
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): September 29, 2003

OraSure Technologies, Inc.

(Exact name of issuer as specified in charter)

Delaware
(State or Other Jurisdiction
of Incorporation or Organization)

001-16537
(Commission file number)

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

220 East First Street
Bethlehem, Pennsylvania 18015-1360
(Address of principal executive offices)

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

Item 5. Other Events and Regulation FD Disclosure.

OraSure Technologies, Inc. (the “Company”) issued a press release announcing the filing of an application with the U.S. Food and Drug Administration for pre-market approval of its OraQuick® Rapid HIV-1 Antibody Test for use in detecting HIV-1 antibodies in oral fluid and plasma samples. The information contained in the press release dated September 29, 2003 is incorporated herein by reference and attached to this Current Report on Form 8-K as Exhibit 99.

Item 7. Financial Statements and Exhibits

(c) Exhibits

<u>Exhibit Number</u>	<u>Description</u>
99	Press Release dated September 29, 2003, announcing the filing of an application with the U.S. Food and Drug Administration for pre-market approval of its OraQuick® Rapid HIV-1 Antibody Test for use in detecting HIV-1 antibodies in oral fluid and plasma samples.

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.

Date: September 29, 2003

ORASURE TECHNOLOGIES, INC.

By: /s/ JACK E. JERRETT

Jack E. Jerrett
Senior Vice President, General Counsel and Secretary

Index to Exhibits

Exhibit Number

Description

99

Press Release dated September 29, 2003, announcing the filing of an application with the U.S. Food and Drug Administration for pre-market approval of its OraQuick[®] Rapid HIV-1 Antibody Test for use in detecting HIV-1 antibodies in oral fluid and plasma samples.

[GRAPHIC REMOVED HERE]

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OraSure Seeks FDA Approval of Oral Fluid and Plasma Claims for OraQuick[®] Rapid HIV-1 Antibody Test

BETHLEHEM, PA – (BW HealthWire) – September 29, 2003 – OraSure Technologies, Inc. (NASDAQ NM:OSUR), a market leader in oral fluid diagnostics, announced that it is filing an application today with the U.S. Food and Drug Administration (“FDA”) for pre-market approval of its OraQuick[®] Rapid HIV-1 Antibody Test for use in detecting HIV-1 antibodies in both oral fluid, or saliva, and plasma samples. Under applicable regulations, the FDA has 180 days to respond to the submission.

“This filing is the next major step in our efforts to expand the versatility of the OraQuick[®] test,” said Mike Gausling, Chief Executive Officer of OraSure Technologies. “If FDA approval is received, the oral fluid claim is expected to provide advantages over competing blood or urine HIV tests that should broaden the appeal of OraQuick[®], particularly in the public health market where HIV testing often occurs in the field or other nontraditional settings. In addition, the plasma claim is expected to enhance the usefulness of the OraQuick[®] test in hospitals and physicians’ laboratories where blood or plasma samples are routinely collected and tested for a range of diseases or conditions.”

OraQuick[®] is the first rapid, point-of-care test approved by the FDA to detect antibodies to HIV-1 in fingerstick and venipuncture whole blood specimens within approximately 20 minutes. OraSure received FDA approval of the OraQuick[®] test for fingerstick whole blood on November 7, 2002 and for venipuncture whole blood on September 5, 2003. On January 31, 2003, OraSure received a CLIA

(Clinical Laboratory Improvements Amendments of 1988) waiver for the test, permitting its use by more than 180,000 sites in the United States, including outreach clinics, community-based organizations and physicians' offices.

OraSure has also completed the necessary clinical trials and filed for FDA approval for use of the OraQuick[®] device to detect antibodies to a second type of the HIV virus, known as HIV-2. This action was taken by OraSure in anticipation of obtaining access to an HIV-2 patent license, either directly from the holder of certain patents covering the HIV-2 virus or through another third party.

About OraSure Technologies

OraSure Technologies develops, manufactures and markets oral fluid specimen collection devices using proprietary oral fluid technologies, diagnostic products including immunoassays and other *in vitro* diagnostic tests, and other medical devices. These products are sold in the United States as well as internationally to various clinical laboratories, hospitals, clinics, community-based organizations and other public health organizations, distributors, government agencies, physicians' offices, and commercial and industrial entities.

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.

Important Information

This press release contains certain forward-looking statements, including with respect to sales, markets, regulatory filings and approvals, 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 products and up-converting phosphor technology products; ability to fund research and development and other projects and operations; ability to maintain new or existing product distribution channels; reliance on sole supply sources for critical product components; availability of related products produced by third parties; ability to obtain and timing of obtaining necessary regulatory approvals; ability to comply with applicable regulatory requirements; history of losses and ability to achieve sustained profitability; volatility of our stock price; uncertainty relating to patent protection and potential patent infringement claims; availability of licenses to patents or other technology; 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; ability to meet financial covenants in agreements with financial institutions; ability to retain qualified personnel; 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 consolidations and inventory practices; equipment failures and ability to obtain needed raw materials and components; the impact of terrorist attacks and civil unrest; ability to complete consolidation or restructuring activities; ability to identify, complete and realize the full benefits of potential acquisitions; and general political, business and economic conditions. These and other factors are discussed more fully in the Securities and Exchange Commission ("SEC") filings of OraSure Technologies, including its registration statements, its Annual Report on Form 10-K for the year ended December 31, 2002, its Quarterly Reports on Form 10-Q, and its other filings with the SEC. 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.

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