
**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): November 4, 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 November 4, 2009, OraSure Technologies, Inc. issued a press release announcing its financial results for the quarter ended September 30, 2009 and providing financial guidance for the fourth 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 November 4, 2009, announcing financial results of OraSure Technologies, Inc. for the quarter ended September 30, 2009 and providing financial guidance for the fourth 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: November 4, 2009

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 November 4, 2009, announcing financial results of OraSure Technologies, Inc. for the quarter ended September 30, 2009 and providing financial guidance for the fourth quarter 2009.



Company Contact:

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

OraSure Announces 2009 Third Quarter Financial Results

BETHLEHEM, PA – November 4, 2009 – (Globe Newswire) – OraSure Technologies, Inc. (NASDAQ: OSUR), a market leader in oral fluid diagnostics, today announced revenues of \$21.6 million for the three months ended September 30, 2009, compared to \$16.9 million recorded for the three months ended September 30, 2008.

The revenue increase for the third quarter reflects double digit growth in sales of the Company's infectious disease testing, cryosurgical systems and insurance risk assessment testing products, partially offset by lower sales of its substance abuse testing products. A major contributor to the higher quarterly infectious disease testing revenues was the elimination of a \$2.2 million backlog of orders for the Company's OraQuick® rapid HIV-1/2 test that existed as of June 30, 2009 as a result of manufacturing issues experienced by the Company during the second quarter. License and product revenues remained flat in the third quarter of 2009 compared to the third quarter of 2008.

The Company recorded net income of \$1.8 million, or \$0.04 per share on a fully diluted basis for the third quarter of 2009, compared to a net loss of \$1.8 million, or \$0.04 per share for the third quarter of 2008.

During the fourth quarter of 2008, the Company established a full valuation allowance against its net deferred tax asset. As a result, the Company will not record Federal income tax expense or benefit in 2009. The Company recorded an income tax benefit of \$991,000 for the three months ended September 30, 2008.

"We are pleased with our third quarter results and especially with the strong growth experienced across multiple product lines," said Douglas A. Michels, President and CEO of OraSure Technologies. "Resolution of the OraQuick® manufacturing issue during the quarter allowed us to resume normal production and restore critical inventory levels of this important product. With that issue behind us, we continue to focus on accelerating the growth of our business and completion of our major clinical development programs as quickly as possible."

For the nine months ended September 30, 2009, the Company recorded revenues of \$56.1 million, an increase of 4% compared to revenues of \$53.9 million for the nine months ended September 30, 2008. The Company recorded a net loss of \$5.0 million, or \$0.11 per share, for the nine months ended September 30, 2009, compared to a net loss of \$2.0 million, or \$0.04 per share, for the nine months ended September 30, 2008, on a GAAP¹ basis. Results for the first nine months of 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. Results for the first nine months of 2008 included a \$4.9 million pre-tax gain related to a lump sum payment received under a litigation settlement agreement entered into during that period. Excluding these items, the Company would have reported, on a non-GAAP basis, a \$2.0 million pre-tax loss for the first nine months of 2009 compared to an \$8.0 million pre-tax loss for the first nine months of 2008.

Gross margin in the third quarter of 2009 was 64% compared to 58% in the third quarter of 2008. Gross margin was favorably impacted in the current quarter primarily by increased absorption of the Company's fixed costs as a result of the return to full-scale manufacturing of the OraQuick[®] rapid HIV-1/2 test and replenishment of finished goods inventories for this product. Gross margin also benefited in the quarter by the Company's switch in January 2009 to a direct selling model in the U.S. hospital market.

Operating expenses for the third quarter of 2009 decreased to \$12.1 million, from \$13.0 million in the comparable period in 2008. This decrease was primarily attributable to a \$1.2 million decrease in research and development costs associated with the Company's OraQuick[®] HCV and OraQuick[®] HIV OTC clinical development programs. Operating expenses for the nine months ended September 30, 2009 were \$40.1 million, compared to \$36.8 million for the comparable period in 2008. A \$6.2 million decrease in research and development costs in the first nine months of 2009 was offset by the \$3.0 million impairment charge described above and a \$1.6 million increase in general and administrative expenses resulting primarily from higher legal fees related to pending patent infringement litigation. In addition, operating expenses for the nine months ended September 30, 2008 included the \$4.9 million litigation settlement gain discussed above.

Cash, cash equivalents and short-term investments totaled \$83.0 million and working capital was \$92.1 million at September 30, 2009, compared to \$82.5 million and \$90.9 million, respectively, at December 31, 2008. Cash flow provided by operating activities for the nine months ended September 30, 2009 was \$2.7 million, an improvement of \$6.4 million when compared to the \$3.7 million used in operating activities for the nine months ended September 30, 2008.

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

Fourth Quarter 2009 Outlook

The Company expects total revenues for the fourth quarter of 2009 to range from approximately \$19.0 to \$19.5 million. The Company is currently projecting a loss per share for the fourth quarter of 2009 of approximately \$0.08 to \$0.09. Research and development expenses are expected to increase during the fourth quarter due to higher costs associated with the OraQuick® HCV clinical studies. In addition, fourth quarter sales and marketing expenses are expected to increase as a result of product pre-launch activities and additional market research studies to be completed in the same period.

Financial Data

	Condensed Financial Data (In thousands, except per-share data and percentages) Unaudited			
	Three months ended September 30,		Nine months ended September 30,	
	2009	2008	2009	2008
Results of Operations				
Revenues	\$21,609	\$16,860	\$56,139	\$53,895
Cost of products sold	7,706	7,145	21,384	22,393
Gross profit	13,903	9,715	34,755	31,502
Operating expenses:				
Research and development	2,925	4,167	8,710	14,864
Sales and marketing	5,228	5,327	15,540	15,505
General and administrative	3,975	3,562	12,866	11,293
Litigation settlement	—	—	—	(4,884)
Impairment of patent and product rights	—	—	3,028	—
Total operating expenses	12,128	13,056	40,144	36,778
Operating income (loss)	1,775	(3,341)	(5,389)	(5,276)
Other income, net	24	588	411	2,194
Income (loss) before income taxes	1,799	(2,753)	(4,978)	(3,082)
Income tax benefit	—	(991)	—	(1,079)
Net income (loss)	\$ 1,799	\$ (1,762)	\$ (4,978)	\$ (2,003)
Earnings (loss) per share:				
Basic and Diluted	\$ 0.04	\$ (0.04)	\$ (0.11)	\$ (0.04)
Weighted average shares:				
Basic	45,880	46,692	45,863	46,774
Diluted	46,024	46,692	45,863	46,774

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 measure 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, 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, as well as the \$4.9 million pre-tax gain related to a lump sum payment received pursuant to a litigation settlement agreement entered into during the first quarter of 2008, since such significant or 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.

	Nine months ended September 30,		Change
	2009	2008	
Loss before income taxes, as reported under GAAP	\$(4,978)	\$(3,082)	\$(1,896)
Pre-tax impairment charge adjustment	3,028	—	3,028
Pre-tax litigation settlement	—	(4,884)	4,884
Loss before income taxes, non-GAAP	<u>\$(1,950)</u>	<u>\$(7,966)</u>	<u>\$ 6,016</u>

Market Revenues	Three months ended September 30,				
	Dollars		%	Percentage of Total Revenues	
	2009	2008	Change	2009	2008
Infectious disease testing	\$13,540	\$ 9,743	39%	63%	58%
Substance abuse testing	3,269	3,581	(9)	15	21
Cryosurgical systems	2,682	1,671	61	12	10
Insurance risk assessment	1,416	1,163	22	7	7
Product revenues	<u>20,907</u>	<u>16,158</u>	29	97	96
Licensing and product development	702	702	—	3	4
Total revenues	<u>\$21,609</u>	<u>\$16,860</u>	28%	<u>100%</u>	<u>100%</u>

	Nine months ended September 30,					
	Dollars		%	Percentage of Total Revenues		
	2009	2008	Change	2009	2008	
Market Revenues						
Infectious disease testing	\$33,407	\$29,260	14%	59%	54%	
Substance abuse testing	8,890	10,554	(16)	16	20	
Cryosurgical systems	7,728	7,726	—	14	14	
Insurance risk assessment	4,552	4,395	4	8	8	
Product revenues	54,577	51,935	5	97	96	
Licensing and product development	1,562	1,960	(20)	3	4	
Total revenues	<u>\$56,139</u>	<u>\$53,895</u>	4%	<u>100%</u>	<u>100%</u>	
OraQuick® Revenues						
	Three months ended September 30,		%	Nine months ended September 30,		%
	2009	2008	Change	2009	2008	Change
Direct to U.S. Public Health	\$ 8,611	\$ 6,157	40%	\$20,957	\$19,273	9%
Hospital Market	3,156	1,799	75	8,401	5,489	53
International	1,415	957	48	2,370	2,303	3
Total OraQuick® revenues	<u>\$13,182</u>	<u>\$ 8,913</u>	48%	<u>\$31,728</u>	<u>\$27,065</u>	17%
Intercept® Revenues						
	Three months ended September 30,		%	Nine months ended September 30,		%
	2009	2008	Change	2009	2008	Change
Workplace testing	\$ 1,068	\$ 1,193	(10)%	\$ 2,871	\$ 3,480	(18)%
Criminal Justice	736	637	16	1,918	1,965	(2)
International	479	481	—	1,524	1,570	(3)
Direct	282	303	(7)	645	904	(29)
Total Intercept® revenues	<u>\$ 2,565</u>	<u>\$ 2,614</u>	(2)%	<u>\$ 6,958</u>	<u>\$ 7,919</u>	(12)%
Cryosurgical Systems Revenues						
	Three months ended September 30,		%	Nine months ended September 30,		%
	2009	2008	Change	2009	2008	Change
Professional domestic	\$ 1,220	\$ 903	35%	\$ 2,969	\$ 2,942	1%
Professional international	337	401	(16)	1,601	1,802	(11)
OTC domestic	(122)	—	N/A	57	—	N/A
OTC international	1,247	367	240	3,101	2,982	4
Total cryosurgical systems revenues	<u>\$ 2,682</u>	<u>\$ 1,671</u>	61%	<u>\$ 7,728</u>	<u>\$ 7,726</u>	— %

Balance Sheets	September 30, 2009	December 31, 2008
<u>Assets</u>		
Cash, cash equivalents and short-term investments	\$ 83,027	\$ 82,523
Accounts receivable, net	12,329	11,571
Inventories	9,430	10,704
Other current assets	1,233	1,418
Property and equipment, net	20,419	21,235
Other non-current assets	1,236	4,467
Total assets	<u>\$ 127,674</u>	<u>\$ 131,918</u>
<u>Liabilities and Stockholders' Equity</u>		
Current portion of long-term debt	\$ 524	\$ 558
Accounts payable	2,943	3,926
Accrued expenses	10,481	10,796
Long-term debt	7,917	8,301
Other liabilities	2	12
Stockholders' equity	105,807	108,325
Total liabilities and stockholders' equity	<u>\$ 127,674</u>	<u>\$ 131,918</u>

Additional Financial Data	Nine months ended September 30,	
	2009	2008
Capital expenditures	\$ 989	\$ 1,949
Depreciation and amortization	\$ 2,360	\$ 2,122
Purchase and retirement of common stock	\$ 309	\$ 2,524
Cash flows provided by (used in) operating activities	\$ 2,688	\$ (3,743)
Accounts receivable – days sales outstanding	60 days	63 days

Conference Call

The Company will host a conference call and audio webcast to discuss the Company's 2009 third quarter financial results, business developments and fourth 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 888-797-2983 (Domestic) or 913-981-5550 (International) and reference Conference ID #6762345, 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 November 11, 2009, by dialing 888-203-1112 (Domestic) or 719-457-0820 (International) and entering the Conference ID #6762345.

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; 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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