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ORASURE TECHNOLOGIES INC

Form 8-K

June 17, 2002

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

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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.

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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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99                    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.