
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 22, 2004

OraSure Technologies, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-16537
(Commission File Number)

36-4370966
(I.R.S. 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

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 Securities 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))
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Item 7.01 – Regulation FD Disclosure

On December 22, 2004, OraSure Technologies, Inc. (the “Company”) issued a press release (i) announcing that The Centers for Disease Control and Prevention will purchase approximately \$2.3 million of the Company’s OraQuick® *ADVANCE*™ Rapid HIV-1/2 Antibody Tests, and (ii) updating the Company’s financial guidance for 2005. 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 December 22, 2004, (i) announcing that The Centers for Disease Control and Prevention will purchase approximately \$2.3 million of the Company’s OraQuick® <i>ADVANCE</i> ™ Rapid HIV-1/2 Antibody Tests, and (ii) updating the Company’s financial guidance for 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.

ORASURE TECHNOLOGIES, INC.

Date: December 22, 2004

By: /s/ Jack E. Jerrett

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

Index to Exhibits

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OraSure Technologies, Inc.

diagnostic solutions for the new millennium

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**CDC TO PURCHASE \$2.3 MILLION WORTH OF
ORAQUICK® ADVANCE™ RAPID HIV-1/2 ANTIBODY TESTS**

- Company Updates Financial Guidance for 2005 -

BETHLEHEM, PA – December 22, 2004 – OraSure Technologies, Inc. (Nasdaq NM:OSUR), the market leader in oral fluid diagnostics, announced today that The Centers for Disease Control and Prevention (“CDC”) will purchase approximately \$2.3 million of the Company’s OraQuick® ADVANCE™ Rapid HIV-1/2 Antibody Tests. The CDC purchase is expected to be fulfilled by September 30, 2005.

This is the first bulk purchase of the OraQuick® ADVANCE™ test. Two other bulk purchases of the Company’s OraQuick® Rapid HIV-1 Antibody test totaling \$4 million were previously made by the CDC in June and December of 2003. The CDC is purchasing the OraQuick® ADVANCE™ tests for further distribution to and use by state health departments, clinics and other entities in the public health sector in the United States.

“We are extremely grateful for the CDC’s continuing support of rapid HIV testing and are very pleased to announce this procurement of our new OraQuick® ADVANCE™ test,” said Douglas A. Michels, President and CEO of OraSure Technologies. “We believe our OraQuick® ADVANCE™ test is the most versatile and comprehensive rapid HIV test available, and OraSure is committed to working with the CDC and other government and state agencies to implement rapid HIV testing on a large scale across the country.”

“With today’s third bulk purchase of OraSure’s rapid HIV test by the CDC, I am optimistic that expanded distribution of the test will result in increased identification of infected individuals, a critical step in addressing the significant public health problems that the spread of HIV/AIDS poses for our country,” said Senator Rick Santorum (R-PA), Chairman of the Senate Republican Conference. “OraSure’s rapid HIV test plays an important role in complementing our public health strategies for research, prevention initiatives and efforts to expand access to quality health care and services for those who need them.”

The OraQuick® ADVANCE™ Rapid HIV-1/2 Antibody Test, manufactured and sold by OraSure Technologies, is 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 can detect antibodies to both HIV-1 and HIV-2 in 20 minutes, using oral fluid, finger-stick or venipuncture whole blood and plasma specimens.

Updated Financial Guidance for 2005

As previously announced, OraSure expects total revenues for 2005 to increase by 25% over 2004 levels, to approximately \$67.5 million. In addition, OraSure expects to achieve full-year profitability for 2005, with net income ranging from \$0.06 to \$0.08 per share.

About OraSure Technologies

OraSure Technologies develops, manufactures and markets oral fluid specimen collection devices and tests and other diagnostic products using its proprietary technologies, 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 clinical laboratories, hospitals, clinics, community-based organizations and other public health organizations, distributors, government agencies, physicians' offices, and commercial and industrial entities. For more information on the Company, please visit www.orasure.com.

Important Information

This press release contains certain forward-looking statements, including with respect to revenues, net income 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 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; 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.

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