
**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): **January 6, 2022**

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 January 9, 2022, Exact Sciences Corporation (the “Company”) announced certain preliminary financial information for the quarter and full year ended December 31, 2021. A copy of the press release is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangement of Certain Officers.

Per the request of Kevin Conroy, Chief Executive Officer, and Jeffrey Elliott, Chief Financial Officer and Chief Operating Officer, on January 6, 2022 the Company’s Human Capital Committee approved the issuance of restricted stock units to Mr. Conroy and Mr. Elliott in lieu of one-half of their base salary for 2022.

7.01. Regulation FD Disclosure.

On January 9, 2022, the Company issued a press release announcing the acquisition of PreventionGenetics LLC. A copy of the press release is being furnished as Exhibit 99.2 to this Current Report on Form 8-K.

On January 9, 2022, the Company issued a press release announcing the entry into an exclusive license agreement with OncXerna Therapeutics, Inc. A copy of the press release is being furnished as Exhibit 99.3 to this Current Report on Form 8-K.

The Company posted the PowerPoint presentation that it plans to present at the 2022 J.P. Morgan Healthcare Conference on January 9, 2022 to the Company's website, www.exactsciences.com, on the Events & Presentations page under the Investor Relations tab.

The information set forth under this Item 7.01, including Exhibit 99.1, Exhibit 99.2, and Exhibit 99.3, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or incorporated by reference in any filing under the Securities Act or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

9.01. Financial Statements and Exhibits.

Exhibits

The exhibits furnished as a part of this Current Report on Form 8-K are listed in the Exhibit Index attached hereto and incorporated herein by reference.

The information furnished in this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, 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 into any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

<u>Exhibit No.</u>	<u>Exhibit Description</u>
99.1	Press release, dated January 9, 2022, issued by Exact Sciences Corporation, furnished herewith
99.2	Press release, dated January 9, 2022, issued by Exact Sciences Corporation, furnished herewith
99.3	Press release, dated January 9, 2022, 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: January 10, 2022

By: /s/ Jeffrey T. Elliott
Jeffrey T. Elliott
Executive Vice President, Chief Financial Officer and Chief Operating Officer

Investor Relations Contact:

Megan Jones
 meganjones@exactsciences.com
 608-535-8815

Media Contact:

Katie Boyce
 kboyce@exactsciences.com
 608-710-3903

For Immediate Release

Exact Sciences Announces Preliminary Fourth Quarter 2021 Results

- Expected total fourth quarter revenue of \$472-475M, including Screening revenue of \$277-278M, Precision Oncology revenue of \$148.5-149.5M, and COVID-19 testing revenue of \$46.5-47.5M
- Total 2021 revenue, excluding COVID-19 testing, increased 29% compared to 2020, including 30% increase in Screening revenue and 27% increase in Precision Oncology revenue
- Screening revenue growth driven by Cologuard rescreens, Cologuard use in 45-49 age group, expansion of primary care sales team, and increased in-person sales calls

MADISON, Wis., Jan. 9, 2022 — Exact Sciences Corp. (Nasdaq: EXAS) today announced that the company expects to report revenue between \$472 million and \$475 million for the fourth quarter ended Dec. 31, 2021.

"The Exact Sciences team delivered outstanding results to finish 2021, setting us up for years of strong growth and a clear path to profitability," said Kevin Conroy, chairman and CEO of Exact Sciences. "Our goal is to make earlier cancer detection a routine part of medical care. Led by our top brands, Cologuard® and Oncotype DX®, and an exciting pipeline of tests in colon cancer screening, multi-cancer early detection, and minimal residual disease and recurrence monitoring, we plan to fundamentally change how cancer patients are diagnosed and treated."

Preliminary, Unaudited Fourth Quarter 2021 Financial Results

For the three-month period ended Dec. 31, 2021, as compared to the same period of 2020:

- Total revenue between \$472 million and \$475 million, an increase of 2 percent
- Total revenue, excluding COVID-19 testing, increased 16 percent
- Screening revenue between \$277 million and \$278 million, an increase of 11 percent
- Precision Oncology revenue between \$148.5 million and \$149.5 million, an increase of 27 percent
- COVID-19 testing revenue between \$46.5 million and \$47.5 million, a decrease of 53 percent

Preliminary, Unaudited 2021 Financial Results

For the twelve-month period ended Dec. 31, 2021, as compared to the same period of 2020:

- Total revenue between \$1,765.3 million and \$1,768.3 million, an increase of 18 percent
- Total revenue, excluding COVID-19 testing, increased 29 percent
- Screening revenue between \$1,061.6 million and \$1,062.6 million, an increase of 30 percent
- Precision Oncology revenue between \$561.1 million and \$562.1 million, an increase of 27 percent
- COVID-19 testing revenue between \$142.5 million and \$143.5 million, a decrease of 39 percent

For the fourth quarter and 2021, Screening includes laboratory service revenue from Cologuard tests and revenue from Biomatrix products. Precision Oncology includes laboratory service revenue from global Oncotype and GEM ExTra laboratory service revenue.

Exact Sciences has not completed preparation of its financial statements for the fourth quarter or full year of 2021. The revenue ranges presented in this news release for the fourth quarter of 2021 and for the year ended Dec. 31, 2021 are preliminary and unaudited and are thus inherently uncertain and subject to change as we complete our financial results for the fourth quarter of 2021. Exact Sciences is in the process of completing its customary year-end close and review procedures as of and for the year ended Dec. 31, 2021, and there can be no assurance that final results for this period will not differ from these estimates. During the course of the preparation of Exact Sciences' consolidated financial statements and related notes as of and for the year ended Dec. 31, 2021, the company's independent registered public accountants may identify items that could cause final reported results to be materially different from the preliminary financial estimates presented herein.

Exact Sciences plans to report 2021 financial results during its February 2022 earnings call.

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. The Cologuard test 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. 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 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 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 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 Acquires PreventionGenetics to Accelerate Availability of Hereditary Cancer Testing for More Patients

PreventionGenetics' comprehensive genetic testing portfolio complements Exact Sciences' advanced cancer tests, enabling disease prevention and earlier cancer detection to benefit patients across decades of life

Foundational laboratory and skilled team with experience in sequencing, informatics, and genetic counseling will support entrance into hereditary cancer testing

MADISON, Wis., January 9, 2022 – Exact Sciences Corp. (NASDAQ: EXAS) announced today it has acquired PreventionGenetics, a genetic testing laboratory, to complement its advanced cancer diagnostics portfolio and support its entrance into hereditary cancer testing (HCT). PreventionGenetics provides the clinical lab, expertise, and foundational technology necessary to accelerate the availability of HCT and help more patients know their germline risk of cancer and other diseases.

“PreventionGenetics is a natural fit with Exact Sciences, and we’re thrilled to have their talented team join in our mission to make earlier cancer detection a routine part of medical care,” said Kevin Conroy, Exact Sciences chairman and CEO. “We share in PreventionGenetics’ belief that genetics can transform medicine, improve lives, and help eradicate cancer. With our deep relationships in primary care and PreventionGenetics’ strong reputation among genetics specialists, Exact Sciences can help more people understand their inherited risk of cancer to catch it earlier and treat it more effectively.”

Nearly 300,000 health care providers and more than 200 large U.S. health systems rely on Exact Sciences’ Cologuard® and Oncotype DX® tests in primary care, women’s health, oncology, and other specialties. In partnership with the PreventionGenetics team, Exact Sciences plans to leverage its unmatched commercial reach in diagnostics to expand hereditary cancer and genetic testing throughout the U.S. and globally.

PreventionGenetics is a CLIA-certified and CAP-accredited clinical DNA testing laboratory, providing more than 5,000 predefined genetic tests for nearly all clinically relevant genes, additional custom panels, and comprehensive germline whole exome and whole genome sequencing tests. With a goal to improve lives through genetic testing, PreventionGenetics offers tests spanning decades of life including proactive health and wellness, cancer risk and screening, pediatric and adult-onset rare diseases, and others. These high-quality genetic tests are supported by deep sequencing capabilities and more than 100 peer-reviewed publications.

Like Exact Sciences, the PreventionGenetics team is relentless in their pursuit of quality. This focus, combined with a best-in-class customer experience and turnaround times, has earned PreventionGenetics a strong reputation and brand recognition among genetics specialists and counselors.

Transaction Terms

Under the terms of the agreement, PreventionGenetics received total consideration of \$190 million, comprised of 50% in Exact Sciences common stock and 50% in cash. PreventionGenetics expects preliminary, unaudited 2021 revenue of approximately \$36 million and \$43 million in adjusted EBITDA. XMS Capital served as financial advisor to Exact Sciences and K&L Gates served as its legal advisor. CrossTree Capital served as financial advisor to PreventionGenetics, and Winston & Strawn served as legal advisor.

About PreventionGenetics

Founded in 2004 and located in Marshfield, Wisconsin, PreventionGenetics is a CLIA and ISO 15189:2012 accredited laboratory. PreventionGenetics delivers clinical genetic testing of the highest quality at fair prices with exemplary service to people around the world. PreventionGenetics has 25 PhD geneticists on staff and provides tests for nearly all clinically relevant genes including the powerful and comprehensive germline whole genome sequencing test, PGnome® and whole exome sequencing test, PGxome®.

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 the Cologuard® and Oncotype® tests, 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

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Exact Sciences Media Contact: Katie Boyce, kboyce@exactsciences.com, 608-710-3903

Exact Sciences Investor Contact: Megan Jones, meganjones@exactsciences.com, 608-535-8815



Exact Sciences and OncXerna Announce Licensing Agreement to Help Predict Immunotherapy Response for More Patients

Agreement grants a license to Exact Sciences for OncXerna's Xerna™ TME Panel adding to its comprehensive tumor profiling solution, GEM ExTra®

Arrangement expands Exact Sciences' ability to support immuno-oncology clinical development programs

MADISON, Wis., and WALTHAM, Mass., January 9, 2022 – Exact Sciences Corp. (NASDAQ: EXAS) and OncXerna Therapeutics, Inc., a precision medicine company, announced today they have entered an exclusive license agreement to bring OncXerna's Xerna TME Panel lab services to more U.S. patients. The Xerna TME (tumor microenvironment) Panel is an innovative gene expression score that helps identify patients likely to respond to anti-angiogenic and immunotherapies. The agreement allows Exact Sciences to provide more critical answers to cancer patients and physicians facing difficult therapy selection decisions while supporting biopharma partners in patient selection for their therapeutic programs.

“As the role of immunotherapy in cancer treatment grows, a critical unmet need among oncologists and healthcare professionals is being able to predict a patient's response to specific drugs prior to starting treatment,” said Matt Franklin, general manager of Precision Oncology for Exact Sciences. “The immunotherapy prediction ability of OncXerna's Xerna TME Panel, coupled with the comprehensive profiling capabilities of Exact Sciences' GEM ExTra test, has the potential to significantly impact patient outcomes.”

The Xerna TME Panel uses proprietary RNA-based gene expression data and a machine learning-based algorithm to classify patients based on the interplay between angiogenic and immunogenic dominant biologies of the TME. Early clinical evidence suggests that it may be the first RNA TME signature to predict immunotherapy benefit.¹ Exact Sciences plans to offer the Xerna TME Panel as part of its GEM ExTra test, further enhancing its sequencing offerings. GEM ExTra includes a comprehensive whole exome genomic profile and deep transcriptome analysis to identify actionable alterations associated with targeted therapy benefit or resistance. The Xerna TME Panel will provide additional insights into the benefit of immunotherapy alone or in combination with other therapies from the same patient sample.

Laura Benjamin, CEO of OncXerna Therapeutics, commented, “With this licensing agreement, Exact Sciences can now expand their GEM ExTra offering beyond genomic and transcriptomic-profiling options and provide customers with an expression signature to analyze biologies that are relevant for emerging therapeutics from across the industry. OncXerna continues to use the Xerna TME Panel to support its two internal clinical programs and is pleased to make it available more broadly to accelerate additional advances in precision oncology.”

In the future, Exact Sciences expects to provide clinicians broad access to the Xerna TME Panel through its existing Precision Oncology team and to biopharma partners as a companion diagnostic.

About the Xerna TME™ Panel

The Xerna TME Panel uses proprietary RNA-based gene expression data and a machine learning-based algorithm to classify patients based on the interplay between angiogenic and immunogenic dominant biologies of the tumor microenvironment (TME). The Xerna TME Panel is an investigational assay and has not been approved by the FDA.

¹Chau, I. Phase 2 Study of Baviximab, a First-in-class Antibody Targeting Phosphatidylserine, Plus Pembrolizumab in Advanced Gastric or Gastroesophageal Junction Cancer. Poster presented at: The European Society for Medical Oncology; September 16-21, 2021.

About OncXerna Therapeutics

OncXerna Therapeutics is a clinical stage oncology company developing novel monoclonal antibodies to treat solid tumors. In combination with its innovative precision medicine platform, the Xerna TME Panel, OncXerna leverages artificial intelligence technologies and RNA expression-based biomarkers to match a specific patient's tumor with the drugs best suited to treat that tumor. Our current clinical pipeline includes the company's lead product candidate, Navicixizumab, which is a bispecific antibody that targets both VEGF and DLL4 to treat solid tumors and is currently entering a Phase 2/3 study for the treatment of ovarian cancer. By integrating our novel Xerna TME Platform with our deep expertise in clinical development, we believe we can accelerate the development, approval and commercialization of drug product candidates and bring meaningful new treatments to patients at an earlier point in time in their disease progression. For more information, please visit oncxerna.com, or follow us on LinkedIn and Twitter.

About Exact Sciences' Therapy Selection Program and GEM ExTra® test

Exact Sciences' therapy selection program includes two comprehensive genomic profiling (CGP) tests to help physicians identify the genomic mutations driving advanced cancers, leading patients to better care through targeted cancer treatments. The GEM ExTra test detects damage in tumor genes and provides a complete biological picture of certain refractory, rare, or aggressive cancers. With an extensive panel of approximately 20,000 genes and 169 introns, the GEM ExTra test is one of the most comprehensive genomic (DNA) and transcriptomic (RNA) panels available today. The GEM ExTra test provides physicians, academic medical centers, and biopharma researchers with vital interpreted information to understand changes to a patient's tumor genomic profile and recommend therapeutic treatment plans.² For patients with advanced and metastatic cancer, the company offers the Oncotype MAP® test, a rapid, comprehensive tumor profiling panel, which delivers results in three to five business days³ and allows physicians to understand a patient's tumor profile and recommend actionable targeted therapies or clinical trials.

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Exact Sciences Media Contact: Stephanie Spanos, sspanos@exactsciences.com, 608-556-4380

Exact Sciences Investor Contact: Megan Jones, meganjones@exactsciences.com, 608-535-8815

OncXerna Investor and Media Contact: Ashley R. Robinson, LifeSci Partners, LLC, arr@lifesciadvisors.com

² Science Translational Medicine, 15 Apr 2015: Vol. 7, Issue 283, pp. 283ra53, DOI: 10.1126/scitranslmed.aaa7161

³ Exact Sciences internal data on file. Turnaround time based on qualified sample receipt.