



OraSure Technologies Announces Fourth Quarter and Year-end 2000 Results

February 26, 2001

BETHLEHEM, Pa.--(BW HealthWire)--Feb. 26, 2001--

-- Product Revenue Up 20% --

-- First International OraQuick Shipments Initiated --

-- UPLink System FDA Submission --

OraSure Technologies, Inc. (Nasdaq:OSUR), the market leader for oral fluid diagnostics of infectious disease and drugs-of-abuse, today announced its fourth quarter and full-year financial results for 2000.

OraSure Technologies was formed as a result of the merger of Epitope Inc., a Nasdaq-traded company, and STC Technologies, Inc., a privately held company, on September 29, 2000.

Total revenue in the fourth quarter ended December 31, 2000, rose 15% to \$7.8 million compared to \$6.8 million a year ago. Total revenue for the year ended December 31, 2000, rose 20% to \$28.8 million compared to \$24.0 million for 1999. For both periods, product revenue (excluding license and product development revenue) increased approximately 20%. This increase was primarily the result of a 44% increase in revenue from OraSure(R) collection device sales into the life insurance and public health markets.

The net loss, including non-recurring merger costs, was \$3.7 million or \$(0.10) for the quarter, and \$12.7 million or \$(0.36) per share for the year ended December 31, 2000. Excluding the effect of non-recurring merger-related charges of \$1.7 million and \$7.6 million for the quarter and the year respectively, the Company had a net loss of \$2.0 million or \$(0.05) per share for the quarter and \$5.1 million or \$(0.15) per share for the year ended December 31, 2000. These results compare to the prior year results of a net loss of \$0.5 million or \$(0.02) per share in the comparable quarter and a net loss of \$4.2 million or \$(0.14) per share in the comparable year end period.

Overall gross margins remained relatively constant at 63% and 61% for the quarter and the year ended December 31, 2000, respectively. During 2000, the Company expensed approximately \$1.1 million of obsolete inventory as a result of expired inventory, the discontinuation of the Serum Western Blot product line and manufacturing inefficiencies related to the start-up of the OraQuick(R) product line. Without these one-time items, gross margin would have been 65% for the year 2000.

Gross margins are anticipated to improve in the future as a result of (1) the restructuring of the manufacturing operations, (2) merger-related efficiencies, (3) the operating efficiencies and capital cost savings expected from the scale up of OraQuick manufacturing, and (4) the previously announced discontinuation of the unprofitable Serum Western Blot product line.

During 2000, the Company continued to make substantial investments in the sales and marketing and research and development of OraQuick, UPT, and Intercept. For the quarter ended and year ended December 31, 2000, sales and marketing expenses increased 15% to \$1.9 million and 22% to \$6.9 million, respectively. For the quarter ended and year ended December 31, 2000, research and development expenses increased 167% to \$3.8 million and 86% to \$10.4 million, respectively.

The Company is targeting revenue growth of 50% for 2001 to approximately \$43.0 million as new products come on-line throughout the year and expects to achieve profitability in the second half of 2001, and for the year as a whole. Merger Related Items

During the fourth quarter, the Company incurred \$1.7 million of non-recurring period integration costs. The one-time costs consisted of approximately \$1.0 million of employee severance costs and approximately \$700,000 of integration costs. The merger related period costs were originally estimated at \$1.7 million in the Company's Registration Statement on Form S-4 in connection with last year's merger of the Company's predecessors, Epitope, Inc. and STC Technologies, Inc. Additional manufacturing restructuring costs are expected to be approximately \$400,000 in the first quarter of 2001.

The Company anticipates that it will exceed the total integration savings target of approximately \$2.0 million per year that was originally estimated in connection with the merger. Total annual savings from the integration of the overhead structure are expected to be approximately \$2.5 million in 2001, and approximately \$4.0 million in 2002. Company Progress

"OraSure Technologies is off to an excellent start since the merger in September. We have far exceeded our expectations for merger synergies, and laid the groundwork for low cost, high quality manufacturing in the future," said Robert D. Thompson, Chief Executive Officer of OraSure Technologies. "Our new products are showing extraordinary promise, both in the laboratory and in the marketplace. Our momentum continues to build."

OraQuick HIV-1/2 is OraSure Technologies' rapid point-of-care HIV-1/2 device, which can utilize an oral fluid, blood or serum sample for testing. The Company has made the following progress with OraQuick HIV-1/2, which was introduced for sale outside the U.S. at the International AIDS conference in Durban, South Africa in July 2000:

- Completed a distribution agreement with Edison Africa for sale of OraQuick in Sub-Saharan Africa with a minimum of \$5.0 million of revenues expected in year one. Received registration in South Africa and began initial shipments of product in the fourth quarter of 2000.
- Completed third party clinical study in Thailand, with the results demonstrating 100% sensitivity and 99.9% specificity in blood and oral fluid.
- The Center for Disease Control publicly released the most recent results of its ongoing multi-product, rapid HIV tests study in its presentation

at the Center for Disease Control's Rapid Diagnostics Meeting on February 2, 2001. OraQuick demonstrated 100% sensitivity and 99.5% specificity in whole blood samples.

- Working to develop distribution in over 36 countries. The Company is at various stages of market development, ranging from contract negotiation and registration filing to full product launch.
- Signed an agreement for the manufacturing of OraQuick in Thailand in January 2001. Production in Thailand is anticipated to start in March 2001, with manufacturing capacity of up to 20,000 units per day expected by May 2001. In addition to the economic benefits, the Company believes that capacity can be quickly increased to meet higher demand levels.
- U.S. clinical trials have continued, with the Company experiencing difficulty in recruiting known positive subjects. Due to the critical need for an FDA approved rapid HIV test, the Company, after consultation with the FDA and CDC, has opted to submit an application for approval for testing whole blood, serum and plasma in the second quarter of 2001. This decision was based on the realization that a whole blood clinical trial could be more quickly completed than one involving oral fluid. The Company will continue its original study and expects to submit an application for oral fluid testing in the third quarter of 2001.

UPLink(TM) is the Company's first product line based on the exciting new UPT(TM) label technology. UPLink is designed to be a rapid point-of-care system, providing instrument-detected quantitative results in about 10 minutes on a variety of samples, including, but not limited to, oral fluid, blood, serum, urine, and stool samples.

The Company made the following progress with UPLink and UPT:

- Submitted UPLink to FDA for 510(k) clearance for its UPLink 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. The Company expects to commence shipments of the rapid, point-of-care instrument drugs-of-abuse testing system in the second half of 2001. In 1998, the domestic market for laboratory-based, drugs-of-abuse testing was approximately \$1.5 billion, involving over 42 million specimens.
- Commenced work on the initial two assays under an agreement with Meridian BioScience. The Company expects to submit a series of UPLink tests for FDA approval for Meridian BioScience, beginning in the third quarter of 2001. The Company also expects to ship UPLink products for international sale under the Meridian Supply Agreement in the second half of 2001.
- In Spring, 2001 the Company expects to present data at the Oak Ridge Conference validating the use of a lateral flow, rapid test for DNA detection using the UPLink platform.

Intercept (TM) is the Company's oral fluid drugs-of-abuse system that provides a convenient alternative to costly, inconvenient and often embarrassing urine-based testing. This new testing system detects drugs of abuse without the need to collect urine and enables "next-day" reporting on negative results and a 48 to 72 hour turnaround for confirmed positives.

The Company has made the following progress with Intercept:

- Workplace pilot programs in process, beginning in the first quarter 2001.
- Targeting the drug rehabilitation and criminal justice markets through the Company's own sales force. In January 2001, the Company announced its first client, Bendiner Schlessinger, which is expected to generate \$500,000 in annual revenues.
- Received FDA clearance for Methadone and Barbiturates with the Intercept oral fluid tests.

The Company is also working on developing an oral fluid syphilis test, currently funded under phase II of an National Institute of Health Small Business Innovative Research grant, using a modified version of the OraSure(R) Oral Fluid Collection device, and the Company anticipates commencing clinical trials in the first half of 2001. Also in development is an oral fluid hepatitis C testing service using available blood testing kits that will be adapted to oral fluid testing. The Company is looking to launch this product in the first half of 2002. Internet Audio Broadcast

OraSure will host a conference call with analysts to discuss these results beginning at 11:00 a.m. Eastern Standard Time today. In order to listen to the conference call, please go to OraSure's web site, www.orasure.com, at least ten minutes prior to the start of the call to register, download and install any necessary audio software. In addition, a replay will be archived on OraSure's web site shortly after the call has ended and will be available for 30 days.

A replay of the call can also be accessed until March 1 by dialing 888/203-1112 (Domestic) or 719/457-0820 (International) and entering the confirmation number 423573.

OraSure Technologies, Inc.
Condensed Financial Data
(In thousands, Except Per-Share Data)
(Unaudited)

	Quarter ended December 31, -----		Year ended December 31, -----	
	2000	1999	2000	1999 (1)
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Results of Operations				
Revenues	\$ 7,786	\$ 6,783	\$ 28,788	\$ 24,046
Operating costs and expenses	9,962	7,121	35,327	28,136

Merger related expenses	1,688	--	7,608	--
Other income (expense), net	211	(153)	1,424	(93)
Net loss	(3,653)	(541)	(12,747)	(4,233)
Basic and diluted net loss per share	(0.10)	(0.02)	(0.36)	(0.14)
Shares used in computing basic and diluted net loss per share	36,361	30,887	35,002	30,597

(1) As a result of the merger between Epitepe, Inc. and STC Technologies, Inc. on September 29, 2000 and the subsequent change in the Company's fiscal year-end from September 30 to December 31, the Condensed Financial Data for the year ended December 31, 1999 reflects results for the twelve-month periods ended September 30, 1999 and December 31, 1999 for Epitepe, Inc. and STC Technologies, Inc., respectively, on a consolidated basis.

Product Revenue Summary

Three Months Ended December 31,

	Dollars		Change	Percentage of Total Revenues	
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	2000	1999	%	2000	1999
Product Revenue					
Oral Specimen collection devices	\$ 2,889	\$ 2,197	31%	37%	32%
OraQuick	80	--	N/A	1%	0%
Histofreezer cryosurgical systems	2,098	1,660	26%	27%	24%
Reagents	1,847	1,708	8%	24%	25%
Western Blot HIV Confirmatory Tests	474	400	19%	6%	6%
Other product revenue	310	458	-32%	4%	7%
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	7,698	\$ 6,423	20%	99%	95%
License and product development	88	360	-76%	1%	5%
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Total Revenues	7,786	6,783	15%	100%	100%
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Year Ended December 31,

	Dollars		Change	Percentage of Total Revenues	
	-----		-----	-----	
	2000	1999	%	2000	1999
Product Revenue					
Oral Specimen collection devices	\$11,239	\$ 7,806	44%	39%	32%
OraQuick	80	--	N/A	0%	0%
Histofreezer cryosurgical systems	6,779	5,744	18%	24%	24%
Reagents	6,726	6,158	9%	23%	26%
Western Blot HIV Confirmatory Tests	1,897	2,133	-11%	7%	9%
Other product revenue	1,374	1,307	5%	5%	5%
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	28,095	23,148	21%	98%	96%
License and product development	693	898	-23%	2%	4%
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Total Revenues	\$28,788	\$24,046	20%	100%	100%
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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 revenues, earnings, expenses, gross margins, integration savings, manufacturing capacity, regulatory filings, publication of technical data, and product development, performance, shipments 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 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; 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; 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 Epitepe, 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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