
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): **February 21, 2019**

EXACT SCIENCES CORPORATION

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-35092
(Commission
File Number)

02-0478229
(I.R.S. Employer
Identification No.)

441 Charmany Drive
Madison, WI 53719
(Address of Principal Executive Offices)(Zip Code)

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

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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.

2.02. Results of Operations and Financial Condition.

On February 21, 2019, Exact Sciences Corporation announced its financial results for the quarter and full year ended December 31, 2018. A copy of the press release is being furnished as Exhibit 99 to this Current Report on Form 8-K.

The information in this Current Report on Form 8-K and Exhibit 99 attached hereto is intended to be furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

9.01. Financial Statements and Exhibits.

Exhibits

The exhibits required to be filed as a part of this Current Report on Form 8-K are listed below and incorporated herein by reference.

Exhibit No.	Exhibit Description
99	Press release, dated February 21, 2019 issued by Exact Sciences Corporation, furnished herewith.

SIGNATURES

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

EXACT SCIENCES CORPORATION

Date: February 21, 2019

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

Investor Contact:

Megan Jones
Exact Sciences Corp.
meganjones@exactsciences.com
608-535-8815

Media Contact:

J.P. Fielder
Exact Sciences Corp.
jpfelder@exactsciences.com
608-210-5220

For Immediate Release

Total 2018 revenue increased 71 percent to \$454 million, and 934,000 people were screened with Cologuard

- Fourth quarter revenue increased 64 percent to \$143.0 million
- Fourth quarter Cologuard test volume increased 66 percent to 292,000 completed tests, expanding estimated market share to 4.1 percent
- Nearly 15,000 healthcare providers ordered their first Cologuard test during the fourth quarter, and approximately 147,000 have ordered since the test was launched

MADISON, Wis., Feb. 21, 2019 — Exact Sciences Corp. (Nasdaq: EXAS) today announced that the company generated revenue of \$454.5 million and completed approximately 934,000 Cologuard tests during the year ended Dec. 31, 2018. Full-year 2018 revenue and Cologuard test volume grew 71 percent and 64 percent from 2017, respectively.

During the fourth quarter of 2018, the company generated revenue of \$143.0 million and completed approximately 292,000 Cologuard tests. Fourth-quarter 2018 revenue and test volume grew 64 percent and 66 percent from the same period of 2017, respectively.

“The Exact Sciences team made tremendous progress in 2018, and we look forward to helping more people get screened for colorectal cancer in 2019 through our partnership with Pfizer,” said Kevin Conroy, chairman and CEO of Exact Sciences. “Our team continues working hard to advance our pipeline of liquid biopsy tests to deliver additional life-changing innovations in early cancer detection.”

Fourth-Quarter 2018 Financial Results

For the three-month period ended December, 31 2018, as compared to the same period of 2017 (where applicable):

- Revenue was \$143.0 million, an increase of 64 percent, and test volume was 292,000, an increase of 66 percent
- Average Cologuard recognized revenue per test was \$486, a decrease of 2 percent
- Average Cologuard cost per test was \$129, an improvement of 4 percent
- Gross margin was 73 percent, an increase of 20 basis points
- Operating expenses were \$154.1 million, an increase of 77 percent
- Net loss was \$54.0 million or \$0.44 per share, compared to \$21.8 million or \$0.18 per share
- Non-cash interest expense related to convertible debt was \$8.4 million, or \$0.07 per share
- Cash utilization was \$61.0 million including \$17.9 million related to the Biomatrix acquisition, compared to \$37.8 million
- Cash, cash equivalents and marketable securities were \$1.1 billion at the end of the quarter
- Nearly 15,000 healthcare providers ordered their first Cologuard test during the fourth quarter, and approximately 147,000 have ordered since the test was launched

2019 Outlook

- The company anticipates revenue of \$710-\$730 million during 2019.

The company's guidance for revenue is a forward-looking statement. It is subject to various risks and uncertainties that could cause the company's actual results to differ materially from the anticipated targets. There can be no assurance the company will meet these financial projections. See the cautionary information about forward-looking statements in the "Safe Harbor Statement" section of this press release.

Fourth-Quarter Conference Call & Webcast

Company management will host a conference call and webcast on Thursday, Feb. 21, 2019 at 5 p.m. ET to discuss fourth-quarter 2018 results. The webcast will be available at www.exactsciences.com. Domestic callers should dial 877-201-0168 and international callers should dial +1-647-788-4901.

An archive of the webcast will be available at www.exactsciences.com. A replay of the conference call will be available by calling 800-585-8367 domestically or 416-621-4642 internationally. The access code for the replay of the call is 7363029. The webcast, conference call and replay are open to all interested parties.

About Cologuard

Cologuard was approved by the FDA in August 2014 and results from Exact Sciences' prospective 90-site, point-in-time, 10,000-patient pivotal trial were published in the *New England Journal of Medicine* in March 2014. Cologuard is included in the American Cancer

Society's (2018) colorectal cancer screening guidelines and the recommendations of the U.S. Preventive Services Task Force (2016) and National Comprehensive Cancer Network (2016). Cologuard is indicated to screen adults of either sex, 50 years or older, who are at average risk for colorectal cancer. Cologuard is not for everyone and is not a replacement for diagnostic colonoscopy or surveillance colonoscopy in high-risk individuals. False positives and false negatives do occur. Any positive test result should be followed by a diagnostic colonoscopy. Following a negative result, patients should continue participating in a screening program at an interval and with a method appropriate for the individual patient. Cologuard performance when used for repeat testing has not been evaluated or established. Medicare and most major insurers cover Cologuard. For more information about Cologuard, visit www.cologuardtest.com. Rx Only.

About Exact Sciences Corp.

Exact Sciences Corp. is a molecular diagnostics company focused on the early detection and prevention of some of the deadliest forms of cancer. The company has exclusive intellectual property protecting its non-invasive, molecular screening technology for the detection of colorectal cancer. For more information, please visit the company's website at www.exactsciences.com, follow Exact Sciences on Twitter @ExactSciences or find Exact Sciences on Facebook.

Forward-Looking Statements

This news release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, that are intended to be covered by the "safe harbor" created by those sections. Forward-looking statements, which are based on certain assumptions and describe our future plans, strategies and expectations, can generally be identified by the use of forward-looking terms such as "believe," "expect," "may," "will," "should," "would," "could," "seek," "intend," "plan," "goal," "project," "estimate," "anticipate" or other comparable terms. All statements other than statements of historical facts included in this news release regarding our strategies, prospects, financial condition, operations, costs, plans and objectives are forward-looking statements. Examples of forward-looking statements include, among others, statements we make regarding expected future operating results, anticipated results of our sales and marketing efforts, expectations concerning payer reimbursement and the anticipated results of our product development efforts. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Our actual results and financial condition may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements. Important factors that could cause our actual results and financial condition to differ materially from those indicated in the forward-looking statements include, among others, the following: our

ability to successfully and profitably market our products and services; the acceptance of our products and services by patients and healthcare providers; our ability to meet demand for our products and services; the willingness of health insurance companies and other payers to cover our products and services and adequately reimburse us for such products and services; the amount and nature of competition from other cancer screening and diagnostic products and services; the effects of the adoption, modification or repeal of any healthcare reform law, rule, order, interpretation or policy; the effects of changes in pricing, coverage and reimbursement for our products and services, including without limitation as a result of the Protecting Access to Medicare Act of 2014; recommendations, guidelines and quality metrics issued by various organizations such as the U.S. Preventive Services Task Force, the American Cancer Society, and the National Committee for Quality Assurance regarding cancer screening or our products and services; our ability to successfully develop new products and services; our ability to effectively utilize strategic partnerships, such as our Promotion Agreement with Pfizer, Inc., and acquisitions; our success establishing and maintaining collaborative, licensing and supplier arrangements; our ability to maintain regulatory approvals and comply with applicable regulations; and the other risks and uncertainties described in the Risk Factors and in Management's Discussion and Analysis of Financial Condition and Results of Operations sections of our most recently filed Annual Report on Form 10-K and our subsequently filed Quarterly Reports 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.

EXACT SCIENCES CORPORATION
Selected Unaudited Financial Information
Condensed Consolidated Statements of Operations
(Amounts in thousands, except per share data)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2018	2017	2018	2017
Laboratory service revenue	\$ 142,981	\$ 87,406	\$ 454,462	\$ 265,989
Cost of sales	38,160	23,495	117,982	79,196
Gross margin	104,821	63,911	336,480	186,793
Operating expenses:				
Research and development	20,932	12,675	68,210	42,139
General and administrative	56,432	33,598	178,293	109,040
Sales and marketing	76,773	40,627	249,448	153,924
Total operating expenses	154,137	86,900	495,951	305,103
Loss from operations	(49,316)	(22,989)	(159,471)	(118,310)
Other income (expense)				
Investment income	6,321	1,320	21,203	3,932
Interest expense	(10,972)	(51)	(36,789)	(206)
Total other income	(4,651)	1,269	(15,586)	3,726
Net loss before tax	(53,967)	(21,720)	(175,057)	(114,584)
Income tax benefit	(7)	(44)	(92)	187
Net loss	\$ (53,974)	\$ (21,764)	\$ (175,149)	\$ (114,397)
Net loss per share - basic and diluted	\$ (0.44)	\$ (0.18)	\$ (1.43)	\$ (0.99)
Weighted average common shares outstanding - basic and diluted	122,981	119,950	122,207	115,684

EXACT SCIENCES CORPORATION
Selected Unaudited Financial Information
Condensed Consolidated Balance Sheets
(Amounts in thousands)

	December 31, 2018	December 31, 2017
Assets		
Cash and cash equivalents	\$ 160,430	\$ 77,491
Marketable securities	963,752	347,224
Accounts receivable, net	44,239	26,419
Inventory, net	39,148	26,027
Prepaid expenses and other current assets	20,498	10,055
Property and equipment, net	245,259	79,986
Intangibles, Net	46,281	24,205
Other long-term assets	4,415	7,153
Total assets	<u>\$ 1,524,022</u>	<u>\$ 598,560</u>
Liabilities and stockholders' equity		
Total current liabilities	\$ 136,590	\$ 68,124
Convertible notes, net	\$ 664,749	\$ —
Long term debt	24,073	4,269
Other long-term liabilities	9,475	5,749
Lease incentive obligation, less current portion	8,194	—
Total stockholders' equity	680,941	520,418
Total liabilities and stockholders' equity	<u>\$ 1,524,022</u>	<u>\$ 598,560</u>