

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): October 24, 2001

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)
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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") issued a press release on October 24, 2001, announcing financial results for the third quarter of 2001 and certain other matters, including financial performance guidance for the fourth quarter of 2001 and total year 2002. A copy of the press release is attached to this Report as Exhibit 99 and is incorporated herein by reference.

The Company is also filing an updated set of "Frequently Asked Questions" and the answers to these questions. The Frequently Asked Questions reflect information that experience has demonstrated to be often asked by analysts and investors.

OraSure Technologies, Inc.

Frequently Asked Questions

See "Important Information Regarding the Answers to Frequently Asked Questions" below (Revised through October 31, 2001)

What is OraSure Technologies, Inc. and how long has it been in business?

OraSure Technologies, Inc. resulted from the September 29, 2000, merger between Epitope, Inc. (Nasdaq NM: EPTO) and STC Technologies, Inc., a closely held private company. Our combined Company leverages expertise in oral fluid testing for infectious disease and drugs of abuse in order to extend the reach of oral fluid testing to the benefit of millions of people. Epitope was incorporated in 1981 and STC Technologies was founded under the name of SolarCare, Inc. in 1987. Neither of these companies continues to exist as a separate corporate entity.

What are OraSure Technologies' main products?

OraSure Technologies' four platform technologies -- OraQuick(R), OraSure(R), UPT(TM) and UPlink(TM)-- provide the foundation for our growing line of products.

What is Up-Converting Phosphor Technology (UPT(TM))?

UPT(TM) is a proprietary label technology that can be applied to the detection of minute quantities of various substances such as antibodies, antigens, proteins, and DNA. UPT(TM) utilizes phosphorescent particles that up-convert infrared energy to visible light. When used in conjunction with antibodies or DNA probes, UPT(TM) particles produce virtually no background interference, which dramatically increases the sensitivity of any test system. In addition to elimination of interference, these particles are stable in a variety of biological specimens, allow simultaneous detection of multiple biological markers, and permit miniaturization of the test platform.

What is UPT(TM) expected to do for the Company?

UPT(TM) is a major new label technology, improving sensitivity by up to three orders of magnitude over existing label technologies. It has a broad array of potential applications, including:

- o Human clinical diagnosis for infectious disease, cancer, drugs of abuse, allergies, therapeutic drug monitoring, thyroid and cardiac conditions.
- o Biological warfare testing.
- o Biological diagnostic systems for food and environmental testing.
- o Genomics and pharmacogenomics.
- o Veterinary testing.
- o Surgical imaging.

What are OraSure Technologies' primary markets?

OraSure Technologies' primary markets today include insurance risk assessment testing, public health infectious disease testing, and correctional health and workplace drug testing. There are an estimated 34 million HIV-infected people in the world, making it a significant public health issue - both domestically and internationally. Approximately 40 million tests for drugs of abuse are performed annually in the United States. OraSure Technologies currently sells oral fluid diagnostic products to more than 170 life insurance companies in the U.S. market.

Do OraSure Technologies' products have FDA clearance/approval?

OraSure Technologies' OraSure(R) HIV-1 Oral Specimen Collection Device is the only FDA-approved oral fluid sample collection device available for use in testing for antibodies to the HIV-1 virus. The OraSure(R) HIV-1 Western Blot is an FDA-approved confirmatory test for use with an OraSure(R) HIV-1 oral fluid sample. Also, Intercept(R), Q.E.D. (R), Histofreezer(R), and selected MICRO-PLATE and AUTO-LYTE(R) assays have FDA clearance.

For what products is the Company seeking FDA clearance/approval?

OraSure Technologies commenced U.S. clinical trials in August 2000 for OraQuick(R) HIV and an application for pre-market approval was submitted to the FDA in the second quarter of 2001 for whole blood, plasma and serum applications. The Company responded to the FDA's first round of questions on the application and the FDA's review is proceeding as expected. The Company expects to submit for FDA approval of oral fluid applications during the first quarter of 2002. Also, the ULink(TM) rapid detection system, including six drugs of abuse assays, was submitted to the FDA for 510(k) clearance in the second quarter of 2001. Because this is the first reader-based oral fluid point-of-care testing system submitted to the FDA and due to ULink's(TM) broad clinical utility, the FDA has requested approximately 60 additional test samples for each of the six drug assays. As a result, the Company is expecting clearance of all drugs of abuse assays by the first quarter of 2002. FDA submission of an OraSure(R) device-based hepatitis test is expected in the first quarter of 2002.

Who are OraSure Technologies' customers?

OraSure Technologies' develops, manufactures and markets medical devices and diagnostic products for use by insurance companies, public health agencies, clinical laboratories, physicians' offices, and workplace sites. OraSure Technologies is the leading supplier of oral fluid collection devices and related assays to the life insurance industry and public health markets for the detection of antibodies to HIV and other conditions. In addition, OraSure Technologies supplies oral fluid testing solutions for drugs of abuse testing and is developing new oral fluid tests for Hepatitis C and syphilis. OraSure Technologies intends to leverage its UPT(TM) platform into development and licensing opportunities in a variety of markets, such as testing for chemical and biological warfare agents, food testing, environmental testing, and genomics.

Where are OraSure Technologies' products currently distributed?

OraSure Technologies generally has worldwide coverage for its products

Who are OraSure Technologies' principal partners?

OraSure Technologies' FDA-approved OraSure(R) HIV-1 Western Blot kit is marketed and distributed under an exclusive arrangement with Organon Teknika Corporation.

In May 1999, OraSure Technologies contracted with LabOne, Inc. to market and provide oral fluid analysis for the Intercept(R) Drugs of Abuse product line in North America for workplace drug testing. LabOne also provides laboratory services for some of OraSure Technologies' public health clients.

In March 2000, OraSure Technologies signed a research and development agreement with Drager, a European manufacturer and supplier of medical products for the purpose of developing the ULink(TM) system for rapid detection of drugs of abuse in oral fluid. Drager will distribute the product worldwide for roadside drug testing and in select criminal justice applications.

In September 2000, OraSure Technologies signed a research and development agreement with Meridian Bioscience (formerly Meridian Diagnostics). Meridian and OraSure Technologies will work together to develop, manufacture and sell a broad range of point-of-care tests for the rapid detection of parasites, gastrointestinal, and upper respiratory diseases using the ULink(TM) system. Meridian will distribute the products worldwide.

What are OraSure Technologies' priorities for 2002?

- o FDA pre-market approval of OraQuick(R)HIV for whole blood, serum, plasma and oral fluid applications.
- o FDA 510(k) clearance of the UPLink(TM) drugs of abuse rapid detection system by the end of first quarter 2002.
- o International market launch of UPLink(TM) drugs of abuse and infectious disease testing systems by the Company's partners, Drager and Meridian Biosciences, during the first half of 2002.
- o Complete development and licensing arrangements for new UPT(TM) applications.
- o Launch OraQuick(R)HIV in the United States and increase penetration in international markets.
- o Expand Intercept(R) penetration in the criminal justice, drug rehabilitation, and workplace testing markets.
- o Achieve a revenue increase of 30% or more and strong earnings growth during 2002.

How do I get more information?

You can reach OraSure Technologies' Investor Relations team via email at [investorinfo@orasure.com](mailto:investorinfo@orasure.com) or by calling Shannon Morin at 610-882-1820.

## Important Information Regarding the Answers to Frequently Asked Questions

The foregoing "Frequently Asked Questions" contain certain "forward-looking statements," within the meaning of the Federal securities laws. These include statements about expected revenues, earnings, future product performance or development, expected regulatory filings and approvals, and views of future industry or market conditions. Forward-looking statements are not guarantees of future performance or results. Known and unknown factors could cause actual performance or results to be materially different from those expressed or implied in these statements. Some of these factors are: 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; 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; equipment failures and ability to obtain needed raw materials and components; the impact of terrorist attacks and civil unrest; and general political, business and economic conditions. These and other factors that could cause the forward-looking statements to be materially different are described in greater detail in the Company's filings with the Securities and Exchange Commission, including its most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q. Although forward-looking statements help to provide complete information about future prospects, they may not be reliable.

The forward-looking statements contained in the answers to the "Frequently Asked Questions" may become outdated over time. The Company does not assume any responsibility for updating any forward-looking statements. From time-to-time, statements made by the Company may modify or replace prior statements found in the "Frequently Asked Questions" or other releases and investors should refer to the most recently dated material available. Presenting information in the "Frequently Asked Questions" or updating this information from time to time should not be deemed an acknowledgement that such information is material or otherwise required to be disclosed.

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: October 31, 2001

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 October 24, 2001 by OraSure Technologies, Inc. announcing third-quarter 2001 financial results and certain other matters.

[GRAPHIC OMITTED][GRAPHIC OMITTED]

Company Contact:

Rich Hooper  
Chief Financial Officer  
610-882-1820, ext. 3042  
Investorinfo@orasure.com  
www.orasure.com

OraSure Technologies Reports PROFIT ON RECORD revenues

Bethlehem, PA - (October 24, 2001) - OraSure Technologies, Inc. (Nasdaq NM:OSUR), the market leader for oral fluid diagnostics, today announced record third quarter revenues of \$8.6 million, a 19 percent increase over the \$7.2 million reported in the same period a year ago. The net profit for the quarter was \$16,000, an improvement of \$7.9 million over the third quarter of 2000, which included a one-time charge of \$5.9 million for merger-related expenses. Excluding revenue from the prior period for the discontinued Serum Western Blot product, total revenue would have increased by 27 percent in the third quarter. Cash flow from operations, as measured by EBITDA (earnings before interest expense, taxes, depreciation and amortization), was \$620,000 for the quarter. This was the Company's second consecutive quarter of positive cash flow.

For the first nine months of 2001, revenues were also a record of \$24.5 million, 17 percent above the comparable period in 2000. The net loss for the nine-month period was \$1.4 million, an improvement of \$7.7 million over the first nine months of 2000, which included a one-time charge of \$5.9 million for merger-related expenses. Excluding revenue from the prior period for the discontinued Serum Western Blot product, total revenue would have increased by 24 percent in the first nine months.

Robert D. Thompson, Chief Executive Officer of OraSure Technologies, Inc., stated, "We are very pleased with the strong revenue growth and achieving profitability. Our Intercept(R) and OraQuick(R) products have driven our growth this year. Intercept(R) is showing strong momentum, as oral fluid drug testing gains marketplace acceptance, in both the occupational health and correctional health settings. This momentum will be aided by the recent inclusion of oral fluid drug testing in the new draft federal drug program guidelines for all uses, including pre-employment, random, and post-accident testing. We shipped our first OraQuick(R) order to the Centers for Disease Control and Prevention (CDC) for use in more than fifteen African countries participating in the LIFE Initiative. Additionally, OraQuick(R) was selected for use in the CDC's MIRIAD Project, a program focused on reducing mother-to-child transmission of HIV in the United States." The Company showed significant improvement in its cost structure during the third quarter. Gross margins improved to 67% from 57% in the comparable quarter of 2000. Operating expenses totaled approximately \$5.7 million for the quarter, a decline of \$700,000 from the total of \$6.4 million recorded in the comparable quarter of 2000, reflecting synergies from the merger.

The Company announced today it has received FDA feedback on its OraQuick(R) submission filed in late June. The FDA responded to the OraQuick(R) submission in a very timely manner with its first round of questions on the data submitted. The Company promptly answered those questions, and the FDA's review is progressing as anticipated.

The FDA also responded to the Company's UPLink(TM) submission, which was filed in late June. Because this is the first reader-based oral fluid point-of-care testing system submitted to the FDA, and due to UPLink's(TM) very broad clinical utility, the FDA has requested approximately sixty additional trial samples for each of the six drug assays. Consequently, the Company is now expecting full clearance of all of the drugs of abuse assays in the first quarter of 2002. However, the Company expects revenue in the fourth quarter of 2001 and first quarter of 2002 from initial UPLink(TM) reader shipments to development partners.

"Despite our impressive revenue gains, we are disappointed with the unforeseen delays of OraQuick(R) orders from our African distributor, which were the result of government purchase process delays in Africa," said Mr. Thompson. "We expect to work through these delays and continue to develop these opportunities in the future," he added.

In light of these developments, the Company's new revenue projection for the fourth quarter of 2001 is set in excess of \$10 million, more than 28 percent higher than revenues in the fourth quarter of 2000. The Company also expects to report a net profit in the fourth quarter. Excluding revenues from the

discontinued Serum Western Blot product line, projected fourth quarter 2001 revenues would represent growth of more than 35 percent over 2000.

For 2002, the Company expects revenue growth of at least 30 percent over 2001, and continued strong growth in earnings. Mr. Thompson continued, "We are positioning the Company to achieve even higher growth. The key milestones include FDA approval of both the OraQuick(R) HIV and ULink(TM) Drugs of Abuse products in the United States, the recruiting of new marketing partners for ULink(TM), Intercept(R), and OraQuick(R), and the execution of additional joint development agreements to pursue new markets with our platform technologies."

## Internet Audio Broadcast

OraSure Technologies will host a conference call with analysts to discuss these results beginning at 11:00 a.m. Eastern Time (8:00 a.m. Pacific Time) today. In order to listen to the conference call, please go to OraSure Technologies' web site, [www.orasure.com](http://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 Technologies' 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 October 29, 2001, by dialing (888) 203-1112 (Domestic) or (719) 457-0820 (International) and entering the access code 683274.

### Important Information

This press release contains certain forward-looking statements, including with respect to revenues, earnings, and product development, performance, regulatory approvals, 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; 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; 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 filings of OraSure Technologies, including its Annual Report on Form 10-K for the year ended December 31, 2000. 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.

Condensed Financial Data

(In thousands, Except Per-Share Data)  
(Unaudited)

	Three months ended		Nine months ended	
	September 30,		September 30,	
	2001	2000	2001	2000
<b>Results of Operations</b>				
Revenues	\$ 8,599	\$ 7,222	\$ 24,510	\$21,002
Cost of goods sold	2,873	3,097	8,580	8,211
Gross margin	5,726	4,125	15,930	12,791
Operating expenses	5,737	6,418	17,332	17,128
Merger related costs	-	5,920	-	5,920
Manufacturing restructuring costs	-	-	450	-
Operating Income (loss)	(11)	(8,213)	(1,852)	(10,257)
Other income (expense), net	27	289	427	1,162
Net income (loss)	16	(7,924)	(1,425)	(9,095)
Earnings (loss) per common share:				
Basic	\$ 0.00	\$ (0.22)	\$(0.04)	\$ (0.26)
Diluted	\$ 0.00	\$ (0.22)	\$(0.04)	\$ (0.26)
Average shares of common stock outstanding:				
Basic	37,057	35,370	36,741	34,546
Diluted	39,009	35,370	36,741	34,546

Product Revenue Summary  
Three Months Ended September 30,

	Dollars			Percentage of Total Revenues	
	2001	2000	% Change	2001	2000
	Product Revenues				
Oral specimen collection devices	\$3,139	2,856	10%	36%	40%
OraQuick(R)	415	-	N/A	5%	0%
Histofreezer(R)cryosurgical systems	1,954	1,737	12%	23%	24%
Immunoassay tests	2,027	1,445	40%	23%	20%
Western Blot HIV confirmatory tests	143	538	(73)%	2%	7%
Other product revenues	559	291	92%	7%	4%
	8,237	6,867	20%	96%	95%
License and product development	362	355	2%	4%	5%
Total revenues	\$8,599	\$7,222	19%	100%	100%

Nine Months Ended September 30,

	Dollars		%	Percentage of Total Revenues	
	2001	2000	Change	2001	2000
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Product Revenues					
Oral specimen collection devices	\$9,855	\$8,271	19%	40%	39%
OraQuick(R)	655	-	N/A	3%	0%
Histofreezer(R)cryosurgical systems	4,733	4,681	1%	19%	22%
Immunoassay tests	5,835	4,959	18%	24%	24%
Western Blot HIV confirmatory tests	471	1,424	(67)%	2%	7%
Other product revenues	1,658	1,062	56%	7%	5%
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	23,207	20,397	14%	95%	97%
License and product development	1,303	605	115%	5%	3%
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Total revenues	\$ 24,510	\$21,002	17%	100%	100%
	=====	=====		=====	=====

## About OraSure Technologies

OraSure Technologies, Inc. is the market leader for oral fluid diagnostics. The Company develops, manufactures and markets medical devices and diagnostic products for use by insurance companies, public health agencies, clinical laboratories, physicians' offices and workplace sites. For more information on the Company, please visit [www.orasure.com](http://www.orasure.com).