

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): May 13, 2002

OraSure Technologies, Inc.  
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(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)
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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 May 13, 2002, announcing receipt of notification from the U.S. Food and Drug Administration that the OraQuick(R) Rapid HIV-1 Antibody Test is approvable, subject to the Company meeting certain conditions. A copy of the press release is attached to this Report as Exhibit 99 and is incorporated herein by reference.

Item 7. - Financial Statements and Exhibits.

(c) Exhibits.

Exhibits are listed on the attached exhibit index following the signature page of this Report.

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: May 13, 2002

By: /s/ Jack E. Jerrett

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Jack E. Jerrett  
Vice President, General Counsel  
and Secretary

EXHIBIT INDEX

Exhibit

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99

Press Release issued May 13, 2002 by the Company announcing receipt of notification from the U.S. Food and Drug Administration that the OraQuick(R) Rapid HIV-1 Antibody Test is approvable, subject to the Company meeting certain conditions.

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[LOGO] ORASURE TECHNOLOGIES, INC.

Company Contact:

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

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www.orasure.com  
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ORASURE RECEIVES FDA APPROVABLE LETTER FOR  
ORAQUICK(R) HIV-1 TEST

BETHLEHEM, PA - May 13, 2002 (BW HealthWire) - OraSure Technologies, Inc. (Nasdaq NM:OSUR), the market leader in oral fluid diagnostics, announced today that it has received notification from the U.S. Food and Drug Administration ("FDA") that the OraQuick(R) Rapid HIV-1 Antibody Test is approvable, subject to the Company meeting certain conditions. The OraQuick(R) test is intended to detect HIV-1 antibodies in finger stick whole blood within 20 minutes.

Sam Niedbala, OraSure's Chief Science Officer, stated, "We are extremely pleased with the FDA's response to our application. The receipt of this notification is a major milestone for the Company. We now know the steps required to obtain final approval to begin selling the OraQuick(R) test in the United States. Subject to receipt of final approval, we intend to begin selling the OraQuick(R) test in the second half of this year, as previously announced."

Final approval is subject to the Company submitting product labeling and resolving specific validation and design control issues identified during the FDA's recent pre-approval inspection of the Company's manufacturing facilities. The Company intends to resolve all issues identified by the FDA as soon as possible.

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](http://www.orasure.com).

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#### Important Information

This press release contains certain forward-looking statements, including with respect to sales, markets, 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 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 and its Annual Report on Form 10-K for the year ended December 31, 2001. 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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