
**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 11, 2009

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 11, 2009, OraSure Technologies, Inc. issued a press release announcing its financial results for the quarter and full year ended December 31, 2008 and providing an update on financial guidance for the first quarter 2009. 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 11, 2009, announcing financial results of OraSure Technologies, Inc. for the quarter and full year ended December 31, 2008 and providing an update on financial guidance for the first quarter 2009.

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 11, 2009

By: /s/ Jack E. Jerrett

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

Index to Exhibits

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Company Contact:

Ronald H. Spair
Chief Financial Officer
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www.orasure.com

OraSure Announces Fourth Quarter and Full Year 2008 Financial Results

BETHLEHEM, PA – February 11, 2009 – (BW HealthWire) – OraSure Technologies, Inc. (NASDAQ: OSUR), a market leader in oral fluid diagnostics, today announced revenues of \$71.1 million and \$17.2 million for the year and quarter ended December 31, 2008, respectively. This compares to revenues of \$82.7 million and \$19.8 million for the year and quarter ended December 31, 2007, respectively.

The Company recorded 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 these 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. Excluding the impact of this non-cash charge, the Company's net loss on a non-GAAP basis would have been \$5.3 million, or \$0.11 per share, and \$3.3 million, or \$0.07 per share, for the year and quarter ended December 31, 2008, respectively. These results compare to net income of \$2.5 million, or \$0.05 per fully-diluted share for the year ended December 31, 2007, and net income of \$27,000, or break-even earnings per share for the fourth quarter of 2007.

“We have recorded a full valuation allowance against our net deferred tax asset, in accordance with GAAP, as a result of the continued unprecedented volatility in the global economy and our expectation of a loss for 2009,” said Ronald H. Spair, OraSure Technologies Inc.'s Chief Financial Officer. “Establishing this valuation allowance, however, does not change our view of the Company's long-term financial outlook or the expected utilization of our net operating loss carryforwards or other deferred tax assets in the future upon returning to profitability. In addition, we finished 2008 with strong liquidity as we had \$82.5 million of cash, cash

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

equivalents and short-term investments and \$91.0 million of working capital at year end.”

For the year ended December 31, 2008, increased sales of the Company’s OraQuick *ADVANCE*[®] rapid HIV-1/2 antibody test, coupled with increased sales in the insurance risk assessment market and higher licensing and product development revenues, were offset by an expected decline in sales of the Company’s cryosurgical wart removal and substance abuse testing products.

For the quarter ended December 31, 2008, increased sales of the Company’s Intercept[®] oral fluid drug testing products and higher licensing and product development revenues, were offset by lower sales of the OraQuick *ADVANCE*[®] HIV-1/2 test to Abbott Laboratories, in anticipation of the transition of the U.S. hospital business to a direct sales model in 2009, coupled with the expected decline in sales of the Company’s cryosurgical wart removal products.

“Despite the challenges we faced during 2008 and the current uncertain economic climate, we are starting the new year on a positive note,” said Douglas A. Michels, President and Chief Executive Officer of OraSure Technologies. “Our newly expanded sales force is now selling OraQuick *ADVANCE*[®] directly into the U.S. hospital market, our sales and marketing group has been realigned and strengthened, and we recently received FDA approval of a twelve-month shelf life for OraQuick *ADVANCE*[®]. We have also made significant progress on our strategic initiatives by filing for FDA approval of our OraQuick[®] HCV test and advancing the clinical development of our OraQuick[®] HIV OTC test and the fully automated oral fluid substance abuse assays.”

The Company’s gross margins were 58% and 56% for the year and quarter ended December 31, 2008, respectively. Gross margins decreased from 61% for the full year 2007 and from 58% for the quarter ended December 31, 2007. The decrease in gross margin for both the year and fourth quarter was largely due to a less favorable product mix, driven primarily by significant declines in cryosurgical product revenues, and increases in manufacturing scrap and spoilage expense. Although scrap and spoilage for the full year exceeded 2007 levels, OraQuick[®] scrap and spoilage was down sequentially in each quarter of 2008. The majority of scrap and spoilage charges in the fourth quarter were related to products other than OraQuick[®] and are not expected to recur. Scrap and spoilage charges for 2009 are expected to be significantly lower than 2008 levels.

For the full year 2008, operating expenses increased to \$57.5 million from \$51.5 million in 2007. Operating expenses for the quarter ended December 31, 2008 were \$15.8 million, compared to \$13.0 million for the fourth quarter of 2007. These increases were primarily attributable to higher research and development costs and higher sales and marketing expenses.

Research and development costs increased in both the year and the quarter ended December 31, 2008 as a result of planned incremental costs incurred for the Company’s OraQuick[®] HIV-OTC and OraQuick[®] HCV clinical development

programs. In addition, during the fourth quarter of 2008, the Company recorded a \$1.0 million charge related to a patent license milestone payment required upon filing of the Company's OraQuick® HCV pre-market approval application with the U.S. Food and Drug Administration.

Sales and marketing expenses also increased for both the year and the quarter ended December 31, 2008. The net increases experienced in these periods were primarily due to higher staffing related costs, driven by an increase in the Company's direct sales force for the hospital market, as well as by recent organizational changes, partially offset by a decline in reimbursable cryosurgical distributor advertising and promotional costs.

General and administrative expenses for the full year 2008 decreased as a result of lower compensation costs, bank charges, consulting fees and legal expenses. Fourth quarter 2008 general and administrative expenses increased as a result of an accrual for costs associated with the termination of the Company's OraQuick® distribution agreement with Abbott Laboratories, coupled with an increase in legal fees associated with the patent infringement lawsuit filed against the Company by Inverness Medical and Church & Dwight. By contrast, fourth quarter 2007 legal expenses reflected the award of certain legal fees to the Company in connection with the Company's arbitration with Prestige Brands.

Cash, cash equivalents and short-term investments totaled \$82.5 million and working capital was \$91.0 million at December 31, 2008, compared to \$95.6 million and \$105.6 million, respectively, at December 31, 2007.

First Quarter 2009 Outlook

The Company expects total revenues for the first quarter of 2009 to range from approximately \$16.5 to \$17.0 million. The Company is currently projecting a loss per share for the first quarter of 2009 of approximately \$0.07.

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

Unaudited

	Three months ended		Year ended	
	December 31,		December 31,	
	2008	2007	2008	2007
Results of Operations				
Revenues	\$ 17,209	\$19,809	\$ 71,104	\$82,686
Cost of products sold	7,583	8,281	29,976	32,403
Gross profit	9,626	11,528	41,128	50,283
Operating expenses:				
Research and development	5,392	4,240	20,255	14,136
Sales and marketing	5,411	5,063	20,917	20,062
General and administrative	4,994	3,668	16,287	17,304
Total operating expenses	15,797	12,971	57,459	51,502
Operating loss	(6,171)	(1,443)	(16,331)	(1,219)
Other income, net	506	1,070	7,583	5,513
Pre-tax income (loss)	(5,665)	(373)	(8,748)	4,294
Income tax provision (benefit)	23,607	(400)	22,527	1,821
Net income (loss)	\$(29,272)	\$ 27	\$(31,275)	\$ 2,473
Earnings (loss) per share				
Basic and Diluted	\$ (0.64)	\$ —	\$ (0.67)	\$ 0.05
Weighted average shares:				
Basic	45,882	46,625	46,550	46,325
Diluted	45,882	47,336	46,550	46,878

Non-GAAP Financial Measures

The Company's management considers the use of non-GAAP financial measures helpful in assessing the Company's current periods' financial performance, especially in comparison to the same periods of the prior year. As such, the Company has presented non-GAAP net income (loss) and non-GAAP basic and diluted earnings (loss) per share in the table below. While the Company believes that disclosing the following non-GAAP financial measures allows for greater transparency in the review of its underlying financial performance, it does not consider such measures to be substitutes for, or superior to, net income (loss) or basic and diluted earnings (loss) per share as determined in accordance with GAAP. For purposes of calculating the non-GAAP net loss and non-GAAP basic and diluted loss per share for the current periods, the Company excluded the \$26.0 million increase to the income tax provision related to establishing a full valuation allowance against the Company's deferred tax asset, since such a significant adjustment is not expected to recur on a quarterly or annual basis.

The following table reconciles the GAAP net income (loss) and GAAP basic and diluted earnings (loss) per share to the non-GAAP net income (loss) and non-GAAP basic and diluted earnings (loss) per share for the periods indicated.

	Three months ended December 31,		Year ended December 31,	
	2008	2007	2008	2007
Net income (loss), as reported under GAAP	\$ (29,272)	\$ 27	\$ (31,275)	\$ 2,473
Tax adjustment	25,978	—	25,978	—
Net income (loss), non-GAAP	<u>\$ (3,294)</u>	<u>\$ 27</u>	<u>\$ (5,297)</u>	<u>\$ 2,473</u>
Earnings (loss) per share:				
Basic and Diluted, as reported under GAAP	\$ (0.64)	\$ —	\$ (0.67)	\$ 0.05
Tax adjustment	0.57	—	0.56	—
Basic and Diluted, non-GAAP	<u>\$ (0.07)</u>	<u>\$ —</u>	<u>\$ (0.11)</u>	<u>\$ 0.05</u>
Weighted average shares:				
Basic	<u>45,882</u>	<u>46,625</u>	<u>46,550</u>	<u>46,325</u>
Diluted	<u>45,882</u>	<u>47,336</u>	<u>46,550</u>	<u>46,878</u>

	Three months ended December 31,				
	Dollars		% Change	Percentage of Total Revenues	
	2008	2007		2008	2007
Market Revenues					
Infectious disease testing	\$ 8,837	\$ 9,444	(6)%	51%	48%
Substance abuse testing	3,452	3,390	2	20	17
Cryosurgical systems	2,928	5,343	(45)	17	27
Insurance risk assessment	1,690	1,605	5	10	8
Product revenues	16,907	19,782	(15)	98	100
Licensing and product development	302	27	1,019	2	—
Total revenues	<u>\$17,209</u>	<u>\$19,809</u>	(13)%	<u>100%</u>	<u>100%</u>

	December 31, 2008	December 31, 2007
Balance Sheets		
<u>Assets</u>		
Cash, cash equivalents and short-term investments	\$ 82,523	\$ 95,566
Accounts receivable, net	11,571	11,296
Inventories	10,704	9,410
Current deferred income taxes	—	5,061
Other current assets	1,418	2,455
Property and equipment, net	21,235	20,911
Deferred income taxes	—	17,266
Other non-current assets	4,467	5,387
Total assets	<u>\$ 131,918</u>	<u>\$ 167,352</u>
<u>Liabilities and Stockholders' Equity</u>		
Current portion of long-term debt	\$ 558	\$ 557
Accounts payable	3,926	5,616
Accrued expenses	10,796	11,996
Long-term debt	8,301	8,818
Other liabilities	12	311
Stockholders' equity	108,325	140,054
Total liabilities and stockholders' equity	<u>\$ 131,918</u>	<u>\$ 167,352</u>

	Year ended December 31,	
	2008	2007
Additional Financial Data		
Capital expenditures	\$ 2,643	\$ 5,504
Depreciation and amortization	\$ 3,177	\$ 2,736
Purchase and retirement of common stock	\$ 5,121	—
Cash flows from operating activities	\$ (2,670)	\$ 11,584
Accounts receivable – days sales outstanding	60 days	50 days

Conference Call

The Company will host a conference call and audio webcast to discuss the Company's 2008 fourth quarter and full-year financial results, business developments and first quarter 2009 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 888-742-2024 (Domestic) or 706-643-0033 (International) and reference Conference ID #83800004, 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 16, 2009, by

dialing 800-642-1687 (Domestic) or 706-645-9291 (International) and entering the Conference ID #83800004.

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, 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; 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; 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, 2007, 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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