
**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 10, 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 February 10, 2010, OraSure Technologies, Inc. issued a press release announcing its financial results for the quarter and full year ended December 31, 2009 and providing financial guidance for the first quarter 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 February 10, 2010, announcing financial results of OraSure Technologies, Inc. for the quarter and full year ended December 31, 2009 and providing financial guidance for the first quarter 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: February 10, 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 February 10, 2010, announcing financial results of OraSure Technologies, Inc. for the quarter and full year ended December 31, 2009 and providing financial guidance for the first quarter 2010.



OraSure Technologies, Inc.

Company Contact:

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

OraSure Announces Fourth Quarter and Full Year 2009 Financial Results

BETHLEHEM, PA – February 10, 2010 – (Globe Newswire) – OraSure Technologies, Inc. (NASDAQ: OSUR), a market leader in oral fluid diagnostics, today announced revenues of \$77.0 million and \$20.9 million for the year and quarter ended December 31, 2009, respectively. This compares to revenues of \$71.1 million and \$17.2 million for the year and quarter ended December 31, 2008.

The Company recorded a net loss of \$7.8 million or \$0.17 per share, and \$2.8 million or \$0.06 per share, on a GAAP¹ basis, for the year and quarter ended December 31, 2009, respectively. This compares to a net loss of \$31.3 million or \$0.67 per share and \$29.3 million or \$0.64 per share, on a GAAP¹ basis for the year and quarter ended December 31, 2008, respectively. The net loss for the 2008 periods includes a non-cash charge of \$26.0 million reflected in the income tax provision, which resulted from establishing a full valuation allowance against the Company's net deferred tax asset.

For the year ended December 31, 2009, revenues increased 8% compared to the year ended December 31, 2008. The increase reflects revenue growth of 21% in the Company's infectious disease testing business and increased sales of the Company's cryosurgical systems and insurance risk assessment testing products. Partially offsetting these increases were a decline in substance abuse testing sales and a reduction in licensing and product development revenues.

For the quarter ended December 31, 2009, revenues increased 21% compared to the quarter ended December 31, 2008. This increase reflects 44% growth in the Company's infectious disease testing revenues and increased sales of cryosurgical systems products. These increases were partially offset by lower substance abuse testing and insurance risk assessment sales.

¹ GAAP is defined as U.S. Generally Accepted Accounting Principles

“We ended 2009 with a strong fourth quarter – exceeding our quarterly guidance on both the top and bottom lines,” said Douglas A. Michels, President and CEO of OraSure Technologies. “In 2009, we improved on several key metrics – growing our revenues, improving our gross margin, and reducing our use of cash flow from operations. We also continued to advance our major clinical programs, all of which provide significant momentum heading into 2010.”

Results for the year ended December 31, 2009 included a \$3.0 million pre-tax impairment charge related to the net book value of previously capitalized payments under a Hepatitis C (“HCV”) patent license agreement and \$1.5 million in expense associated with the settlement of patent infringement litigation with Inverness Medical. Results for the fourth quarter ended December 31, 2009 also include the litigation settlement expense. Results for the year ended December 31, 2008 included a \$4.9 million pre-tax gain related to a lump sum payment received as a result of the settlement of patent infringement litigation during the year. Excluding the impact of these items, the Company’s pre-tax loss, on a non-GAAP basis, would have been \$4.0 million and \$2.0 million for the year and quarter ended December 31, 2009, respectively. These results would compare to a pre-tax loss on a non-GAAP basis of \$13.6 million and \$5.7 million for the year and quarter ended December 31, 2008.

The Company’s gross margin was 61% and 59% for the year and quarter ended December 31, 2009, respectively. This compares to gross margin of 58% for the full year 2008 and 56% for the quarter ended December 31, 2008. Gross margin for both 2009 periods benefited from the Company’s switch in January 2009 to a direct selling model in the U.S. hospital market as well as increased manufacturing efficiencies. Gross margin for the fourth quarter of 2009 also benefited from a reduction in scrap and spoilage expense.

Operating expenses for the year and quarter ended December 31, 2009 were \$55.9 million and \$15.8 million, respectively. This compares to \$52.6 million and \$15.8 million for the year and quarter ended December 31, 2008.

A \$6.9 million decrease in research and development costs in the full year of 2009 was offset by the \$3.0 million impairment charge and \$1.5 million litigation settlement described above. Research and development costs were lower as a result of reduced clinical trial spending on the Company’s OraQuick® HIV OTC and OraQuick® HCV tests. The research and development decrease was also offset by a \$307,000 increase in sales and marketing expenses and a \$561,000 increase in general and administrative expenses. In addition, operating expenses for the full year of 2008 included the \$4.9 million litigation settlement gain discussed above.

Fourth quarter operating expenses remained flat as decreases in research and development and general and administrative expenses were offset by an increase in sales and marketing costs and the litigation settlement expense.

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. This compares to an income tax provision of \$22.5 million and \$23.6 million for the full year and fourth quarter of 2008, respectively. As previously disclosed, in the fourth quarter of 2008 the Company recorded a \$26.0 million valuation allowance against its net deferred tax asset.

Cash, cash equivalents and short-term investments totaled \$79.7 million and working capital was \$89.4 million at December 31, 2009, compared to \$82.5 million and \$90.9 million, respectively, at December 31, 2008. Cash flow used in operating activities for the year ended December 31, 2009 was \$293,000, an improvement of \$2.2 million when compared to the \$2.5 million used in operating activities for the year ended December 31, 2008.

First Quarter 2010 Outlook

The Company expects total revenues for the first quarter of 2010 to range from approximately \$19.0 to \$19.5 million and is projecting a net loss per share for the first quarter of 2010 of approximately \$0.06 to \$0.07.

Non-GAAP Financial Measures

The Company's management considers the use of non-GAAP financial measures helpful in assessing the Company's current period's financial performance, especially in comparison to the same period of the prior year. As such, the Company has presented non-GAAP loss before income taxes in the table below.

While the Company believes that disclosing the following non-GAAP financial measures allow for greater transparency in the review of its underlying financial performance, it does not consider such measures to be substitutes for, or superior to, loss before income taxes as determined in accordance with GAAP. For purposes of calculating the non-GAAP loss before income taxes, the Company excluded the \$3.0 million pre-tax impairment of patent and product rights which occurred during the second quarter of 2009, the \$1.5 million pre-tax litigation settlement expense incurred during the fourth quarter of 2009, and the \$4.9 million pre-tax gain related to a lump sum litigation settlement payment received during the first quarter of 2008, since comparable transactions did not occur during the comparative periods.

The following table reconciles the GAAP loss before income taxes to the non-GAAP loss before income taxes for the periods indicated, as well as the period-to-period change.

	Three months ended December 31,		Change
	2009	2008	
Loss before income taxes, as reported under GAAP	<u>\$(3,457)</u>	<u>\$ (5,665)</u>	\$2,208
Pre-tax litigation settlement	1,451	—	1,451
Loss before income taxes, non-GAAP	<u>\$(2,006)</u>	<u>\$ (5,665)</u>	<u>\$3,659</u>

	Year ended December 31,		Change
	2009	2008	
Loss before income taxes, as reported under GAAP	<u>\$(8,435)</u>	<u>\$ (8,748)</u>	\$ 313
Pre-tax impairment of patent and product rights	3,028	—	3,028
Pre-tax litigation settlement	1,451	(4,884)	6,335
Loss before income taxes, non-GAAP	<u>\$(3,956)</u>	<u>\$(13,632)</u>	<u>\$9,676</u>

Financial Data

	Condensed Financial Data (In thousands, except per-share data and percentages) Unaudited			
	Three months ended December 31,		Year ended December 31,	
	2009	2008	2009	2008
Results of Operations				
Revenues	\$20,887	\$ 17,209	\$77,026	\$ 71,104
Cost of products sold	8,512	7,583	29,896	29,976
Gross profit	<u>12,375</u>	<u>9,626</u>	<u>47,130</u>	<u>41,128</u>
Operating expenses:				
Research and development	4,661	5,392	13,371	20,255
Sales and marketing	5,684	5,411	21,224	20,917
General and administrative	3,982	4,994	16,848	16,287
Litigation settlement	1,451	—	1,451	(4,884)
Impairment of patent and product rights	—	—	3,028	—
Total operating expenses	<u>15,778</u>	<u>15,797</u>	<u>55,922</u>	<u>52,575</u>
Operating loss	(3,403)	(6,171)	(8,792)	(11,447)
Other income (expense), net	(54)	506	357	2,699
Loss before income taxes	<u>(3,457)</u>	<u>(5,665)</u>	<u>(8,435)</u>	<u>(8,748)</u>
Income tax provision (benefit)	(622)	23,607	(622)	22,527
Net loss	<u>\$ (2,835)</u>	<u>\$ (29,272)</u>	<u>\$ (7,813)</u>	<u>\$ (31,275)</u>
Loss per share:				
Basic and Diluted	<u>\$ (0.06)</u>	<u>\$ (0.64)</u>	<u>\$ (0.17)</u>	<u>\$ (0.67)</u>
Weighted average shares:				
Basic and Diluted	<u>45,921</u>	<u>45,882</u>	<u>45,878</u>	<u>46,550</u>

Market Revenues	Three months ended December 31,				
	Dollars		% Change	Percentage of Total Revenues	
	2009	2008		2009	2008
Infectious disease testing	\$12,691	\$ 8,837	44%	61%	51%
Substance abuse testing	3,137	3,452	(9)	15	20
Cryosurgical systems	3,160	2,928	8	15	17
Insurance risk assessment	1,604	1,690	(5)	8	10
Product revenues	20,592	16,907	22	99	98
Licensing and product development	295	302	(2)	1	2
Total revenues	<u>\$20,887</u>	<u>\$17,209</u>	21%	<u>100%</u>	<u>100%</u>

Market Revenues	Year ended December 31,				
	Dollars		% Change	Percentage of Total Revenues	
	2009	2008		2009	2008
Infectious disease testing	\$46,098	\$38,096	21%	60%	54%
Substance abuse testing	12,026	14,006	(14)	16	20
Cryosurgical systems	10,888	10,655	2	14	15
Insurance risk assessment	6,157	6,085	1	8	8
Product revenues	75,169	68,842	9	98	97
Licensing and product development	1,857	2,262	(18)	2	3
Total revenues	<u>\$77,026</u>	<u>\$71,104</u>	8%	<u>100%</u>	<u>100%</u>

OraQuick® Revenues	Three months ended December 31,			Year ended December 31,		
	2009	2008	% Change	2009	2008	% Change
	Direct to U.S. Public Health	\$ 7,351	\$ 6,177	19%	\$28,308	\$25,450
Hospital Market	2,598	1,137	128	10,998	6,625	66
International	2,141	930	130	4,511	3,234	39
Total OraQuick® revenues	<u>\$12,090</u>	<u>\$ 8,244</u>	47%	<u>\$43,817</u>	<u>\$35,309</u>	24%

Intercept® Revenues	Three months ended December 31,			Year ended December 31,		
	2009	2008	% Change	2009	2008	% Change
Workplace testing	\$ 1,025	\$ 1,270	(19)%	\$ 3,895	\$ 4,750	(18)%
Criminal Justice	675	698	(3)	2,593	2,663	(3)
International	479	598	(20)	2,003	2,168	(8)
Direct	272	299	(9)	917	1,204	(24)
Total Intercept® revenues	\$ 2,451	\$ 2,865	(14)%	\$ 9,408	\$10,785	(13)%

Cryosurgical Systems Revenues	Three months ended December 31,			Year ended December 31,		
	2009	2008	% Change	2009	2008	% Change
Professional domestic	\$ 933	\$ 970	(4)%	\$ 3,902	\$ 3,911	— %
Professional international	318	725	(56)	1,919	2,529	(24)
OTC domestic	87	—	N/A	144	—	N/A
OTC international	1,822	1,233	48	4,923	4,215	17
Total cryosurgical systems revenues	\$ 3,160	\$ 2,928	8%	\$10,888	\$10,655	2%

Balance Sheets	December 31, 2009	December 31, 2008
<u>Assets</u>		
Cash, cash equivalents and short-term investments	\$ 79,670	\$ 82,523
Accounts receivable, net	13,693	11,571
Inventories	8,845	10,704
Other current assets	2,610	1,418
Property and equipment, net	20,014	21,235
Other non-current assets	2,159	4,467
Total assets	\$ 126,991	\$ 131,918
<u>Liabilities and Stockholders' Equity</u>		
Current portion of long-term debt	\$ 510	\$ 558
Accounts payable	3,370	3,926
Accrued expenses	11,503	10,796
Long-term debt	7,792	8,301
Other liabilities	9	12
Stockholders' equity	103,807	108,325
Total liabilities and stockholders' equity	\$ 126,991	\$ 131,918

Additional Financial Data	Year ended December 31,	
	2009	2008
Capital expenditures	\$ 1,200	\$ 2,643
Depreciation and amortization	\$ 3,050	\$ 3,387
Purchase and retirement of common stock	\$ 309	\$ 5,121
Cash flows used in operating activities	\$ 293	\$ 2,460
Accounts receivable – days sales outstanding	65 days	60 days

Conference Call

The Company will host a conference call and audio webcast to discuss the Company's 2009 fourth quarter and full-year financial results, business developments and first quarter 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 888-221-3902 (Domestic) or 913-312-0417 (International) and reference Conference ID #5213543, 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 February 17, 2010, by dialing 888-203-1112 (Domestic) or 719-457-0820 (International) and entering the Conference ID #5213543.

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 revenues, expenses, net income/loss, earnings/loss per share and products. Actual results could be significantly different. Factors that could affect results include the 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 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 credit crisis; 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 and extended shelf life; 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 and ability to utilize net operating loss carryforwards or other deferred tax assets; volatility of the Company's 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 changes in international funding sources; loss or impairment of sources of capital; ability to meet financial covenants in agreements with financial institutions; ability to retain qualified personnel; exposure to patent infringement, 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 Securities and Exchange Commission ("SEC") filings of OraSure Technologies, including its registration statements, its Annual Report on Form 10-K for the year ended December 31, 2008, its Quarterly Reports on Form 10-Q, and its other filings with the SEC. 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.

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