

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): November 7, 2002

OraSure Technologies, Inc.

(Exact name of issuer as specified in charter)

DELAWARE
(State or Other
Jurisdiction
of Incorporation or
Organization)

1-10492
(Commission
file
number)

36-4370966
(I.R.S. Employer
Identification
Number)

150 Webster Street
Bethlehem, Pennsylvania 18015
(Address of principal executive offices)

(610) 882-1820
(Registrant's telephone number, including area code)

Item 5 - Other Events.

OraSure Technologies, Inc. (the "Company") issued a press release on November 7, 2002, announcing the receipt of U.S. Food and Drug Administration ("FDA") approval of the Company's OraQuick(R) Rapid HIV-1 Antibody Test for the detection of HIV-1 antibodies in finger-stick whole blood samples. A copy of the press release is attached to this Report as Exhibit 99 and is incorporated herein by reference.

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.

OraSure Technologies, Inc.

Date: November 7, 2002

By: /s/ Jack E. Jerrett

Jack E. Jerrett
Vice President, General Counsel
and Secretary

EXHIBIT INDEX

Exhibit

99 Press Release issued November 7, 2002 by OraSure Technologies announcing the receipt of U.S. Food and Drug Administration ("FDA") approval of the Company's OraQuick(R) Rapid HIV-1 Antibody Test for the detection of HIV-1 antibodies in finger-stick whole blood samples.

[LOGO] OraSure Technologies, Inc.
diagnostic solutions for the new millennium

Company Contacts:

Financial/Investors
Ronald H. Spair
Chief Financial Officer
610-882-1820
Investorinfo@orasure.com
www.orasure.com

Media
William E. Bruckner
Vice President, Strategic Marketing
610-882-1820

ORASURE RECEIVES FDA APPROVAL FOR
ORAQUICK(R) RAPID HIV-1 TEST

- Investor Conference Call and Press Conference at 2:15 P.M. Eastern Time -

BETHLEHEM, PA - November 7, 2002 - OraSure Technologies, Inc. (Nasdaq NM:OSUR), the market leader in oral fluid diagnostics, announced today that it has received approval from the U.S. Food and Drug Administration ("FDA") for its OraQuick(R) Rapid HIV-1 Antibody Test. Pursuant to this approval, the Company can manufacture and market the OraQuick(R) test in the United States for the detection of HIV-1 antibodies in finger-stick whole blood samples.

OraQuick(R) is the first FDA-approved rapid, point-of-care test designed to detect antibodies to HIV-1 within approximately 20 minutes. The FDA approval is based on clinical data submitted by OraSure indicating that the OraQuick(R) test had sensitivity of 99.6% and specificity of 100% in the clinical studies performed with finger-stick whole blood specimens. Sensitivity is a measure of the accuracy for detecting positive specimens, and specificity is a measure of the accuracy for identifying negative specimens.

"We are very pleased to be the first company in the United States to receive FDA approval for a rapid, point-of-care HIV-1 test," said Mike Gausling, OraSure's Chief Executive Officer. "OraQuick(R) represents an important advance for rapid diagnostic testing, and an important milestone for the Company as we continue to build our leadership position in the point-of-care market."

On June 17, 2002, OraSure announced that it had entered into an agreement with Abbott Laboratories for the co-exclusive distribution of the OraQuick(R) test in the United States. Abbott Laboratories is the market leader for the distribution of infectious disease testing

products, and is expected to focus its efforts on selling the OraQuick(R) test to hospitals and physicians' office laboratories. Sales from OraSure to Abbott are expected to begin in the next 30 to 60 days.

"OraQuick(R) is an important tool to assist in the rapid detection of HIV, and our collaboration with OraSure will ensure that this innovative technology is made widely available to the health care professionals and patients who need it," said Ed Michael, vice president, immunoassay and clinical chemistry, Abbott Laboratories.

With this FDA approval, OraQuick(R) will be available for sale to the nearly 40,000 qualified locations in the United States certified under CLIA (Clinical Laboratory Improvement Act of 1988) to perform moderately complex diagnostic tests. An estimated 17 million HIV tests are conducted annually in the United States at these locations.

"We are extremely pleased with the accuracy of the OraQuick(R) test", added R. Sam Niedbala, Ph.D., OraSure's Chief Science Officer. "Development of this product and receipt of FDA approval are the culmination of extensive efforts by our research and development, manufacturing, regulatory and quality groups."

Conference Call/Audio Webcast

OraSure Technologies will host a conference call with analysts and an audio webcast to discuss the OraQuick(R) FDA approval beginning at 2:15 p.m. Eastern Time (11:15 a.m. Pacific Time) today. On the call will be Mike Gausling, Chief Executive Officer, Ronald H. Spair, Chief Financial Officer, Mike Formica, Senior Vice President, Operations, and Eve Damiano, Vice President, Regulatory Affairs.

In order to listen to the conference call, please either dial 888-742-2024 (Domestic) or 706-643-0033 (International) or go to OraSure Technologies' web site, www.orasure.com, and click on the Investor Info link at the top of the page, at least ten minutes prior to the start of the call, to register and download and install any necessary audio software. A replay of the call will be archived on OraSure Technologies' web site shortly after the call has ended and will be available for seven days. A replay of the call can also be accessed until November 12, 2002, by dialing 800-642-1687 (Domestic) or 706-645-9291 (International) and entering the Conference ID #6610260.

The webcast will also be distributed over the CCBN (Corporate Communications Broadcast Network) Investor Distribution Network. Institutional investors can access the call via CCBN's password protected event management site, StreetEvents (www.streetevents.com).

About OraSure Technologies

OraSure Technologies develops, manufactures and markets oral fluid specimen collection devices and tests and other diagnostic products using its proprietary technologies, including immunoassays and other in vitro diagnostic tests and other medical devices. These products are sold in the United States and certain foreign countries to government

agencies, clinical laboratories, physicians' offices, hospitals, commercial and industrial entities, and various distributors.

OraSure Technologies is the leading supplier of oral-fluid collection devices and assays to the life insurance industry and public health markets for the detection of antibodies to HIV-1. In addition, the Company supplies oral-fluid testing solutions for drugs of abuse testing. For more information on the Company, please go to www.orasure.com.

About Abbott Laboratories

Abbott is a leader in HIV testing, beginning with the licensure of the first HIV test in the United States in 1985. Since then, Abbott has continually improved the diagnostic effectiveness of its tests, targeting sensitivity to detect HIV infections earlier and developing advanced technology to automate HIV testing for patient diagnosis, managing therapy and screening donated blood. Abbott also has developed important HIV therapeutics including Norvir, Abbott's first protease inhibitor, and Kaletra, an advanced-generation protease inhibitor, for the treatment of HIV/AIDS.

Abbott is a global, broad-based health care company devoted to the discovery, development, manufacture and marketing of pharmaceuticals, nutritionals, and medical products, including devices and diagnostics. The company employs approximately 70,000 people and markets its products in more than 130 countries. For more information on Abbott, please go to www.abbott.com.

Important Information

This press release contains certain forward-looking statements, including with respect to sales, markets and products. Actual results could be significantly different. Factors that could affect results include the ability to market products; impact of competitors, competing products and technology changes; ability to develop, commercialize and market new products; market acceptance of oral fluid testing or other products; ability to fund research and development and other projects and operations; ability to obtain and timing of obtaining necessary regulatory approvals; ability to develop product distribution channels; uncertainty relating to patent protection and potential patent infringement claims; ability to enter into international manufacturing agreements; obstacles to international marketing and manufacturing of products; ability to sell products internationally; loss or impairment of sources of capital; exposure to product liability and other types of litigation; changes in international, federal or state laws and regulations; changes in relationships with strategic partners and reliance on strategic partners for the performance of critical activities under collaborative arrangements; changes in accounting practices or interpretation of accounting requirements; customer inventory practices and consolidations; equipment failures and ability to obtain needed raw materials and components; the impact of terrorism and civil unrest; and general business, political and economic conditions. These and other factors are discussed more fully in the Securities and Exchange Commission filings of OraSure Technologies, including its registration statements, its Annual Report on Form 10-K for the year ended December 31, 2001, and its most recent Quarterly Report on Form 10-Q. Although forward-looking statements help to provide complete information about future prospects, readers should keep in mind that forward-looking statements may not be reliable. The forward-looking statements are made

as of the date of this press release and OraSure Technologies undertakes no duty to update these statements.

#