

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): June 17, 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)

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" or "OraSure") and Abbott Laboratories ("Abbott") jointly issued a press release on June 17, 2002, announcing agreements for the co-exclusive distribution of the Company's OraQuick(R) rapid test for the detection of antibodies to the Human Immunodeficiency Virus Type 1 ("HIV-1") and for a non-exclusive sublicense of certain lateral-flow patents for which Abbott is the exclusive licensor. A copy of the press release is attached to this Report as Exhibit 99.

OraQuick(R) is a rapid, point-of-care test designed to detect antibodies to HIV-1 within 20 minutes, and is the only rapid device in the world designed to use oral fluid and whole blood samples. In June 2001, OraSure submitted an application with the U.S. Food and Drug Administration ("FDA") for pre-market approval of the OraQuick(R) device to test finger-stick whole blood specimens for HIV-1. On May 11, 2002, OraSure received notification from the FDA that its application was approvable, subject to OraSure meeting certain conditions. OraSure intends to file an application for use of the device with oral fluid specimens later in 2002.

Under the terms of the distribution agreement, Abbott was appointed as co-exclusive distributor of the OraQuick(R) HIV-1 device in the United States, and is expected to focus primarily on the hospital and physician's office laboratory markets. The agreement also permits OraSure to sell OraQuick(R) directly in the United States, and OraSure expects to sell primarily in the public health and criminal justice markets in which it already has a direct sales force to sell its products.

The distribution agreement contains certain minimum purchase commitments by Abbott. Pursuant to these commitments, the Company expects to receive product revenues of up to approximately \$4 million through the end of 2003. These expected revenues and the timing of their receipt are subject to the Company's receipt of final FDA approval of the OraQuick(R) test during the third quarter of 2002 and market acceptance of this product in the United States.

The foregoing contains certain forward-looking statements with respect to revenues, products 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 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; 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 Company's Securities and Exchange Commission filings, including its registration statements, its Annual Report on Form 10-K for the year ended December 31, 2001, and most recent Quarterly Report on Form 10-Q. 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 Report and the Company undertakes no duty to update these statements.

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: June 17, 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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Press Release issued June 17, 2002 by OraSure Technologies, Inc. and Abbott Laboratories announcing distribution agreement for the OraQuick(R) rapid HIV-1 test and sublicense of certain lateral flow technology.

For Immediate Release

Media contact  
Don Braakman  
Abbott Laboratories  
847-937-1237

Financial contacts  
John Thomas  
Abbott Laboratories  
847-938-2655

Ronald H. Spair  
OraSure Technologies, Inc.  
610-882-1820

ABBOTT AND ORASURE TECHNOLOGIES ENTER DISTRIBUTION AGREEMENT

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FOR ORAQUICK(R) RAPID HIV-1 TEST IN THE UNITED STATES  
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- Abbott to focus on hospital and physician's office laboratory markets; OraSure also sublicenses certain lateral-flow patents -

ABBOTT PARK, Ill., and BETHLEHEM, Pa., - June 17, 2002 - Abbott Laboratories (NYSE: ABT) and OraSure Technologies (Nasdaq NM:OSUR) today announced agreements for the co-exclusive distribution of OraSure Technologies' OraQuick(R) rapid test for the detection of antibodies to the Human Immunodeficiency Virus Type 1 (HIV-1) and for a non-exclusive sublicense of certain lateral-flow patents for which Abbott is the exclusive licensor.

OraQuick is a rapid, point-of-care test designed to detect antibodies to HIV-1 within 20 minutes, and is the only rapid device in the world designed to use oral fluid and whole blood samples. In June 2001, OraSure submitted an application to the U.S. Food and Drug Administration (FDA) for pre-market approval of the OraQuick device to test finger-stick whole blood specimens for HIV-1. On May 11, 2002, OraSure received notification from the FDA that its application was approvable, subject to OraSure meeting certain conditions. OraSure intends to file an application for use of the device with oral fluid specimens later in 2002.

"Abbott Laboratories is the market leader and a terrific partner for the distribution of infectious disease products, especially to the hospital and physician's office laboratory markets," said Mike Gausling, president and CEO, OraSure Technologies. "We look forward to collaborating with Abbott to rapidly expand the distribution and use of our OraQuick rapid HIV-1 test, once we receive FDA approval to sell this product in the United States. The distribution agreement is a validation of the quality, performance and versatility of the OraQuick device, and we look forward to collaborating with Abbott to make OraQuick a huge success."

"Our collaboration with OraSure will provide an important tool to assist in the rapid detection of HIV and represents Abbott's continuing commitment to improve diagnostic testing and medical care for people living with HIV and AIDS," said James Koziarz, Ph.D., vice president, Diagnostic Products Research and Development, Abbott Laboratories.

Under the terms of the distribution agreement, Abbott was appointed as co-exclusive distributor of the OraQuick HIV-1 device in the United States, and is expected to focus primarily on the hospital and physician's office laboratory markets. The agreement also permits OraSure Technologies to sell OraQuick directly in the United States, and OraSure expects to sell primarily in the public health and criminal justice markets in which it already has a direct sales force to sell its products.

Under the sublicense, OraSure will receive non-exclusive rights to certain lateral-flow patents issued in the United States and other countries, which are exclusively licensed to Abbott. Lateral-flow generally refers to the use of a test strip through which a sample flows and which provides a test result on a portion of the strip downstream from where the sample is applied. OraSure's sublicense to this technology initially extends to the field of human in vitro diagnostics with an option to expand to certain other diagnostic fields, in exchange for which OraSure will pay up-front fees and ongoing royalties.

#### 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, OraSure supplies oral fluid testing solutions for drugs of abuse testing. For more information on OraSure, please go to [www.orasure.com](http://www.orasure.com). OraQuick is a registered trademark of OraSure Technologies.

#### About Abbott Laboratories

Abbott is a leader in HIV testing, beginning with the licensure of the first HIV test in the United States in 1985. Since then, Abbott has continually improved the diagnostic effectiveness of its tests, targeting sensitivity to detect HIV infections earlier and developing advanced technology to automate HIV testing for patient diagnosis, managing therapy and screening donated blood. Abbott also has developed important HIV therapeutics including Norvir, Abbott's first protease inhibitor, and Kaletra, an advanced-generation protease inhibitor, for the treatment of HIV/AIDS.

Abbott is a global, broad-based health care company devoted to the discovery, development, manufacture and marketing of pharmaceuticals, nutritionals, and medical products, including devices and diagnostics. The company employs approximately 70,000 people and markets its products in more than 130 countries. For more information on Abbott, please go to [www.abbott.com](http://www.abbott.com).

#### --Private Securities Litigation Reform Act of 1995 -- A Caution Concerning Forward-Looking Statements

For Abbott: Some statements in this news release may be forward-looking statements for purposes of the Private Securities Litigation Reform Act of 1995. Abbott cautions that these forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those indicated in the forward-looking statements. Economic, competitive, governmental, technological and other factors that may affect Abbott's operations are discussed in Exhibit 99.1 of our 2001 Form 10-K and in our periodic reports on Form 10-Q and Form 8-K, and are incorporated by reference. Abbott undertakes no obligation to release publicly any revisions to forward-looking statements as the result of subsequent events or developments.

For OraSure: This press release contains certain forward-looking statements, including with respect to sales, markets, products, and regulatory submissions. 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 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, its Annual Report on Form 10-K for the year ended December 31, 2001 and its most recent Quarterly Report on Form 10-Q. 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.