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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 8-K**

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**CURRENT REPORT**

**PURSUANT TO SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934**

**Date of Report (Date of earliest event reported): November 9, 2010**

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**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**

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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))
  - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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**Item 2.02 – Results of Operations and Financial Condition.**

On November 9, 2010, OraSure Technologies, Inc. issued a press release announcing its financial results for the quarter ended September 30, 2010, and providing financial guidance for the fourth quarter of 2010. A copy of the press release is attached as Exhibit 99 to this Form 8-K and is incorporated herein by reference.

**Item 9.01 – Financial Statements and Exhibits.**

**(d) Exhibits**

<u>Exhibit Number</u>	<u>Description</u>
99	Press Release, dated November 9, 2010, announcing financial results of OraSure Technologies, Inc. for the quarter ended September 30, 2010, and providing financial guidance for the fourth quarter of 2010.

**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: November 9, 2010

By: /s/ Jack E. Jerrett

Jack E. Jerrett

Senior Vice President, General Counsel and Secretary

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**Index to Exhibits**

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99	Press Release, dated November 9, 2010, announcing financial results of OraSure Technologies, Inc. for the quarter ended September 30, 2010, and providing financial guidance for the fourth quarter of 2010.



OraSure Technologies, Inc.

Company Contact:

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Chief Financial Officer  
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### OraSure Announces 2010 Third Quarter Financial Results

**BETHLEHEM, PA** – November 9, 2010 – (Globe Newswire) – OraSure Technologies, Inc. (NASDAQ: OSUR), a market leader in oral fluid diagnostics, today announced revenues of \$19.0 million for the three months ended September 30, 2010, compared to \$21.6 million recorded for the three months ended September 30, 2009. Revenues in the third quarter of 2009 were higher primarily because they included the elimination of a \$2.2 million backlog for OraQuick® HIV orders which existed at June 30, 2009. Revenues in the current quarter also reflect increased sales of the Company's cryosurgical systems and insurance risk assessment products, offset by decreased sales of its substance abuse testing products and lower licensing and product development revenues.

The Company recorded net income of \$274,000, or \$0.01 per share, for the third quarter of 2010, compared to net income of \$1.8 million, or \$0.04 per share, for the third quarter of 2009.

"We exceeded our guidance on both the top and bottom lines and our business performed well during the third quarter," said Douglas A. Michels, President and CEO of OraSure Technologies. "We also made good progress on our clinical programs in support of a finger stick whole blood claim and CLIA waiver for our OraQuick® HCV test and the final phase of clinical studies for our at-home HIV test."

For the nine months ended September 30, 2010, the Company recorded revenues of \$56.2 million compared to revenues of \$56.1 million for the nine months ended September 30, 2009. The Company recorded a net loss of \$2.5 million, or \$0.05 per share, for the nine months ended September 30, 2010, compared to a net loss of \$5.0 million, or \$0.11 per share, for the nine months ended September 30, 2009. The net loss for the nine months ended September 30, 2009 included a

\$3.0 million pre-tax impairment charge related to the net book value of payments previously capitalized under an HCV patent license agreement.

Gross margin in the third quarter of 2010 was 62%, compared to 64% in the third quarter of 2009. For the first nine months of 2010, gross margin was 63%, compared to 62% in the same period of 2009. Gross margin in the third quarter of 2009 benefited from the significant increase in production required to fill the backlog of OraQuick® HIV orders existing at June 30, 2009. Gross margin in the third quarter of 2010 is more representative of normal production levels and benefited from a more favorable product mix and lower scrap. Gross margin for the nine-month period ended September 30, 2010 reflects the receipt of \$2.0 million in HCV milestone payments, a more favorable product mix and an improvement in scrap and spoilage levels when compared to the same period in 2009.

Operating expenses for the third quarter of 2010 decreased to \$11.5 million, from \$12.1 million in the comparable period in 2009 primarily as a result of a decrease in sales and marketing expenses. Operating expenses for the nine months ended September 30, 2010 were \$37.8 million, compared to \$40.1 million for the same period in 2009. Increases in research and development and sales and marketing expenses for the first nine months of 2010 were offset by a decrease in general and administrative expense and the absence of a \$3.0 million impairment charge recorded in 2009.

Cash, cash equivalents and short-term investments totaled \$73.7 million and working capital was \$78.4 million at September 30, 2010, compared to \$79.7 million and \$89.4 million, respectively, at December 31, 2009. Working capital declined due to 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 and the reduction of cash, cash equivalents and short-term investments. Cash flow provided by operating activities for the three months ended September 30, 2010 was \$3.3 million, compared to \$4.3 million for the three months ended September 30, 2009.

#### **Fourth Quarter 2010 Outlook**

The Company expects total revenues for the fourth quarter of 2010 to range from approximately \$18.0 to \$18.5 million.

The Company also anticipates an increase in research and development expenses during the fourth quarter of 2010, primarily related to the initiation of CLIA waiver studies for its OraQuick® HCV test, the commencement of the final OraQuick® HIV over-the-counter clinical trial and the ongoing development of a next generation OraQuick® HIV test. These expenditures, together with the projected revenues for the period, are expected to produce a net loss per share of approximately \$0.08 to \$0.09 for the fourth quarter of 2010.

**Financial Data**
**OraSure Technologies, Inc.**
**Condensed Financial Data**  
(In thousands, except per-share data)

	Unaudited			
	Three months ended September 30,		Nine months ended September 30,	
	2010	2009	2010	2009
<b>Results of Operations</b>				
Revenues	\$19,034	\$21,609	\$56,197	\$56,139
Cost of products sold	7,220	7,706	20,802	21,384
Gross profit	<u>11,814</u>	<u>13,903</u>	<u>35,395</u>	<u>34,755</u>
Operating expenses:				
Research and development	3,008	2,925	9,143	8,710
Sales and marketing	4,593	5,228	15,898	15,540
General and administrative	3,924	3,975	12,776	12,866
Impairment of patent and product rights	—	—	—	3,028
Total operating expenses	<u>11,525</u>	<u>12,128</u>	<u>37,817</u>	<u>40,144</u>
Operating income (loss)	289	1,775	(2,422)	(5,389)
Other income (expense), net	(15)	24	(52)	411
Income (loss) before income taxes	274	1,799	(2,474)	(4,978)
Income taxes	—	—	—	—
Net income (loss)	<u>\$ 274</u>	<u>\$ 1,799</u>	<u>\$ (2,474)</u>	<u>\$ (4,978)</u>
Earnings (loss) per share:				
Basic and Diluted	<u>\$ 0.01</u>	<u>\$ 0.04</u>	<u>\$ (0.05)</u>	<u>\$ (0.11)</u>
Weighted average shares:				
Basic	<u>46,214</u>	<u>45,880</u>	<u>46,176</u>	<u>45,863</u>
Diluted	<u>46,566</u>	<u>46,024</u>	<u>46,176</u>	<u>45,863</u>

	Three months ended September 30,				
	Dollars		%	Percentage of Total Revenues	
	2010	2009		Change	2010
<b>Market Revenues (Unaudited)</b>					
Infectious disease testing	\$10,843	\$13,540	(20)%	57%	63%
Substance abuse testing	3,019	3,269	(8)	16	15
Cryosurgical systems	3,008	2,682	12	16	12
Insurance risk assessment	1,529	1,416	8	8	7
Product revenues	<u>18,399</u>	<u>20,907</u>	(12)	97	97
Licensing and product development	635	702	(10)	3	3
Total revenues	<u>\$19,034</u>	<u>\$21,609</u>	(12)%	<u>100%</u>	<u>100%</u>

Market Revenues (Unaudited)	Nine months ended September 30,				
	Dollars		% Change	Percentage of Total Revenues	
	2010	2009		2010	2009
Infectious disease testing	\$30,297	\$33,407	(9)%	54%	59%
Substance abuse testing	8,785	8,890	(1)	16	16
Cryosurgical systems	9,122	7,728	18	16	14
Insurance risk assessment	4,471	4,552	(2)	8	8
Product revenues	52,675	54,577	(3)	94	97
Licensing and product development	3,522	1,562	125	6	3
Total revenues	<u>\$56,197</u>	<u>\$56,139</u>	0%	<u>100%</u>	<u>100%</u>

OraQuick® Revenues	Three months ended September 30,		% Change	Nine months ended September 30,		% Change
	2010	2009		2010	2009	
	Domestic	\$10,102	\$11,767	(14)%	\$28,083	\$29,358
International	436	1,415	(69)	1,089	2,370	(54)
Total OraQuick® revenues	<u>\$10,538</u>	<u>\$13,182</u>	(20)%	<u>\$29,172</u>	<u>\$31,728</u>	(8)%

Intercept® Revenues	Three months ended September 30,		% Change	Nine months ended September 30,		% Change
	2010	2009		2010	2009	
	Domestic	\$ 1,913	\$ 2,086	(8)%	\$ 5,391	\$ 5,434
International	562	479	17	1,522	1,524	0
Total Intercept® revenues	<u>\$ 2,475</u>	<u>\$ 2,565</u>	(4)%	<u>\$ 6,913</u>	<u>\$ 6,958</u>	(1)%

Cryosurgical Systems Revenues	Three months ended September 30,		% Change	Nine months ended September 30,		% Change
	2010	2009		2010	2009	
	Professional domestic	\$ 1,690	\$ 1,220	39%	\$ 4,476	\$ 2,969
Professional international	326	337	(3)	865	1,601	(46)
Over-the-counter	992	1,125	(12)	3,781	3,158	20
Total cryosurgical systems revenues	<u>\$ 3,008</u>	<u>\$ 2,682</u>	12%	<u>\$ 9,122</u>	<u>\$ 7,728</u>	18%



Balance Sheets (Unaudited)	September 30, 2010	December 31, 2009
<u>Assets</u>		
Cash, cash equivalents and short-term investments	\$ 73,694	\$ 79,670
Accounts receivable, net	13,145	13,693
Inventories	7,979	8,845
Other current assets	2,024	2,610
Property and equipment, net	19,890	20,014
Other non-current assets	4,778	2,159
Total assets	<u>\$ 121,510</u>	<u>\$ 126,991</u>
<u>Liabilities and Stockholders' Equity</u>		
Current portion of long-term debt	\$ 7,917	\$ 510
Accounts payable	2,795	3,370
Accrued expenses	7,686	11,503
Long-term debt	—	7,792
Other liabilities	—	9
Stockholders' equity	103,112	103,807
Total liabilities and stockholders' equity	<u>\$ 121,510</u>	<u>\$ 126,991</u>
	<b>Nine months ended September 30,</b>	
<b>Additional Financial Data (Unaudited)</b>	<u>2010</u>	<u>2009</u>
Capital expenditures	\$ 1,643	\$ 989
Depreciation and amortization	\$ 2,101	\$ 2,360
Purchase and retirement of common stock	\$ —	\$ 309
Cash flows provided by operating activities	\$ 241	\$ 2,688
Accounts receivable – days sales outstanding	64 days	60 days

### Conference Call

The Company will host a conference call and audio webcast to discuss the Company's 2010 third quarter financial results, business developments and certain 2010 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 #20945862, or go to OraSure Technologies' web site, [www.orasure.com](http://www.orasure.com), 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 November 16, 2010, by

dialing 800-642-1687 (Domestic) or 706-645-9291 (International) and entering the Conference ID #20945862.

### **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](http://www.orasure.com).

### **Important Information**

This press release contains certain forward-looking statements, including with respect to expected revenues, earnings/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.

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