
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 17, 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 on November 17, 2003, announcing that it will be submitting additional data to the U.S. Food and Drug Administration in support of an HIV-2 claim for the Company’s OraQuick® Rapid HIV-1 Antibody Test. The information contained in the press release 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 November 17, 2003, announcing that OraSure Technologies, Inc. will be submitting additional data to the U.S. Food and Drug Administration in support of an HIV-2 claim for its OraQuick® Rapid HIV-1 Antibody Test.

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 17, 2003

By: /s/ JACK E. JERRETT

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

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Exhibit Number

Description

99

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[ORASURE TECHNOLOGIES, INC. LOGO]

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**ORASURE TO SUBMIT ADDITIONAL DATA TO FDA FOR ORAQUICK® HIV-2
CLAIM**

BETHLEHEM, PA – November 17, 2003 – OraSure Technologies, Inc. (Nasdaq NM:OSUR), the market leader in oral fluid diagnostics, announced today that it will be submitting a small amount of additional data to the U.S. Food and Drug Administration (“FDA”) in support of an HIV-2 claim for its OraQuick® Rapid HIV-1 Antibody Test.

In June 2003, the Company submitted an application to the FDA for approval of the OraQuick® test for use in detecting HIV-2 antibodies. In response to a recent request by the FDA, OraSure will provide test data for a small number of additional positive HIV-2 samples in order to meet certain technical statistical standards required by the FDA for approval of the claim. OraSure intends to obtain and submit the additional data to the FDA during December of this year, and anticipates a prompt response from the FDA on this submission.

“We certainly continue to expect to receive FDA approval of an HIV-2 claim, based on the strong performance of our OraQuick® test in the studies performed in support of this claim,” said Mike Gausling, Chief Executive Officer of OraSure Technologies. “The request for additional data does not change this expectation, and we intend to move quickly to satisfy what we believe is the final requirement for approval of an HIV-2 claim.”

OraQuick® is a rapid, point-of-care test designed to detect antibodies to HIV within 20 minutes. OraSure has FDA approval of the OraQuick® device to test finger-stick and venipuncture whole blood specimens for antibodies to the Human Immunodeficiency Virus

Type 1, or HIV-1. In addition, OraSure has received a CLIA (Clinical Laboratory Improvement Amendments of 1988) waiver for this test, thereby permitting the test to be used in more than 180,000 sites in the United States, such as outreach clinics, community-based organizations and physicians' offices.

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 products and regulatory submissions and actions. 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 (including our ability to implement a direct sales effort or other alternative distribution for OraQuick[®]); 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; ability to obtain licenses to patents (including HIV-2 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 (including the outcome of our dispute with Abbott Laboratories); 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.