



OraSure Submits Additional Data to FDA for OraQuick HIV-2 Claim

December 15, 2003

BETHLEHEM, Pa., Dec 15, 2003 (BUSINESS WIRE) -- OraSure Technologies, Inc. (Nasdaq:OSUR), the market leader in oral fluid diagnostics, announced today that it has submitted the additional data requested by the U.S. Food and Drug Administration ("FDA") in support of an HIV-2 claim for its OraQuick(R) Rapid HIV-1 Antibody Test.

In June 2003, the Company submitted an application to the FDA for approval of the OraQuick(R) test for use in detecting HIV-2 antibodies. On November 14, 2003, the FDA requested that OraSure provide test data for a small number of additional positive HIV-2 samples in order to meet certain technical statistical standards required by the FDA for approval of the claim. Testing of the samples has been completed, and the resulting data has been submitted to the FDA. The Company believes that the data fully meets the FDA's requirements for approval of the claim.

"The additional data continues to support the strong performance of our OraQuick(R) test, and we remain optimistic of receiving a positive response from the FDA regarding our submission," said Mike Gausling, Chief Executive Officer of OraSure Technologies. "We also look forward to completing our work with the FDA not only on our HIV-2 claim, but also on our submissions for oral fluid and plasma claims. Assuming FDA approval of these claims, we believe OraQuick(R) will arguably be the most versatile rapid HIV test in the world."

OraQuick(R) is a rapid, point-of-care test designed to detect antibodies to HIV within 20 minutes. OraSure has received FDA approval of the OraQuick(R) device to test finger-stick and venipuncture whole blood specimens for antibodies to the Human Immunodeficiency Virus Type 1, or HIV-1. In addition, OraSure has received a CLIA (Clinical Laboratory Improvement Amendments of 1988) waiver for this test, thereby permitting the test to be used in more than 180,000 sites in the United States, such as outreach clinics, community-based organizations and physicians' offices. The Company currently has submissions pending with the FDA for approval of claims for detecting antibodies to HIV-2 and for use of the device to test oral fluid and plasma samples.

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 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; 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 (including the outcome of our dispute with Abbott Laboratories); 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, 2002, 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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