
**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 16, 2021**

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.)

**5505 Endeavor Lane
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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.01 par value per share	EXAS	The Nasdaq Stock Market LLC

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 Conditions.

On February 16, 2021, Exact Sciences Corporation announced its financial results for the quarter and full year ended December 31, 2020. 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 16, 2021, issued by Exact Sciences Corporation, furnished herewith.
104	The cover page from this Current Report on Form 8-K, formatted in Inline XBRL.

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 16, 2021

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

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For Immediate Release

Exact Sciences Announces Fourth Quarter 2020 Results

MADISON, Wis., Feb. 16, 2021 — Exact Sciences Corp. (Nasdaq: EXAS) today announced that the company generated revenue of \$466.3 million for the fourth quarter ended Dec. 31, 2020 and \$1,491.4 million for the full year ended Dec. 31, 2020.

“Exact Sciences finished another transformative year by delivering strong fourth quarter results against a challenging backdrop because of the pandemic,” said Kevin Conroy, chairman and CEO of Exact Sciences. “We are a leader in cancer diagnostics because of our people, scientific platform, and market-leading Cologuard and Oncotype tests. We aim to extend this leadership throughout the cancer continuum and bring additional tests to patients to help improve cancer outcomes.”

Fourth Quarter 2020 Financial Results

For the three-month period ended December 31, 2020, as compared to the same period of 2019 (where applicable):

- Total revenue was \$466.3 million
- Screening revenue was \$249.7 million, an increase of 9 percent
- Precision Oncology revenue was \$117.6 million
- COVID-19 testing revenue was \$99.1 million
- Gross margin including amortization of acquired intangible assets was 74 percent, and non-GAAP gross margin excluding amortization of acquired intangible assets was 79 percent
- During the fourth quarter of 2020, the Company acquired Base Genomics, which was treated as an asset acquisition under U.S. GAAP and resulted in a \$412.6 million charge to research and development expense
- Net loss was \$(436.8) million, or \$(2.79) per share, compared to net income of \$78.0 million, or \$0.56 and \$0.54 per basic and diluted share.
- EBITDA was \$(375.5) million and adjusted EBITDA was \$87.9 million
- Non-cash interest expense related to convertible debt was \$21.3 million, compared to \$11.5 million
- Cash, cash equivalents and marketable securities were \$1,840.0 million at the end of the quarter

Screening includes laboratory service revenue from Cologuard and revenue from Biomatrix products. Precision Oncology includes laboratory service revenue from global Oncotype products.

Non-GAAP Disclosure

In addition to the company's financial results determined in accordance with U.S. GAAP, the company provides non-GAAP measures that it determines to be useful in evaluating its operating performance. The company presents EBITDA, adjusted EBITDA, as well as non-GAAP gross margin and non-GAAP gross profit. EBITDA and adjusted EBITDA consist of net loss after adjustment for those items shown in the table below. The company defines non-GAAP gross profit and non-GAAP gross margin as GAAP gross profit and GAAP gross margin, respectively, excluding amortization of acquired intangible assets. The amortization of acquisition-related intangible assets used in the calculation of non-GAAP gross profit and non-GAAP gross margin pertain only to the amortization associated with developed technology acquired and recorded through purchase accounting transactions. The amortization of these intangible assets will recur in future periods until such intangible assets have been fully amortized. The company believes that these non-GAAP measures are useful in evaluating the company's operating performance. The company uses this non-GAAP financial information to evaluate ongoing operations and for internal planning

and forecasting purposes. Non-GAAP financial information, when taken collectively, may be helpful to investors because it provides consistency and comparability with past financial performance. However, non-GAAP financial information is presented for supplemental information purposes only, has limitations as an analytical tool and should not be considered in isolation or as a substitute for financial information presented in accordance with U.S. GAAP. For example, non-GAAP gross margin and non-GAAP gross profit exclude the amortization of acquired intangible assets although such measures include the revenue associated with the acquisitions. For a reconciliation of these non-GAAP measures to GAAP, see below "EBITDA and Adjusted EBITDA Reconciliations" and "Non-GAAP Gross Profit and Non-GAAP Gross Margin Reconciliations."

Fourth Quarter Conference Call & Webcast

Company management will host a conference call and webcast on Tuesday, February 16, 2021, at 5 p.m. ET to discuss fourth quarter and full-year 2020 results. The webcast will be available at www.exactsciences.com. Domestic callers should dial 833-235-7650 and international callers should dial +1-647-689-4171. The access code for both domestic and international callers is 2892148.

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 +1-416-621-4642 internationally. The access code for the replay of the call is 2892148. 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 45 years of age and older who are at average risk for colorectal cancer by detecting certain DNA markers and blood in the stool. Do not use Cologuard if you have had precancer, have inflammatory bowel disease and certain hereditary syndromes, or have a personal or family history of colorectal cancer. Cologuard is not a replacement for colonoscopy in high risk patients. Cologuard performance in adults ages 45-49 is estimated based on a large clinical study of patients 50 and older. Cologuard performance in repeat testing has not been evaluated.

The Cologuard test result should be interpreted with caution. A positive test result does not confirm the presence of cancer. Patients with a positive test result should be referred for diagnostic colonoscopy. A negative test result does not confirm the absence of cancer. Patients with a negative test result should discuss with their doctor when they need to be tested again.

Medicare and most major insurers cover Cologuard. For more information about Cologuard, visit www.cologuardtest.com. Rx Only.

About Oncotype DX

The Oncotype DX® portfolio of breast, colon and prostate cancer tests applies advanced genomic science to reveal the unique biology of a tumor in order to optimize cancer treatment decisions. In breast cancer, the Oncotype DX Breast Recurrence Score® test is the only test that has been shown to predict the likelihood of chemotherapy benefit as well as recurrence in invasive breast cancer. Additionally, the Oncotype DX Breast DCIS Score test predicts the likelihood of recurrence in a pre-invasive form of breast cancer called DCIS. In prostate cancer, the Oncotype DX Genomic Prostate Score® test predicts disease aggressiveness and further clarifies the current and future risk of the cancer prior to treatment intervention, and the Oncotype DX AR-V7 Nucleus Detect™ test helps determine which patients with metastatic castration-resistant prostate cancer (mCRPC) are resistant to androgen receptor (AR)-targeted therapies. The Oncotype DX AR-V7 Nucleus Detect test is performed by Epic Sciences at its centralized, CLIA-certified laboratory in San Diego and offered exclusively by Exact Sciences. With more than 1 million patients tested in more than 90 countries, the Oncotype DX tests have redefined personalized medicine by making genomics a critical part of cancer diagnosis and treatment. To learn more about Oncotype DX tests, visit www.OncotypeIQ.com, www.MyBreastCancerTreatment.org or www.MyProstateCancerTreatment.org.

About Exact Sciences Corp.

A leading provider of cancer screening and diagnostic tests, Exact Sciences relentlessly pursues smarter solutions providing the clarity to take life-changing action, earlier. Building on the success of Cologuard and Oncotype DX, Exact Sciences is investing in its product pipeline to take on some of the deadliest cancers and improve patient care. Exact Sciences unites visionary collaborators to help advance the fight against 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 concerning our expectations, anticipations, intentions, beliefs or strategies regarding the future. These forward-looking statements are based on assumptions that we have made as of the date hereof and are subject to known and unknown risks and uncertainties that could cause actual results, conditions and events to differ materially from those anticipated. Therefore, you should not place undue reliance on forward-looking statements. Examples of forward-looking statements include, among others, statements we make regarding expected future operating results; our strategies, positioning, resources, capabilities and expectations for future events or performance; and the anticipated benefits of our acquisitions, including estimated synergies and other financial impacts.

Important factors that could cause actual results, conditions and events to differ materially from those indicated in the forward-looking statements include, among others, the following: uncertainties associated with the coronavirus (COVID-19) pandemic, including its possible effects on our operations, including our supply chain and clinical studies, and the demand for our products and services; our ability to efficiently and flexibly manage our business amid uncertainties related to COVID-19; 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 for our products and services; the effects of any judicial, executive or legislative action affecting us or the healthcare system; recommendations, guidelines and quality metrics issued by various organizations regarding cancer screening or our products and services; our ability to successfully develop new products and services and assess potential market opportunities; our ability to effectively enter into and 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; our ability to manage an international business and our expectations regarding our international expansion and opportunities; the potential effects of foreign currency exchange rate fluctuations and our efforts to hedge such effects; the possibility that the anticipated benefits from our business acquisitions will not be realized in full or at all or may take longer to realize than expected; the possibility that costs or difficulties related to the integration of acquired businesses' operations will be greater than expected and the possibility that integration efforts will disrupt our business and strain management time and resources; the outcome of any litigation, government investigations, enforcement actions or other legal proceedings, including in connection with acquisitions; our ability to retain and hire key personnel including employees at businesses we acquire. The risks included above are not exhaustive. Other important risks and uncertainties are described in the Risk Factors sections of our most recent Annual Report on Form 10-K and any subsequent Quarterly Reports on Form 10-Q, and in our other reports filed with the Securities and Exchange Commission. 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 share data)

	<u>Three Months Ended December 31,</u>		<u>Twelve Months Ended December 31,</u>	
	<u>2020</u>	<u>2019</u>	<u>2020</u>	<u>2019</u>
Revenue	\$ 466,339	\$ 295,575	\$ 1,491,391	\$ 876,293
Operating expenses:				
Cost of sales (exclusive of amortization of acquired intangible assets)	99,765	70,416	354,324	216,717
Research and development	446,399	43,223	554,052	139,694
Sales and marketing	166,827	119,851	589,919	385,176
General and administrative	145,451	144,386	481,716	352,453
Amortization of acquired intangible assets	23,199	13,779	93,398	16,035
Intangible asset impairment charge	—	—	209,666	—
Total operating expenses	<u>881,641</u>	<u>391,655</u>	<u>2,283,075</u>	<u>1,110,075</u>
Other operating income	—	—	23,665	—
Loss from operations	<u>(415,302)</u>	<u>(96,080)</u>	<u>(768,019)</u>	<u>(233,782)</u>
Other income (expense)				
Investment income, net	1,365	3,113	6,897	26,530
Interest expense	<u>(24,336)</u>	<u>(13,688)</u>	<u>(95,983)</u>	<u>(61,599)</u>
Total other income (expense)	<u>(22,971)</u>	<u>(10,575)</u>	<u>(89,086)</u>	<u>(35,069)</u>
Net loss before tax	<u>(438,273)</u>	<u>(106,655)</u>	<u>(857,105)</u>	<u>(268,851)</u>
Income tax benefit (expense)	1,463	184,628	8,572	184,858
Net loss	<u>\$ (436,810)</u>	<u>\$ 77,973</u>	<u>\$ (848,533)</u>	<u>\$ (83,993)</u>
Net income (loss) per share—basic	<u>\$ (2.79)</u>	<u>\$ 0.56</u>	<u>\$ (5.61)</u>	<u>\$ (0.64)</u>
Net income (loss) per share—diluted	<u>\$ (2.79)</u>	<u>\$ 0.54</u>	<u>\$ (5.61)</u>	<u>\$ (0.64)</u>
Weighted average common shares outstanding—basic	<u>156,470</u>	<u>139,901</u>	<u>151,137</u>	<u>131,257</u>
Weighted average common shares outstanding—diluted	<u>156,470</u>	<u>143,200</u>	<u>151,137</u>	<u>131,257</u>

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

	December 31, 2020	December 31, 2019
Assets		
Cash and cash equivalents	\$ 1,491,288	\$ 177,254
Marketable securities	348,699	146,401
Accounts receivable, net	233,185	130,362
Inventory	92,265	61,724
Prepaid expenses and other current assets	33,157	38,195
Property, plant and equipment, net	450,683	455,325
Operating lease right-of-use assets	125,947	126,444
Goodwill	1,237,672	1,203,197
Intangible assets, net	848,426	1,143,550
Other long-term assets, net	63,770	23,316
Total assets	<u>\$ 4,925,092</u>	<u>\$ 3,505,768</u>
Liabilities and stockholders' equity		
Total current liabilities	\$ 575,844	\$ 236,494
Convertible notes, net, less current portion	1,320,760	803,605
Long-term debt, less current portion	22,342	24,032
Other long-term liabilities	61,582	34,911
Operating lease liabilities, less current portion	121,075	118,665
Total stockholders' equity	2,823,489	2,288,061
Total liabilities and stockholders' equity	<u>\$ 4,925,092</u>	<u>\$ 3,505,768</u>

EXACT SCIENCES CORPORATION
Selected Unaudited Financial Information
EBITDA and Adjusted EBITDA Reconciliations
(Amounts in thousands)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2020	2019	2020	2019
Net income (loss)	\$ (436,810)	\$ 77,973	\$ (848,533)	\$ (83,993)
Interest expense	24,336	13,688	88,029	51,041
Investment income	(1,365)	(3,113)	(6,897)	(26,530)
Depreciation and amortization	39,818	26,071	163,362	50,247
Income tax expense (benefit)	(1,463)	(184,628)	(8,572)	(184,858)
EBITDA	\$ (375,484)	\$ (70,009)	\$ (612,611)	\$ (194,093)
Stock-based compensation	40,437	26,051	143,276	86,708
Loss on settlement of convertible notes	—	—	7,954	10,558
Acquisition and integration costs ⁽¹⁾	10,387	53,663	29,967	62,836
Reduction-in-force severance ⁽²⁾	—	—	2,198	—
CARES Act Funding ⁽³⁾	—	—	(23,665)	—
Intangible asset impairment charge ⁽⁴⁾	—	—	209,666	—
Asset acquisition ⁽⁵⁾	412,568	—	412,568	—
Adjusted EBITDA	\$ 87,908	\$ 9,705	\$ 169,353	\$ (33,991)

(1) Represents acquisition and related integration costs incurred as a result of the company's business combinations and asset acquisition, a majority of which relate to our combination with Genomic Health. The costs primarily consist of legal and other professional service fees and incremental stock-based compensation including the fair value of stock awards assumed by the company in connection with the Genomic Health combination. Legal and other professional service fees were \$9.0 million and \$20.4 million for the three and twelve months ended December 31, 2020, respectively, and \$31.9 million and \$41.0 million for the three months and twelve months ended December 31, 2019, respectively. Incremental stock-based compensation including the fair value of assumed stock awards was \$1.4 million and \$9.6 million for the three and twelve months ended December 31, 2020, respectively, and \$21.8 million for the three months and twelve months ended December 31, 2019.

(2) Represents severance costs as a result of proactive measures the Company put in place to address the impact of the COVID-19 pandemic.

(3) As part of the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act"), the Company received \$23.7 million from the United States Department of Health and Human Services Provider Relief Fund provided to eligible healthcare providers. The CARES Act funds are meant to offset the implications of the COVID-19 pandemic which include increases in the Company's costs and lost revenues.

(4) During the third quarter of 2020, the Company began discussions with Biocartis regarding the termination of its agreements related to the development of an in vitro diagnostic version of the Oncotype DX Breast Recurrence Score test. As a result, and in connection with the preparation of the financial statements, the Company recorded a non-cash, pre-tax impairment loss of \$200.0 million related to the in-process research and development intangible asset that was initially recorded as part of the combination with Genomic Health.

During the third quarter of 2020, the Company abandoned certain research and development assets acquired through an asset purchase agreement with Armune Biosciences, Inc. in 2017. These assets were expected to complement the Company's product pipeline and were expected to have alternative future uses at the time of acquisition; however, due to changes in strategic priorities and efforts during the third quarter of 2020, these assets are no longer expected to be utilized to advance the Company's product pipeline. As a result, and in connection with the preparation of the financial statements, the Company concluded that the intangible asset would need to be written off as of September 30, 2020 which resulted in a non-cash, pre-tax impairment loss of \$9.7 million.

(5) During the fourth quarter of 2020, the Company acquired Base Genomics. The acquisition was treated as an asset acquisition which was recorded to research and development expense.

EXACT SCIENCES CORPORATION
Selected Unaudited Financial Information
Non-GAAP Gross Profit and Non-GAAP Gross Margin
(Amounts in thousands)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2020	2019	2020	2019
Revenue	\$466,339	\$295,575	\$1,491,391	\$876,293
Cost of sales (exclusive of amortization of acquired intangible assets)	\$99,765	\$70,416	\$354,324	\$216,717
Amortization of acquired intangible assets ⁽¹⁾	\$20,553	\$11,981	\$82,127	\$13,254
Gross profit	\$346,021	\$213,178	\$1,054,940	\$646,322
Gross margin	74 %	72 %	71 %	74 %
Amortization of acquired intangible assets ⁽¹⁾	20,553	11,981	82,127	13,254
Non-GAAP gross profit	\$366,574	\$225,159	\$1,137,067	\$659,576
Non-GAAP gross margin	79 %	76 %	76 %	75 %

(1) Includes only amortization of intangible assets identified as developed technology assets through purchase accounting transactions, which otherwise would have been allocated to cost of sales.