, we are seeking opportunities to improve upon Cologuard's performance characteristics. For example, we are evaluating whether new biomarkers would increase specificity while maintaining sensitivity. If we could increase the specificity of Cologuard, we believe that would enhance its adoption as a front-line screening test. We are also evaluating ways that we might make Cologuard even easier for patients to use and opportunities for lowering the cost of providing Cologuard.

The timing of any expansion of Cologuard's indication or of any such enhancements to Cologuard is unknown and would be subject to FDA approval.

#### *Advance Liquid Biopsy*

We also are focusing our research and development efforts on building a pipeline of potential future products and services with a focus on blood-based ("liquid biopsy") tests. We will continue to advance liquid biopsy through biomarker discovery and validation in tissue and blood. We have identified proprietary biomarkers for several cancers, including liver cancer and lung cancer. We have successfully performed validation studies on tissue samples for thirteen cancers and on blood samples for eight cancers.

**Results of Operations**

We have generated significant losses since inception and, as of March 31, 2019, we had an accumulated deficit of approximately \$1.1 billion. We expect to continue to incur losses for the near future, and it is possible we may never achieve profitability.

**Revenue.** Our revenue is primarily generated by performing screening services using our Cologuard test. For the three months ended March 31, 2019 and 2018, we completed approximately 334,000 and 186,000 Cologuard tests, respectively, and generated revenue of \$162.0 million and \$90.3 million, respectively. The increase in revenue was primarily due to an increase in completed Cologuard tests during the current period primarily due to the impact of our larger salesforce, the Pfizer Promotion Agreement, and direct to consumer advertising.

**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 services to process tests and provide results to physicians. We incur expenses for tests in the period in which the activities occur, therefore, gross margin as a percentage of 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 services will continue to fluctuate and be affected by Cologuard test volume, our 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 \$43.3 million for the three months ended March 31, 2019 compared to \$22.9 million for the three months ended March 31, 2018. The increase in cost of sales is primarily due to the increase in completed Cologuard tests. The Company completed approximately 334,000 and 186,000 Cologuard tests for the three months ended March 31, 2019 and 2018, respectively.

<b>(In millions)</b>	<b>Three Months Ended March 31,</b>		
	<b>2019</b>	<b>2018</b>	<b>Change</b>
Production costs	\$ 30.7	\$ 15.5	\$ 15.2
Personnel expenses	7.9	4.3	3.6
Facility and support expenses	3.5	2.3	1.2
Stock-based compensation	1.1	0.7	0.4
Other cost of sales	0.1	0.1	—
Total cost of sales expenses	<u>\$ 43.3</u>	<u>\$ 22.9</u>	<u>\$ 20.4</u>

**Research and development expenses.** Research and development expenses increased to \$32.0 million for the three months ended March 31, 2019 compared to \$14.9 million for the three months ended March 31, 2018. The increase in research and development expenses was primarily due to an increase in direct research and development expenses for our pipeline and improvements to Cologuard as well as personnel costs due to increased headcount.

<b>(In millions)</b>	<b>Three Months Ended March 31,</b>		
	<b>2019</b>	<b>2018</b>	<b>Change</b>
Direct research and development expenses	\$ 18.6	\$ 6.4	\$ 12.2
Personnel expenses	8.1	4.7	3.4
Stock-based compensation	2.7	2.1	0.6
Other research and development	1.7	1.1	0.6
Legal and professional fees	0.9	0.6	0.3
Total research and development expenses	<u>\$ 32.0</u>	<u>\$ 14.9</u>	<u>\$ 17.1</u>

**General and administrative expenses** . General and administrative expenses increased to \$64.0 million for the three months ended March 31, 2019 compared to \$35.6 million for the three months ended March 31, 2018. The increase in general and administrative expenses was primarily a result of increased costs in the areas outlined in the table below to support the overall growth of the Company.

(In millions)	Three Months Ended March 31,		
	2019	2018	Change
Personnel expenses	\$ 30.6	\$ 14.7	\$ 15.9
Facility and support expenses	12.4	7.8	4.6
Stock-based compensation	8.3	7.2	1.1
Professional and legal fees	10.7	4.7	6.0
Other general and administrative	2.0	1.2	0.8
Total general and administrative expenses	<u>\$ 64.0</u>	<u>\$ 35.6</u>	<u>\$ 28.4</u>

**Sales and marketing expenses**. Sales and marketing expenses increased to \$90.9 million for the three months ended March 31, 2019 compared to \$53.4 million for the three months ended March 31, 2018. 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 for our Cologuard test, and expenses incurred related to our Promotion Agreement with Pfizer as further described in Note 4 of our condensed consolidated financial statements included in this Quarterly Report.

(In millions)	Three Months Ended March 31,		
	2019	2018	Change
Direct marketing costs and professional fees	\$ 47.9	\$ 26.4	\$ 21.5
Personnel expenses	35.4	24.0	11.4
Stock-based compensation	4.1	2.5	1.6
Other sales and marketing	3.5	0.5	3.0
Total sales and marketing expenses	<u>\$ 90.9</u>	<u>\$ 53.4</u>	<u>\$ 37.5</u>

**Investment income** . Investment income increased to \$6.7 million for the three months ended March 31, 2019 compared to \$3.7 million for the three months ended March 31, 2018. 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 due to an increase in market interest rates for the three months ended March 31, 2019 when compared to the same period in 2018.

**Interest expense**. Net interest expense increased to \$22.0 million for the three months ended March 31, 2019 compared to \$6.5 million for the three months ended March 31, 2018. Interest expense recorded from our outstanding convertible notes totaled \$11.2 million and \$6.5 million during the three months ended March 31, 2019 and 2018, respectively. In addition to the \$11.2 million in interest expense recorded on outstanding convertible notes, an additional \$10.6 million was recorded as a result of the settlement of convertible notes, as further described in Note 11 of our condensed consolidated financial statements included in this Quarterly Report. \$9.1 million and \$5.1 million of interest expense relates to amortization of debt discount and debt issuance costs for the three months ended March 31, 2019 and 2018, respectively. The remaining \$2.1 million of interest expense for the three months ended March 31, 2019 relates to the stated interest that was paid in cash during the year.

#### **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 March 31, 2019, we had approximately \$285.2 million in unrestricted cash and cash equivalents and approximately \$1.0 billion 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.

## [Table of Contents](#)

Net cash used in operating activities was \$74.4 million for the three months ended March 31, 2019 compared to \$38.5 million for the three months ended March 31, 2018. The principal use of cash in operating activities for the three months ended March 31, 2019 and 2018 was to fund our net loss.

Net cash used in investing activities was \$41.1 million for the three months ended March 31, 2019 compared to \$562.7 million for the three months ended March 31, 2018. The decrease in cash used in investing activities for the three months ended March 31, 2019 compared to the same period in 2018 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 \$10.8 million for the three months ended March 31, 2019. Cash use consisted primarily of purchases of property and equipment of \$10.7 million and \$15.3 million for the three months ended March 31, 2019 and 2018, respectively. There were also minimal purchases of intangible assets during the three months ended March 31, 2019 and 2018. The decrease in purchases of property and equipment during the three months ended March 31, 2019 was primarily the result of timing of payments, as there was approximately \$42.1 million in purchases of property and equipment during the three months ended March 31, 2019 that was not yet paid for including 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 \$240.1 million for the three months ended March 31, 2019 compared to \$672.4 million for the three months ended March 31, 2018. During the three months ended March 31, 2019, we received net cash of \$729.5 million from the issuance of Convertible Notes with a maturity date of March 15, 2027 (the “2027 Notes”), and we used \$493.4 million of cash to settle Convertible Notes with an original maturity date of January 15, 2025 (the “2025 Notes”, and, collectively with the 2025 Notes, the “Notes”). The cash provided by financing activities for the three months ended March 31, 2018 was primarily the result of proceeds from our issuance of the 2025 Notes in January 2018. In addition, during the three months ended March 31, 2019 we received proceeds of \$0.3 million from drawing on our construction loan and \$3.7 million from the exercise of stock options.

We expect that cash and cash equivalents and marketable securities on hand at March 31, 2019 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. Additionally, we may enter into transactions to acquire other businesses, products, services, or technologies as part of our strategic plan. If we are unable to obtain sufficient additional funds to enable us to fund our operations through the completion of such plan, our results of operations and financial condition would be materially adversely affected, and we may be required to delay the implementation of our plan and otherwise scale back our operations. Even if we successfully raise additional funds, we cannot assure that our business will ever generate sufficient cash flow from operations to become profitable.

A table reflecting certain of our specified contractual obligations as of December 31, 2018 was provided in the Management’s Discussion and Analysis of Financial Condition and Results of Operation of our 2018 Form 10-K. During the three months ended March 31, 2019, we issued \$747.5 million in aggregate principal amount of 0.375% Convertible Notes that will mature on March 15, 2027. The holders of the Notes may convert prior to September 15, 2026 only under certain circumstances and may convert at any time after September 15, 2026. The Notes accrue interest at a fixed rate of 0.375% per year, payable semi-annually in arrears on March 15 or September 15 of each year, beginning on September 15, 2019. Of the cash received upon issuance of the Notes, approximately \$494.0 million was used to repay a portion of the outstanding principal balance and accrued interest of the 2025 Notes held by certain Noteholders. Upon repayment of such portion of the outstanding principal balance of the 2025 Notes, there was \$415.1 million in aggregate principal balance remaining under the 2025 Notes. See Note 11 of the condensed consolidated financial statements included in this Quarterly Report for further details.

With the exception of this item, there were no material changes outside the ordinary course of our business in the specified contractual obligations during the three months ended March 31, 2019.

### ***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 2018 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***

**Revenue.** Our revenue is primarily generated by performing screening 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 Accounting Standards Codification 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 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 from our Cologuard test 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 our laboratory 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, 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 that 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.

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 \$1.5 million and \$8.5 million for the three months ended March 31, 2019 and 2018, respectively.

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.

*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.

### *Disaggregation of Revenue*

The following table presents our revenues disaggregated by revenue source for the three months ended March 31, 2019 and 2018, respectively:

<b>(In thousands)</b>	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2019</b>	<b>2018</b>
Medicare Parts B & C	\$ 82,917	\$ 52,475
Commercial	73,351	34,834
Other	5,775	2,987
Total	<u>\$ 162,043</u>	<u>\$ 90,296</u>

### *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 reported in other short-term liabilities on our condensed consolidated balance sheets and were \$0.4 million and \$0.5 million as of March 31, 2019 and December 31, 2018, respectively.

Revenue recognized for the three months ended March 31, 2019 and 2018, which was included in the deferred revenue balance at the beginning of each period was \$0.1 million and \$0.1 million, respectively.

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

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.
  - **Forfeitures** - We record the effects of actual forfeitures at the time they occur.

The fair value of service-based awards for each restricted stock award and restricted stock unit is determined on the date of grant using the closing stock price on that day. The fair value of market measure-based share-based compensation plans are calculated using a Monte Carlo simulation pricing model. The fair value of each option award is estimated on the date of grant using the Black Scholes option pricing model based on the assumptions noted above and as further described in Note 5 in the Notes to Consolidated Financial Statements.

**Convertible Notes.** 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 the 2025 Notes of \$690.0 million and \$218.5 million, in aggregate principal amount of 1.0% Convertible Notes with a maturity date of January 15, 2025. In March 2019 we issued the 2027 Notes of \$747.5 million in aggregate principal amount of 0.375% Convertible Notes with a maturity date of March 15, 2027. In March 2019, we settled approximately \$493.4 million in outstanding 2025 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 2025 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 2025 Notes, which is amortized over the remaining six-and-a-half-year term of the Notes using the effective interest rate method. For the March 2019 offering, we allocated \$275.0 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 eight-year term of the 2027 Notes using the effective interest rate method. In addition, debt issuance costs related to the Notes were \$18.8 million and \$7.4 million, and \$18.0 million for the January 2018, June 2018 and March 2019 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.

**Goodwill.** In 2018, we recognized goodwill of \$15.3 million from the acquisition of Biometrica. We evaluate goodwill impairment on an annual basis or more frequently should an event or change in circumstance occur that indicates that the carrying amount is in excess of the fair value. There were no impairment losses for the three months ended March 31, 2019 or 2018. Refer to Note 2 for further discussion of the goodwill recorded.

### **Recent Accounting Pronouncements**

In February 2016, the Financial Accounting Standards Board issued ASU No. 2016-02, *Leases (Topic 842)* and subsequent amendments to the initial guidance: ASU 2017-13, ASU 2018-10, ASU 2018-11, ASU 2018-20 and ASU 2019-01, (collectively, "Update 2016-02"). Update 2016-02 requires recognition of right-of-use assets and lease liabilities on the balance sheet, including those leases classified as operating leases under previous GAAP. Update 2016-02 provides an option of recognizing a cumulative-effect adjustment to the opening balance of retained earnings upon adoption. The amendments in this update are effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. We adopted Update 2016-02 on January 1, 2019 using the modified retrospective method of adoption. As a result of the adoption, we recorded an opening right-of-use asset balance of \$20.6 million, which is included in other long-term assets in our condensed consolidated financial statements. We also recorded an opening lease liability of \$20.1 million, of which \$3.0 million was classified in other short-term liabilities and \$17.1 million was classified in long-term obligations in our condensed consolidated financial statements. See Note 9 for more detail.

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. We adopted this guidance on January 1, 2019, and it did not have an impact on our condensed consolidated financial statements.

In July 2018, the Financial Accounting Standards Board issued ASU 2018-09, *Codification Improvements*, ("Update 2018-09"). Update 2018-09 provided various minor codification updates and improvements to address comments that the FASB had received regarding unclear or vague accounting guidance. We adopted this guidance on January 1, 2019, and it did not have an impact on our condensed consolidated financial statements.

In August 2018, the Financial Accounting Standards Board issued ASU 2018-13, *Fair Value Measurement (Topic 820); Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement*, ("Update 2018-13"). Update 2018-13 provided an update to the disclosure requirements for fair value measurements under the scope of ASC 820. The guidance is effective for fiscal years beginning after December 15, 2019. We are currently evaluating the impact of the guidance on our condensed consolidated financial statements.

### **Off-Balance Sheet Arrangements**

As of March 31, 2019, we had no off-balance sheet arrangements.

### **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 March 31, 2019 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 March 31, 2019, our disclosure controls and procedures were effective. Disclosure controls and procedures enable us to record, process, summarize and report information required to be included in our Exchange Act filings within the required time period. Our disclosure controls and procedures include controls and procedures designed to ensure that information required to be disclosed by us in the periodic reports filed with the SEC is accumulated and communicated to our management, including our principal executive, financial and accounting officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

During the fiscal quarter covered by this report, there have been no significant changes in internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## **Part II - Other Information**

### **Item 1. Legal Proceedings**

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

### **Item 1A. Risk Factors**

We operate in a rapidly changing environment that involves a number of risks that could materially affect our business, financial condition or future results, some of which are beyond our control. In addition to the other information set forth in this report, the risks and uncertainties that we believe are most important for you to consider are discussed in Part I, “Item 1A. Risk Factors” on the 2018 Form 10-K. Other than the factors set forth below, there have been no material changes to the risk factors described in the 2018 Form 10-K.

***Our indebtedness could adversely affect our business, financial condition and results of operations and our ability to meet our payment obligations under such indebtedness.***

As March 31, 2019, we had outstanding \$1.17 billion of convertible notes and a \$25.0 million construction loan. This level of debt could have significant consequences on our future operations, including:

- increasing our vulnerability to adverse economic and industry conditions;
- making it more difficult for us to meet our payment and other obligations;
- making it more difficult to obtain any necessary future financing for working capital, capital expenditures, debt service requirements or other purposes;
- requiring the dedication of a substantial portion of any cash flow from operations to service our indebtedness, thereby reducing the amount of cash flow available for other purposes, including capital expenditures;
- placing us at a possible competitive disadvantage with competitors that are less leveraged than us or have better access to capital than we have; and
- limiting our flexibility in planning for, or reacting to, changes in our business and the markets in which we compete.

Any of the above-listed factors could have an adverse effect on our business, financial condition and results of operations and our ability to meet our payment obligations under the convertible notes.

Our ability to meet our payment and other obligations under the convertible notes depends on our ability to generate significant cash flow in the future. This, to some extent, is subject to general economic, financial, competitive, legislative and regulatory factors as well as other factors that are beyond our control. We cannot assure you that our business will generate cash flow from operations, or that future borrowings will be available to us, in an amount sufficient to enable us to meet our payment obligations under the convertible notes and to fund other liquidity needs. If we are not able to generate sufficient cash flow to service our debt obligations, we may need to refinance or restructure our debt, including the convertible notes, sell assets, reduce or delay capital investments, or seek to raise additional capital. If we are unable to implement one or more of these alternatives, we may not be able to meet our payment obligations under the convertible notes, and such a default could cause us to be in default on any other currently existing or future outstanding indebtedness.

***Servicing our debt will require a significant amount of cash, and we may not have sufficient cash flow from our business to pay amounts due under our indebtedness, including the convertible notes.***

Our ability to make scheduled payments of the principal of, to pay interest on or to refinance our indebtedness, including the \$747.5 million aggregate principal amount of 1.0% convertible senior notes due 2027 and the \$415.1 million aggregate principal amount of 1.0% convertible senior notes due 2025 depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not generate cash flow from operations in the future sufficient to service our debt, including the convertible notes, and make necessary

capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

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

In February 2018, we entered into a services and license agreement with Mayo Foundation for Medical Education and Research (“Mayo”) under which Mayo agreed to provide us certain services and we acquired rights to use certain intellectual property. As part of the agreement, in February 2019 we issued Mayo 5,750 shares of restricted stock.

We believe that the offer and sale of the securities referenced were exempt from registration under the Securities Act of 1933 (the “Securities Act”) by virtue of Section 4(a)(2) of the Securities Act and/or Regulation D promulgated thereunder as transactions not involving any public offering. Use of this exemption is based on the following facts:

- Neither we nor any person acting on our behalf solicited any offer to buy or sell securities by any form of general solicitation or advertising.
- At the time of the purchase, Mayo was an accredited investor, as defined in Rule 501(a) of the Securities Act.
- Mayo has had access to information regarding Exact and is knowledgeable about us and our business affairs.

**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.

<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Filed with This Report</b>	<b>Incorporated by Reference herein from Form or Schedule</b>	<b>Filing Date</b>	<b>SEC File / Registration Number</b>
3.1	<a href="#">Sixth Amended and Restated Certificate of Incorporation of the Registrant</a>		S-1 (Exhibit 3.3)	12/4/00	333-48812
3.2	<a href="#">First Amendment to Sixth Amended and Restated Certificate of Incorporation of the Registrant</a>		DEF 14A (Appendix B)	6/20/14	001-35092
3.3	<a href="#">Third Amended and Restated By-Laws of the Registrant</a>		10-Q (Exhibit 3.3)	10/30/17	001-35092
10.1*	<a href="#">The Registrant's Executive Deferred Compensation Plan, dated January 1, 2019</a>		10-K (Exhibit 10.22)	2/21/19	001-35092
10.2**	<a href="#">Third Amendment dated effective January 1, 2019 to Amended and Restated License Agreement dated effective January 31, 2015 by and among the Registrant, Mayo Foundation for Medical Education and Research and Exact Sciences Development Company, LLC</a>		10-K (Exhibit 10.30)	2/21/19	001-35092
10.3*	<a href="#">The Registrant's Non-Employee Director Compensation Policy, dated January 29, 2019</a>		10-K (Exhibit 10.20)	2/21/19	001-35092
10.4	<a href="#">Second Supplemental Indenture, dated March 8, 2019, between the Registrant and U.S. Bank National Association, as Trustee</a>		8-K (Exhibit 4.2)	3/8/19	001-35092
31.1	<a href="#">Certification Pursuant to Rule 13(a)-14(a) or Rule 15d-14(a) of Securities Exchange Act of 1934</a>	X			
31.2	<a href="#">Certification Pursuant to Rule 13(a)-14(a) or Rule 15d-14(a) of Securities Exchange Act of 1934</a>	X			
32.1	<a href="#">Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</a>	X			
101	Interactive Data Files	X			

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

\*\* Confidential Treatment requested for certain portions of this Agreement.

**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: April 30, 2019

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

Date: April 30, 2019

By: /s/ Jeffrey T. Elliott  
Jeffrey T. Elliott  
Chief Financial Officer  
( *Principal Financial and Accounting Officer* )

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

I, Kevin T. Conroy, certify that:

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

Date: April 30, 2019

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

---



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

I, Jeffrey T. Elliott, certify that:

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

Date: April 30, 2019

By: /s/ Jeffrey T. Elliott  
Jeffrey T. Elliott  
Chief Financial Officer  
(Principal Financial and Accounting Officer)

---

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

In connection with the Quarterly Report of Exact Sciences Corporation (the "Company") on Form 10-Q for the quarter ended March 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), we, Kevin T. Conroy, President and Chief Executive Officer of the Company and Jeffrey T. Elliott, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to our knowledge, that:

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

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

April 30, 2019

/s/ Jeffrey T. Elliott  
Jeffrey T. Elliott  
Chief Financial Officer

April 30, 2019

---