

UNITED STATES
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 20, 2005

OraSure Technologies, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware

(State or Other Jurisdiction
of Incorporation)

220 East First Street
Bethlehem, Pennsylvania

(Address of Principal Executive Offices)

001-16537

(Commission
File Number)

36-4370966

(I.R.S. Employer
Identification No.)

18015-1360

(Zip Code)

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the Registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 7.01 – Regulation FD Disclosure

On December 20, 2005, OraSure Technologies, Inc. (the “Company”) issued a press release providing an update regarding an increased level of false positive results recently reported by specific clinical sites from the use of the Company’s OraQuick *ADVANCE* Rapid HIV-1/2 Antibody Test with oral fluid. A copy of this press release is attached as Exhibit 99.1 to this Report and is incorporated by reference herein.

Item 9.01 – Financial Statements and Exhibits**(d) Exhibits**

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release dated December 20, 2005

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: December 20, 2005

ORASURE TECHNOLOGIES, INC.

By: /S/ JACK E. JERRETT

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

Index to Exhibits

**Exhibit
Number**

Description

99.1

Press Release dated December 20, 2005

**OraSure Technologies, Inc.**

diagnostic solutions for the new millennium

Investor Contact:

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

Media Contact:

Jennifer Moritz
Zer0 to 5ive
917-748-4006
jmoritz@0to5.com

**ORASURE TECHNOLOGIES PROVIDES UPDATE REGARDING
ORAQUICK® ADVANCE™**

Bethlehem, PA, December 20, 2005 – OraSure Technologies, Inc. (NASDAQ: OSUR) today announced that it has taken several actions in response to recent reports that specific clinical sites in San Francisco and New York City and the L.A. Gay and Lesbian Center have recently experienced an increased level of false positive results using the Company's OraQuick® ADVANCE™ Rapid HIV-1/2 Antibody Test with oral fluid. The purpose of these actions has been to ensure that customers receive the highest quality results with the Company's products and that interested parties receive timely and accurate information regarding this matter.

These actions are as follows:

- Immediately after receiving the reports, the Company initiated a scientific and systematic evaluation of each situation and has been working in collaboration with affected customers, health care officials and government agencies including the Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA) to determine the cause or causes for these unexpected results. These evaluations include the collection of test data, an assessment of test procedures, specimen collection and other clinical variables which could affect results at the sites.
- The Company has already met with each of the agencies experiencing these unexpected results and is working expeditiously to resolve the issues reported at these sites.
- The Company has been contacting its customers throughout the country to determine if they are experiencing any unexpected results or issues with regard to the performance and procedures associated with the test, to answer any questions they may have, and to reinforce the Company's commitment to quality and customer satisfaction.

The findings to date indicate that the majority of sites within the affected regions, as well as many other regions throughout the country, have reported low rates of false positives for oral fluid that are within the label claims for OraQuick® ADVANCE™. This is helping progress the Company's investigation into site specific factors which may be contributing to unexpected results recently reported. The Company has contacted hundreds of customers that represent a large majority of all test usage in the field and will continue to closely monitor test performance throughout the country.

Douglas A. Michels, President and Chief Executive Officer of OraSure Technologies, said: "OraSure's top priority is and always has been to ensure that our customers are satisfied with the performance of our products. We are certainly taking seriously the recent reports from these clinical sites and we have moved aggressively to systematically evaluate each situation as quickly as possible and to report our findings as soon as we are able. Based on our investigation to date, we remain confident in the overall performance of the test and are grateful for the comments from customers, public health officials and others who have also expressed their continued confidence in our product. We believe OraQuick® ADVANCE™ is and will continue to be a valuable tool in the fight against HIV/AIDS."

Background Information

OraQuick® ADVANCE™ is a rapid screening test for antibodies to both HIV-1 and HIV-2, which can be used at the point of care with oral fluid, finger stick and venipuncture whole blood and plasma samples. All screening tests, whether used at the point of care or in the laboratory, will generate a certain percentage of false positive results. Consequently, all specimens that test positive for HIV with a screening test must be confirmed by additional testing using approved methods.

In November 2005, the Centers for Disease Control and Prevention (CDC) presented preliminary post-market surveillance data from the use of OraQuick® ADVANCE™ at 347 sites across the U.S. According to the CDC data, a total of 17,220 oral fluid tests were performed with an indicated specificity of 99.8 percent, which is consistent with the FDA-approved label claims for this product. The full presentation can be found on the web at: http://www.fda.gov/ohrms/dockets/ac/05/slides/5-4190S1_8_files/frame.htm

In December 2005, some specific sites in San Francisco and New York City and the L.A. Gay and Lesbian Center reported levels of false positive results while using OraQuick® ADVANCE™ with oral fluid that are higher than expected based on the previously established performance for the product. Other sites within these same regions have reported performance within the product claims. In all cases, these customers continue to use OraQuick® ADVANCE™ as their rapid test for HIV screening.

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. 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 technical investigations, product performance, and product use and sales. 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 other new products or technology; ability to fund research and development and other projects and operations; ability to obtain and 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; uncertainty and costs of litigation relating to patents and other intellectual property; 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, patent infringement, 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; 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, 2004, 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.

###