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): **November 2, 2021**

EXACT SCIENCES CORPORATION

(Exact Name of Registrant as Specified in Charter)

Delaware	**001-35092**	**02-0478229**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(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 November 2, 2021, Exact Sciences Corporation announced its financial results for the quarter ended September 30, 2021. 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 November 2, 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: November 2, 2021

By: /s/ Jeffrey T. Elliott

Jeffrey T. Elliott

Executive Vice President, Chief Financial Officer and Chief Operating Officer

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For Immediate Release

Exact Sciences announces third quarter 2021 results

MADISON, Wis., November 2, 2021 -- Exact Sciences Corp. (Nasdaq: EXAS) today announced that the company generated revenue of $456.4 million for the third quarter ended September 30, 2021, compared to $408.4 million for the same period of 2020.

"Exact Sciences is entering an exciting period for its pipeline, generating evidence to support innovative tests that will help defeat cancer through earlier detection," said Kevin Conroy, chairman and CEO. "Our powerful commercial engine will help us achieve our mission by getting more people tested with Cologuard®, Oncotype DX®, and our future tests."

Third quarter 2021 financial results

For the three-month period ended September 30, 2021, as compared to the same period of 2020 (where applicable):

- Total revenue was $456.4 million, an increase of 12 percent
- Screening revenue was $280.4 million, an increase of 31 percent
- Precision Oncology revenue was $145.4 million, an increase of 59 percent
- COVID-19 testing revenue was $30.6 million, a decrease of 70 percent
- Gross margin including amortization of acquired intangible assets was 70%, and non-GAAP gross margin excluding amortization of acquired intangible assets was 75%
- Intangible asset impairment of $20.2 million was related to a supply agreement asset recorded as part of the combination with Genomic Health
- Net loss was $166.9 million, or $0.97 per share, compared to a net loss of $202.5 million, or $1.35 per share
- EBITDA was $(119.9) million, and adjusted EBITDA was $(16.3) million
- Cash, cash equivalents, and marketable securities were $1.22 billion at the end of the quarter

Screening includes laboratory service revenue from Cologuard tests and revenue from Biomatrica products. Precision Oncology includes laboratory service revenue from global Oncotype products and laboratory service revenue from Ashion.

2021 outlook

- The company anticipates revenue of $1,722-$1,737 million during 2021, including Screening revenue of $1,050-$1,055 million, Precision Oncology revenue of $547-$552 million, and COVID-19 testing revenue of $125-$130 million.
- Updated revenue guidance has been narrowed toward the high end of our previously expected range of $1,705-$1,745 million, which included Screening revenue of $1,100-$1,125 million, Precision Oncology revenue of $530-$540 million, and COVID-19 testing revenue of $75-$80 million.
- Screening revenue expectations are lower due to the rapid rise in Delta variant cases starting in late July, causing in-person sales calls to significantly decrease in August and September.

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, November 2, 2021, at 5 p.m. ET to discuss third quarter 2021 results. The webcast will be available at www.exactsciences.com. Domestic callers should dial 833-952-1519 and international callers should dial +1-236-714-2125. The access code for both domestic and international callers is 2782364.

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 2782364. The webcast, conference call and replay are open to all interested parties.

About Cologuard
The Cologuard test 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. The Cologuard test is included in the American Cancer Society's (2018) colorectal cancer screening guidelines and the recommendations of the U.S. Preventive Services Task Force (2021) and National Comprehensive Cancer Network (2016). The Cologuard test 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 the Cologuard test if you have had precancer, have inflammatory bowel disease and certain hereditary syndromes, or have a personal or family history of colorectal cancer. The Cologuard test is not a replacement for colonoscopy in high risk patients. The Cologuard test 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 the Cologuard test. For more information about the Cologuard test, visit www.cologuardtest.com.

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. The Oncotype MAP® Pan-Cancer Tissue test is a rapid, comprehensive tumor profiling panel that aids therapy selection for patients with advanced, metastatic, refractory, or recurrent cancer. With more than 1 million patients tested in more than 90 countries, the Oncotype tests have redefined personalized medicine by making genomics a critical part of cancer diagnosis and treatment. To learn more about Oncotype 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 tests, Exact Sciences is investing in its product pipeline to support patients throughout their cancer diagnosis and treatment. 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 cancer and COVID-19 testing 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; our ability to realize the benefits of our recently hired sales representatives and our promotion agreement with Pfizer; 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 obtain and 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 per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenue	$ 456,379	$ 408,363	$ 1,293,275	$ 1,025,052
Operating expenses				
Cost of sales (exclusive of amortization of acquired intangible assets)	115,738	95,061	339,699	254,559
Research and development	75,356	31,471	297,158	107,653
Sales and marketing	196,617	136,481	577,585	423,092
General and administrative	186,541	115,589	621,897	336,265
Amortization of acquired intangible assets	23,940	23,430	70,954	70,199
Intangible asset impairment charge	20,210	209,666	20,210	209,666
Total operating expenses	618,402	611,698	1,927,503	1,401,434
Other operating income	—	—	—	23,665
Loss from operations	(162,023)	(203,335)	(634,228)	(352,717)
Other income (expense)				
Investment income (expense), net	(4,093)	2,523	30,524	5,532
Interest expense	(4,680)	(4,478)	(13,948)	(63,382)
Total other income (expense)	(8,773)	(1,955)	16,576	(57,850)
Net loss before tax	(170,796)	(205,290)	(617,652)	(410,567)
Income tax benefit	3,858	2,752	242,638	5,294
Net loss	$ (166,938)	$ (202,538)	$ (375,014)	$ (405,273)
Net loss per share—basic and diluted	$ (0.97)	$ (1.35)	$ (2.19)	$ (2.71)
Weighted average common shares outstanding—basic and diluted	171,978	150,155	170,978	149,346

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

	September 30, 2021	December 31, 2020
Assets		
Cash and cash equivalents	$ 273,779	$ 1,491,288
Marketable securities	944,688	348,699
Accounts receivable, net	249,572	233,185
Inventory	95,167	92,265
Prepaid expenses and other current assets	52,385	33,157
Property, plant and equipment, net	524,200	451,986
Operating lease right-of-use assets	167,911	125,947
Goodwill	2,242,535	1,237,672
Intangible assets, net	2,044,958	847,123
Other long-term assets, net	59,241	63,770
Total assets	$ 6,654,436	$ 4,925,092
Liabilities and stockholders' equity		
Convertible notes, net, current portion	$ 313,104	$ 312,716
Current liabilities	397,127	320,380
Convertible notes, net, less current portion	1,865,647	1,861,685
Long-term debt, less current portion	21,438	22,342
Other long-term liabilities	436,580	51,342
Operating lease liabilities, less current portion	162,950	121,075
Total stockholders’ equity	3,457,590	2,235,552
Total liabilities and stockholders’ equity	$ 6,654,436	$ 4,925,092

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

(In thousands)	Three Months Ended September 30, 2021	Three Months Ended September 30, 2020	Nine Months Ended September 30, 2021	Nine Months Ended September 30, 2020
Net loss	$ (166,938)	$ (202,538)	$ (375,014)	$ (405,273)
Interest expense	4,680	4,478	13,948	12,563
Depreciation and amortization	46,200	43,143	135,221	123,544
Income tax benefit	(3,858)	(2,752)	(242,638)	(5,294)
EBITDA	$ (119,916)	$ (157,669)	$ (468,483)	$ (274,460)
Stock-based compensation	59,132	37,317	176,095	102,839
Investment expense (income)	4,093	(2,523)	(30,524)	(5,532)
Acquisition and integration costs [1]	10,150	7,706	141,401	19,474
Asset acquisition [2]	—	—	85,337	—
Loss on settlement of convertible notes [3]	—	—	—	50,819
CARES Act Funding [4]	—	—	—	(23,665)
Intangible asset impairment charge [5]	20,210	209,666	20,210	209,666
Legal settlement [6]	10,064	—	10,064	—
Reduction-in-force severance [7]	—	—	—	2,198
Adjusted EBITDA	$ (16,267)	$ 94,497	$ (65,900)	$ 81,339

(1) Represents acquisition and related integration costs incurred as a result of the Company's business combinations and asset acquisitions, a majority of which relates to the acquisition of Thrive Earlier Detection Corp. ("Thrive") for the three and nine months ended September 30, 2021. Stock-based compensation including the incremental fair value of assumed stock awards and accelerated vesting from post-acquisition qualified termination events was $4.5 million and $107.2 million for the three and nine months ended September 30, 2021, respectively. For the nine months ended September 30, 2021, $5.2 million of total stock-based compensation costs were related to stock awards that were cash-settled. Stock-based compensation including the incremental fair value of assumed stock awards and accelerated vesting from post-acquisition qualified termination events was $4.2 million and $8.2 million for the three and nine months ended September 30, 2020. Legal and other professional service fees were $3.9 million and $23.2 million for the three and nine months ended September 30, 2021, respectively. Legal and other professional service fees were $3.5 million and $11.3 million for the three and nine months ended September 30, 2020, respectively. Expense of $1.8 million and $11.0 million was incurred for the three and nine months ended September 30, 2021 resulting from the remeasurement of the contingent consideration liabilities in connection with business combinations.

(2) During the first quarter of 2021, the Company acquired a worldwide exclusive license to the proprietary Targeted Digital Sequencing ("TARDIS") technology from The Translational Genomics Research Institute ("TGen"). The acquisition was treated as an asset acquisition under U.S. GAAP and resulted in a $52.3 million charge to research and development expense. During the second quarter of 2021, the Company acquired PFS Genomics, Inc. The acquisition was treated as an asset acquisition under U.S. GAAP and resulted in a $33.1 million charge to research and development expense.

(3) The loss on settlement of convertible notes represents the difference between (i) the fair value of the consideration transferred and (ii) the sum of the carrying value of the debt at the time of repurchase for $100 million of convertible notes with an original maturity of January 15, 2025.

(4) 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.

(5) During the third quarter of 2021, the Company determined that the supply agreement intangible asset recorded as part of the combination with Genomic Health was impaired due to the performance of the underlying product. As a result, and in connection with the preparation of the financial statements, the Company recorded a non-cash, pre-tax impairment of $20.2 million.

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.

(6) During the third quarter of 2021, the Company presented a settlement offer of approximately $10 million to the United States Department of Justice ("DOJ") concerning the DOJ's investigation of Genomic Health's compliance with the Medicare Date of Service billing regulations, which was accrued for as of September 30, 2021. This represents the Company's best estimate of the probable loss for this matter, but the recorded amount may be materially adversely affected by an ultimate unfavorable resolution of this matter.

(7) 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 $2.2 million for the nine months ended September 30, 2020.

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,	
	2021	2020	2021	2020
Revenue	$ 456,379	$ 408,363	$ 1,293,275	$ 1,025,052
Cost of sales (exclusive of amortization of acquired intangible assets)	115,738	95,061	339,699	254,559
Amortization of acquired intangible assets [(1)]	21,214	20,555	62,957	61,573
Gross profit	$ 319,427	$ 292,747	$ 890,619	$ 708,920
Gross margin	70 %	72 %	69 %	69 %
Amortization of acquired intangible assets [(1)]	21,214	20,555	62,957	61,573
Non-GAAP gross profit	$ 340,641	$ 313,302	$ 953,576	$ 770,493
Non-GAAP gross margin	75 %	77 %	74 %	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.