

**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): **October 27, 2020**

EXACT SCIENCES CORPORATION

(Exact Name of Registrant as Specified in Charter)

DE
(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	NASDAQ

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 October 27, 2020, Exact Sciences Corporation announced its financial results for the quarter ended September 30, 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.

<u>Exhibit No.</u>	<u>Exhibit Description</u>
99	Press release, dated October 27, 2020, issued by Exact Sciences Corporation, furnished herewith.
104	The cover page from this Current Report on Form 8-K, formatted in Inline XBRL.

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For Immediate Release

Exact Sciences Announces Third Quarter 2020 Results

MADISON, Wis., October 27, 2020 — Exact Sciences Corp. (Nasdaq: EXAS) today announced that the company generated revenue of \$408.4 million for the third quarter ended September 30, 2020, compared to \$218.8 million for the same period of 2019.

"The Exact Sciences team delivered a strong quarter and made significant progress towards our vision," said Kevin Conroy, Chairman and CEO. "We're confident in the long-term growth outlook for both Cologuard and Oncotype DX and are excited about our extensive pipeline of liquid biopsy tests. Our team and the depth and breadth of our capabilities position us at the forefront of advanced cancer diagnostics."

Third Quarter 2020 Financial Results

For the three-month period ended September 30, 2020, as compared to the same period of 2019 (where applicable):

- Total revenue was \$408.4 million, compared to \$218.8 million
- Screening revenue was \$214.6 million, a decrease of 2 percent
- Precision Oncology revenue was \$91.6 million
- COVID-19 testing revenue was \$102.2 million
- Gross margin including amortization of acquired intangible assets was 72 percent, and non-GAAP gross margin excluding amortization of acquired intangible assets was 77 percent
- Intangible asset impairment of \$209.7 million was primarily related to a one-time impairment of certain in-process research and development assets related to an in vitro diagnostic version of Oncotype DX
- Net loss was \$219.9 million, or \$1.46 per share, compared to a net loss of \$40.5 million, or \$0.31 per share
- EBITDA was \$(160.2) million and adjusted EBITDA was \$94.5 million
- Non-cash interest expense related to convertible debt was \$20.6 million, compared to \$11.0 million
- Cash, cash equivalents, and marketable securities were \$1.3 billion 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 DX 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."

Third Quarter Conference Call & Webcast

Company management will host a conference call and webcast on Tuesday, October 27, 2020, at 8 a.m. ET to discuss third quarter 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 9947369.

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 9947369. 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 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, expectations, 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, marketing and patient adherence efforts, expectations concerning payer reimbursement, and the anticipated results of our product development efforts, the anticipated benefits of our pending acquisition of Thrive Earlier Detection Corporation ("Thrive"), including estimated synergies and other financial impacts, and the expected timing of completion of the transaction. Forward-looking statements are neither historical facts nor assurances of future performance or events. 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. Actual results, conditions and events 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: uncertainties associated with the coronavirus (COVID-19) pandemic, including its possible effects on our operations, including supply chain, 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 success of our efforts to facilitate patient access to Cologuard via telehealth; 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 the adoption, modification or repeal of any law, rule, order, interpretation or policy relating to the healthcare system, including without limitation as a result of any judicial, executive or legislative action; the effects of changes in pricing, coverage and reimbursement for our products and services, including without limitation as a result of the Protecting Access to Medicare Act of 2014; recommendations, guidelines and quality metrics issued by various organizations such as the U.S. Preventive Services Task Force, the American Society of Clinical Oncology, 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 and assess potential market opportunities; our ability to effectively enter into and utilize strategic partnerships, such as through our Promotion Agreement with Pfizer, Inc., and acquisitions; our success establishing and maintaining collaborative, licensing and supplier arrangements; our ability and the ability of Thrive and Base Genomics Limited ("Base") 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 (including the pending acquisition of Thrive and recent acquisition of Base) cannot 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' (including Thrives and Base's) operations will be greater than expected and the possibility of disruptions to our business during integration efforts and strain on management time and resources; the outcome of any litigation, government investigations, enforcement actions or other legal proceedings; the ability of the Company and Thrive to receive the required regulatory approvals for the pending merger and to satisfy the conditions to the closing of the transaction on a timely basis or at all; the occurrence of events that may give rise to a right of one or both of the Company and Thrive to terminate the merger agreement; possible negative effects of the announcement or the consummation of the pending acquisition of Thrive or recent acquisition of Base on the market price of our common stock and/or on our and/or Thrive's or Base's respective businesses, financial conditions, results of operations and financial performance; significant transaction costs and/or unknown liabilities; risks associated with contracts containing consent and/or other provisions that may be triggered by the pending acquisition of Thrive or the recent acquisition of Base; risks associated with potential transaction-related litigation; the ability of Thrive, Base and the combined company to retain and hire key personnel; 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. You are further cautioned not to place undue reliance upon any such forward-looking statements, which speak only as of the date made. Except as otherwise required by the federal securities laws, 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 September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenue	\$ 408,363	\$ 218,805	\$ 1,025,052	\$ 580,718
Operating expenses				
Cost of sales (exclusive of amortization of acquired intangible assets)	95,061	52,335	254,559	146,301
Research and development	31,471	34,714	107,653	96,471
Sales and marketing	136,481	86,196	423,092	265,325
General and administrative	115,589	80,538	336,265	208,067
Amortization of acquired intangible assets	23,430	748	70,199	2,256
Intangible asset impairment charge	209,666	—	209,666	—
Total operating expenses	611,698	254,531	1,401,434	718,420
Other operating income	—	—	23,665	—
Loss from operations	(203,335)	(35,726)	(352,717)	(137,702)
Other income (expense)				
Investment income, net	2,523	9,093	5,532	23,417
Interest expense	(23,582)	(13,209)	(71,647)	(47,911)
Total other income (expense)	(21,059)	(4,116)	(66,115)	(24,494)
Net loss before tax	(224,394)	(39,842)	(418,832)	(162,196)
Income tax benefit (expense)	4,510	(683)	7,109	230
Net loss	\$ (219,884)	\$ (40,525)	\$ (411,723)	\$ (161,966)
Net loss per share—basic and diluted	\$ (1.46)	\$ (0.31)	\$ (2.76)	\$ (1.26)
Weighted average common shares outstanding—basic and diluted	150,155	129,567	149,346	128,344

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

	September 30, 2020	December 31, 2019
Assets		
Cash and cash equivalents	\$ 806,678	\$ 177,254
Marketable securities	476,324	146,401
Accounts receivable, net	206,606	130,667
Inventory, net	80,427	61,724
Prepaid expenses and other current assets	36,592	40,913
Property, plant and equipment, net	456,455	455,325
Operating lease right-of-use assets	129,837	126,444
Goodwill	1,237,672	1,203,197
Intangible assets, net	871,660	1,143,550
Other long-term assets, net	52,119	20,293
Total assets	<u>\$ 4,354,370</u>	<u>\$ 3,505,768</u>
Liabilities and stockholders' equity		
Total current liabilities	\$ 252,832	\$ 236,494
Convertible notes, net	1,554,967	803,605
Long-term debt, less current portion	22,643	24,032
Other long-term liabilities	62,821	34,911
Operating lease liabilities, less current portion	124,007	118,665
Total stockholders' equity	2,337,100	2,288,061
Total liabilities and stockholders' equity	<u>\$ 4,354,370</u>	<u>\$ 3,505,768</u>

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Net loss	\$ (219,884)	\$ (40,525)	\$ (411,723)	\$ (161,966)
Interest expense	23,582	13,209	63,693	37,353
Investment income	(2,523)	(9,093)	(5,532)	(23,417)
Depreciation and amortization	43,143	9,161	123,544	24,176
Income tax expense (benefit)	(4,510)	683	(7,109)	(230)
EBITDA	\$ (160,192)	\$ (26,565)	\$ (237,127)	\$ (124,084)
Stock-based compensation	37,317	24,348	102,839	60,657
Loss on settlement of convertible notes	—	—	7,954	10,558
Acquisition and integration costs ⁽¹⁾	7,706	—	19,474	—
Reduction-in-force severance ⁽²⁾	—	—	2,198	—
CARES Act Funding ⁽³⁾	—	—	(23,665)	—
Intangible asset impairment charge ⁽⁴⁾	209,666	—	209,666	—
Adjusted EBITDA	\$ 94,497	\$ (2,217)	\$ 81,339	\$ (52,869)

(1) Represents acquisition and related integration costs incurred as a result of the company's combination with Genomic Health. Acquisition and integration costs were \$7.7 million and \$19.5 million for the three months and nine months ended September 30, 2020. 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, severance, and other professional service fees were \$3.5 million and \$11.3 million for the three months and nine months ended September 30, 2020. Incremental stock-based compensation including the fair value of assumed stock awards was \$4.2 million and \$8.2 million for the three months and nine months ended September 30, 2020, respectively.

(2) Represents severance costs as a result of proactive measures the Company put in place to address the impact of the COVID-19 pandemic. The severance cost resulting from this workforce reduction was \$0 and \$2.2 million for the three months and nine months ended September 30, 2020.

(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.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenue	\$ 408,363	\$ 218,805	\$ 1,025,052	\$ 580,718
Cost of sales (exclusive of amortization of acquired intangible assets)	95,061	52,335	254,559	146,301
Amortization of acquired intangible assets (1)	20,555	424	61,573	1,273
Gross profit	\$ 292,747	\$ 166,046	\$ 708,920	\$ 433,144
Gross margin	72 %	76 %	69 %	75 %
Amortization of acquired intangible assets (1)	20,555	424	61,573	1,273
Non-GAAP gross profit	\$ 313,302	\$ 166,470	\$ 770,493	\$ 434,417
Non-GAAP gross margin	77 %	76 %	75 %	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.