

# 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): March 1, 2005

## EXACT SCIENCES CORPORATION

(Exact Name of Registrant as Specified in its Charter)

### Delaware

(State or Other Jurisdiction of Incorporation)

000-32179

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(Commission File Number)

02-0478229

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(IRS Employer Identification No.)

100 Campus Drive, Marlborough, Massachusetts

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(Address of Principal Executive Offices)

01752

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(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 March 1, 2005 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.**

(c) Exhibits:

99.1 Press Release issued by the Company on March 1, 2005, 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

*March 1, 2005*

*By: /s/ Don Hardison  
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Don Hardison  
President and CEO*

## EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release issued by the Company on March 1, 2005, furnished herewith.

## PreGen-Plus Meets All Criteria of Blue Shield's California Technology Assessment Forum

MARLBOROUGH, Mass.--(BUSINESS WIRE)--March 1, 2005--EXACT Sciences Corporation (NASDAQ:EXAS) today announced that the California Technology Assessment Forum (CTAF), a program of the Blue Shield of California Foundation, unanimously agreed at its recent meeting that colorectal cancer screening with PreGen-Plus meets all five of CTAF's assessment criteria for new medical technologies. PreGen-Plus is EXACT Sciences' non-invasive stool-based DNA screening technology for the early detection of colorectal cancer. CTAF has confirmed that it will recommend approval of PreGen-Plus to the Blue Shield of California Foundation Board of Trustees at its meeting in May. Although approval by CTAF does not guarantee coverage of PreGen-Plus by Blue Shield of California, it is a critical first step. CTAF's assessment criteria are substantially similar to the assessment criteria used by other Blue Cross Blue Shield technology assessment groups across the country in evaluating new medical technologies for approval. In order to meet CTAF's assessment criteria, new technologies must, among other things, be supported by convincing medical evidence that their use leads to improved health outcomes. "CTAF's positive review of PreGen-Plus is gratifying on many levels" said Don Hardison, EXACT's President and Chief Executive Officer. "While we have always believed that our technology addressed a critical healthcare need, we now have CTAF's important independent evaluation, in addition to our compelling clinical evidence to date, that our technology improves health outcomes for the general population. With new and costly colorectal cancer treatment drugs coming to market, we believe that our test is a critical prevention tool for those payors looking to reduce costs associated with late stage colorectal cancer. We intend to encourage other large payor organizations across the country to follow CTAF's lead in approving PreGen-Plus to focus on colorectal cancer prevention in the general population."

### **About the California Technology Assessment Forum**

The California Technology Assessment Forum (CTAF) is a program of the Blue Shield of California Foundation. The California Technology Assessment Forum is a community forum dedicated to objectivity and transparency regarding medical technologies; a community forum for dialog and decisions regarding the safety and effectiveness of new and emerging technologies; and a public benefit for California. The California Technology Assessment Forum reviews approximately 15 to 20 new and emerging medical technologies each year. [www.ctaf.org](http://www.ctaf.org).

### **About Blue Shield of California Foundation**

Blue Shield of California Foundation was formed by Blue Shield of California, a not-for-profit corporation with more than 3.2 million members, 4,300 employees and 20 offices throughout California. The Blue Shield of California Foundation provides charitable contributions and conducts research and supports programs with an emphasis on domestic violence prevention, medical technology assessment and reducing the number of uninsured. For more information, visit the Blue Shield of California website at [www.mylifepath.com](http://www.mylifepath.com) or the Foundation at [www.blueshieldcafoundation.org](http://www.blueshieldcafoundation.org).

### **About EXACT Sciences Corporation**

EXACT Sciences Corporation is a leader in applying genomics knowledge to develop patient-friendly screening methods to detect cancer early, to assist physicians in saving patients' lives. Its first commercial test, PreGen-Plus(TM), is used for screening colorectal cancer in the average-risk population. Colorectal cancer, which is the most deadly cancer among non-smokers, is 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 enable early detection of colorectal cancer so that more people can be effectively treated. Founded in 1995, EXACT Sciences is based in Marlborough, Mass. Detailed information on EXACT Sciences and PreGen-Plus can be found on the World Wide Web at [www.exactsciences.com](http://www.exactsciences.com) and [www.pregenplus.com](http://www.pregenplus.com).

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, its business outlook and business momentum (including the size of the potential market for its technologies), the likelihood of third-party reimbursement of its technologies, and the effectiveness and market acceptance of its technologies. 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 ability of EXACT Sciences to become profitable; the success of its strategic relationship with LabCorp; its 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' products and services; the ability to convince medical practitioners to order tests using EXACT Sciences' technologies; the ability to increase the performance of the PreGen-Plus test; the ability of EXACT Sciences or LabCorp to lower costs through automating and simplifying key operational processes; the inclusion of PreGen-Plus in cancer screening guidelines; the number of people who decide to be screened for colorectal cancer using EXACT Sciences' technologies; competition; the ability to comply with federal and state statutes and regulations relating to EXACT Sciences' products and services, including FDA requirements, the U.S. Department of Transportation and the Clinical Laboratory Improvement Amendments; the ability to protect EXACT Sciences' intellectual property and the cost of enforcing or defending EXACT Sciences in litigation relating to intellectual property rights; 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 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.

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