

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

September 9, 2003

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(Date of earliest event reported)

LABORATORY CORPORATION OF AMERICA HOLDINGS

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(Exact name of registrant as specified in its charter)

DELAWARE	1-11353	13-3757370
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(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification Number)

358 SOUTH MAIN STREET, BURLINGTON, NORTH CAROLINA 27215

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(Address of principal executive offices)

336-229-1127

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(Registrant's telephone number, including area code)

ITEM 9. Regulation FD Disclosure

On September 9, 2003, Laboratory Corporation of America -Registered Trademark- Holdings (LabCorp -Registered Trademark-)(NYSE:LH) and EXACT Sciences Corporation (NASDAQ:EXAS) announced that PreGen-Plus-Trademark-, the DNA-based stool test for the early detection of colorectal cancer, is now widely available for use by physicians and patients to screen their patients for colorectal cancer. PreGen-Plus is an effective, easy-to-use and completely non-invasive breakthrough screening option for the more than 80 million Americans who should be screened for colorectal cancer.

Exhibits:

99.1 Press release of the Company dated September 9, 2003.

SIGNATURES

Pursuant to the requirements of the Securities and Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

LABORATORY CORPORATION OF AMERICA HOLDINGS

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(Registrant)

By: /s/ BRADFORD T. SMITH

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Bradford T. Smith  
Executive Vice President  
and Secretary

Date: September 9, 2003

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PHYSICIANS AND PATIENTS NOW USING PREGEN-PLUS-TRADEMARK-  
TO SCREEN FOR COLORECTAL CANCER

Breakthrough DNA-based colon cancer screening technology widely available

MARLBOROUGH, MA and BURLINGTON, NC - (Sept. 9, 2003) - EXACT Sciences Corporation (NASDAQ: EXAS) and Laboratory Corporation of America-Registered Trademark- Holdings (LabCorp-Registered Trademark-, NYSE: LH) today announced that PreGen-Plus-Trademark-, the DNA-based stool test for the early detection of colorectal cancer, is now widely available for use by physicians and patients to screen their patients for colorectal cancer. PreGen-Plus is an effective, easy-to-use and completely non-invasive breakthrough screening option for the more than 80 million Americans who should be screened for colorectal cancer. Based on published studies to date, PreGen-Plus has demonstrated a point sensitivity for colon cancer that is significantly greater than that of fecal occult blood testing (FOBT), the only other non-invasive colorectal cancer screening option available, and comparable to other cancer screening tests such as the Pap smear for cervical cancer.

"Colonoscopies and sigmoidoscopies are invasive and costly. The FOBT is unpopular because of the necessity to scrape samples off your stool and it only tells you if blood is present, not cancer," said Priscilla Savary, Executive Director of the Colorectal Cancer Network. "The DNA screening test is cost-effective, non-invasive, and if it detects the earliest stages of cancer it has a chance to increase survival rates from this terrible disease."

PreGen-Plus: The Patient Perspective:

Patients agree that a non-invasive stool-based test will increase compliance with their doctors' colorectal cancer screening recommendations. In data presented at the most recent Digestive Disease Week conference, patients preferred PreGen-Plus over both fecal occult blood testing and colonoscopy.

PreGen-Plus, which must be ordered by a physician, requires patients to submit a single, whole stool for analysis by LabCorp. Once the physician orders the test, the patient will receive collection materials that he/she then uses to collect the single, whole stool in the privacy of his/her home. The patient then returns the collection materials to LabCorp for testing. Unlike other screening methods, PreGen-Plus does not require any special bowel preparation, stool handling and/or alteration in diet or medications prior to testing.

"When my doctor told me to get a colonoscopy, I knew there were other tests available that were less invasive," said Barbara Wallace, a patient who approached her doctor about ordering PreGen-Plus. "I was very familiar with the fecal occult blood test. With that test, you take samples of the stool, you have to watch your diet, you have to actually touch the stool and put it on a piece of paper. It gets to be very messy. And quite frankly, I was not interested in that."

PreGen-Plus: The Science:

PreGen-Plus is the only non-invasive DNA-based test available for the detection of colorectal cancer and also is among the first

practical commercial applications of the human genome findings. The companies believe this test will have widespread impact on patient screening compliance and mortality. In the laboratory, the human DNA in the stool is extracted and then examined for alterations associated with the presence of colorectal cancer.

PreGen-Plus consists of a panel of 23 individual tests, each looking for the presence of DNA alterations in human DNA isolated from stool. These tests include analyzing the DNA for 21 specific mutations in the APC, K-ras and p53 genes, identifying a marker for microsatellite instability known as Bat-26, and identifying a novel marker known as DNA Integrity Assay (DIAR), all of which have been shown to be associated with the presence of colorectal cancer.

After analysis, the results are sent to the patient's physician within approximately three weeks. If a patient were to receive a positive result from PreGen-Plus, indicating the likely presence of colorectal cancer, he or she would be referred for additional testing as medically appropriate, including colonoscopy. With a negative test result, it is recommended that patients continue their regular screening program.

"The new stool DNA test is not as accurate as colonoscopy, but it is more accurate than the only other purely non-invasive test, which is testing the stool for blood, and it's a lot easier to use," said Dr. Douglas Rex, Professor of Medicine at Indiana University School of Medicine and Director of Endoscopy at Indiana University Hospital. "It's an excellent option for people who are not willing to undergo colonoscopy."

**PreGen-Plus Represents Major Step Forward in Efforts to Raise Screening Rates:**

According to the American Cancer Society, survival rates for colorectal cancer are greater than 90 percent if the disease is detected early. Unfortunately, however, despite the widespread availability of screening tests for more than 20 years, screening rates for colorectal cancer remain alarmingly low, and many people attribute this to the fact that current methods are highly invasive, inconvenient (given the necessary advance preparation) or relatively inaccurate. The availability of PreGen-Plus could allow more people to be effectively screened for colorectal cancer.

"We are pleased to be the exclusive laboratory provider of this important new screening test for colon cancer," said Tom Mac Mahon, LabCorp CEO and Chairman of the Board. "Our mission at LabCorp is to lead the industry in offering medically important new tests, including those for cancer. By bringing physicians and their patients this valuable information, we hope to help them make the best healthcare decisions possible."

"The introduction of PreGen-Plus is the culmination of many years of dedication and hard work," said Don Hardison, President and CEO of EXACT Sciences Corporation. "It is truly gratifying to know EXACT Sciences has developed a technology that has the potential to save the lives of many people at risk for colorectal cancer. The introduction of PreGen-Plus brings us one step closer to meeting our mission of eradicating mortality caused by common cancers."

PreGen-Plus is available only through your doctor or other licensed healthcare professional. More information can be found online at [www.pregenplus.com](http://www.pregenplus.com) or [www.exactsciences.com](http://www.exactsciences.com).

**About EXACT Sciences Corporation:**

EXACT Sciences Corporation is a pioneer in applying genomics to solve large clinical needs. Its DNA-based assay, PreGen-Plus-Trademark-, is intended for the early detection of colorectal cancer in the average-risk population. The Company also has developed PreGen-26-Trademark-, intended to detect colorectal cancer in a high-risk group of patients. Colorectal cancer, which is the most deadly cancer among non-smokers, is curable if detected at an early stage. 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](http://www.exactsciences.com) and [www.pregenplus.com](http://www.pregenplus.com).

**About LabCorp:**

Laboratory Corporation of America-Registered Trademark- Holdings is a pioneer in commercializing new diagnostic technologies and the first in its industry to embrace genomic testing. With annual revenues of \$2.5 billion in 2002, over 24,000 employees nationwide, and more than 200,000 clients, LabCorp offers over 4,000 clinical assays ranging from blood analyses to HIV and genomic testing. LabCorp combines its expertise in innovative clinical testing technology with its Centers of Excellence: The Center for Molecular Biology and Pathology, in Research Triangle Park, NC; National Genetics Institute, Inc. in Los Angeles, CA; ViroMed Laboratories, Inc. based in Minneapolis, MN; The Center for Esoteric Testing in Burlington, NC; and DIANON Systems, Inc. based in Stratford, CT. LabCorp clients include physicians, government agencies, managed care organizations, hospitals, clinical labs, and pharmaceutical companies. To learn more about our growing organization, visit our Web site at: [www.labcorp.com](http://www.labcorp.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' and LabCorp's expectations concerning their future revenues and expenses, their business outlook and business momentum, their clinical trials, the commercial launch of their technologies, and the effectiveness and market acceptance of their 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' and LabCorp's control, which could cause actual results to differ materially from those contemplated in these forward-looking statements. 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 and LabCorp undertake 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 and for additional disclosure regarding these and other risks faced by LabCorp, see the disclosure contained in LabCorp's public filings with the Securities and Exchange Commission, including, without limitation, its most recent Annual Report on Form 10-K and subsequent SEC filings.