

---

---

# 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 16, 2007**

## 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 7.01 Regulation FD Disclosure.**

On October 16, 2007 EXACT Sciences Corporation issued a press release, a copy of which is being furnished as Exhibit 99.1 to this Report on Form 8-K.

The information in this Report on Form 8-K and Exhibit 99.1 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.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits:

99.1 Press Release issued by the registrant on October 16, 2007, 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

October 16, 2007

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

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

## EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release issued by the registrant on October 16, 2007, furnished herewith.

---

**Press Release****For further information:**

**EXACT Sciences Corporation**  
Jeffrey Luber  
President  
EXACT Sciences Corporation  
+1 (508) 683-1211

**EXACT Sciences Announces FDA and Regulatory Update Conference Call;  
Receives Warning Letter From the Food and Drug Administration**

**Marlborough, MA – October 16, 2007** – EXACT Sciences Corporation (NASDAQ: EXAS) announced today that it has received a Warning Letter from the Food and Drug Administration’s (FDA) Office of *In Vitro* Diagnostic Device Evaluation and Safety regarding regulatory matters related to its DNA technology for colorectal cancer screening. According to the letter, the FDA believes that the PreGen-Plus™ assay is a medical device requiring premarket approval or clearance.

“Having spoken with the FDA regarding the letter, we are committed to working collaboratively with them to pursue the appropriate filing strategy for our DNA colorectal cancer screening technology,” said Jeffrey R. Luber, President of EXACT Sciences Corporation. “We have a meeting scheduled with the FDA in the coming weeks and intend to file a 510(k) application with the FDA as soon as possible to resolve these issues. A potential regulatory filing for our patent-protected technology had already been a long-term strategy for EXACT and we will now be accelerating these activities.”

The Company expects that the letter will be publicly available within a few days on the FDA’s website at <http://www.fda.gov/foi/warning.htm>.

EXACT will host a FDA regulatory update call regarding its stool-based DNA technology on Wednesday, October 17, 2007 at 8:30 a.m. ET.

Information for the October 17, 2007 call is as follows:

Domestic callers: 866-825-3354  
International callers: 617-213-8063  
Participant Passcode: 67908163

The conference call replay information is as follows:

Domestic callers: 888-286-8010  
International callers: 617-801-6888  
Participant Passcode: 83488659

---

A live Webcast of the conference call can be accessed at [www.exactsciences.com](http://www.exactsciences.com) through the Investor Relations link. The conference call and the Webcast are open to all interested parties. An archived version of the Webcast will be available at EXACT Sciences' Web site, [www.exactsciences.com](http://www.exactsciences.com), through the Investor Relations link, for one month. A replay of the conference call also will be available for 48 hours, beginning two hours after the completion of the live call.

The webcast is also being distributed over CCBN's Investor Distribution Network to both institutional and individual investors. Individual investors can listen to the call through CCBN's individual investor center at [www.companyboardroom.com](http://www.companyboardroom.com) or by visiting any of the investor sites in CCBN's Individual Investor Network. Institutional investors can access the call via CCBN's password-protected event management site, StreetEvents ([www.streetevents.com](http://www.streetevents.com)).

### **EXACT Sciences Corporation**

EXACT Sciences Corporation uses applied genomics to develop effective, patient-friendly screening technologies for use in the detection of cancer. Certain of its technologies have been licensed to Laboratory Corporation of America Holdings® (LabCorp®) for a stool-based DNA assay developed by LabCorp for colorectal cancer screening in the average-risk population and marketed by LabCorp under the name PreGen-Plus™. Colorectal cancer, which is the most deadly cancer among non-smokers, is generally curable if detected early. 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 from colorectal cancer remain high. EXACT Sciences believes its genomics-based technologies will help enable earlier detection of colorectal cancer so that more people can be effectively treated. EXACT Sciences is based in Marlborough, Mass. PreGen-Plus, the non-invasive colorectal cancer screening testing service offered by LabCorp, has not been approved or cleared by the U.S. Food & Drug Administration.

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, among other things, the regulatory strategy for its DNA technology 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, the clinical performance and market acceptance of its technologies; the reproducibility of its research results in subsequent studies and in clinical practice; the ability of EXACT Sciences to comply with federal and state statutes and regulations relating to EXACT Sciences' products and services, including FDA requirements; the inclusion of fecal DNA screening in colorectal cancer screening guidelines; the success of its strategic relationship with LabCorp; the ability to convince Medicare and other third-party payors to provide adequate reimbursement for EXACT Sciences' technologies; the ability to increase the performance of the PreGen-Plus test; the ability of EXACT Sciences or LabCorp to lower the cost of the PreGen-Plus test through automating and simplifying key operational processes; competition; the possibility that other companies will develop and market novel or improved methods for detecting colorectal cancer; and the ability to raise additional capital on acceptable terms. 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 the 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.

###

---