

EXACT SCIENCES CORP  
Form 10-Q  
October 30, 2018  
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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FORM 10-Q

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

For the quarterly period ended September 30, 2018

OR

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

Commission File Number: 001-35092

EXACT SCIENCES CORPORATION

(Exact name of registrant as specified in its charter)

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

441 Charmany Drive, Madison WI 53719  
(Address of principal executive offices) (Zip Code)

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

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

Indicate by check mark whether the registrant has submitted electronically, 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 October 29, 2018, the registrant had 122,900,430 shares of common stock outstanding.



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EXACT SCIENCES CORPORATION

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## Part I — Financial Information

## EXACT SCIENCES CORPORATION

## Condensed Consolidated Balance Sheets

(Amounts in thousands, except share data - unaudited)

	September 30, 2018	December 31, 2017
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 161,705	\$ 77,491
Marketable securities	1,023,512	347,224
Accounts receivable, net	41,916	26,419
Inventory, net	38,617	26,027
Prepaid expenses and other current assets	23,832	10,055
Total current assets	1,289,582	487,216
Long-term Assets:		
Property, plant and equipment, net	188,486	79,986
Intangibles, net	22,493	24,205
Other long-term assets, net	9,015	7,153
Total assets	\$ 1,509,576	\$ 598,560
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts payable	\$ 32,738	\$ 16,135
Accrued liabilities	68,938	49,126
Accrued interest	1,901	—
Debt, current portion	—	182
Other short-term liabilities	3,158	2,681
Total current liabilities	106,735	68,124
Convertible notes, net	656,341	—
Long-term debt, less current portion	17,080	4,269
Other long-term liabilities	12,691	5,749
Total liabilities	792,847	78,142
Commitments and contingencies		
Stockholders' Equity:		
Preferred stock, \$0.01 par value Authorized—5,000,000 shares issued and outstanding—no shares at September 30, 2018 and December 31, 2017	—	—
Common stock, \$0.01 par value Authorized—200,000,000 shares issued and outstanding—122,889,854 and 120,497,426 shares at September 30, 2018 and December 31, 2017	1,229	1,205

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Additional paid-in capital	1,698,695	1,380,577
Accumulated other comprehensive loss	(1,406)	(750)
Accumulated deficit	(981,789)	(860,614)
Total stockholders' equity	716,729	520,418
Total liabilities and stockholders' equity	\$ 1,509,576	\$ 598,560

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

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## EXACT SCIENCES CORPORATION

## Condensed Consolidated Statements of Operations

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
Laboratory service revenue	\$ 118,291	\$ 72,574	\$ 311,481	\$ 178,583
Cost of sales	30,020	20,729	79,822	55,701
Gross margin	88,271	51,845	231,659	122,882
Operating expenses:				
Research and development	17,631	11,725	47,278	29,464
General and administrative	46,729	30,763	121,861	75,442
Sales and marketing	64,836	37,768	172,675	113,297
Total operating expenses	129,196	80,256	341,814	218,203
Loss from operations	(40,925)	(28,411)	(110,155)	(95,321)
Other income (expense)				
Investment income	6,292	1,334	14,882	2,612
Interest expense	(10,704)	(51)	(25,817)	(155)
Total other income (expense)	(4,412)	1,283	(10,935)	2,457
Net loss before tax	(45,337)	(27,128)	(121,090)	(92,864)
Income tax benefit (expense)	(27)	231	(85)	231
Net loss	\$ (45,364)	\$ (26,897)	\$ (121,175)	\$ (92,633)
Net loss per share—basic and diluted	\$ (0.37)	\$ (0.23)	\$ (0.99)	\$ (0.81)
Weighted average common shares outstanding—basic and diluted	122,671	119,215	121,946	114,246

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



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## EXACT SCIENCES CORPORATION

## Condensed Consolidated Statements of Comprehensive Loss

(Amounts in thousands - unaudited)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
Net loss	\$ (45,364)	\$ (26,897)	\$ (121,175)	\$ (92,633)
Other comprehensive loss, net of tax:				
Unrealized gain (loss) on available-for-sale investments	462	49	(668)	7
Foreign currency translation gain	10	16	12	97
Comprehensive loss	\$ (44,892)	\$ (26,832)	\$ (121,831)	\$ (92,529)

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

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## EXACT SCIENCES CORPORATION

## Condensed Consolidated Statements of Cash Flows

(Amounts in thousands, except share data - unaudited)

	Nine Months Ended September 30,	
	2018	2017
Cash flows from operating activities:		
Net loss	\$ (121,175)	\$ (92,633)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization of property and equipment	14,349	10,507
Loss on disposal of property and equipment	853	301
Deferred tax benefit	—	(231)
Stock-based compensation	44,554	23,002
Amortization of debt discount	18,559	—
Amortization of debt issuance costs	1,597	—
Amortization of other liabilities	(1,809)	(1,199)
Amortization of deferred financing costs	86	40
Amortization of premium on short-term investments	(2,581)	56
Amortization of intangible assets	1,847	645
Changes in assets and liabilities, net of effects of acquisition:		
Accrued interest	1,901	—
Accounts receivable, net	(15,497)	(15,663)
Inventory, net	(12,590)	(11,231)
Prepaid expenses and other current assets	(13,777)	(1,391)
Accounts payable	16,603	8,022
Accrued liabilities	(1,600)	9,306
Other short-term liabilities	87	(29)
Lease incentive obligation	504	(462)
Net cash used in operating activities	(68,089)	(70,960)
Cash flows from investing activities:		
Purchases of marketable securities	(1,081,662)	(345,039)
Maturities of marketable securities	407,287	195,485
Purchases of property and equipment	(97,987)	(24,442)
Business acquisition, net of cash acquired	—	(2,996)
Purchases of intangible assets	—	(8,442)
Internally developed software	(135)	(25)
Net cash used in investing activities	(772,497)	(185,459)
Cash flows from financing activities:		
Proceeds from issuance of convertible notes, net	896,431	—
Proceeds from financing obligation	6,750	—
Proceeds from exercise of common stock options	6,376	3,350
Proceeds from sale of common stock, net of issuance costs	—	253,389
Proceeds in connection with the Company's employee stock purchase plan	2,663	1,629

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Payments of deferred financing costs	(25)	—
Proceeds from construction loan	17,271	—
Payments on mortgage payable	(4,678)	(130)
Net cash provided by financing activities	924,788	258,238
Effects of exchange rate changes on cash and cash equivalents	12	97
Net increase in cash and cash equivalents	84,214	1,916
Cash and cash equivalents, beginning of period	77,491	48,921
Cash and cash equivalents, end of period	\$ 161,705	\$ 50,837
Supplemental disclosure of non-cash investing and financing activities:		
Property and equipment acquired but not paid	\$ 25,714	\$ 3,930
Unrealized gain (loss) on available-for-sale investments	\$ (668)	\$ 7
Issuance of 86,882 and 158,717 shares of common stock to fund the Company's 401(k) matching contribution for 2017 and 2016, respectively	\$ 4,303	\$ 3,008
Interest paid	\$ 4,638	\$ 151

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

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EXACT SCIENCES CORPORATION

Notes to Condensed Consolidated Financial Statements

(Unaudited)

(1) ORGANIZATION AND BASIS OF PRESENTATION

Organization

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

Basis of Presentation

The accompanying condensed consolidated financial statements, which include the accounts of Exact Sciences Corporation and those of its wholly owned subsidiaries and variable interest entities, are unaudited and have been prepared on a basis substantially consistent with the Company’s audited financial statements and notes as of and for the year ended December 31, 2017 included in the Company’s Annual Report on Form 10-K (the “2017 Form 10-K”). These condensed consolidated financial statements are prepared in conformity with accounting principles generally accepted in the United States of America (“GAAP”) and follow the requirements of the Securities and Exchange Commission (“SEC”) for interim reporting. In the opinion of management, all adjustments (consisting only of adjustments of a normal and recurring nature) considered necessary for a fair presentation of the results of operations have been included. The results of the Company’s operations for any interim period are not necessarily indicative of the results of the Company’s operations for any other interim period or for a full fiscal year. The statements should be read in conjunction with the audited financial statements and related notes included in the 2017 Form 10-K. Management has evaluated subsequent events for disclosure or recognition in the accompanying financial statements up to the filing of this report.

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation

The accompanying condensed consolidated financial statements include the accounts of the Company's wholly owned subsidiaries and variable interest entities. All significant intercompany transactions and balances have been eliminated in consolidation.

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

#### Use of Estimates

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

#### Cash and Cash Equivalents

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

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Marketable Securities

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

At September 30, 2018 and December 31, 2017, the Company's investments were comprised of fixed income investments, and all were deemed available-for-sale. The objectives of the Company's investment strategy are to provide liquidity and safety of principal while striving to achieve the highest rate of return consistent with these two objectives. The Company's investment policy limits investments to certain types of instruments issued by institutions with investment grade credit ratings and places restrictions on maturities and concentration by type and issuer. Investments in which the Company has the ability and intent, if necessary, to liquidate, in order to support its current operations (including those with a contractual term greater than one year from the date of purchase), are classified as current. All of the Company's investments are considered current. There were no realized losses for the nine months ended September 30, 2018 and 2017. Realized gains were \$0.2 million and \$17,000 for the nine months ended September 30, 2018 and 2017, respectively.

The Company periodically reviews its 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 nine months ended September 30, 2018, no investments were identified with other-than-temporary declines in value.

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

September 30, 2018

Gains in Accumulated Other Comprehensive	Losses in Accumulated Other Comprehensive	Estimated Fair
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(In thousands)	Amortized Cost	Income (Loss)	Income (Loss)	Value
Corporate bonds	\$ 415,828	104	(473)	\$ 415,459
Asset backed securities	288,286	3	(547)	287,742
U.S. government agency securities	265,563	—	(432)	265,131
Commercial paper	12,081	—	(5)	12,076
Certificates of deposit	43,111	15	(22)	43,104
Total available-for-sale securities	\$ 1,024,869	\$ 122	\$ (1,479)	\$ 1,023,512

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

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

## Changes in Accumulated Other Comprehensive Income (Loss)

The amounts recognized in accumulated other comprehensive income (loss) (“AOCI”) for the nine months ended September 30, 2018 were as follows:

(In thousands)	Cumulative Translation Adjustment	Unrealized Gain (Loss) on Securities	Accumulated Other Comprehensive Income (Loss)
Balance at December 31, 2017	\$ (61)	\$ (689)	\$ (750)
Other comprehensive income (loss) before reclassifications	12	(883)	(871)
Amounts reclassified from accumulated other comprehensive loss	—	215	215
Net current period change in accumulated other comprehensive loss	12	(668)	(656)
Balance at September 30, 2018	\$ (49)	\$ (1,357)	\$ (1,406)

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

(In thousands)	Cumulative Translation Adjustment	Unrealized Gain (Loss) on Securities	Accumulated Other Comprehensive Income (Loss)
Balance at December 31, 2016	\$ (204)	\$ (214)	\$ (418)



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Other comprehensive loss before reclassifications	97	(3)	94
Amounts reclassified from accumulated other comprehensive loss	—	10	10
Net current period change in accumulated other comprehensive loss	97	7	104
Balance at September 30, 2017	\$ (107)	\$ (207)	\$ (314)

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

Details about AOCI Components (In thousands)	Affected Line Item in the Statement of Operations	Nine Months Ended	
		September 30, 2018	September 30, 2017
Change in value of available-for-sale investments			
Sales and maturities of available-for-sale investments	Investment income	\$ 215	\$ 10
Total reclassifications		\$ 215	\$ 10

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## Property, Plant and Equipment

Property, plant and equipment are stated at cost and depreciated using the straight-line method over the assets' estimated useful lives. Maintenance and repairs are expensed when incurred; additions and improvements are capitalized. Property and equipment consisted of the following as of September 30, 2018 and December 31, 2017:

(In thousands)	Estimated Useful Life	September 30, 2018	December 31, 2017
Property, plant and equipment			
Land	(1)	\$ 4,466	\$ 4,466
Leasehold and building improvements	(2)	35,264	17,629
Land improvements	15 years	1,530	1,419
Buildings	30 - 40 years	9,886	7,928
Computer equipment and computer software	3 years	35,355	30,148
Laboratory equipment	3 - 5 years	34,720	23,296
Furniture and fixtures	3 years	7,608	4,531
Assets under construction	(3)	110,928	28,655
Property, plant and equipment, at cost		239,757	118,072
Accumulated depreciation		(51,271)	(38,086)
Property, plant and equipment, net		\$ 188,486	\$ 79,986

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

At September 30, 2018, the Company had \$110.9 million of assets under construction which consisted of \$28.1 million related to laboratory equipment, \$79.9 million related to leasehold and building improvements, and \$2.9 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 \$7.0 million to complete the laboratory equipment, \$188.7 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 2018, 2019 and 2020. The Company assesses its long-lived assets, consisting primarily of property and equipment, for impairment when material events and changes in circumstances indicate that the carrying value may not be recoverable. There were no impairment losses for the periods ended September 30, 2018 and December 31, 2017.

## Software Capitalization Policy

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

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

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## Intangible Assets

## Intangible Assets

Intangible assets consisted of the following:

(In thousands)	September 30, 2018	December 31, 2017
Finite-lived intangible assets		
Finite-lived intangible assets	\$ 23,856	\$ 23,731
Less: Accumulated amortization	(3,342)	(1,505)
Finite-lived intangible assets, net	20,514	22,226
Indefinite-lived intangible assets		
Goodwill	1,979	1,979
Net carrying value	\$ 22,493	\$ 24,205

## Finite-Lived Intangible Assets

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

(In thousands)	Net Balance at September 30, 2018	Weighted Average Remaining Life (Years)
Licensed intellectual property and patents	\$ 19,544	9.8
Developed technology	970	6.2
Total	\$ 20,514	

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

(In thousands)	
2018	\$ 618
2019	2,472
2020	2,467
2021	2,391
2022	2,370
Thereafter	10,196
	\$ 20,514

The Company reviews long-lived assets and certain identifiable intangible assets 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 September 30, 2018 and December 31, 2017.

Patent costs, which have historically consisted of related legal fees, are capitalized as incurred, only if the Company determines that there is some probable future economic benefit to be derived from the transaction. A capitalized patent is amortized over its estimated useful life, beginning when such patent is approved. Capitalized patent costs are expensed upon disapproval, upon a decision by the Company to no longer pursue the patent or when the related intellectual property is either sold or deemed to be no longer of value to the Company. Other than the transactions discussed below, the Company determined that all patent costs incurred during the nine months ended September 30, 2018 and 2017

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should be expensed and not capitalized as the future economic benefit to be derived from the transactions cannot be determined.

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

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

As of September 30, 2018, and December 31, 2017, an intangible asset of \$8.0 million and \$9.0 million, respectively, related to historical milestone payments made under the MDx License Agreement and intangible assets acquired as part of the Royalty Buy-Out Agreement and Patent Purchase Agreement is reported in intangible assets in the Company’s condensed consolidated balance sheets. Amortization expense was \$0.3 million and \$0.3 million for the three months ended September 30, 2018 and 2017, respectively. Amortization expense was \$1.0 million and \$0.6 million for the nine months ended September 30, 2018 and 2017, respectively.

On December 15, 2017, the Company entered into an asset purchase agreement (the “Armune Purchase Agreement”) with Armune BioScience, Inc. (“Armune”), pursuant to which the Company acquired intellectual property and certain other assets underlying Armune’s APIFINY®, APIFINY® PRO and APIFINY® ACTIVE SURVEILLANCE prostate cancer diagnostic tests. The 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 ability to meet these events is subject to many risks and is therefore uncertain. The Company will not record the contingent consideration until it is probable that the milestones

will be met. There is no other consideration due to Armune beyond the milestone payments and the Company is not subject to future royalty obligations should a product be developed and commercialized. In connection with the Armune Purchase Agreement, Armune terminated a license agreement pursuant to which it licensed certain patent rights and know-how from the Regents of the University of Michigan (“University of Michigan”), and the Company entered into a license agreement with the University of Michigan with respect to such patent rights and know-how, as well as certain additional intellectual property rights. Pursuant to the Company’s agreement with the University of Michigan, it is required to pay the University of Michigan a low single-digit royalty on its net sales of products using the licensed intellectual property.

The Company accounted for the transaction as an asset acquisition under GAAP. The asset is comprised of a portfolio of biomarkers and related technology and know-how, which is a group of complementary assets concentrated in a single identifiable asset. The transaction costs directly related to the asset acquisition were added to the asset in accordance with GAAP. As such, the collective asset value from the acquisition resulted in an intangible asset of \$12.2 million. The intellectual property asset, which includes related transaction costs, is being amortized on a straight-line

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basis over the period the Company expects to be benefited, which is in line with the legal life of the patents acquired. The Company capitalized these costs as there is a reasonable expectation that the assets acquired will be used in an alternative manner in the future, that is not contingent on future development subsequent to acquisition, and the Company anticipates there to be economic benefit from these alternative uses. For the three and nine months ended September 30, 2018, the Company recorded amortization expense of \$0.2 million and \$0.7 million, respectively. At September 30, 2018 and December 31, 2017, the net balance of \$11.5 million and \$12.2 million, respectively, is reported in net intangible assets in the Company's condensed consolidated balance sheets.

During the third quarter of 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 September 30, 2018 and 2017, the Company recorded amortization expense of \$36,000 and \$20,000, respectively. For the nine months ended September 30, 2018, and 2017 the Company recorded amortization expense of \$0.1 million and \$20,000, respectively. At September 30, 2018 and December 31, 2017 the net balance of \$0.8 million and \$0.9 million, respectively, is reported in net intangible assets in the Company's condensed consolidated balance sheets.

## Goodwill

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

## Investment in Privately-Held Company

On November 30, 2017, the Company made a \$3.0 million cash investment (the "2017 Biomatrix Investment") in Biomatrix, Inc. ("Biomatrix"), then a privately held company specializing in the collection and preservation of biological materials. The Company made the 2017 Biomatrix Investment in connection with entering into an agreement for Biomatrix to supply certain products to the Company. In the 2017 Biomatrix Investment, the Company acquired shares of Biomatrix's Series E Preferred Stock representing 10 percent, of Biomatrix's then-outstanding shares of capital stock on an as-converted basis.

The 2017 Biomatrix Investment did not constitute a variable interest entity, as the Company did not have control over the supplier's business. Additionally, as the ownership percentage was below 20 percent, the equity method was not used to account for the investment. There were no quoted prices or observable pricing inputs available for Biomatrix's stock. Therefore, the Company has accounted for the 2017 Biomatrix Investment at cost, less any impairments, plus or minus changes resulting from observable price changes in orderly transactions for an identical or similar investment. The carrying value of the 2017 Biomatrix Investment was \$3.0 million as of September 30, 2018, and is reported in other long-term assets in the Company's condensed consolidated balance sheets. There were



no adjustments to the carrying value, upward or downward, during the three and nine months ended September 30, 2018.

On October 2, 2018, the Company completed an acquisition of all of Biomatrix's outstanding equity interests for an aggregate purchase price of \$20.0 million net of cash received, debt repaid and certain other adjustments. The transaction is subject to a post-closing working capital adjustment, which the Company will fund with cash on hand (to the extent any additional amounts are payable by the Company) (the "2018 Biomatrix Acquisition"). Contingent consideration for an additional \$20.0 million could be earned based upon certain revenue milestones being met. The purchase price was also reduced by the value attributable to the 2017 Biomatrix Investment discussed above. The purchase price for the 2018 Biomatrix Acquisition will be preliminarily allocated to the underlying assets acquired and liabilities assumed based upon their estimated fair values at the date of acquisition and is subject to change as the Company completes its analysis of their fair values during the measurement period, not to exceed one year as permitted

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under GAAP. Due to the transaction closing subsequent to September 30, 2018, the Company will complete the preliminary purchase price allocation and include the applicable disclosures in its 2018 Annual Report on Form 10-K.

## Net Loss Per Share

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

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

(In thousands)	September 30,	
	2018	2017
Shares issuable upon exercise of stock options	2,856	4,042
Shares issuable upon the release of restricted stock awards	6,280	6,164
Shares issuable upon conversion of convertible notes	12,044	—
	21,180	10,206

## Revenue Recognition

The Company's laboratory service revenues are generated from laboratory 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 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.

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- Once the Company delivers a patient's test result to the ordering physician the contract with a patient has commercial substance, as the Company is legally able to collect payment and bill an insurer and/or patient, depending on payer contract status or patient insurance benefit status.
- The Company's consideration is deemed to be variable, and the Company considers collection of such consideration to be probable to the extent that it is unconstrained.

### Performance obligations

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

### Transaction price

The transaction price is the amount of consideration 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.

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

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

The Company limits the amount of variable consideration included in the transaction price to the unconstrained portion of such consideration. In other words, the Company recognizes revenue up to the amount of variable consideration that is not subject to a significant reversal until additional information is obtained or the uncertainty associated with the additional payments or refunds is subsequently resolved. Differences between original estimates

and subsequent revisions, including final settlements, represent changes in the estimate of variable consideration and are included in the period in which such revisions are made. Revenue recognized from changes in transaction prices was \$2.4 million and \$14.2 million for the three and nine months ended September 30, 2018.

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

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

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basis revenue recognition beginning with the period ended March 31, 2017. Approximately \$1.0 million of this one-time impact relates to tests completed in the prior year and for which the Company's accrual revenue recognition criteria were not met until 2017.

## Allocate transaction price

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

## Point in time recognition

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

## Disaggregation of Revenue

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

	Three Months Ended September 30,	
(In thousands)	2018	2017
Medicare Parts B & C	\$ 65,870	\$ 47,041
Commercial	48,624	22,838
Other	3,797	2,695
Total	\$ 118,291	\$ 72,574

	Nine Months Ended September 30,	
(In thousands)	2018	2017
Medicare Parts B & C	\$ 178,052	\$ 119,746
Commercial	123,045	52,686

Other	10,384	6,151
Total	\$ 311,481	\$ 178,583

#### 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 \$0.5 million and \$0.2 million as of September 30, 2018 and December 31, 2017, respectively.

Revenue recognized for the three months ended September 30, 2018 and 2017, which was included in the deferred revenue balance at the beginning of each period was \$0.1 million and \$38,000, respectively. Revenue recognized for the nine months ended September 30, 2018 and 2017, which was included in the deferred revenue balance at the beginning of each period was \$0.1 million and \$44,000, respectively.

#### Practical expedients

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

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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:

(In thousands)	September 30, 2018	December 31, 2017
Raw materials	\$ 12,214	\$ 10,344
Semi-finished and finished goods	26,403	15,683
Total inventory	\$ 38,617	\$ 26,027

## Foreign Currency Translation



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

#### Reclassifications

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

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(3) MAYO LICENSE AGREEMENT

Overview

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

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

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

As part of the February 2015 amendment and restatement of the license agreement, the Company agreed to pay MAYO an additional \$5.0 million, payable in five annual installments, through 2019. The Company paid MAYO the annual installment of \$1.0 million in the first quarter of each of 2015, 2016 and 2018. The Company paid MAYO the 2017 installment in December 2016. The Company records the \$1.0 million installments to prepaid expenses and other current assets and amortizes each installment over a twelve-month period commencing on February 1 of each year. For the three and nine months ended September 30, 2018 and 2017 the Company has recorded \$0.3 million and \$0.7 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 \$0.7 million and \$3.4 million for the three and nine months ended September 30, 2018. The Company made payments of \$0.9 million and \$3.5 million for the three and

nine months ended September 30, 2018. The Company recorded an estimated liability of \$1.7 million for research and development efforts as of September 30, 2018. The Company incurred charges of \$1.1 million and \$3.2 million for the three and nine months ended September 30, 2018. The Company made payments of \$0.3 million and \$2.2 million for the three and nine months ended September 30, 2018. The Company recorded an estimated liability of \$1.9 million for research and development efforts as of September 30, 2017.

#### (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 other sales and marketing services. The Company and Pfizer committed in the Promotion Agreement to invest specified amounts in the advertising and promotion of Cologuard. The Company will be obligated to pay Pfizer a promotion fee based on incremental gross profits over specified baselines and pay Pfizer royalties for Cologuard related revenues for a specified period after the expiration or termination of the Promotion Agreement. The initial term of Promotion Agreement runs through December 31, 2021. As of September 30, 2018, no work has been performed under the Promotion Agreement and as such there is no impact on the Company’s condensed consolidated financial statements.

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(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 awards, restricted stock units (“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 \$16.5 million and \$44.6 million in stock-based compensation expense during the three and nine months ended September 30, 2018. The Company recorded \$10.8 million and \$23.0 million in stock-based compensation expense during the three and nine months ended September 30, 2017.

In connection with the April 25, 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 vest on December 31, 2018. It was determined that the continuing service to be provided by the Company’s former Chief Operating Officer to the Company through December 31, 2018 is substantive and, as a result, the Company will recognize the additional non-cash stock-based compensation expense for the modified awards evenly over the transition term of April 25, 2018 through December 31, 2018. During the three and nine months ended September 30, 2018, the Company recorded \$1.4 million and \$2.5 million, respectively, of non-cash stock-based compensation expense for the modified awards.

Determining Fair Value

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

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

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

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

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

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The fair value of each option is based on the assumptions in the following table:

	Three Months Ended September 30, 2018		Nine Months Ended September 30, 2018	
	2017	2018	2017	2018
Option Plan Shares				
Risk-free interest rates	(1)	2.06%	2.73% - 2.79%	2.06% - 2.13%
Expected term (in years)	(1)	6.56	5.45 - 6.43	6.56 - 6.59
Expected volatility	(1)	62.5%	61.82% - 66.17%	62.5% - 62.9%
Dividend yield	(1)	0%	0%	0%
Weighted average fair value per share of options granted during the period	(1)	\$ 27.03	\$ 24.55	\$ 25.18
ESPP Shares				
Risk-free interest rates	(2)	(2)	2.05% - 2.5%	0.98% - 1.28%
Expected term (in years)	(2)	(2)	0.5 - 2	0.5 - 2
Expected volatility	(2)	(2)	51.75% - 65.39%	66.4% - 85.5%
Dividend yield	(2)	(2)	0%	0%
Weighted average fair value per share of stock purchase rights granted during the period	(2)	(2)	\$ 18.68	\$ 13.05

(1) The Company did not grant options under its 2010 Stock Plan during the period indicated.

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

### Stock Option and Restricted Stock Activity

A summary of stock option activity under the Stock Plans during the nine months ended September 30, 2018 is as follows:

Options	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value(1)
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(Aggregate intrinsic value in thousands)

Outstanding, January 1, 2018	3,360,461	\$ 11.89	6.4	
Granted	343,566	44.37		
Exercised	(848,061)	7.52		
Forfeited	—	—		
Outstanding, September 30, 2018	2,855,966	\$ 17.10	6.7	\$ 176,558
Exercisable, September 30, 2018	1,329,452	\$ 10.52	4.8	\$ 90,931

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- (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 \$78.92 market price of the Company's common stock at September 28, 2018. The total intrinsic value of options exercised during the nine months ended September 30, 2018 and 2017 was \$40.1 million and \$11.2 million, respectively.

As of September 30, 2018, there was \$127.8 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 2.9 years.

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

	Restricted Shares and RSUs	Weighted Average Grant Date Fair Value
Outstanding, January 1, 2018	6,148,778	\$ 15.76
Granted	1,504,700	48.55
Released	(1,209,608)	20.84
Forfeited	(164,161)	32.78
Outstanding, September 30, 2018	6,279,709	\$ 22.14

**(6) FAIR VALUE MEASUREMENTS**

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

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

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



Fixed-income securities and mutual funds are valued using a third-party pricing agency. The valuation is based on observable inputs including pricing for similar assets and other observable market factors. There has been no material change from period to period. The estimated fair value of the Company's long-term debt 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 and Note 10 for further detail on the Company's long-term debt.

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The following table presents the Company's fair value measurements as of September 30, 2018 along with the level within the fair value hierarchy in which the fair value measurements in their entirety fall.

(In thousands)	Fair Value at September 30, 2018	Fair Value Measurement at September 30, 2018 Using:		
		Quoted Prices Significant in Active Markets for Identical Assets (Level 1)	Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash and cash equivalents				
Cash and money market	\$ 92,318	\$ 92,318	\$ —	\$ —
U.S. government agency securities	63,694	—	63,694	—
Commercial paper	5,693	—	5,693	—
Available-for-sale Marketable securities				
Corporate bonds	415,459	—	415,459	—
Asset backed securities	287,742	—	287,742	—
U.S. government agency securities	265,131	—	265,131	—
Certificates of deposit	43,104	—	43,104	—
Commercial paper	12,076	—	12,076	—
Total	\$ 1,185,217	\$ 92,318	\$ 1,092,899	\$ —

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

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

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Certificates of deposit	6,646	—	6,646	—
Total	\$ 424,715	\$ 61,297	\$ 363,418	\$ —

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

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

(In thousands)	September 30, 2018		12 months or greater		Total	
	Fair Value	Gross Unrealized Loss	Fair Value	Gross Unrealized Loss	Fair Value	Gross Unrealized Loss
Marketable securities						
Corporate bonds	\$ 258,664	\$ (382)	\$ 24,871	\$ (91)	\$ 283,535	\$ (473)
U.S. government agency securities	250,157	(410)	14,975	(21)	265,132	(431)
Asset backed securities	246,362	(472)	22,004	(76)	268,366	(548)
Certificates of deposit	28,446	(22)	—	—	28,446	(22)
Commercial paper	12,076	(5)	—	—	12,076	(5)
Total	\$ 795,705	\$ (1,291)	\$ 61,850	\$ (188)	\$ 857,555	\$ (1,479)

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

(In thousands)	Due one year or less		Due after one year through four years	
	Cost	Fair Value	Cost	Fair Value
Marketable securities				
Corporate bonds	\$ 318,313	\$ 317,926	\$ 97,515	\$ 97,533
U.S. government agency securities	186,406	186,135	79,157	78,996
Asset backed securities	65,931	65,792	222,355	221,950
Certificates of deposit	39,216	39,197	3,895	3,907
Commercial paper	12,081	12,076	—	—
Total	\$ 621,947	\$ 621,126	\$ 402,922	\$ 402,386

**(7) NEW MARKET TAX CREDIT**

As more fully described in the 2017 Form 10-K, during the fourth quarter of 2014, the Company received approximately \$2.4 million in net proceeds from financing agreements related to working capital and capital

improvements at one of its Madison, Wisconsin facilities. This financing arrangement was structured with an unrelated third party financial institution, an investment fund, and its majority owned community development entity in connection with the Company's participation in transactions qualified under the federal New Markets Tax Credit ("NMTC") program, pursuant to Section 45D of the Internal Revenue Code of 1986, as amended. The \$2.4 million was recorded in Other Long-Term Liabilities on the condensed consolidated balance sheets. The benefit of this net \$2.4 million contribution will be recognized as a decrease in expenses, included in cost of sales, as the Company amortizes the contribution liability over the seven-year compliance period as it is being earned through the Company's on-going compliance with the conditions of the NMTC program. The Company has recorded \$0.1 million and \$0.3 million as a decrease of expenses for the three and nine months ended September 30, 2018. At September 30, 2018, the remaining balance of \$1.1 million is included in other long-term liabilities in the Company's condensed consolidated balance sheets. The Company recorded \$0.1 million and \$0.3 million as a decrease of expenses for the three and nine months ended September 30, 2017. At September 30, 2017, the remaining balance of \$1.4 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.

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(8) LONG-TERM DEBT

Building Purchase Mortgage

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

On September 28, 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. 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 September 30, 2018. A portion of the proceeds received from the sale were used to repay the mortgage on the facility, and as of September 30, 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 build-to-suit lease discussed in more detail below.

Prior to their repayment on September 28, 2018, borrowings under the credit agreement bore interest at 4.15%. The Company made interest-only payments on the outstanding principal balance for the period between July 12, 2015 and September 12, 2015. 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 due on the maturity date of June 12, 2019.

Additionally, the Company previously recorded \$73,000 in mortgage issuance 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 and \$13,000 in amortization of mortgage issuance costs for each of the three and nine months ended September 30, 2018 and 2017. As of September 30, 2018, the outstanding balance of the mortgage issuance costs was written down to \$0 due to the sale of the facility and the payoff of the mortgage.

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, at the election of 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 agreed in the Revolving Loan Agreement to various financial covenants including minimum liquidity and minimum tangible net worth. As of September 30, 2018, the Company is in compliance with all covenants.

As of September 30, 2018, the Company has not drawn any 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.

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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 is required to first invest at least \$16.4 million of its own cash into the construction project. The Company fulfilled its required initial investment and made its first draw on the Construction Loan in June 2018. In accordance with the Construction Loan Agreement, the Company will make monthly interest-only payments through November 2019. Starting in December 2019, the Company will make monthly payments toward the outstanding principal balance due plus accrued interest. As of September 30, 2018, the Company has drawn \$17.3 million from the Construction Loan. For the three and nine months ended September 30, 2018, the Company incurred interest of \$0.1 million, which is accrued for as an interest reserve and represents a portion of the \$17.3 million loan balance as of September 30, 2018. The Company capitalized the \$0.1 million to the construction project.

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 and \$34,000 in amortization of deferred financing costs related to the Construction Loan for the three and nine months ended September 30, 2018. There was no amortization expense recorded for the three and nine months ended September 30, 2017.

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

**Build-to-Suit Leases**

The Company evaluates whether it is the accounting owner of leased assets during the construction period when the Company is involved in the construction of the leased asset. Due to funding provided by the Company for costs related to the construction of the Company's new Madison, WI, headquarters, under build-to-suit lease accounting, as



of September 30, 2018, the Company is considered, for accounting purposes only, the owner of the construction project. The Company will contribute \$4.5 million towards the project. All project construction costs incurred over that amount are to be paid by the landlord but will be included in assets under construction and a corresponding liability by the Company. As of September 30, 2018, and December 31, 2017, the Company recorded \$2.4 million and \$0, respectively, in construction costs related to this project, all of which are being funded by the Company's \$4.5 million contribution to date.

The construction project is expected to be completed in 2020. Upon completion the Company will evaluate whether the arrangement meets the criteria for sale-leaseback accounting treatment.

#### (9) WISCONSIN ECONOMIC DEVELOPMENT TAX CREDITS

During the first quarter of 2015, the Company entered into an agreement with the Wisconsin Economic Development Corporation ("WEDC") to earn \$9.0 million in refundable tax credits if the Company expends \$26.3 million in capital investments and establishes and maintains 758 full-time positions in the state of Wisconsin over a seven-year period. The tax credits earned 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.

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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 September 30, 2018, the Company has earned \$9.0 million of tax credits and has received payment of \$2.4 million from the WEDC. The unpaid portion is \$6.6 million, of which \$1.9 million is reported in prepaid expenses and other current assets and \$4.7 million is reported in other long-term assets, reflecting when collection of the refundable tax credits is expected to occur. As of September 30, 2018, the Company also has recorded a \$2.4 million liability in other short-term liabilities and a \$2.8 million liability in other long-term liabilities, reflecting when the expected benefit of the tax credit amortization will reduce future operating expenses.

During the three and nine months ended September 30, 2018, the Company amortized \$0.6 million and \$1.6 million, respectively, of the tax credits earned as a reduction of operating expenses. During the three and nine months ended September 30, 2017, the Company amortized \$0.3 million and \$0.9 million, respectively, of the tax credits earned as a reduction of operating expenses.

(10) CONVERTIBLE NOTES

On January 17, 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.

On June 12, 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 “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.

Prior to July 15, 2024, the Notes are convertible only upon the occurrence of certain events and during certain periods, as set forth in the Indenture, and thereafter, until the close of business on the second scheduled trading day

immediately preceding the Maturity Date. The Notes will be convertible into cash, shares of the Company's common stock (plus, if applicable, cash in lieu of any fractional share), or a combination of cash and shares of the Company's common stock, at the Company's election. On or after July 15, 2024, until the close of business on the second scheduled trading day immediately preceding the maturity date, holders may convert their Notes at any time.

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

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

The Notes are the Company's senior unsecured obligations and (i) rank senior in right of payment to all of its future indebtedness that is expressly subordinated in right of payment to the Notes; equal in right of payment to all of the

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

Under current accounting guidance, an entity must separately account for the liability and equity components of convertible debt instruments (such as the January 2018 Notes and June 2018 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. The equity component is not re-measured as long as it continues to meet the conditions for equity classification. 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. The equity component is not re-measured as long as it continues to meet the conditions for equity classification.

The Company allocated the total transaction costs of approximately \$18.8 million related to the issuance of the January 2018 Notes to the liability and equity components of the January 2018 Notes based on their relative values, with \$13.1 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 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 September 30, 2018, consisted of the following:

(In thousands)	
Principal	\$ 908,500
Debt discount, net	(235,135)
Deferred financing costs	(17,024)
Net carrying amount	\$ 656,341

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(11) RELATED PARTY TRANSACTION

In May 2017, the Company entered into a professional services agreement for recruiting and related services with a firm whose principal is a non-employee director. In accordance with the agreement, the Company is expected to make cash payments totaling up to an aggregate of \$0.5 million under the agreement during 2017 and 2018. The Company incurred charges of \$0.2 million and \$0.3 million for the three and nine months ended September 30, 2018. The Company made payments of \$0.2 million and \$0.3 million for the three and nine months ended September 30, 2018. The Company incurred charges of \$0.1 million and \$0.2 million for the three and nine months ended September 30, 2017. The Company made payments of \$0.1 million and \$0.2 million for the three and nine months ended September 30, 2017.

In November 2017, the Company made a \$3.0 million equity investment in Biomatrix, as further described in Note 2. The Company incurred \$0.1 million and \$0.2 million in purchases from the supplier for the three and nine months ended September 30, 2018. In June 2018, the Company loaned Biomatrix \$1.0 million pursuant to a Senior Secured Promissory Note and Security Agreement, which is reported in prepaid expenses and other current assets on the Company's condensed consolidated balance sheets. As discussed in Note 2 above, on October 2, 2018, the Company acquired the remaining outstanding equity interests of Biomatrix.

(12) RECENT ACCOUNTING PRONOUNCEMENTS

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

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

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

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

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

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

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

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

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 is currently evaluating the impact of the guidance on its condensed consolidated financial statements, and does not anticipate that this guidance will have a material impact.

In July 2018, the Financial Accounting Standards Board issued ASU 2018-11, Leases (Topic 842); Targeted Improvements, (“Update 2018-11”). Update 2018-11 provided companies an alternative adoption method of ASU 2016-02 discussed above, by providing an option of recognizing a cumulative-effect adjustment to the opening balance of retained earnings upon adoption. The Company will adopt ASU 2018-11 in fiscal year 2019, and the Company is currently evaluating the impact of this guidance on its 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.

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

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

Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, that are intended to be covered by the "safe harbor" created by those sections. Forward-looking statements, which are based on certain assumptions and describe our future plans, strategies and expectations, can generally be identified by the use of forward-looking terms such as "believe," "expect," "may," "will," "should," "would," "could," "seek," "intend," "plan," "goal," "estimate," "anticipate" or other comparable terms. All statements other than statements of historical facts included in this Quarterly Report on Form 10-Q regarding our strategies, prospects, financial condition, operations, costs, plans and objectives are forward-looking statements. Examples of forward-looking statements include, among others, statements we make regarding expected future operating results, anticipated results of our sales and marketing efforts, expectations concerning payer reimbursement and the anticipated results of our product development efforts. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Our actual results and financial condition may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements. Important factors that could cause our actual results and financial condition to differ materially from those indicated in the forward-looking statements include, among others, the following: our ability to successfully and profitably market our products and services; the acceptance of our products and services by patients and healthcare providers; our ability to meet demand for our products and services; the willingness of health insurance companies and other payers to cover our products and services and adequately reimburse us for our 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 healthcare reform law, rule, order, interpretation or policy; the effects of changes in the pricing, coverage and reimbursement for our products and services, including without limitation as a result of the Protecting Access to Medicare Act of 2014; recommendations, guidelines and quality metrics issued by various organizations such as the U.S. Preventive Services Task Force, the American Cancer Society and the National Committee for Quality Assurance regarding cancer screening or our products and services; our ability to successfully develop new products and services; our ability to effectively utilize strategic partnerships 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 the 2017 Form 10-K and subsequently filed Quarterly Report(s) on Form 10-Q.

We undertake no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

## Overview

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

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### Our Cologuard Test

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

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

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

It is widely accepted that colorectal cancer is among the most preventable, yet least prevented cancers. Colorectal cancer can take up to 10-15 years to progress from a pre-cancerous lesion to metastatic cancer and death. Patients who are diagnosed early in the progression of the disease—with pre-cancerous lesions or polyps or early-stage cancer—are more likely to have a complete recovery and to be treated less expensively. Of the more than 85 million people who are at average-risk for colorectal cancer in the U.S., 38 percent have not been screened according to current guidelines. Poor compliance with screening guidelines has meant that nearly two-thirds of colorectal cancer diagnoses are made in the disease's late stages. The five-year survival rates for stages 3 and 4 are 70 percent and 13 percent, respectively. We believe the large underserved population of unscreened and inadequately screened patients represents a significant opportunity for a patient-friendly screening test.

Our Cologuard test is a non-invasive stool-based DNA (“sDNA”) screening test that utilizes a multi-target approach to detect DNA and hemoglobin biomarkers associated with colorectal cancer and pre-cancer. Eleven biomarkers are targeted that have been shown to be strongly associated with colorectal cancer and pre-cancer. Methylation, mutation, and hemoglobin results are combined in the laboratory analysis through a proprietary algorithm to provide a single positive or negative reportable result.

On August 11, 2014 the U.S. Food and Drug Administration (“FDA”) approved Cologuard for use as the first and only sDNA non-invasive colorectal cancer screening test. Our submission to the FDA for Cologuard included the results of our pivotal DeeP-C clinical trial that had over 10,000 patients enrolled at 90 sites in the U.S. and Canada. The results of our DeeP-C clinical trial for Cologuard were published in the New England Journal of Medicine in April 2014. The peer-reviewed study, “Multi-target Stool DNA Testing for Colorectal-Cancer Screening,” highlighted the performance of Cologuard in the trial population:

- Cancer Sensitivity: 92%
- Stage I and II Cancer Sensitivity: 94%
- High-Grade Dysplasia Sensitivity: 69%
- Specificity: 87%

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

### Our Cologuard Commercialization Strategy

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

#### Physicians and Patients

Our sales team actively engages with physicians and their staff to emphasize the need for colorectal cancer screening, educate them on the value of Cologuard, and enroll them in our physician ordering system to enable them to prescribe the test. We focus on specific physicians based on a combination of their Cologuard order history and ordering

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potential and also on physician groups and larger regional and national health systems. We recently expanded our physician engagement and Cologuard marketing campaign through a Promotion Agreement (“Promotion Agreement”) with Pfizer Inc. (“Pfizer”). The Promotion Agreement is discussed in more detail below.

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

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

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

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

After the launch of Cologuard, we initiated a significant public relations effort to engage patients in the U.S., and launched demographically-targeted direct-to-patient advertising campaigns in digital, social, print, and other channels. In 2016, we began a national television advertising campaign, with a majority of placements in national cable and

syndicated programming widely viewed by our target patient demographic. In the second quarter of 2018, we extended our television advertising campaign to highlight the accuracy, ease of use, and commercial coverage of Cologuard. In the remainder of 2018, we plan to increase our television advertising efforts, accelerate our investment in digital and social media, and embark upon strategic branded partnerships designed to increase awareness for Cologuard.

We are focused on strengthening our Cologuard core business by increasing the size of our nationwide salesforce. We advanced this goal in August 2018 by entering into a Promotion Agreement with Pfizer. Under the terms of the Promotion Agreement, Pfizer will 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. We will be obligated to pay Pfizer a promotion fee based on incremental gross profits over specified baselines and pay Pfizer royalties for Cologuard related revenues for a specified period after the expiration or termination of the Promotion Agreement. The initial term of Promotion Agreement runs through December 31, 2021.

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Payers

Successful commercialization of our Cologuard test depends, in large part, on the availability of adequate reimbursement from government insurance plans, managed care organizations and private insurance plans.

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

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

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

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



as prior authorizations and post-payment review or audits, may require that we, patients, or physicians provide the payer with extensive medical records and other information.

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

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directly, and we may need to rely on states to take enforcement action, which they may choose not to do. It is also possible that the ACA Mandate will be repealed or significantly modified in the future.

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

## Our Clinical Lab Facilities

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

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

## Future Product Opportunities

### Potential Expansion of Cologuard's Indication

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

## Product Pipeline

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

The ACS estimates that liver cancer will be diagnosed in 42,000 Americans and cause 30,000 deaths in 2018, three-fourths of which will be hepatocellular carcinoma (“HCC”). Incidence and mortality rates are both increasing at approximately 3 percent per year. People who have been diagnosed with cirrhosis of the liver or Hepatitis B are at high risk of developing HCC. Evidence shows that HCC testing in these high-risk groups leads to earlier detection and improved outcomes. The NCCN and American Association for the Study of Liver Diseases (“AASLD”) guidelines recommend that these two groups be tested for HCC every six months using ultrasound and the blood-based biomarker alpha-fetoprotein (“AFP”). However, ultrasound and AFP are documented to have poor sensitivity for early stage cancer, which is the primary target of testing. We are currently seeking to develop a blood-based biomarker test to serve as an alternative to ultrasound and AFP for use in HCC testing. We published a small case-control study in 2016 showing high accuracy for detecting HCC using a blood-based panel of methylation markers. In June 2018, we announced significant progress toward developing a panel of blood-based, DNA biomarkers that could accurately detect HCC. The biomarker

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panel was shown to be 95 percent sensitive for detecting HCC across all stages. Sensitivity among patients with curable-stage disease was 91 percent, and the panel has overall specificity of 93 percent. These results came from using DNA extracted from blood samples of 244 people, including 95 diagnosed across all stages of HCC, 51 with cirrhosis, and 98 healthy volunteers. Researchers tested the samples against 15 biomarkers to identify the combination of six biomarkers that yielded the most accurate detection of HCC.

The ACS estimates that, in the U.S. in 2018, lung cancer will be diagnosed in 234,000 people and cause 154,000 deaths. Currently, more than half of lung cancer cases are diagnosed at an advanced stage, after symptoms appear, when the five-year survival rate is in the low single digits. We are currently seeking to develop a blood-based biomarker test to aid in the early detection of lung cancer in individuals with lung nodules discovered through a computerized tomography (“CT”) or other scan. Such a test may help reduce the number of unnecessary biopsies and other follow-up procedures, and thereby reduce costs and improve health outcomes.

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

## How We Recognize Revenue

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

Our average reimbursement per test, as further defined below, was approximately \$470 and \$428 through September 30, 2018 and 2017, respectively. This cumulative average Cologuard reimbursement rate will change over time due to a number of factors, such as medical coverage decisions by payers, changes in the payer mix, the effects of contracts signed with payers, changes in allowed amounts by payers, our ability to successfully win appeals for payment, settlements reached with payers regarding previously denied claims and our ability to collect cash payments from payers and individual patients. Historical average reimbursement is not necessarily indicative of future average reimbursement.

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

## Results of Operations

We have generated significant losses since inception and, as of September 30, 2018, we had an accumulated deficit of approximately \$981.8 million. We expect to continue to incur losses for the near future, and it is possible we may never achieve profitability.

Laboratory service revenue. Our laboratory service revenue is generated by performing screening services using our Cologuard test. For the three months ended September 30, 2018 and 2017, we completed approximately 241,000 and 161,000 Cologuard tests, respectively, and generated laboratory service revenue of \$118.3 million and \$72.6 million,

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respectively. For the nine months ended September 30, 2018 and 2017, we completed approximately 642,000 and 395,000 Cologuard tests, respectively, and generated laboratory service revenue of \$311.5 million and \$178.6 million, respectively. The increase in revenue was primarily due to an increase in completed Cologuard tests and an increase in average revenue recognized per test during the current period.

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

Cost of sales includes costs related to inventory production and usage, shipment of test collection kits, royalties and the cost of laboratory services to process tests and provide results to physicians. We incur expense for tests in the period in which the activities occur, therefore, gross margin as a percentage of laboratory service revenue may vary due to costs being incurred in one period that relate to revenues recognized in a later period.

We expect that gross margin for our laboratory services will continue to fluctuate and be affected by Cologuard test volume, operating efficiencies, patient compliance rates, payer mix, the levels of reimbursement, and payment patterns of payers and patients.

**Cost of Sales.** Cost of sales increased to \$30.0 million for the three months ended September 30, 2018 compared to \$20.7 million for the three months ended September 30, 2017. Cost of sales increased to \$79.8 million for the nine months ended September 30, 2018 compared to \$55.7 million for the nine months ended September 30, 2017. The increase in cost of sales is primarily due to the increase in completed Cologuard tests. The Company completed approximately 241,000 and 161,000 Cologuard tests for the three months ended September 30, 2018 and 2017, respectively. The Company completed approximately 642,000 and 395,000 Cologuard tests for the nine months ended September 30, 2018 and 2017, respectively.

(In millions)	Three Months Ended		
	September 30,		
	2018	2017	Change
Production costs	\$ 20.4	\$ 15.0	\$ 5.4
Personnel expenses	5.4	3.0	2.4
Facility and support expenses	3.1	2.2	0.9
Stock-based compensation	1.0	0.5	0.5
Other cost of sales	0.1	—	0.1
Total cost of sales expenses	\$ 30.0	\$ 20.7	\$ 9.3

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(In millions)	Nine Months Ended		
	September 30,		
	2018	2017	Change
Production costs	\$ 54.9	\$ 40.5	\$ 14.4
Personnel expenses	14.4	8.1	6.3
Facility and support expenses	7.8	5.7	2.1
Stock-based compensation	2.5	1.2	1.3
Other cost of sales	0.2	0.2	—
Total cost of sales expenses	\$ 79.8	\$ 55.7	\$ 24.1

Research and development expenses. Research and development expenses increased to \$17.6 million for the three months ended September 30, 2018 compared to \$11.7 million for the three months ended September 30, 2017. Research and development expenses increased to \$47.3 million for the nine months ended September 30, 2018 compared to \$29.5 million for the nine months ended September 30, 2017. The increase in research and development expenses was

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primarily due to an increase in personnel costs and stock-based compensation due to an increased headcount and an increase in direct research and development expenses for our pipeline.

(In millions)	Three Months Ended		
	September 30,		
	2018	2017	Change
Direct research and development expenses	\$ 7.1	\$ 4.7	\$ 2.4
Personnel expenses	4.8	3.8	1.0
Stock-based compensation	3.1	2.1	1.0
Other research and development	1.6	0.6	1.0
Legal and professional fees	1.0	0.5	0.5
Total research and development expenses	\$ 17.6	\$ 11.7	\$ 5.9

(In millions)	Nine Months Ended		
	September 30,		
	2018	2017	Change
Direct research and development expenses	\$ 19.4	\$ 11.8	\$ 7.6
Personnel expenses	13.7	10.1	3.6
Stock-based compensation	7.9	4.4	3.5
Other research and development	4.0	1.7	2.3
Legal and professional fees	2.3	1.5	0.8
Total research and development expenses	\$ 47.3	\$ 29.5	\$ 17.8

General and administrative expenses. General and administrative expenses increased to \$46.7 million for the three months ended September 30, 2018 compared to \$30.8 million for the three months ended September 30, 2017. General and administrative expenses increased to \$121.9 million for the nine months ended September 30, 2018 compared to \$75.4 million for the nine months ended September 30, 2017. The increase in general and administrative expenses was primarily a result of increased personnel costs, facility and support costs, and stock-based compensation to support the overall growth of the Company.

Three Months  
Ended  
September 30,