EXACT SCIENCES CORP

Form 10-Q August 01, 2018 Table of Contents
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-Q
QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended June 30, 2018
OR
TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
Commission File Number: 001-35092
EXACT SCIENCES CORPORATION
(Exact name of registrant as specified in its charter)

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

Non-accelerated filer Smaller reporting company

Emerging growth company

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

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

As of July 31, 2018, the registrant had 122,753,839 shares of common stock outstanding.

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Part I — Financial Information

#### **EXACT SCIENCES CORPORATION**

Condensed Consolidated Balance Sheets

(Amounts in thousands, except share data - unaudited)

	June 30,	December 31,
A COSTITION	2018	2017
ASSETS		
Current Assets:	A 227 662	<b></b>
Cash and cash equivalents	\$ 225,662	\$ 77,491
Marketable securities	996,500	347,224
Accounts receivable, net	36,268	26,419
Inventory, net	35,409	26,027
Prepaid expenses and other current assets	16,465	10,055
Total current assets	1,310,304	487,216
Long-term Assets:		
Property, plant and equipment, net	140,467	79,986
Intangibles, net	23,108	24,205
Other long-term assets, net	8,773	7,153
Total assets	\$ 1,482,652	\$ 598,560
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 10,992	\$ 16,135
Accrued liabilities	60,046	49,126
Accrued interest	4,154	
Debt, current portion	4,588	182
Other short-term liabilities	3,182	2,681
Total current liabilities	82,962	68,124
Convertible notes, net	647,923	<del></del>
Long-term debt, less current portion	878	4,269
Other long-term liabilities	6,501	5,749
Total liabilities	738,264	78,142
Total natification	750,201	70,112
Commitments and contingencies		
Stockholders' Equity:		
Preferred stock, \$0.01 par value Authorized—5,000,000 shares issued and		
outstanding—no shares at June 30, 2018 and December 31, 2017		_
Common stock, \$0.01 par value Authorized—200,000,000 shares issued and		
outstanding—122,604,714 and 120,497,426 shares at June 30, 2018 and		
December 31, 2017	1,226	1,205
Additional paid-in capital	1,681,465	1,380,577
Accumulated other comprehensive loss	(1,878)	(750)

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

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

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## EXACT SCIENCES CORPORATION

Condensed Consolidated Statements of Operations

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

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

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

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#### **EXACT SCIENCES CORPORATION**

Condensed Consolidated Statements of Comprehensive Loss

(Amounts in thousands - unaudited)

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

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

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#### **EXACT SCIENCES CORPORATION**

Condensed Consolidated Statements of Cash Flows

(Amounts in thousands, except share data - unaudited)

	Six Months Er 2018	nded June 30, 2017
Cash flows from operating activities:		
Net loss	\$ (75,811)	\$ (65,736)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization of property and equipment	8,808	6,756
Loss on disposal of property and equipment	96	91
Stock-based compensation	28,056	12,224
Amortization of debt discount	10,822	
Amortization of debt issuance costs	920	_
Amortization of other liabilities	(1,136)	(769)
Amortization of deferred financing costs	49	26
Amortization of premium on short-term investments	(1,392)	57
Amortization of intangible assets	1,228	290
Changes in assets and liabilities, net of effects of acquisition:	,	
Accrued interest	4,154	_
Accounts receivable, net	(9,849)	(14,065)
Inventory, net	(9,382)	(5,577)
Prepaid expenses and other current assets	(6,410)	242
Accounts payable	(5,143)	1,527
Accrued liabilities	(9,798)	(268)
Other short-term liabilities	69	
Lease incentive obligation	683	(308)
Net cash used in operating activities	(64,036)	(65,510)
Cash flows from investing activities:	(01,000)	(,)
Purchases of marketable securities	(894,856)	(188,248)
Maturities of marketable securities	245,842	146,475
Purchases of property and equipment	(44,364)	(8,648)
Purchases of intangible assets	—	(8,442)
Internally developed software	(131)	<del>-</del>
Net cash used in investing activities	(693,509)	(58,863)
Cash flows from financing activities:	(0,0,0,0)	(==,===)
Proceeds from issuance of convertible notes, net	896,425	
Proceeds from exercise of common stock options	5,645	772
Proceeds from sale of common stock, net of issuance costs	—	253,463
Proceeds in connection with the Company's employee stock purchase plan	2,661	1,629
Payments of deferred financing costs	(24)	
Proceeds from construction loan	1,097	
Payments on mortgage payable	(90)	(86)
Net cash provided by financing activities	905,714	255,778
The cash provided by illianous activities	703,717	233,110

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

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

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

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

#### Principles of Consolidation

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

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

#### Use of Estimates

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

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Cash and Cash Equivalents

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

Marketable Securities

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

At June 30, 2018 and December 31, 2017, the Company's investments were comprised of fixed income investments, and all were deemed available-for-sale. The objectives of the Company's investment strategy are to provide liquidity and safety of principal while striving to achieve the highest rate of return consistent with these two objectives. The Company's investment policy limits investments to certain types of instruments issued by institutions with investment grade credit ratings and places restrictions on maturities and concentration by type and issuer. Investments in which the Company has the ability and intent, if necessary, to liquidate, in order to support its current operations (including those with a contractual term greater than one year from the date of purchase), are classified as current. All of the Company's investments are considered current. There were no realized losses for the six months ended June 30, 2018 and 2017. Realized gains were \$0.1 million and \$10,000 for the six months ended June 30, 2018 and 2017, respectively.

We periodically review our investments in unrealized loss positions for other-than-temporary impairments. This evaluation includes, but is not limited to, significant quantitative and qualitative assessments and estimates regarding credit ratings, collateralized support, the length of time and significance of a security's loss position, our intent not to sell the security, and whether it is more likely than not that we will have to sell the security before recovery of its cost basis. For the six months ended June 30, 2018, no investments were identified with other-than-temporary declines in value.

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

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

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

	December 31,	, 2017					
		Gains	in Accumulated	Los	ses in Accumulated		
		Other	Comprehensive	Oth	er Comprehensive	$\mathbf{E}$	stimated Fair
(In thousands)	Amortized Co	ostIncom	e (Loss)	Inco	ome (Loss)	V	alue
Corporate bonds	\$ 181,639	\$	10	\$	(344)	\$	181,305
Asset backed securities	94,700		_		(185)		94,515
U.S. government agency							
securities	54,974		_		(162)		54,812
Commercial paper	9,953		_		(7)		9,946
Certificates of deposit	6,647		1		(2)		6,646
Total available-for-sale securities	\$ 347,913	\$	11	\$	(700)	\$	347,224

Changes in Accumulated Other Comprehensive Income (Loss)

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

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

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

		Accumulated
Cumulative	Unrealized	Other
Translation	Gain (Loss)	Comprehensive

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

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

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

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#### Property and Equipment

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

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

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

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

#### Software Capitalization Policy

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

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

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Intangible Assets

Intangible Assets

Intangible assets consisted of the following:

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

Finite-Lived Intangible Assets

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

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

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

## (In thousands)

2018	,	\$ 1,237
		•
2019		2,474
2020		2,469
2021		