
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 24, 2005**

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))
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Item 7.01 Regulation FD Disclosure.

On January 24, 2005, Exact Sciences Corporation issued a press release announcing its financial results for the fourth quarter and year ended December 31, 2004. A copy of the press release 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 January 24, 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

January 24, 2005

By: /s/ Don Hardison
Don Hardison
President & Chief Executive Officer

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release issued by the Company on January 24, 2005, furnished herewith.

**EXACT SCIENCES ANNOUNCES FOURTH QUARTER AND
YEAR-END 2004 RESULTS**

MARLBOROUGH, Mass. — (January 24, 2005) — EXACT Sciences Corporation (NASDAQ: EXAS) announced today financial results for the fourth quarter and year ended December 31, 2004.

For the quarter ended December 31, 2004, revenues totaled \$1.3 million, versus revenues of \$1.2 million for the quarter ended December 31, 2003. For the twelve months ended December 31, 2004, revenues totaled \$4.9 million, versus \$2.9 million for the same time period of 2003. For the fourth quarter and year ended December 31, 2004, revenues reflect the amortization of up-front license fee payments from Laboratory Corporation of America® Holdings (LabCorp®), royalties on PreGen-Plus™ tests, and sales of Effipure™ units to LabCorp. For the year ended December 31, 2004, over 4,300 PreGen-Plus tests were accessioned by LabCorp.

Net loss for the quarter ended December 31, 2004 totaled \$4.6 million, or \$0.17 per share, compared to a net loss of \$5.7 million, or \$0.30 per share, for the quarter ended December 31, 2003. Net loss for the twelve months ended December 31, 2004 was \$18.5 million, or \$0.73 per share, versus a net loss of \$28.3 million, or \$1.50 per share for the twelve months ended December 31, 2003.

As of December 31, 2004, EXACT Sciences had approximately \$50 million in cash, cash equivalents and short-term investments.

“Both EXACT Sciences and LabCorp continue to be encouraged by the potential of PreGen-Plus,” commented Don Hardison, EXACT Sciences’ President and CEO. “Our experience to date, which includes the results of certain sales initiatives that we and LabCorp implemented during the last quarter, has provided us with insights that we will be using in 2005 to drive our sales and marketing efforts.”

Operating Highlights

Commercial

- Post-market data indicate that more than half of the people who have used PreGen-Plus had never been screened for colorectal cancer before, by any method. In addition, the data also indicate that more than 90 percent found the test easy/very easy to use, and more than 90 percent were likely/very likely to use the test again.
 - A paper describing positive patient perception and preference data for PreGen-Plus versus fecal occult blood testing (FOBT) and colonoscopy is in press, and should be published in the first quarter of 2005.
 - Through 2004, over 1,600 physician accounts had ordered at least one PreGen-Plus test.
 - In November, the Company announced the expansion of its agreement with the Johns Hopkins University, to include the PIK3CA gene, which has been determined to play an important role in colorectal carcinogenesis and which the Company may incorporate into future versions of PreGen-Plus.
 - The Company completed and filed a national coverage decision memorandum with the Centers for Medicare and Medicaid Services seeking Medicare coverage of PreGen-Plus.
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Clinical/Applied Research

- A manuscript discussing the results from the Company's multi-center study of PreGen-Plus versus FOBT, which was completed in the third quarter of 2003, was published in the December 23, 2004 issue of the *New England Journal of Medicine*. The study found that the version of PreGen-Plus used was four-times more sensitive than the most widely-used FOBT in detecting colorectal cancer. The version of PreGen-Plus that is commercially available differs from the version used in the study, as it incorporates certain technical improvements. Additionally, research results suggest that improved sample handling methods may also play a role in greater sensitivity than that demonstrated in the multi-center study.
- Research data describing the positive impact of the Effipure™ sample preparation technology on the sensitivity of the PreGen-Plus technology was published in the fourth quarter 2004 issue of the *Journal of Molecular Diagnostics*.
- Anthony Shuber, the Company's Chief Technology Officer, presented data relating to a next-generation version of PreGen-Plus at the Conference on Colon Cancer in Murine Models and the Human, hosted by Jackson Laboratory. At the meeting, Mr. Shuber described a reconfigured assay panel that demonstrated improved sensitivity in colorectal cancer tissues. The Company intends to validate these results in stool samples.

Financial

- The Company continues to account for PreGen-Plus royalties on a cash basis. In 2005, the Company expects to devote greater attention and resources to direct sales and marketing efforts and to focus its research and development spending on those areas directly related to improving test performance.

Fourth Quarter and Year-End 2004 Conference Call

EXACT Sciences will host a conference call discussing the Company's fourth quarter and year-end 2004 operating and financial results and operating and research plans for the future, at 8:30 a.m. EDT on Tuesday, January 25, 2005. 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 #: 3354608	

About EXACT Sciences Corporation

EXACT Sciences Corporation is a leader in rapidly applying genomics knowledge to develop effective, patient-friendly screening methods to detect cancer early, to assist physicians in saving 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, 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 (including the size of the potential market for its technologies), the likelihood of third-party reimbursement of its technologies and the future inclusion of its products in reimbursement guidelines, 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 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 SEC filings.

EXACT SCIENCES CORPORATION
Selected Unaudited Financial Information
Statement of Operations Data

	Three Months Ended December 31,	
	2004	2003
	In thousands, except per share data	
Revenues:		
Product royalty	\$ 68	\$ 8
License fees	1,129	1,155
Product revenue	78	6
Total revenues	1,275	1,169
Gross Profit (Loss):		
Product royalty	63	7
License fees	1,129	1,155
Product revenue	(89)	1
Total gross profit	1,103	1,163
Operating Expenses:		
Research and development	2,609	3,167
Selling, general and administrative	3,151	3,678
Stock-based compensation	98	131
Total operating expenses	5,858	6,976
Loss from operations	(4,755)	(5,813)
Interest income	205	102
Net loss	\$ (4,550)	\$ (5,711)
Net loss per share:		
Basic and diluted	\$ (0.17)	\$ (0.30)
Weighted average common shares outstanding:		
Basic and diluted	26,167	19,093

EXACT SCIENCES CORPORATION
Selected Unaudited Financial Information
Statement of Operations Data

	Year Ended December 31,	
	2004	2003
In thousands, except per share data		
Revenues:		
Product royalty	\$ 166	\$ 8
License fees	4,514	2,871
Product revenue	255	22
Total revenues	4,935	2,901
Gross Profit (Loss):		
Product royalty	155	7
License fees	4,514	2,871
Product revenue	(221)	1
Total gross profit	4,448	2,879
Operating Expenses:		
Research and development	10,901	17,084
Selling, general and administrative	12,244	13,515
Stock-based compensation	498	1,118
Total operating expenses	23,643	31,717
Loss from operations	(19,195)	(28,838)
Interest income	672	498
Net loss	\$ (18,523)	\$ (28,340)
Net loss per share:		
Basic and diluted	\$ (0.73)	\$ (1.50)
Weighted average common shares outstanding:		
Basic and diluted	25,334	18,911

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

	<u>December 31,</u> <u>2004</u>	<u>December 31,</u> <u>2004</u>
Assets		
Cash and cash equivalents	\$ 13,092	\$ 14,200
Short-term investments	37,188	13,607
Prepaid expenses	1,835	1,283
Property and equipment, net	1,954	2,919
Patent costs, net and other assets	2,042	2,672
Total assets	<u>\$ 56,111</u>	<u>\$ 34,681</u>
Liabilities and stockholders' equity		
Total current liabilities	6,858	6,724
Deferred licensing fees, less current portion	11,270	15,729
Total stockholders' equity	37,983	12,228
Total liabilities and stockholders' equity	<u>\$ 56,111</u>	<u>\$ 34,681</u>
