UNITED STATES 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): February 9, 2011

OraSure Technologies, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware (State or Other Jurisdiction of Incorporation) 001-16537 (Commission File Number) 36-4370966 (I.R.S. Employer Identification No.)

220 East First Street Bethlehem, Pennsylvania (Address of Principal Executive Offices)

18015-1360 (Zip Code)

Registrant's telephone number, including area code: 610-882-1820

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the Registrant under any of the following provisions:

□ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

Dere-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 2.02 – Results of Operations and Financial Condition.

On February 9, 2011, OraSure Technologies, Inc. (the "Company") issued a press release announcing its financial results for the quarter and full year ended December 31, 2010 and providing financial guidance for the first quarter of 2011. A copy of the press release is attached as Exhibit 99 to this Form 8-K and is incorporated herein by reference.

The information in this Current Report and attached Exhibit shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that section, nor shall such information and Exhibit be deemed incorporated by reference in any filing under the Securities Act of 1933, except as shall be expressly set forth by specific reference in such a filing. The fact that the information and Exhibit are being furnished should not be deemed an admission as to the materiality of any information contained therein. The Company undertakes no duty or obligation to publicly update or revise the information contained in this Current Report or attached Exhibit.

Item 9.01 - Financial Statements and Exhibits.

(d) Exhibits

Exhibit	
Number	Description

99

Press Release, dated February 9, 2011, announcing financial results of OraSure Technologies, Inc. for the quarter and full year ended December 31, 2010 and providing financial guidance for the first quarter of 2011.

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.

Date: February 9, 2011

ORASURE TECHNOLOGIES, INC.

By: Jack E. Jerrett

Jack E. Jerrett Senior Vice President, General Counsel and Secretary

Index to Exhibits

<u>Exhibit No.</u> 99 Description

Press Release, dated February 9, 2011, announcing financial results of OraSure Technologies, Inc. for the quarter and full year ended December 31, 2010 and providing financial guidance for the first quarter of 2011.



Company Contact:

Ronald H. Spair Chief Financial Officer 610-882-1820 <u>Investorinfo@orasure.com</u> <u>www.orasure.com</u>

OraSure Announces Fourth Quarter and Full Year 2010 Financial Results

BETHLEHEM, PA – February 9, 2011 – (GlobeNewswire) – OraSure Technologies, Inc. (NASDAQ: OSUR), a market leader in oral fluid diagnostics, today announced revenues of \$75.0 million and \$18.8 million for the year and quarter ended December 31, 2010, respectively. This compares to revenues of \$77.0 million and \$20.9 million for the year and quarter ended December 31, 2009.

The Company recorded a net loss of \$3.5 million, or \$0.08 per share, and \$1.0 million, or \$0.02 per share, for the year and quarter ended December 31, 2010, respectively. This compares to a net loss of \$7.8 million, or \$0.17 per share, and \$2.8 million, or \$0.06 per share, for the year and quarter ended December 31, 2009, respectively. Fourth quarter and full year 2009 results include \$1.5 million in pre-tax litigation settlement expense. Also included in the full year 2009 results is a \$3.0 million pre-tax impairment charge related to the net book value of payments previously capitalized under an HCV patent license agreement.

"We exceeded our fourth quarter guidance on both the top and bottom lines and are pleased to have ended 2010 on a strong note," said Douglas A. Michels, President and CEO of OraSure Technologies. "During this past year, we also made good progress advancing our clinical programs, most notably with the receipt of a venous whole blood approval and the FDA submission for a finger stick whole blood claim for our OraQuick[®] HCV test. We also initiated the final clinical study phase for our at-home HIV test and expanded our infectious disease portfolio by acquiring rights to a rapid flu test. I believe OraSure is very well positioned to begin 2011."

For the year ended December 31, 2010, revenues decreased 3% compared to the year ended December 31, 2009, primarily as a result of lower sales of infectious disease products partially offset by an increase in sales of the Company's cryosurgical systems products and an increase in licensing and product

development revenues. The decrease in the Company's infectious disease revenues was largely due to lower international sales. This decrease was offset by higher sales of the Company's Histofreezer® cryosurgical product to physician offices in the United States. Current year licensing and product development revenue includes \$2.0 million in milestone payments received under the terms of a collaboration agreement for the development and promotion of the Company's OraQuick® rapid HCV test.

For the quarter ended December 31, 2010, revenues decreased 10% compared to the quarter ended December 31, 2009, primarily as a result of lower sales of infectious disease products in the international marketplace and lower cryosurgical systems sales primarily due to the absence in the current quarter of stocking orders associated with the launch of the Company's over-the-counter ("OTC") cryosurgical product in Brazil.

The Company's gross margin was 63% and 64% for the year and quarter ended December 31, 2010, respectively. This compares to gross margin of 61% for the full year 2009 and 59% for the quarter ended December 31, 2009. Full year 2010 gross margin increased largely as a result of the receipt of \$2.0 million in milestone payments under the Company's HCV collaboration agreement with Merck. Gross margin in the fourth quarter of 2010 benefited from a reduction in royalty expense related to the Company's OraQuick[®] HIV product.

Operating expenses for the year ended December 31, 2010 were \$50.7 million, a \$5.2 million decrease from the \$55.9 million reported in 2009. Prior year results include the \$3.0 million impairment charge and \$1.5 million litigation settlement expense mentioned above. Research and development costs were comparable year over year at \$13.2 million and \$13.4 million for 2010 and 2009, respectively. Sales and marketing expenses decreased slightly from \$21.2 million in 2009 to \$20.7 million in 2010 primarily due to lower relocation expenses. General and administrative costs remained relatively unchanged at \$16.8 million in each year.

Fourth quarter operating expenses decreased \$2.9 million from \$15.8 million in 2009 to \$12.9 million in the fourth quarter of 2010. Fourth quarter 2009 expenses included the \$1.5 million litigation settlement expense mentioned above. Research and development expenses for the fourth quarter of 2010 decreased approximately \$613,000 from the comparable period in 2009 as lower clinical trial expenses related to the Company's OraQuick[®] HCV test were partially offset by higher costs related to the clinical development of the Company's OraQuick[®] HIV OTC test. Sales and marketing expenses decreased approximately \$854,000 in the fourth quarter of 2010 primarily as a result of lower market research and travel costs. General and administrative expenses for the fourth quarter of 2010 remained flat at approximately \$4.0 million compared to \$3.9 million for the fourth quarter of 2009.

In the full year and the fourth quarter of 2009, the Company recorded an income tax benefit of \$622,000, primarily related to refundable alternative minimum taxes paid in previous years.

Cash, cash equivalents and short-term investments totaled \$75.7 million and working capital was \$77.8 million at December 31, 2010, compared to \$79.7 million and \$89.4 million, respectively, at December 31, 2009. This change in working capital reflects the reclassification of the Company's remaining unpaid principal balance of its debt obligation to a current liability as a result of its maturity in June 2011 as well as the reduction of cash, cash equivalents and short-term investments. Cash flow provided by operating activities for the year ended December 31, 2010 was \$3.9 million compared to \$293,000 used in operating activities for the year ended December 31, 2010 was \$3.9 million compared to \$293,000 used in operating activities for the year ended December 31, 2010 was \$3.9 million compared to \$293,000 used in operating activities for the year ended December 31, 2010 was \$3.9 million compared to \$293,000 used in operating activities for the year ended December 31, 2010 was \$3.9 million compared to \$293,000 used in operating activities for the year ended December 31, 2010 was \$3.9 million compared to \$293,000 used in operating activities for the year ended December 31, 2010 was \$3.9 million compared to \$293,000 used in operating activities for the year ended December 31, 2010 was \$3.9 million compared to \$293,000 used in operating activities for the year ended December 31, 2010 was \$3.9 million compared to \$293,000 used in operating activities for the year ended December 31, 2009.

First Quarter 2011 Outlook

The Company expects total revenues for the first quarter of 2011 to range from approximately \$16.75 million to \$17.25 million and is projecting a net loss per share for the first quarter of 2011 of approximately \$0.08.

OraSure Technologies, Inc.

	Condensed Financial Data (In thousands, except per-share data)				
	Unaudited				
	Three months ended December 31,		Year e Decem	oer 31,	
	2010	2009	2010	2009	
Results of Operations	¢10.017	¢ 20.007		¢77.000	
Revenues	\$18,817	\$20,887	\$75,015	\$77,026	
Cost of products sold	6,853	8,512	27,656	29,896	
Gross profit	11,964	12,375	47,359	47,130	
Operating expenses:					
Research and development	4,048	4,661	13,192	13,371	
Sales and marketing	4,830	5,684	20,727	21,224	
General and administrative	4,018	3,982	16,794	16,848	
Litigation settlement		1,451	—	1,451	
Impairment of patent and product rights				3,028	
Total operating expenses	12,896	15,778	50,713	55,922	
Operating loss	(932)	(3,403)	(3,354)	(8,792)	
Other income (expense), net	(91)	(54)	(143)	357	
Loss before income taxes	(1,023)	(3,457)	(3,497)	(8,435)	
Income tax benefit	_	(622)	_	(622)	
Net loss	\$ (1,023)	\$ (2,835)	\$ (3,497)	\$ (7,813)	
Loss per share:					
Basic and Diluted	<u>\$ (0.02)</u>	<u>\$ (0.06</u>)	<u>\$ (0.08</u>)	<u>\$ (0.17)</u>	
Weighted average shares:					
Basic and Diluted	46,221	45,921	46,187	45,878	

		Three months ended December 31,			
		Dollars	%	Percentage of Total Revenues	
Market Revenues (Unaudited)	2010	2009	Change	2010	2009
Infectious disease testing	\$11,43	7 \$12,691	(10)%	61%	61%
Substance abuse testing	2,88	6 3,137	(8)	15	15
Cryosurgical systems	2,84	4 3,160	(10)	15	15
Insurance risk assessment	1,35	5 1,604	(16)	7	8
Product revenues	18,52	2 20,592	(10)	98	99
Licensing and product development	29	5 295	_	2	1
Total revenues	\$18,81	7 \$20,887	(10)%	100%	100%

		Year ended December 31,				
		Dollars		%		ntage of Revenues
		2010	2009	Change	2010	2009
Market Revenues (Unaudited)						
Infectious disease testing		\$41,738	\$46,098	(9)%	55%	60%
Substance abuse testing		11,671	12,026	(3)	16	16
Cryosurgical systems		11,965	10,888	10	16	14
Insurance risk assessment		5,825	6,157	(5)	8	8
Product revenues		71,199	75,169	(5)	95	98
Licensing and product development		3,816	1,857	105	5	2
Total revenues		\$75,015	\$77,026	(3)%	100%	100%
		Three months ended December 31,		Year ended December 31,		%
	2010	2009	% Change	2010	2009	Change
OraQuick® Revenues						
Domestic	\$10,137	\$ 9,949	2%	\$38,218	\$39,306	(3)%
International	829	2,141	(61)	1,919	4,511	(57)
Total OraQuick [®] revenues	\$10,966	\$12,090	(9)%	\$40,137	\$43,817	(8)%
		Three months ended December 31,			Year ended December 31,	
	2010	2009	% Change	2010	2009	% Change
Intercept® Revenues						
Domestic	\$ 1,883	\$ 1,972	(5)%	\$ 7,274	\$ 7,405	(2)%
International	454	479	(5)	1,976	2,003	(1)
Total Intercept [®] revenues	\$ 2,337	\$ 2,451	(5)%	\$ 9,250	\$ 9,408	(2)%
		Three months ended December 31,		Year ended December 31,		%
	2010	2009	% Change	2010	2009	Change
Cryosurgical Systems Revenues						
Professional domestic	\$ 1,492	\$ 933	60%	\$ 5,967	\$ 3,902	53%
Professional international	520	318	64	1,385	1,919	(28)
Over-the-counter	832	1,909	(56)	4,613	5,067	(9)
Total cryosurgical systems revenues	\$ 2,844	\$ 3,160	(10)%	\$11,965	\$10,888	10%

	Dece	mber 31, 2010	Dec	ember 31, 2009
Balance Sheets (Unaudited)	Dett	<u>1110EI 31, 2010</u>	Dec	<u>ember 51, 2005</u>
Assets				
Cash, cash equivalents and short-term investments	\$	75,738	\$	79,670
Accounts receivable, net		12,471		13,693
Inventories		7,346		8,845
Prepaid expenses		1,930		2,610
Property and equipment, net		19,611		20,014
Other non-current assets		5,424		2,159
Total assets	\$	122,520	\$	126,991
Liabilities and Stockholders' Equity				
Current portion of long-term debt	\$	7,791	\$	510
Accounts payable		2,899		3,370
Accrued expenses		8,987		11,503
Long-term debt				7,792
Other liabilities		—		9
Stockholders' equity		102,843		103,807
Total liabilities and stockholders' equity	\$	122,520	\$	126,991
			Year ended December 31,	
			2010	2009
Additional Financial Data (Unaudited)				
Capital expenditures			\$ 2,106	\$ 1,200
Depreciation and amortization			\$ 3,012	\$ 3,050
Cash flows provided by (used in) operating activities			\$ 3,887	\$ (293)
Accounts receivable – days sales outstanding			61 days	65 days

Conference Call

The Company will host a conference call and audio webcast to discuss the Company's 2010 fourth quarter and full-year financial results, business developments and first quarter 2011 financial guidance, beginning today at 5:00 p.m. Eastern Time (2:00 p.m. Pacific Time). On the call will be Douglas A. Michels, President and Chief Executive Officer, and Ronald H. Spair, Chief Financial Officer and Chief Operating Officer. The call will include prepared remarks by management and a question and answer session.

In order to listen to the conference call, please either dial 877-348-9357 (Domestic) or 970-315-0488 (International) and reference Conference ID #41326273, or go to OraSure Technologies' web site, <u>www.orasure.com</u>, and click on the Investor Info link. A replay of the call will be archived on OraSure Technologies' web site shortly after the call has ended and will be available for seven days. A replay of the call can also be accessed until February 16, 2011, by

dialing 800-642-1687 (Domestic) or 706-645-9291 (International) and entering the Conference ID #41326273.

About OraSure Technologies

OraSure Technologies develops, manufactures and markets oral fluid specimen collection devices and tests and other diagnostic products using proprietary technologies, including immunoassays and other in vitro diagnostic tests and other medical devices. These products are sold in the United States and certain foreign countries to clinical laboratories, hospitals, clinics, community-based organizations and other public health organizations, distributors, government agencies, physicians' offices, and commercial and industrial entities. For more information on the Company, please visit www.orasure.com.

Important Information

This press release contains certain forward-looking statements, including with respect to expected revenues, loss per share, and expected clinical development, regulatory filings and approvals. Forward-looking statements are not guarantees of future performance or results. Known and unknown factors that could cause actual performance or results to be materially different from those expressed or implied in these statements include, but are not limited to: ability to market and sell products, whether through an internal, direct sales force or third parties; ability to manufacture products in accordance with applicable specifications, performance standards and quality requirements; changes in relationships, including disputes or disagreements, with strategic partners or other parties and reliance on strategic partners for the performance of critical activities under collaborative arrangements; failure of distributors or other customers to meet purchase forecasts or minimum purchase requirements for the Company's products; impact of replacing distributors and success of direct sales efforts; inventory levels at distributors and other customers; impact of competitors, competing products and technology changes; impact of the economic downturn, high unemployment and poor credit conditions; reduction or deferral of public funding available to customers; competition from new or better technology or lower cost products; ability to develop, commercialize and market new products; market acceptance of oral fluid testing or other products; changes in market acceptance of products based on product performance, extended shelf life or other factors; continued bulk purchases by customers, including governmental agencies, and the ability to fully deploy those purchases in a timely manner; ability to fund research and development and other products and operations; ability to obtain and maintain new or existing product distribution channels; reliance on sole supply sources for critical product components; availability of related products produced by third parties or products required for use of our products; ability to obtain, and timing and cost of obtaining, necessary regulatory approvals for new products or new indications or applications for existing products; ability to comply with applicable regulatory requirements; history of losses and ability to achieve sustained profitability; ability to utilize net operating loss carry forwards or other deferred tax assets; volatility of our stock price; uncertainty relating to patent protection and potential patent infringement claims; uncertainty and costs of litigation relating to patents and other intellectual property; availability of licenses to patents or other

technology; ability to enter into international manufacturing agreements; obstacles to international marketing and manufacturing of products; ability to sell products internationally, including the impact of changes in international funding sources and testing algorithms; 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; changes in international, federal or state laws and regulations; 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 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 Company's Securities and Exchange Commission filings, including its registration statements, Annual Report on Form 10-K for the year ended December 31, 2009, Quarterly Reports on Form 10-Q, and other filings with the SEC. Although forward-looking statements help to provide 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.