

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): January 31, 2003

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)

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.

OraSure Technologies, Inc. (the "Company") issued a press release on January 31, 2003, announcing that it had submitted an application to the U.S. Food and Drug Administration (the "FDA") for a waiver under the Clinical Laboratory Improvements Amendments of 1988 ("CLIA") for the Company's OraQuick(R) Rapid HIV-1 Antibody Test (the "OraQuick(R) Test"). A copy of the press release is attached to this Report as Exhibit 99.1 and is incorporated herein by reference.

The Company issued a second press release on January 31, 2003, announcing that the FDA has approved the Company's application for a CLIA waiver for the OraQuick(R) Test. A copy of the press release is attached to this Report as Exhibit 99.2 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: January 31, 2003

By: /s/ Jack E. Jerrett

Jack E. Jerrett
Vice President, General Counsel
and Secretary

EXHIBIT INDEX

Exhibit

- 99.1 Press Release issued January 31, 2003 by OraSure Technologies announcing that it has submitted an application to the U.S. Food and Drug Administration for a waiver under the Clinical Laboratory Improvements Amendments of 1988 ("CLIA") for the Company's OraQuick(R) Rapid HIV-1 Antibody Test.

- 99.2 Press Release issued January 31, 2003 by OraSure Technologies announcing that the U.S. Food and Drug Administration has approved a CLIA waiver for the Company's OraQuick(R) Rapid HIV-1 Antibody Test.

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Media Contact:

William Bruckner
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ORASURE APPLIES FOR CLIA WAIVER
ON ORAQUICK(R) RAPID HIV-1 ANTIBODY TEST

BETHLEHEM, PA - January 31, 2003 - OraSure Technologies, Inc. (Nasdaq NM:OSUR), the market leader in oral fluid diagnostics, announced today that it has submitted to the U.S. Food and Drug Administration (FDA) an application for a waiver under the Clinical Laboratory Improvements Amendments of 1988 (CLIA) for its OraQuick(R) Rapid HIV-1 Antibody Test. With an approved CLIA waiver, the OraQuick(R) test, which provides HIV-1 test results in just 20 minutes, would be available for use by sites in the United States that are CLIA-waived, including outreach clinics, community-based organizations and physicians' offices.

On November 7, 2002, the Company received FDA approval to manufacture and market the OraQuick(R) test in the United States for the detection of HIV-1 antibodies in finger-stick whole blood samples. Under that approval, the test is categorized as moderately complex and was restricted to use only in the nearly 40,000 laboratories in the United States certified under CLIA to perform moderately complex diagnostic tests. At the time of the approval, United States Health and Human Services Secretary, Tommy G. Thompson, strongly urged OraSure to submit an application for a CLIA waiver in order to expand the potential use of the test.

"We are very pleased to be able to quickly respond to Secretary Thompson's request and submit our application for a CLIA waiver for our OraQuick(R) Rapid HIV-1 Antibody Test," said Mike Gausling, Chief Executive Officer of OraSure Technologies. "I believe the study results in our application strongly support a CLIA waiver, and we look forward to working with the FDA once again as they review our submission."

The OraQuick(R) test has a sensitivity of 99.6% and specificity of 100% based on clinical studies performed by OraSure in support of its FDA approval. Sensitivity is a measure of the accuracy for detecting positive specimens, and specificity is a measure of the accuracy for identifying negative specimens.

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About OraSure Technologies

OraSure Technologies develops, manufactures and markets oral fluid specimen collection devices using proprietary oral fluid technologies and diagnostic products, 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.

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.

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[LOGO] OraSure Technologies, Inc.

diagnostic solutions for the new millennium

Exhibit 99.2

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ORASURE RECEIVES CLIA WAIVER
FOR ORAQUICK(R) RAPID HIV-1 ANTIBODY TEST

BETHLEHEM, PA - January 31, 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), through its Center for Devices and Radiological Health, has approved a waiver under the Clinical Laboratory Improvements Amendments of 1988 (CLIA) for the Company's OraQuick(R) Rapid HIV-1 Antibody Test.

This waiver was granted on the basis of information contained in the Company's application received by the FDA on January 30, 2003. With this waiver, the OraQuick(R) test, which provides HIV-1 test results in just 20 minutes, can now be used by a larger number of sites in the United States, including outreach clinics, community-based organizations and physicians' offices.

"We are very excited about the CLIA waiver and the opportunity to make the OraQuick(R) test available to all who need it," said Mike Gausling, Chief Executive Officer of OraSure Technologies. "This waiver is the result of a comprehensive and exhaustive review by the FDA following their initial approval of OraQuick(R) last year. The agency's continued cooperation and collaboration with OraSure on this product is very much appreciated."

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