OraSure Technologies Seeks FDA Clearance for UPlink Point-of-Care Reader

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BETHLEHEM, Pa.--(BW HealthWire)--Feb. 15, 2001--OraSure Technologies, Inc., (Nasdaq:OSUR) today announced that it has filed a 510(k) application with the U.S. Food and Drug Administration (FDA) for its UPlink(TM) reader and three oral fluid drugs-of-abuse assays cocaine, opiates and amphetamines.

Two additional drugs-of-abuse assays, marijuana and PCP, are expected to be submitted within the next two months. UPlink is designed to be a highly sensitive, point-of-care diagnostic system capable of performing up to ten tests on one sample in less than ten minutes. The 510(k) application must be cleared by the FDA before commercial distribution of these products is permitted in certain markets in the United States.

OraSure's President and Chief Executive Officer Robert D. Thompson said, "This is a watershed event for the company, as we reached this key milestone one month ahead of schedule. After years of development efforts, we believe we have a very competitive product that is well suited for a broad set of applications, and we are currently on schedule for market launch in the third quarter."

The first target application for UPlink is expected to be a point-of-care oral fluid drug screen, to be performed onsite in the workplace, at occupational health clinics, at drug rehabilitation clinics and in criminal justice settings. In 1998, the domestic market for laboratory-based, drugs-of-abuse testing was approximately $1.5 billion, involving over 42 million specimens.

The same basic point-of-care system that has been submitted to the FDA is also expected to be used for other applications, such as roadside drug testing under a development and distribution agreement with Drager A.G. and gastrointestinal and respiratory infectious disease testing under a development and distribution agreement with Meridian Diagnostics.

"UPlink has all the advantages inherent in oral fluid drug testing cost savings, portability, convenience and direct observation of collection. UPlink will permit companies and clinics to perform testing immediately upon sample collection, eliminating the cost and delay of shipping samples to a lab," continued Mr. Thompson.

Many of the tests commonly performed in laboratories can be performed accurately and quickly at the point of care with UPlink, eliminating unnecessary costs and providing the opportunity for immediate treatment and counseling. The ability of UPlink to provide multiple test results simultaneously on one sample makes it ideal for a broad set of applications.

"UPlink is expected to extend our reach beyond oral fluid infectious disease and drugs of abuse testing into large new segments of the in-vitro diagnostics market. Over the next few years, Orasure Technologies plans to expand the UPlink platform into a full range of immunodiagnostic tests including thyroid testing, cancer testing, cardiac testing, and therapeutic drug monitoring," concluded Mr. Thompson.

About OraSure

OraSure Technologies, Inc. develops, manufactures and markets medical devices and diagnostic products for use by public- and private-sector clients, clinical laboratories, physicians' offices and workplace testing. 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. In addition, the company supplies oral fluid testing solutions for drugs-of-abuse testing. For more information on the company please visit www.orasure.com.

This press release contains certain forward-looking statements, including with respect to product development, performance, commercialization, regulatory approval, benefits and markets. Actual results could be significantly different. Factors that could affect results include 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 obtain 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; 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 collaborate arrangements; changes in accounting practices or interpretation of accounting requirements; equipment failures and ability to obtain needed raw materials and components; and general business and economic conditions. These and other factors are discussed more fully in the Securities and Exchange Commission (SEC) filings of OraSure Technologies, including the Registration Statement on Form S-4 filed with the SEC on August 31, 2000 and the Quarterly Report on Form 10-Q for the quarter ended September 30, 2000, and in the Epitope, Inc. Annual Report on Form 10-K for 1999. 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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