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): **December 22, 2004**

EXACT SCIENCES CORPORATION

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction of Incorporation)

000-32179	**02-0478229**
(Commission File Number)	(IRS Employer Identification No.)
100 Campus Drive, Marlborough, Massachusetts	**01752**
(Address of Principal Executive Offices)	(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 December 22, 2004, 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 December 22, 2004, 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

December 22, 2004

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

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release issued by the Company on December 22, 2004, furnished herewith.

Exhibit 99.1

Press Release

NEW ENGLAND JOURNAL OF MEDICINE REPORTS THAT STOOL-BASED DNA TEST IS FOUR-TIMES MORE SENSITIVE THAN FECAL OCCULT BLOOD TEST FOR COLORECTAL CANCER SCREENING

EXACT Sciences' colorectal cancer screening test — PreGen-Plus™ — provides a more sensitive, non-invasive screening option for average risk 50-year-old+ Americans

MARLBOROUGH, Mass. — (December 23, 2004) — EXACT Sciences Corporation (NASDAQ:EXAS) today announced that the *New England Journal of Medicine* has published the results of the Company's multi-center study, the first-ever study of its stool-based DNA test, PreGen-Plus, versus the most widely used fecal occult blood test, Hemoccult® II. Researchers found that the Company's non-invasive stool-based DNA test for colorectal cancer was four-times more sensitive than the fecal occult blood test (FOBT), the only other entirely non-invasive colorectal cancer screening test available today. The stool-based DNA test was able to detect all stages of colorectal cancer in an average-risk, asymptomatic population, including the earliest-stage, most curable colorectal cancers.

EXACT Sciences' work in applied genomics led to the development of its stool-based DNA technologies, which are the first practical applications of the decoding of the human genome to be used broadly for testing in the average-risk, asymptomatic population. The Company's researchers have worked with leading research institutions throughout in the country in the continuing development, refinement and validation of its DNA-based technologies.

Colorectal cancer is the second leading cause of cancer mortality in the United States. Despite the guideline recommendations endorsing regular screening for all Americans over the age of 50, nearly 60 percent have never been screened for colorectal cancer. Professional organizations recommend colorectal cancer screening for adults aged 50 years and older because early diagnosis results in a greater than 90 percent five-year survival rate.

"The results of this study indicate that the stool-based DNA test is a more sensitive test than the FOBT for the detection of colorectal cancer," said Thomas Imperiale, M.D., lead investigator for the study, professor of medicine at the Indiana University School of Medicine and a research scientist at the Regenstrief Institute, Inc. "A simple, non-invasive test that detects colorectal cancer with reasonable sensitivity and specificity might overcome barriers to screening among persons who are not willing to have a more invasive test, such as colonoscopy."

The primary endpoint of the study was to determine the relative performance of stool-based DNA screening to the most widely-used FOBT (Hemoccult II) in the detection of invasive colorectal cancer. This primary endpoint was achieved with high statistical significance, as the stool-based DNA test was four-times more sensitive than the FOBT in the detection of invasive colorectal cancer (52 percent versus 13 percent, P=0.003). In addition, the stool-based DNA test was more than four-times as sensitive in detecting the earliest stage, most curable cancers (56.5 percent versus 13.0 percent, P=0.0006). A secondary finding was that stool-based DNA testing was twice as sensitive as the FOBT in detecting adenomas that exhibit high-grade dysplasia (adenomas highly likely to progress to cancer). The version of the stool-based DNA test used in this study was designed to detect invasive cancer, and was not expected to detect pre-cancerous adenomas.

The rationale and primary endpoint for the study were based on screening guidelines that state that newer screening tests do not have to provide results from a clinical trial with mortality from colorectal cancer as an endpoint, but should demonstrate, at the minimum, equivalence in sensitivity, specificity and safety to currently available screening tests. Hemoccult II was chosen as the comparator as it is the only fecal occult blood test, and only colorectal cancer screening test, proven to reduce the incidence and risk of death from colorectal cancer. Hemoccult II is the most widely-used fecal occult blood test on the market. The study was designed by the authors, with advice from a panel of national experts on colorectal cancer, cancer screening and prevention, and study design.

“It is important that people have options for colorectal cancer screening,” said Dr. Paul C. Schroy III, MD, MPH, Boston University School of Medicine. “While there are several screening tests available, far too many people are not getting screened for what could be a curable disease. Stool-based DNA testing is a novel screening option that offers a convenient, non-invasive and potentially more acceptable alternative to existing screening tests for an average-risk patient population. Any test that increases the number of people who get screened effectively for colorectal cancer is a test that should be made available to patients as a standard of care.”

PreGen-Plus works by isolating the human DNA from a single stool sample collected in the privacy of one’s own home, and analyzing that DNA for alterations associated with current, active colorectal cancer. The test, which must be ordered by a physician, removes many of the common barriers associated with other available methods, including invasiveness, discomfort and inconvenience. PreGen-Plus does not require any special bowel preparation, stool handling or changes in diet prior to testing. It also does not carry the risks associated with invasive tests, such as colon perforation, hemorrhage, or infection, or sedation-related issues associated with colonoscopy.

The molecular genetics of colorectal cancer provide the basis for the analysis of stool DNA. Eighty-five percent of colorectal cancers result from chromosomal instability, with acquired mutations progressively accumulating in the adenomatous polyposis coli (*APC*) and *p53* tumor suppressor genes, and in the *k-ras* oncogene. The other 15 percent arises from malfunction to genes involved in DNA mismatch repair, manifested by microsatellite instability. Colorectal cancer may also be detectable by DNA markers associated with disordered apoptosis. PreGen-Plus consists of a panel of 23 individual tests each looking for the presence of DNA alterations in human DNA isolated from stool. The test analyzes the DNA for 21 specific point alterations in the APC, k-ras and p53 genes, a marker for microsatellite instability known as Bat-26, and a novel marker known as DNA Integrity Assay (DIA®), all of which have been associated with the presence of cancer.

“These data, combined with other studies that showed strong sensitivity, as well as overall patient preference for stool-based DNA testing, demonstrate the important role that PreGen-Plus can play in increasing colorectal cancer screening rates ,” said Don Hardison, EXACT Sciences’ President and CEO. “PreGen-Plus has been used by thousands of patients to date, and post-market data show that more than half of those patients had never been screened for colorectal cancer before. We believe that PreGen-Plus can address the needs of patients who are currently not undergoing colonoscopy as part of their normal screening once they reach age 50, and can bring more people into the screened population. Our goal is to reduce mortality associated with colorectal cancer — and we know, by the fact that we have already detected early stage cancers in patients, that we are beginning to achieve that goal.”

About Colorectal Cancer Screening

Today, there are several colorectal cancer screening options, yet there is confusion among patients as to which ones may be right for them. Colonoscopy remains the reference standard, but many patients in rural areas do not have access to colonoscopy, and patients in urban areas often experience long waits for an appointment. Still other patients remain unwilling to undergo colonoscopy due to fear of the preparation and invasiveness of the procedure. While physicians strongly recommend colonoscopy, it is important to offer options to ensure that every American aged 50 and older gets screened regardless of access or other barriers.

Other available screening options include flexible sigmoidoscopy and barium enema. Flexible sigmoidoscopy is similar to colonoscopy, but examines only about one-third of the colon. Barium enema is an older technique that some doctors use, but it is also less sensitive than a colonoscopy. The fecal occult blood test (FOBT) measures blood in stool that is undetectable to the naked eye. Blood in the stool, however, is only an indirect marker of colorectal neoplasia, as many tumors may not bleed, or bleed intermittently; in addition, the detected blood could result from another problem, such as hemorrhoids. Virtual colonoscopy, using CAT scan technology, takes less time to perform but is not entirely non-invasive and requires the same preparation as colonoscopy.

About the Study
These data were published in an article entitled “Fecal DNA versus Fecal Occult Blood for Colorectal-Cancer Screening in an Average-Risk Population” in the December 23 issue of the *New England Journal of Medicine* . This multi-center study is the largest study to date involving the stool-based DNA test, as well as fecal occult blood testing, in community practice. It is also the first head-to-head comparison of a stool-based, multitarget DNA panel versus Hemoccult II in asymptomatic, average-risk adults aged 50 years and older.

Study design and rationale
The rationale for the study was based on screening guidelines which state that newer screening tests do not require mortality reduction as an endpoint, but should have comparable or better performance in terms of sensitivity, specificity, and safety, among other features, when compared to other acceptable tests. Hemoccult II (SmithKline Diagnostics, Sunnyvale, CA) was chosen as the comparator because guaiac-based FOBT is the only test method proven to reduce the mortality associated with colorectal cancer, and Hemoccult II is the most widely-used guaiac-based test.

However, the sensitivity of fecal occult blood testing for colorectal cancer and especially for colorectal adenomas is low because neoplasms may not bleed, or bleed intermittently, and thus cannot be detected by FOBT. A simple, non-invasive test that detects tumor-specific markers, such as altered DNA, with reasonable sensitivity and specificity might overcome barriers to screening among patients who are not willing to have the more sensitive but more invasive colonoscopy.

The study was conducted at 81 sites, including private practice and university-based settings. Patient enrollment occurred between August 2001 and March 2003. All participants sequentially provided a stool sample for DNA testing, completed three Hemoccult II cards over three days, and underwent screening colonoscopy. Study enrollment was designed to identify an adequate number of persons with colorectal cancer. The primary endpoint for the study was to determine the relative performance of stool-based DNA screening to the most widely-used FOBT.

As this study was initiated more than three years ago, the stool-based DNA test that is now commercially available represents a newer version of the technology and different sample handling techniques than what was used in this study. Sample handling techniques affect the stability of the DNA in a sample; techniques employed in this study, which are different from those used commercially, did not optimize DNA stability and may have impacted the point sensitivity of the stool-based DNA test. In addition, the currently available test also incorporates a new sample preparation technology, Effipure™, which has been shown to enhance the test’s sensitivity by increasing the amount of DNA purified from a stool sample. The Company continues to focus its applied research efforts on the development of future generations of its stool-based DNA technologies.

Previous studies using stool-based DNA testing demonstrated a sensitivity of 62 percent to 91 percent for cancer and 27 percent to 82 percent for advanced adenomas, with a specificity of 93 percent to 96 percent in persons with a normal colonoscopy. However, those studies assessed persons with a great range of clinical presentations of colorectal cancer, from asymptomatic to advanced, symptomatic lesions.

Study population
The target population consisted of asymptomatic persons at average risk for colorectal cancer. All participants were at least 50 years old. Enrollment was stratified by age, with a minimum of three-quarters of persons aged 65 years or older, to mimic the well-known increase in the frequency of colorectal cancer with age. Exclusion criteria included gastrointestinal bleeding within the last month; change in bowel habits or abdominal pain; previous colorectal cancer or polyps; prior resection of any part of the colon; iron deficiency anemia; or other coexistent visceral cancer. Individuals who had undergone colonoscopy, sigmoidoscopy or double contrast barium enema within the preceding 10 years or a positive fecal occult blood test within six months were excluded, as were those with inflammatory bowel disease, familial adenomatous polyposis or hereditary non-polyposis colon cancer, more than one first degree relative with colorectal cancer, or any first degree relative with colorectal cancer before age 50. Persons unwilling or unable to undergo colonoscopy were excluded.

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 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 forward-looking statements which are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. This press release contains express or implied forward-looking statements relating to, among other things, EXACT Sciences' expectations concerning its future revenues and expenses, its business outlook and business momentum, its clinical trials, the commercial launch 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, 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 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 lack of market acceptance of PreGen-26, PreGen-Plus, and other PreGen technologies to screen for colorectal cancer; the inability of EXACT Sciences to control its commercial partners' operations, performance or sales performance, including sales of products utilizing EXACT Sciences' technologies; the inability of EXACT Sciences' commercial partners to create a market for and sell products using EXACT Sciences' technologies; the loss of support of key scientific collaborators; the failure to comply with federal and state statutes and regulations relating to EXACT Sciences' products and services, including FDA requirements, and relating to the operation of EXACT Sciences' laboratory, including the Clinical Laboratory Improvement Amendments; competition; and the inability to protect EXACT Sciences' intellectual property and the cost of enforcing or defending EXACT Sciences in litigation relating to intellectual property rights. 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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