
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): **April 26, 2004**

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**

ITEM 12. RESULTS OF OPERATIONS AND FINANCIAL CONDITION

On April 26, 2004 EXACT Sciences Corporation announced its financial results for the three months ended March 31, 2004. A copy of the press release is attached hereto as Exhibit 99.1. The information in this Form 8-K and Exhibit 99.1 attached hereto shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, except as shall be expressly set forth by specific reference in such filing.

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

April 26, 2004

By: /s/ Don M. Hardison
Don M. Hardison
President and Chief Executive
Officer

EXHIBIT INDEX

| Exhibit Number | Description |
|-----------------------|------------------------------------|
| 99.1 | Press Release dated April 26, 2004 |

4

**FOR IMMEDIATE RELEASE****For further information:****Media:**

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EXACT SCIENCES ANNOUNCES FIRST QUARTER 2004 RESULTS

MARLBOROUGH, Mass. – (April 26, 2004) – EXACT Sciences Corporation (NASDAQ: EXAS) announced today financial results for the first quarter ending March 31, 2004.

For the quarter ending March 31, 2004, revenues totaled \$1.2 million, versus revenues of \$0.4 million for the quarter ending March 31, 2003. For the first quarter of 2004, revenues reflect the amortization of up-front license fee payments from Laboratory Corporation of America® Holdings (LabCorp®), royalties on PreGen-Plus™ tests accessioned by LabCorp, and sales of Effipure™ units to LabCorp.

Net loss for the quarter ending March 31, 2004 totaled \$5.3 million, or \$0.23 per share, compared to a net loss of \$7.9 million, or \$0.42 per share, for the quarter ending March 31, 2003. The decrease in net loss for the first quarter of 2004 versus the net loss for the first quarter of 2003 was due primarily to the completion of the Company's multi-center study in the fourth quarter of 2003, and the corresponding elimination of expense associated with conducting the study. This decrease was partially offset by expenses associated with the departure of certain employees in the first quarter.

As of March 31, 2004, EXACT Sciences had approximately \$65 million in cash, cash equivalents and short-term investments available to fund its operations. In February, the Company completed a 6.9 million share public offering of common stock, with net proceeds to the Company of approximately \$43 million.

“In the first quarter of 2004, we continued our focus on creating market traction for PreGen-Plus, and on increasing the performance of PreGen-Plus in detecting colorectal cancer and advanced adenomas,” commented Don Hardison, EXACT Sciences' President and CEO. “In terms of our commercial efforts, we, along with LabCorp, have instituted several programs related to PreGen-Plus that we believe will provide additional support to LabCorp's sales force. We are encouraged by the month-over-month increases in the number of PreGen-Plus tests accessioned at LabCorp in the first quarter of this year, and while growth rates may fluctuate over the remainder of the year, we believe that the traction we achieve in 2004 will provide good momentum for PreGen-Plus sales as we enter 2005. It is clear from our market research that we have the opportunity to increase colorectal cancer screening rates with PreGen-Plus, as we are already drawing new, previously unscreened people into the screened population.

“Our applied research efforts continue to be concentrated on developing new technologies that we believe will increase the performance of PreGen-Plus. As we move into the second quarter of 2004, and the rest of the year, we are excited about

- more -

these new developments, and the promise that PreGen-Plus represents – and already has demonstrated – in reducing the mortality associated with colorectal cancer through early detection, and by increasing the number of people who are screened for this disease.”

Operating Highlights

Commercial

- Since the commercial launch of PreGen-Plus, LabCorp has accessioned more than 1,000 tests. In the first quarter of 2004, the number of tests accessioned by LabCorp increased by more than 80% versus the number of tests accessioned in the fourth quarter of 2003.
- Based on the sales volume to date, and the strong growth seen in 2004, the Company has set a goal of 10,000 tests accessioned by LabCorp in 2004. Reaching this level of accessions would represent average quarterly growth of approximately 80%, and would result in a strong run rate entering 2005.
- More than 60 third-party payors have paid for PreGen-Plus to date. Of the claims that have been submitted to date, there have been very few denials of coverage. For the claims that have been submitted and paid, the average payment is greater than 80% of the billed price.
- Based on market research, over 50% of the people who have used PreGen-Plus had not previously been screened for colorectal cancer. And, of the half who had been screened previously, most had been screened with a fecal occult blood test (FOBT). The Company believes that this data supports its conviction that PreGen-Plus has the opportunity to increase colorectal cancer screening rates.

Clinical

- A manuscript discussing the results from the Company’s multi-center study of PreGen-Plus versus FOBT was submitted to a peer-reviewed journal at the end of 2003. The timing of any acceptance and publication of the manuscript by a peer-reviewed medical journal is outside of the control of the Company.

Research and Development

- The Company will present data discussing the positive effect of Effipure, the Company’s novel sample prep technology, on the performance of the PreGen-Plus assay at this year’s Digestive Disease Week conference that will be held in May, in New Orleans, Louisiana. The abstract that was submitted was accepted for an oral presentation.
- The applied research group at the Company continues to work on new technologies that the Company believes will result in increased performance of PreGen-Plus. The Company expects that data regarding the progress of certain of these efforts will be presented at scientific or medical conferences over the next twelve months.

Financial

- Given the positive experience to date with certain sales and marketing programs, the Company believes that expanding its efforts in these areas would further enhance market traction of PreGen-Plus. Accordingly, the Company expects that its operating expenses for 2004 will approach approximately \$26 million, an increase of \$2 million over the guidance provided at the end of last year. The majority of this increase will be in marketing and sales, and will begin to be realized in the second quarter of this year. The Company will continue to

evaluate the effectiveness of these programs over the course of the year, and intends to capitalize on future opportunities that it believes will support increased market penetration of PreGen-Plus.

- The Company will continue to account for royalty payments received from LabCorp on a cash basis, and intends to do so for the foreseeable future, until such time as the Company believes it has sufficient information to warrant any change in its accounting method.
- The Company continues an active search to identify and hire a Chief Financial Officer. Stephen Read, EXACT Sciences' Vice President and Controller, is currently serving as the Company's interim CFO.

First Quarter 2004 Conference Call

EXACT Sciences will host a conference call discussing the Company's first quarter 2004 operating and financial results, as well as expectations for the future, at 8:30 a.m. EDT on Tuesday, April 27, 2004. A live Webcast of the conference call, as well as an archived version following the completion of the call, will be available at www.exactsciences.com by clicking on the Investor Relations link. The conference call and Webcast are open to all interested parties.

Information for the call is as follows:

Domestic callers: 877-809-1575

International callers: 706-679-5918

A replay of the conference call will be available two hours following the completion of the conference call, for 48 hours. Information for the replay is as follows:

Domestic callers: 800-642-1687

International callers: 706-645-9291

PIN #: 6682510

About EXACT Sciences Corporation

EXACT Sciences Corporation is the leader in rapidly applying genomics knowledge to develop effective, patient-friendly screening methods to detect cancer early, so that physicians can save patients' lives. Its first commercial test, PreGen-Plus™, 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, however, 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 and 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 future sales volumes, revenues and expenses, its business outlook and business momentum, the results of its clinical studies, the achievement of milestones and catalysts, including the future inclusion of its products in reimbursement guidelines, the coverage of its products by peer-reviewed journals, the acceptance of its products by Medicare, the

Company's marketing and sales strategies and programs and their likely future success, the development of new technologies to enhance the sensitivity of its products in the detection of cancer, 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 inability of EXACT Sciences to become profitable; the success of its strategic relationship with LabCorp; its ability to license certain technologies or obtain raw materials; the inability to convince Medicare and other third-party payors to provide adequate reimbursement for EXACT Sciences' products and services; the failure to convince medical practitioners to order tests using EXACT Sciences' technologies; the inability to increase the performance of the PreGen-Plus test; the inability of EXACT Sciences or LabCorp to lower costs through automating and simplifying key operational processes; the exclusion of PreGen-Plus from cancer screening guidelines; the uncertainty regarding how many people decide to be screened for colorectal cancer using EXACT Sciences' technologies; competition; the failure 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 inability 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 inability 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 SEC filings.

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EXACT SCIENCES CORPORATION
Selected Unaudited Financial Information
Statement of Operations Data

| In thousands, except per share data | Three Months Ended March 31, | |
|--|---|-------------|
| | 2004 | 2003 |
| Revenues: | | |
| Product royalty | \$ 22 | \$ — |
| License fees | 1,128 | 405 |
| Product revenue | 27 | 3 |
| Total revenues | 1,177 | 408 |
| Gross Profit (Loss): | | |
| Product royalty | 21 | — |
| License fees | 1,128 | 405 |
| Product revenue | (4) | — |
| Total gross profit | 1,145 | 405 |
| Operating Expenses: | | |
| Research and development | 3,134 | 5,013 |
| Selling, general and administrative | 3,294 | 3,114 |
| Stock-based compensation | 126 | 328 |
| Total operating expenses | 6,554 | 8,455 |
| Loss from operations | (5,409) | (8,050) |
| Interest income | 118 | 167 |
| Net loss | \$ (5,291) | \$ (7,883) |
| Net loss per share: | | |
| Basic and diluted | \$ (0.23) | \$ (0.42) |
| Weighted average common shares outstanding: | | |
| Basic and diluted | 22,949 | 18,808 |

EXACT SCIENCES CORPORATION
Condensed Unaudited Balance Sheet Data
(In thousands)

| | <u>March 31,</u> <u>2004</u> | <u>December 31,</u> <u>2003</u> |
|---|---------------------------------|------------------------------------|
| Assets | | |
| Cash and cash equivalents | \$ 24,179 | \$ 14,200 |
| Short-term investments | 41,190 | 13,607 |
| Prepaid expenses | 1,864 | 1,283 |
| Property and equipment, net | 2,544 | 2,919 |
| Patent costs, net and other assets | 2,577 | 2,672 |
| Total assets | <u>\$ 72,354</u> | <u>\$ 34,681</u> |
| Liabilities and stockholders' equity | | |
| Total current liabilities | 7,197 | 6,724 |
| Deferred licensing fees, less current portion | 14,601 | 15,729 |
| Total stockholders' equity | 50,556 | 12,228 |
| Total liabilities and stockholders' equity | <u>\$ 72,354</u> | <u>\$ 34,681</u> |

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