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): March 26, 2004

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

(c) Exhibits

Exhibit Number	Description
99.1	Press Release dated March 26, 2004, announcing that OraSure Technologies, Inc. (the "Company") will need to submit additional performance data to the U.S. Food and Drug Administration ("FDA") in order to obtain 510(k) clearance of its UP*link*® Oral Fluid Drug Detection System.
99.2	Press Release dated March 26, 2004, announcing that the FDA has approved oral fluid and plasma claims for the Company's OraQuick® Rapid HIV-1/2 Antibody Test.

Item 9. Regulation FD Disclosure.

The Company issued a press release on March 26, 2004, announcing that it will need to submit additional performance data to the FDA in order to obtain 510(k) clearance of its UP*link*® Oral Fluid Drug Detection System. 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 March 26, 2004, announcing that the FDA has approved oral fluid and plasma claims for its OraQuick® Rapid HIV-1/2 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 99.2.

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: March 29, 2004

By: /s/ Jack E. Jerrett

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

Index to Exhibits

Exhibit No.	Description
99.1	Press Release dated March 26, 2004, announcing that OraSure Technologies, Inc. (the "Company") will need to submit additional performance data to the U.S. Food and Drug Administration ("FDA") in order to obtain 510(k) clearance of its UP*link*® Oral Fluid Drug Detection System.
99.2	Press Release dated March 26, 2004, announcing that the FDA has approved oral fluid and plasma claims for the Company's OraQuick® Rapid HIV-1/2 Antibody Test.

Exhibit 99.1

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:
William F. Bruckner
Vice President, Strategic Marketing
610-882-1820

ORASURE REQUIRED TO SUBMIT ADDITIONAL DATA FOR FDA CLEARANCE OF UP*LINK*® ORAL FLUID RAPID DRUG DETECTION SYSTEM

BETHLEHEM, PA. – March 26, 2004 **–** (BW HealthWire) - OraSure Technologies, Inc. (NASDAQ NM:OSUR), a market leader in oral fluid diagnostics, today announced that it will need to submit additional performance data to the U.S. Food and Drug Administration ("FDA") in order to obtain 510(k) clearance of its UP*link*® Oral Fluid Drug Detection System.

In September 2003, OraSure submitted an application with the FDA for 510(k) clearance of its UP*link*® analyzer and oral fluid assays for the rapid detection of drugs of abuse commonly identified by the National Institute for Drug Abuse ("NIDA") as the NIDA-5 panel of drugs, i.e., cocaine, opiates, amphetamine/methamphetamine, PCP and marijuana. The FDA has notified the Company that a new application will be required containing additional performance data that demonstrates that the UP*link*® system is substantially equivalent to another FDA-approved device before 510(k) clearance can be granted.

"We are obviously disappointed with the FDA's decision to require additional data and a new 510(k) application," said Mike Gausling, President and Chief Executive Officer of OraSure Technologies. "However, we remain confident in the performance of the UP*link*® system and will continue to work with the FDA to gather the additional data needed to submit a new 510(k) application for this product. We are also moving forward full steam with our plans to launch the UP*link*® system through our partner, Dräger, in the roadside testing market in Europe beginning in April. In addition, we still plan to conduct beta site testing of this product here in the United States later this year and obtain additional market research in anticipation of a potential domestic launch in 2005 once FDA clearance is obtained."

As previously announced, OraSure expects 2004 revenues to grow 25% over 2003 to at least $50 million. In addition, the Company expects to achieve profitability for the year as a whole.

About UP*link*®

UP*link*® is OraSure's first product platform based on its proprietary Up-Converting Phosphor Technology (UPT™). UP*link*® is a point-of-care system comprised of an oral fluid sample collector, test cassette, and analyzer, which is designed to deliver instrument-read results for simultaneously detecting the full NIDA-5 panel of drugs in a single oral fluid sample. The Company believes the UP*link*® point-of-care oral fluid detection system will offer several important advantages over traditional lab-based urine drug tests, including reduced costs and turn around time, the ability to perform accurate drug testing for a full NIDA-5 panel virtually anywhere, treatment of test subjects with greater dignity, and reduced risk of sample adulteration.

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 revenues, profitability, 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 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(R)); 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; 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 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.

# # #

Exhibit 99.2

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:
William F. Bruckner
Vice President, Strategic Marketing
610-882-1820

ORASURE RECEIVES FDA APPROVAL OF ORAQUICK® ORAL FLUID AND PLASMA CLAIMS

First and Only Oral Fluid Rapid HIV Test Approved in U.S. by the FDA

Press Conference Footage and B-Roll Available via Satellite Uplink, March 26, at 2 PM EST

BETHLEHEM, PA – March 26, 2004 **–** OraSure Technologies, Inc. (Nasdaq NM: OSUR), the market leader in oral fluid diagnostics, announced today that it has received U.S. Food and Drug Administration ("FDA") approval of its OraQuick® Rapid HIV Antibody Test for use with oral fluid **–** making the test the first and only rapid HIV test to be approved in the U.S. by the FDA for use with oral fluid. The test was also approved for use on plasma samples.

The approval was announced today by Secretary of Health and Human Services Tommy G. Thompson and officials from the FDA and Centers for Disease Control and Prevention ("CDC") at a press conference in Washington, D.C.

"This oral test provides another important option for people who might be afraid of a blood test," said HHS Secretary Tommy G. Thompson. "It will improve care for these people and improve the public health as well."

Secretary Thompson's sentiments were echoed by leaders both at home and abroad.

"The FDA's approval of additional claims for OraSure's new HIV test is a giant step forward in combating the global AIDS crisis. This simple test, which can use an oral fluid sample as opposed to a painful blood draw, gives new hope to those at risk of this dreaded disease," said Senator Specter (R-PA). "OraQuick® is a U.S. manufactured test that produces results in 20 minutes. The approval reaffirms this Administration's commitment to work in conjunction with private and government partners to fight the HIV virus. OraQuick® must be the new standard test for HIV testing, both in the U.S. and abroad."

Senator Rick Santorum (R-PA) also commented that, "This rapid test meets a critical global need as well as an important local need. The manufacturer of this new, oral fluid rapid HIV test technology right here in Pennsylvania will help grow the economy."

- more -

“More than 40 million people worldwide are living with HIV/AIDS, the majority of whom do not know they are harboring the most deadly virus in history and therefore spreading it to children and loved ones,” said George W. Haley, former U.S. Ambassador to the Republic of the Gambia and brother of esteemed author Alex Haley. “Countries battling the war against AIDS should have complete access to the same technology that we use on ourselves and our families here in America. Because of its design, OraQuick® can be used virtually anywhere, at anytime, and by anyone, with minimal cost, training and safety issues. Now is the time to scale up rapid testing and this simple test is one of the answers.”

“We are extremely excited and honored that Secretary Thompson has personally announced this FDA approval. Today marks the culmination of a successful collaboration between government and the private sector,” said Mike Gausling, President and Chief Executive Officer of OraSure Technologies. “As the only FDA approved rapid HIV test that can be used on oral fluid, we have delivered a revolutionary technology. Its simplicity will enable more people to be tested and to receive treatment sooner. It is a major breakthrough for rapid diagnostic testing and an important milestone for the Company as we continue to build our leadership position in the oral fluid diagnostics market.”

The OraQuick® HIV-1/2 test is the first and only rapid, point-of-care test approved by the FDA for use with oral fluid, fingerstick and venipuncture whole blood, and plasma samples. Specifically, the FDA approved the use of the test in detecting antibodies to HIV-1 in oral fluid and antibodies to both HIV-1 and HIV-2 in plasma samples and has required the Company to perform certain post marketing studies. The OraQuick® HIV-1/2 test had received prior FDA approval for use in detecting antibodies to both virus types in finger stick and venipuncture whole blood samples. OraSure is seeking a license to certain HIV-2 patents held by Bio-Rad Laboratories and is cautiously optimistic that a license will be obtained in the near future.

INTERVIEW FOOTAGE AND B-ROLL AVAILABLE MARCH 26

A satellite uplink with press conference and interview footage and b-roll will be available via satellite on Friday, March 26 at 2 p.m. EST. Coordinates for the satellite uplink are:

Date:	Friday, March 26, 2004
TIME:	2:00 p.m. to 2:15 p.m. EST
KU Band:	Satellite SBS6, Transponder 2

March 26, 10:30 AM press conference - U.S. Secretary of Health and Human Services Tommy G. Thompson and officials from FDA and CDC announce the approval of oral fluid and plasma claims for the OraQuick® HIV-1/2 test, the first rapid HIV test for use with oral fluid, finger-stick and venipuncture whole blood and plasma samples.

Press conference location:
U.S. Department of Health and Human Services
200 Independence Ave, S.W.,
Washington, DC 20201

Additional B-roll includes: Demonstration of new OraQuick® Oral Fluid HIV test procedure; demonstration of OraQuick® finger stick HIV Test procedure; footage of OraQuick® manufacturing process; footage of OraSure Technologies Headquarters.

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.

- more -

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, regulatory submissions and approvals 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 (including OraSure's 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; 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.

# # #