# **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): May 4, 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

ck 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 isions:
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))

#### Item 2.02 – Results of Operations and Financial Condition.

On May 4, 2011, OraSure Technologies, Inc. issued a press release announcing its financial results for the quarter ended March 31, 2011 and providing financial guidance for the second 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.

# Item 9.01 – Financial Statements and Exhibits.

# (d) Exhibits

Exhibit
Number Description

Press Release, dated May 4, 2011, announcing financial results of OraSure Technologies, Inc. for the quarter ended March 31, 2011 and providing financial guidance for the second quarter of 2011.

# Signatures

Date: May 4, 2011

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.

By: /s/ Jack E. Jerrett

Jack E. Jerrett

Senior Vice President, General Counsel and Secretary

# **Index to Exhibits**

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Press Release, dated May 4, 2011, announcing financial results of OraSure Technologies, Inc. for the quarter ended March 31, 2011 and providing financial guidance for the second quarter of 2011.



Company Contact:

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

#### **OraSure Announces 2011 First Quarter Financial Results**

**BETHLEHEM, PA** – May 4, 2011 – (Globe Newswire) – OraSure Technologies, Inc. (NASDAQ: OSUR), a market leader in oral fluid diagnostics, today announced total revenues of \$17.4 million for the three months ended March 31, 2011, compared to \$17.9 million recorded for the three months ended March 31, 2010.

Product revenues for the quarter increased 3% as higher sales of the Company's infectious disease and substance abuse testing products were partially offset by lower sales of its cryosurgical systems and insurance risk assessment products. The higher product revenues were offset by a reduction in licensing and product development revenues caused by the absence of a \$1.0 million milestone payment received in the first quarter of 2010 under the terms of the Company's collaboration with Merck related to the development and promotion of the OraQuick® rapid HCV test.

The Company reported a net loss of \$2.6 million, or \$0.06 per share, for the first quarter of 2011, compared to a net loss of \$2.2 million, or \$0.05 per share, for the first quarter of 2010.

Cash used in operating activities for the three months ended March 31, 2011 was \$2.0 million, an improvement of \$3.0 million when compared to the \$5.0 million used during the three months ended March 31, 2010.

"Our financial results for the first quarter came in better than expected," said Douglas A. Michels, President and CEO of OraSure Technologies, Inc. "We exceeded our guidance for both revenues and the bottom line. Despite continued economic and funding challenges, we made solid progress on our goals for the quarter, including the ongoing clinical development of our OraQuick® HIV OTC test, which is a testament to the quality of our team."

Gross margin in the first quarter of 2011 was 65%, compared to 64% in the first quarter of 2010. Gross margin for the current period benefited from increased manufacturing efficiencies and a more favorable product mix.

Operating expenses for the first quarter of 2011 increased to \$13.8 million, from \$13.6 million in the comparable period of 2010, primarily as a result of higher research and development expenses due to clinical trial spending related to the Company's OraQuick® HIV over-the-counter product study. This increase was partially offset by lower sales and marketing and general and administrative expenses.

Cash, cash equivalents and short-term investments totaled \$72.4 million and working capital was \$76.0 million at March 31, 2011, compared to \$75.7 million and \$77.8 million, respectively, at December 31, 2010.

#### **Second Quarter 2011 Outlook**

The Company expects total revenues for the second quarter of 2011 to range from approximately \$17.75 to \$18.25 million. The Company is currently projecting a loss per share for the second quarter of 2011 of approximately \$0.07 to \$0.08.

#### **Financial Data**

# Condensed Financial Data (In thousands, except per-share data) (<u>Unaudited</u>)

	 Three months ended March 31,		arch 31,	
	 2011		2010	
Results of Operations				
Revenues	\$ 17,414	\$	17,945	
Cost of products sold	 6,147		6,541	
Gross profit	 11,267		11,404	
Operating expenses:				
Research and development	4,420		3,107	
Sales and marketing	4,932		5,694	
General and administrative	 4,468		4,779	
Total operating expenses	13,820		13,580	
Operating loss	(2,553)		(2,176)	
Other expense	 (45)		(19)	
Pre-tax loss	 (2,598)		(2,195)	
Income tax benefit	_		_	
Net loss	\$ (2,598)	\$	(2,195)	
Loss per share				
Basic and diluted	\$ (0.06)	\$	(0.05)	
Weighted average shares:				
Basic and diluted	 46,518	_	46,112	

	Three months ended March					
Market Revenues (Unaudited)	D <sub>0</sub>	2010	% <u>Change</u>	Percenta Total Rev 2011		
Infectious disease testing	\$ 9,962	\$ 9,481	5%	57%	53%	
Substance abuse testing	3,061	2,713	13	18	15	
Cryosurgical systems	2,710	2,994	(9)	15	17	
Insurance risk assessment	1,317	1,384	(5)	8	7	
Product revenues	17,050	16,572	3	98	92	
Licensing and product development	364	1,373	(73)	2	8	
Total revenues	\$17,414	\$17,945	(3)%	100%	100%	

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OraQuick® HIV Revenues		nths ended ch 31,	% <u>Change</u>
Domestic	\$8,866	\$ 8,733	2%
International	698	324	115%
Total OraQuick® HIV revenues	\$9,564	\$ 9,057	6%
Intercept <sup>®</sup> Revenues		nths ended ch 31, 	% <u>Change</u>
Domestic	\$1,877	\$ 1,528	23%
International	519	517	
Total Intercept® revenues	\$2,396	\$ 2,045	17%
Cryosurgical Systems Revenues		nths ended ch 31, 	% <u>Change</u>
Professional domestic	\$1,342	\$ 1,210	11%
Professional international	339	270	26
Over-the-counter	1,029	1,514	(32)
Total cryosurgical systems revenues	\$2,710	\$ 2,994	(9)%

Balance Sheets (Unaudited)		March 31, 2011		December 31, 2010	
<u>Assets</u>					
Cash, cash equivalents and short-term investments	\$	72,439	\$	75,738	
Accounts receivable, net		12,120		12,471	
Inventories		7,750		7,346	
Other current assets		1,938		1,930	
Property and equipment, net		19,850		19,611	
Other non-current assets		5,096		5,424	
Total assets	\$	119,193	\$	122,520	
Liabilities and Stockholders' Equity					
Current portion of long-term debt	\$	7,667	\$	7,791	
Accounts payable		3,506		2,899	
Accrued expenses		7,048		8,987	
Stockholders' equity		100,972		102,843	
Total liabilities and stockholders' equity	\$	119,193	\$	122,520	

		Three months ended March 31,			
Additional Financial Data (Unaudited)	_	2011		2010	
Capital expenditures	\$	882	\$	532	
Depreciation and amortization	\$	829	\$	650	
Stock based compensation	\$	973	\$	891	
Cash used in operating activities	\$	2,049	\$	5,004	
Accounts receivable – days sales outstanding		63 days		61 days	

#### **Conference Call**

The Company will host a conference call and audio webcast to discuss the Company's 2011 first quarter financial results, business developments and certain 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 #61775799, or go to OraSure Technologies' web site, <a href="www.orasure.com">www.orasure.com</a>, 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 May 11, 2011, by dialing 800-642-1687 (Domestic) or 706-645-9291 (International) and entering the Conference ID #61775799.

#### **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 and earnings/loss per share. 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; 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, 2010, 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.