

---

---

# 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): **July 10, 2008**

## EXACT SCIENCES CORPORATION

(Exact Name of Registrant as Specified in its Charter)

**Delaware**

(State or Other Jurisdiction of Incorporation)

**000-32179**

(Commission File Number)

**02-0478229**

(IRS Employer Identification No.)

**100 Campus Drive, Marlborough, Massachusetts**

(Address of Principal Executive Offices)

**01752**

(Zip Code)

Registrant's telephone number, including area code: **(508) 683-1200**

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 ( *see* General Instruction A.2. below):

- ☐ 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))
- 
- 
-

**Item 8.01            Other Events.**

On July 10, 2008, EXACT Sciences Corporation issued a press release, a copy of which is being filed as Exhibit 99.1 to this Report on Form 8-K and is incorporated herein by reference.

**Item 9.01            Financial Statements and Exhibits.**

(d)       Exhibits:

99.1       Press Release issued by the registrant on July 10, 2008.

## 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

July 10, 2008

By: /s/ Charles R. Carelli, Jr.

---

Charles R. Carelli, Jr.  
Senior Vice President, Chief Financial  
Officer, Treasurer and Secretary

## EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description</u>
-----------------------	--------------------

99.1	Press Release issued by the registrant on July 10, 2008.
------	--

**Press Release**

---

**For further information:**

**EXACT Sciences Corporation**  
Jeffrey R. Luber  
President & Chief Executive Officer  
+1 (508) 683-1275

---

**EXACT Sciences Provides Regulatory Update for its Version 2 Stool-based DNA Technology for Colorectal Cancer Screening**

**Marlborough, MA — July 10, 2008** — EXACT Sciences Corporation (NASDAQ: EXAS) today announced that it has confirmed with the U.S. Food and Drug Administration (FDA) the clinical performance characteristics and the minimum number of average-risk cancer samples that will be required for validation of its Version 2 stool-based DNA technology for colorectal cancer screening. In order to bolster the statistical power of the clinical study, EXACT intends to accrue more clinical samples than the threshold that the FDA indicated would be acceptable. As a result, the Company believes that the clinical study, as well as the contemporaneous requisite technical studies, will take approximately six to nine months to complete based on expected enrollment rates. This timing would allow for an anticipated *de novo* 510 (k) filing in the third quarter of 2009, and potential clearance or approval of its Version 2 technology in the first quarter of 2010. EXACT estimates that total study and regulatory costs will range from \$6.5 to \$8.5 million. The Company's current cash and short term investments provide for approximately \$2 million through the end of 2008 to begin the clinical and technical validation studies.

"We are very pleased to be moving forward with greater clarity regarding the minimum size and clinical performance requirements of our clinical study," said Jeffrey R. Luber, President and Chief Executive Officer of EXACT Sciences. "Confirmation from the FDA on these points has been a critical precondition for planning and execution purposes, enabling us to retain a CRO and begin site recruitment efforts."

The prospective, multi-center study, which is expected to include approximately 30 sites participating across the United States and Canada, is currently designed to screen up to 5,000 asymptomatic individuals aged 50 or older who are at average risk for developing colorectal cancer (CRC). This study population would be expected to yield a minimum of 25 acceptable CRC cases. Clinical samples will be collected prior to colonoscopy from this screening population. The clinical study is powered to exceed the FDA's minimum sensitivity performance threshold of a 95 percent confidence interval with a lower bound of 50 percent. Accordingly, the more cancer samples obtained in the study, the greater the likelihood of achieving a 95 percent confidence interval. For example, the Company believes that with 25 cancers, a sensitivity of approximately 72 percent would meet the FDA's minimum criteria. This study, as well as results from a prior Version 2 technology

---

study recently accepted by a major gastroenterology journal, would further validate Version 2 under the American Cancer Society's CRC screening guidelines, which require a test to identify the majority of CRCs in a screening population.

The clinical study will be managed by Averion International Corp., a leading international clinical research organization with proven expertise in supporting global clinical trials. Dr. Philip Lavin, Executive Chairman of Averion International Corp., will have direct responsibility at Averion for oversight of the study. Dr. Lavin has served on multiple FDA Advisory panels since 1983. Averion has helped clients achieve more than 50 FDA product approvals, including oncology-related tests such as prostate specific antigen (PSA) and CA-125.

### **About Colorectal Cancer**

Colorectal cancer is the most deadly cancer among non-smoking men and women in the United States, and the second most deadly cancer overall. The American Cancer Society estimates that nearly 150,000 cases will be diagnosed and 50,000 deaths are anticipated in 2008 due to this disease. Despite the availability of colorectal cancer screening and diagnostic tests for more than 20 years, the rate of early detection of colorectal cancer remains low, and deaths remain high. It is estimated that roughly one-third of colorectal cancer-related deaths could be saved if more people underwent regular screening. Early diagnosis results in a greater than 90 percent, five-year survival rate.

### **EXACT Sciences Corporation**

EXACT Sciences Corporation uses applied genomics to develop, patient-friendly screening technologies for use in the detection of cancer. EXACT maintains an exclusive license agreement with Laboratory Corporation of America<sup>®</sup> Holdings (LabCorp<sup>®</sup>) relating to the Company's intellectual property. EXACT Sciences' stool-based DNA technology is included in the colorectal cancer screening guidelines of the American Cancer Society and the U.S. Multi-Society Task Force on Colorectal Cancer (a group comprised of representatives from the American College of Gastroenterology, American Gastroenterological Association, and American Society for Gastrointestinal Endoscopy), and the American College of Radiology. EXACT Sciences is based in Marlborough, Mass.

Certain statements made in this press release that are not based on historical information are express or implied forward-looking statements relating to, among other things, EXACT Sciences' expectations concerning the size, timing, and costs of its clinical and technical studies and management's plans, objectives and strategies. These statements are neither promises nor guarantees, but are subject to a variety of risks and uncertainties, many of which are beyond EXACT Sciences' control, and which could cause actual results to differ materially from those contemplated in these forward-looking statements. In particular, the risks and uncertainties include, among other things, EXACT Sciences' ability to secure FDA approval or clearance for any of its products; changes in FDA guidance or policy; the ability to raise additional capital on acceptable terms; the clinical performance and market acceptance of its technologies; the reproducibility of its research results in subsequent studies and in clinical practice; sufficient investment in the sales and marketing of EXACT Sciences' technologies; the success of its strategic relationship with LabCorp; EXACT Sciences' ability to license certain technologies or obtain raw materials for its technologies; the ability to convince Medicare and other third-party payors to provide adequate reimbursement for EXACT Sciences' technologies; the ability to convince medical practitioners to order tests using EXACT Sciences' technologies; the ability to increase the performance its technologies; the ability of EXACT Sciences or LabCorp to lower the cost of stool-based DNA screening technologies through automating and simplifying key operational processes; the number of people who decide to be screened for colorectal cancer using EXACT Sciences' technologies; competition; the ability to protect EXACT Sciences' intellectual property and the cost of enforcing or defending EXACT Sciences in litigation relating to intellectual property rights; and the possibility that other companies will develop and market novel or improved methods for detecting colorectal cancer. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak

---

only as of the date hereof. EXACT Sciences undertakes no obligation to update or revise the information contained in this press release, whether as a result of new information, future events or circumstances or otherwise. For additional disclosure regarding these and other risks faced by EXACT Sciences, see the disclosure contained in EXACT Sciences' public filings with the Securities and Exchange Commission including, without limitation, its most recent Annual Report on Form 10-K and subsequent Quarterly Reports on Form 10-Q filed with the SEC.

###

---