

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)  
**October 20, 2004**

**OraSure Technologies, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or Other Jurisdiction  
of Incorporation)

**001-16537**  
(Commission  
File Number)

**36-4370966**  
(IRS Employer  
Identification No.)

**220 East First Street**  
**Bethlehem, Pennsylvania**  
(Address of principal executive offices)

**18015-1360**  
(Zip Code)

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

---

(Former name or former address, if changed since last report)

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 8.01 – Other Events.**

On October 20, 2004, the Company issued a press release announcing the launch of its OraQuick® ADVANCE Rapid HIV-1/2 Antibody Test and the completion of a previously announced assessment of a subset of data from an isolated clinical trial of the test using oral fluid samples. A copy of the press release is attached as Exhibit 99 to this Form 8-K and is incorporated herein by reference.

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

<u>Exhibit Number</u>	<u>Description</u>
99	Press release, dated October 20, 2004, announcing the launch of the Company's OraQuick® ADVANCE Rapid HIV-1/2 Antibody Test and the completion of a previously announced assessment of a subset of data from an isolated clinical trial of the test using oral fluid samples.

## 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: October 20, 2004

By: /s/ Jack E. Jerrett

---

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

**Index to Exhibits**

<b><u>Exhibit No.</u></b>	<b><u>Description</u></b>
99	Press release, dated October 20, 2004, announcing the launch of the Company's OraQuick® ADVANCE Rapid HIV-1/2 Antibody Test and the completion of a previously announced assessment of a subset of data from an isolated clinical trial of the test using oral fluid samples.



**OraSure Technologies, Inc.**

diagnostic solutions for the new millennium

Exhibit 99

Investor Contact:

Ronald H. Spair  
Chief Financial Officer  
610-882-1820

[Investorinfo@orasure.com](mailto:Investorinfo@orasure.com)

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

Media Contacts:

Ron Ticho or Jennifer Moritz

Zer0 to 5ive

610-360-0205 or 718-623-0355

[rticho@orasure.com](mailto:rticho@orasure.com) or [jmoritz@0to5.com](mailto:jmoritz@0to5.com)

**ORASURE ANNOUNCES LAUNCH of  
ORAQUICK® ADVANCE RAPID HIV-1/2 ANTIBODY TEST**

*- Initial Shipments Expected in Early November 2004 -*

**BETHLEHEM, PA** – October 20, 2004 – OraSure Technologies, Inc. (NASDAQ: OSUR), the market leader in oral fluid diagnostics, announced today that it is launching its OraQuick® ADVANCE Rapid HIV-1/2 Antibody Test, the first and only U.S. Food and Drug Administration (“FDA”) approved and CLIA (Clinical Laboratory Improvements Amendments Act of 1988) waived rapid point-of-care test that provides accurate results for both HIV-1 and HIV-2 in 20 minutes, using oral fluid, finger-stick or venipuncture whole blood or plasma specimens. Shipments of the new test are expected to begin in early November 2004. The new product is being unveiled on October 21, 2004 at the United States Conference on AIDS (USCA) in Philadelphia, PA.

“The OraQuick® ADVANCE test truly represents the next generation of HIV antibody tests,” said Douglas A. Michels, President and Chief Executive Officer of OraSure Technologies. “OraQuick ADVANCE is the only FDA-approved rapid HIV test available that can be used with oral fluid and also the only FDA-approved rapid test that can screen for both HIV-1 and HIV-2. We believe it is the most versatile and comprehensive rapid HIV test available and are committed to making the test available to the widest possible range of customers in the United States and abroad.”

Earlier in 2004, OraSure announced that its OraQuick® Rapid HIV-1/2 Antibody Test had received approval from the FDA for use in detecting antibodies to both HIV-1 and HIV-2 in oral fluid, finger stick and venous whole blood, and plasma samples. Also in June 2004, OraSure announced that the OraQuick® HIV-1/2 test had received a CLIA waiver, which will allow the test to be used by more than 180,000 sites in the United States, including outreach clinics, community-based organizations, and physicians’ offices.

*-more-*

The launch follows the successful completion of a previously announced assessment conducted by the Company regarding a subset of data from an isolated clinical trial of the new oral fluid test. As part of the assessment, the Company executed a study that mirrored the use of the test in the field, in which over 12,000 test readings were reviewed. The results from that study, in addition to data analyzed from several independent studies involving over 7,000 oral fluid samples, clearly indicate that the test is operating within its specifications.

OraSure Technologies will unveil the new OraQuick<sup>®</sup> ADVANCE test in Booth #505 at the United States Conference on AIDS (USCA), taking place October 21-24, 2004, at the Philadelphia Marriott Hotel in Philadelphia, Pennsylvania.

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

#### **Important Information**

This press release contains certain forward-looking statements, including with respect to products, sales and markets. 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; 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 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; 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, 2003, 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.

###