
**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): August 4, 2010

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))
 - 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 August 4, 2010, OraSure Technologies, Inc. issued a press release announcing its financial results for the quarter ended June 30, 2010, providing financial guidance for the third quarter of 2010 and providing an update on certain regulatory and clinical developments. 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 August 4, 2010, announcing financial results of OraSure Technologies, Inc. for the quarter ended June 30, 2010, providing financial guidance for the third quarter of 2010 and providing an update on certain regulatory and clinical developments.

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: August 4, 2010

By: /s/ Jack E. Jerrett

Jack E. Jerrett

Senior Vice President, General Counsel and Secretary

Index to Exhibits

Exhibit No.

Description

99

Press Release, dated August 4, 2010, announcing financial results of OraSure Technologies, Inc. for the quarter ended June 30, 2010, providing financial guidance for the third quarter of 2010 and providing an update on certain regulatory and clinical developments.



Company Contact:

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Chief Financial Officer
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OraSure Announces 2010 Second Quarter Financial Results

- OraSure Also Provides Update on OraQuick® HIV Shelf Life Extension and OraQuick® HCV Clinical Program -

BETHLEHEM, PA – August 4, 2010 – (Globe Newswire) – OraSure Technologies, Inc. (NASDAQ: OSUR), a market leader in oral fluid diagnostics, today announced revenues of \$19.2 million for the three months ended June 30, 2010, compared to \$17.3 million recorded for the three months ended June 30, 2009.

Revenues in the current quarter reflect increases for each of the Company's product lines and include a \$1.0 million milestone payment received under the terms of a collaboration agreement for the development and promotion of the Company's OraQuick® rapid HCV test in international markets. Second quarter 2009 revenues reflect the impact of a manufacturing issue related to the Company's OraQuick® rapid HIV-1/2 antibody test during that quarter, which resulted in a \$2.2 million back log of orders as of June 30, 2009.

The Company recorded a net loss of \$553,000, or \$0.01 per share, for the second quarter of 2010, compared to a net loss of \$5.2 million, or \$0.11 per share, for the second quarter of 2009. Second quarter 2009 results 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.

"Our financial performance exceeded our guidance for the second quarter, with increased sales across all product lines and the early receipt of an HCV milestone payment from Merck," said Douglas A. Michels, President and CEO of OraSure Technologies. "We also received several important regulatory approvals during the quarter for our OraQuick ADVANCE® HIV and OraQuick® HCV tests. In addition, a pre-market approval supplement was recently sent to the FDA seeking approval of our OraQuick® HCV test with fingerstick whole blood and we are working to address recent FDA comments with respect to an oral fluid claim for the

OraQuick® HCV Test. During the remainder of the year, we intend to continue advancing our OraQuick® HCV and HIV OTC clinical programs.”

For the six months ended June 30, 2010, the Company recorded revenues of \$37.2 million, an increase of 8% when compared to revenues of \$34.5 million for the six months ended June 30, 2009. The Company recorded a net loss of \$2.7 million, or \$0.06 per share, for the six months ended June 30, 2010, compared to a net loss of \$6.8 million, or \$0.15 per share, for the six months ended June 30, 2009. The net loss for the six months ended June 30, 2009 includes the \$3.0 million pre-tax impairment charge described above.

Gross margin in the second quarter of 2010 was 63%, compared to 57% in the second quarter of 2009. For the first six months of 2010, gross margin was also 63%, compared to 60% in the first half of 2009. Gross margin for the current quarter and six month periods benefited from the \$1.0 million HCV milestone payment, a more favorable product revenue mix and an improvement in scrap and spoilage levels when compared to 2009.

Operating expenses for the second quarter of 2010 decreased to \$12.7 million, from \$15.2 million in the comparable period in 2009. This decrease was primarily attributable to the \$3.0 million impairment charge recorded in the second quarter of 2009 and a decrease in general and administrative costs, partially offset by higher research and development and sales and marketing expenses. Operating expenses for the six months ended June 30, 2010 were \$26.3 million, compared to \$28.0 million for the comparable period in 2009. Increases in research and development and sales and marketing expenses for the first six months of 2010 were partially offset by a decrease in general and administrative expense and the absence of the \$3.0 million impairment charge recorded in the first half of 2009.

Cash, cash equivalents and short-term investments totaled \$74.5 million and working capital was \$77.0 million at June 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 June 30, 2010 was \$1.9 million, compared to \$1.0 million generated for the three months ended June 30, 2009.

Third Quarter 2010 Outlook

The Company expects total revenues for the third quarter of 2010 to range from approximately \$17.5 to \$18.0 million. The Company is currently projecting a loss per share for the third quarter of 2010 of approximately \$0.03 to \$0.04.

OraQuick ADVANCE® HIV Shelf Life

The Company's OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test previously has had a shelf life of 12 months from the date of manufacture. The U.S. Food and Drug Administration ("FDA") recently approved an extension of this dating to 18 months. The Company has also recently received approval to extend dating to 18 months in Europe. As a result, the Company will soon be selling its OraQuick® HIV test, both domestically and internationally, with an 18-month shelf life.

OraQuick® HCV Clinical Update

As previously disclosed, the FDA required the Company to conduct an additional clinical study in support of the Company's premarket approval ("PMA") application for use of its OraQuick® HCV Rapid Antibody test with fingerstick whole blood and oral fluid specimens. The Company completed the study and was prepared to submit a PMA supplement for both claims once a venous whole blood claim was approved by the FDA. In advance of submitting the PMA supplement, and in connection with discussions related to the CLIA (Clinical Laboratory Improvement Amendments of 1988) waiver protocols for this product, the Company shared its additional clinical data for fingerstick whole blood and oral fluid with the FDA. The FDA has recently provided feedback on this data to the Company.

The FDA's primary comments related to the lower sensitivity of the OraQuick® HCV test for oral fluid and fingerstick whole blood when compared to venous whole blood. As a result of these comments, the Company has decided to separate the PMA submissions for the fingerstick whole blood and oral fluid claims. A PMA supplement for fingerstick whole blood was recently sent to the FDA.

The Company intends to continue to pursue an oral fluid claim for its OraQuick® HCV test. However, the filing of a PMA supplement for oral fluid has been delayed pending additional discussions with the FDA. The Company also believes it is likely that more clinical data will be needed to support an oral fluid PMA submission for the OraQuick® HCV test.

Financial Data
Condensed Financial Data
(In thousands, except per-share data)

Unaudited

	Three months ended June 30,		Six months ended June 30,	
	2010	2009	2010	2009
Results of Operations				
Revenues	\$19,218	\$17,274	\$37,163	\$34,530
Cost of products sold	7,040	7,394	13,582	13,678
Gross profit	12,178	9,880	23,581	20,852
Operating expenses:				
Research and development	3,029	2,433	6,135	5,785
Sales and marketing	5,610	5,289	11,305	10,312
General and administrative	4,074	4,435	8,852	8,892
Impairment of patent and product rights	—	3,028	—	3,028
Total operating expenses	12,713	15,185	26,292	28,017
Operating loss	(535)	(5,305)	(2,711)	(7,165)
Other income (expense), net	(18)	145	(37)	387
Loss before income taxes	(553)	(5,160)	(2,748)	(6,778)
Income tax benefit	—	—	—	—
Net loss	<u>\$ (553)</u>	<u>\$ (5,160)</u>	<u>\$ (2,748)</u>	<u>\$ (6,778)</u>
Loss per share:				
Basic and Diluted	<u>\$ (0.01)</u>	<u>\$ (0.11)</u>	<u>\$ (0.06)</u>	<u>\$ (0.15)</u>
Weighted average shares:				
Basic and Diluted	<u>46,202</u>	<u>45,871</u>	<u>46,157</u>	<u>45,854</u>

	Three months ended June 30,				
	Dollars		% Change	Percentage of Total Revenues	
	2010	2009		2010	2009
Market Revenues (Unaudited)					
Infectious disease testing	\$ 9,974	\$ 9,417	6%	52%	54%
Substance abuse testing	3,052	2,932	4	16	17
Cryosurgical systems	3,120	2,901	8	16	17
Insurance risk assessment	1,558	1,499	4	8	9
Product revenues	17,704	16,749	6	92	97
Licensing and product development	1,514	525	188	8	3
Total revenues	<u>\$19,218</u>	<u>\$17,274</u>	11%	<u>100%</u>	<u>100%</u>

Market Revenues (Unaudited)	Six months ended June 30,				
	Dollars		% Change	Percentage of Total Revenues	
	2010	2009		2010	2009
Infectious disease testing	\$19,454	\$19,867	(2)%	52%	58%
Substance abuse testing	5,766	5,622	3	16	16
Cryosurgical systems	6,114	5,046	21	16	15
Insurance risk assessment	2,942	3,134	(6)	8	9
Product revenues	34,276	33,669	2	92	98
Licensing and product development	2,887	861	235	8	2
Total revenues	<u>\$37,163</u>	<u>\$34,530</u>	8%	<u>100%</u>	<u>100%</u>

OraQuick® Revenues	Three months ended June 30,		% Change	Six months ended June 30,		% Change
	2010	2009		2010	2009	
	Domestic	\$ 9,248	\$ 8,291	12%	\$17,979	\$17,591
International	317	496	(36)	655	953	(31)
Total OraQuick® revenues	<u>\$ 9,565</u>	<u>\$ 8,787</u>	9%	<u>\$18,634</u>	<u>\$18,544</u>	0%

Intercept® Revenues	Three months ended June 30,		% Change	Six months ended June 30,		% Change
	2010	2009		2010	2009	
	Domestic	\$ 1,949	\$ 1,771	10%	\$ 3,477	\$ 3,348
International	443	523	(15)	960	1,045	(8)
Total Intercept® revenues	<u>\$ 2,392</u>	<u>\$ 2,294</u>	4%	<u>\$ 4,437</u>	<u>\$ 4,393</u>	1%

Cryosurgical Systems Revenues	Three months ended June 30,		% Change	Six months ended June 30,		% Change
	2010	2009		2010	2009	
	Professional domestic	\$ 1,575	\$ 807	95%	\$ 2,787	\$ 1,749
Professional international	270	636	(58)	539	1,265	(57)
Over-the-counter	1,275	1,458	(13)	2,788	2,032	37
Total cryosurgical systems revenues	<u>\$ 3,120</u>	<u>\$ 2,901</u>	8%	<u>\$ 6,114</u>	<u>\$ 5,046</u>	21%

Balance Sheets (Unaudited)	June 30, 2010	December 31, 2009
<u>Assets</u>		
Cash, cash equivalents and short-term investments	\$ 74,546	\$ 79,670
Accounts receivable, net	13,021	13,693
Inventories	8,881	8,845
Other current assets	2,403	2,610
Property and equipment, net	19,958	20,014
Other non-current assets	5,124	2,159
Total assets	<u>\$ 123,933</u>	<u>\$ 126,991</u>
<u>Liabilities and Stockholders' Equity</u>		
Current portion of long-term debt	\$ 8,042	\$ 510
Accounts payable	3,005	3,370
Accrued expenses	10,796	11,503
Long-term debt	—	7,792
Other liabilities	2	9
Stockholders' equity	102,088	103,807
Total liabilities and stockholders' equity	<u>\$ 123,933</u>	<u>\$ 126,991</u>
<u>Additional Financial Data (Unaudited)</u>		
	Six months ended June 30,	
	2010	2009
Capital expenditures	\$ 1,113	\$ 741
Depreciation and amortization	\$ 1,331	\$ 1,673
Purchase and retirement of common stock	\$ —	\$ 309
Cash flows used in operating activities	\$ 3,080	\$ 1,641
Accounts receivable – days sales outstanding	62 days	58 days

Conference Call

The Company will host a conference call and audio webcast to discuss the Company's 2010 second 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 #88789490, or go to OraSure Technologies' web site, 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 August 11, 2010, by dialing 800-642-1687 (Domestic) or 706-645-9291 (International) and entering the Conference ID #88789490.

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, 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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