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 18, 2003

ORASURE TECHNOLOGIES, INC.

(Exact name of issuer as specified in charter)

DELAWARE	**001-16537**	**36-4370966**
(State or Other Jurisdiction of Incorporation or Organization)	**(Commission file number)**	**(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 December 15, 2003, announcing that it has submitted the additional data requested by the U.S. Food and Drug Administration ("FDA") in support of an HIV-2 claim for its 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 99.1.

The Company also issued a press release on December 17, 2003, announcing that the FDA has successfully completed a facility inspection required for the transfer of the Company's in-house and third party contract manufacturing operations from Oregon to Bethlehem, Pennsylvania. The information contained in the press release is incorporated herein by reference and attached to this Current Report on Form 8-K as Exhibit 99.2.

Item 7. Financial Statements, Pro Forma Financial Information and Exhibits.

(c) Exhibits

Exhibit Number	Description
99.1	Press Release dated December 15, 2003, announcing that the Company has submitted the additional data requested by the FDA in support of an HIV-2 claim for its OraQuick® Rapid HIV-1 Antibody Test.
99.2	Press Release dated December 17, 2003, announcing that the FDA has successfully completed a facility inspection required for the transfer of the Company's in-house and third party contract manufacturing operations from Oregon to Bethlehem, Pennsylvania.

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: December 18, 2003

By: /s/ Jack E. Jerrett

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

Index to Exhibits

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Exhibit 99.1

[LOGO]

Investor Contact:
Ronald H. Spair
Chief Financial Officer
610-882-1820
Investorinfo@orasure.com
www.orasure.com

Media Contact:
William F. Bruckner
Vice President, Strategic Marketing
610-882-1820
wbruckner@orasure.com

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

BETHLEHEM, PA – December 15, 2003 – OraSure Technologies, Inc. (Nasdaq NM:OSUR), the market leader in oral fluid diagnostics, announced today that it has submitted the additional data requested by 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. On November 14, 2003, the FDA requested that OraSure 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. Testing of the samples has been completed, and the resulting data has been submitted to the FDA. The Company believes that the data fully meets the FDA's requirements for approval of the claim.

"The additional data continues to support the strong performance of our OraQuick® test, and we remain optimistic of receiving a positive response from the FDA regarding our submission," said Mike Gausling, Chief Executive Officer of OraSure Technologies. "We also look forward to completing our work with the FDA not only on our HIV-2 claim, but also on our submissions for oral fluid and plasma claims. Assuming FDA approval of these claims, we believe OraQuick® will arguably be the most versatile rapid HIV test in the world."

OraQuick® is a rapid, point-of-care test designed to detect antibodies to HIV within 20 minutes. OraSure has received 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. The Company currently has submissions pending with the FDA for approval of claims for detecting antibodies to HIV-2 and for use of the device to test oral fluid and plasma samples.

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 approvals. 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.

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Exhibit 99.2

[LOGO]

Investor Contact:
Ronald H. Spair
Chief Financial Officer
610-882-1820
Investorinfo@orasure.com
www.orasure.com

Media Contact:
William F. Bruckner
Vice President, Strategic Marketing
610-882-1820
wbruckner@orasure.com

FDA COMPLETES INSPECTION OF ORASURE MANUFACTURING FACILITY

– Manufacturing Consolidation Expected To Save $1 Million Annually –

BETHLEHEM, PA – December 17, 2003 – OraSure Technologies, Inc. (Nasdaq NM:OSUR), the market leader in oral fluid diagnostics, announced today that the U.S. Food and Drug Administration ("FDA") has successfully completed a facility inspection required for the transfer of the Company's in-house and third party contract manufacturing operations from Oregon to Bethlehem, Pennsylvania.

In August and October, 2003, the Company submitted pre-market approval ("PMA") supplements to the FDA seeking approval to transfer manufacturing of its oral fluid Western Blot HIV-1 confirmatory test and OraSure® oral fluid collection device, respectively, to its new manufacturing facilities in Bethlehem, Pennsylvania. These submissions contained data demonstrating that the Western Blots and OraSure® devices manufactured in Pennsylvania met the same quality and performance standards as those made in Oregon.

The FDA has 135 days from the filing date to respond to the Company's submissions. As part of its review process, the FDA conducted a pre-approval inspection of the Company's Pennsylvania facilities and issued no written observations (i.e., "483's") at the conclusion of the inspection.

"We are very pleased that the FDA has just completed its inspection of our new, world class manufacturing facility," said Mike Gausling, Chief Executive Officer of OraSure Technologies. "This inspection represents a significant milestone in completing the product transfers, and is a testimony to our commitment to quality, especially by our regulatory, operations and quality teams."

When finally approved by the FDA and completed, the transfer is expected to result in annual cost savings of roughly $1 million. Approximately half of this amount is expected to result from the closure of the Company's facility in Beaverton, Oregon, which is not expected to occur before December 31, 2004. The balance of the savings is anticipated to begin after the Company begins manufacturing the Western Blot and OraSure® products, as well as its Intercept® oral fluid collection device, in Pennsylvania. Manufacturing of these products is expected to commence shortly after FDA approval of the pending PMA supplements.

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.

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