
**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 5, 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 August 5, 2009, OraSure Technologies, Inc. issued a press release announcing its financial results for the quarter ended June 30, 2009 and providing financial guidance for the third 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 August 5, 2009, announcing financial results of OraSure Technologies, Inc. for the quarter ended June 30, 2009 and providing financial guidance for the third 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: August 5, 2009

By: */s/ Jack E. Jerrett*

Jack E. Jerrett

Senior Vice President, General Counsel and Secretary

Index to Exhibits

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OraSure Technologies, Inc.

Company Contact:

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

**OraSure Announces 2009 Second Quarter Financial Results
and Resumption of Full-Scale OraQuick® Production**

BETHLEHEM, PA – August 5, 2009 – (Globe Newswire) – OraSure Technologies, Inc. (NASDAQ: OSUR), a market leader in oral fluid diagnostics, today announced revenues of \$17.3 million for the three months ended June 30, 2009, compared to \$18.9 million recorded for the three months ended June 30, 2008. The Company also announced the resolution of the previously disclosed manufacturing issue related to its OraQuick® rapid HIV-1/2 antibody test and the resumption of full-scale production of that product.

The decrease in revenue for the second quarter was primarily caused by lower sales of infectious disease products as a direct result of a manufacturing issue related to the Company's OraQuick® test. Due to difficulty experienced in manufacturing a component of the Company's OraQuick® test during the second quarter of 2009, the Company was unable to manufacture sufficient quantities of the test needed to meet full customer demand. As a result, inventory levels were reduced and the Company had a \$2.2 million back log of orders for its OraQuick® HIV-1/2 test as of June 30, 2009 that under normal circumstances would have shipped in the second quarter. The Company recently identified the root cause for the manufacturing issue and implemented corrective action, allowing it to resume full-scale manufacturing of OraQuick®.

"Our infectious disease business performed well during the second quarter, and we expect that to continue now that we have resolved the recent manufacturing issue experienced with our OraQuick® test," said Douglas A. Michels, President and CEO of OraSure Technologies. "The issue was detected during routine in-process quality control testing. A root cause was identified and corrective action was implemented, allowing us to resume full-scale production. Had we not experienced this manufacturing challenge, we believe our revenues for the quarter would have exceeded our previously announced guidance."

The Company recorded a net loss of \$5.2 million, or \$0.11 per share, for the second quarter of 2009, compared to a net loss of \$2.2 million, or \$0.05 per share for the second quarter of 2008, on a GAAP¹ basis. Operating results for the second quarter 2009 included a \$3.0 million pre-tax impairment charge related to the net book value of payments previously capitalized under a Hepatitis C (“HCV”) patent license agreement. On a non-GAAP basis, the Company would have reported a \$2.1 million pre-tax loss during the second quarter of 2009, excluding the impairment charge, compared to a pre-tax loss for the second quarter of 2008 of \$3.1 million.

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 \$821,000 for the three months ended June 30, 2008.

For the six months ended June 30, 2009, the Company recorded revenues of \$34.5 million, a decrease of 7% when compared to revenues of \$37.0 million for the six months ended June 30, 2008. The Company recorded a net loss of \$6.8 million, or \$0.15 per share, for the six months ended June 30, 2009, compared to a net loss of \$242,000, or \$0.01 per share, for the six months ended June 30, 2008, on a GAAP basis. Results for the first six months of 2009 included the \$3.0 million pre-tax impairment charge described above and results for the first six months of 2008 included a \$4.9 million pre-tax gain related to a lump sum payment received under a settlement and licensing agreement entered into during that period. Excluding these items, the Company would have reported, on a non-GAAP basis, a \$3.8 million pre-tax loss for the first six months of 2009 compared to \$5.2 million pre-tax loss for the first six months of 2008.

Gross margin in the second quarter of 2009 was 57% compared to 59% in the second quarter of 2008. Gross margin was favorably impacted in the current quarter by the Company’s switch in January 2009 to a direct sales model for the OraQuick *ADVANCE*® HIV-1/2 test in the U.S. hospital market. However, this favorable impact was more than offset by a less favorable revenue mix and increased product support costs as the Company worked to resolve the manufacturing issue related to its OraQuick® HIV-1/2 test during the current quarter.

Operating expenses for the second quarter of 2009 increased to \$15.2 million, from \$15.0 million in the comparable period in 2008. This increase was primarily attributable to the \$3.0 million pre-tax impairment charge described above offset by a \$3.7 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 six months ended June 30, 2009 were \$28.0 million, compared to \$28.6 million for the comparable period in 2008. A \$4.9 million decrease in research and development costs in the first six months of 2009 was offset by the \$3.0 million pre-tax impairment charge and a \$1.2 million increase in general and administrative expenses resulting primarily from higher legal fees related to pending patent infringement litigation.

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

Cash, cash equivalents and short-term investments totaled \$79.2 million and working capital was \$89.3 million at June 30, 2009, compared to \$82.5 million and \$90.9 million, respectively, at December 31, 2008.

Third Quarter 2009 Outlook

The Company expects total revenues for the third quarter of 2009 to range from approximately \$19.0 to \$19.5 million. The Company is currently projecting a loss per share for the third quarter of 2009 of approximately \$0.05 to \$0.06.

Financial Data

	Condensed Financial Data (In thousands, except per-share data and percentages)			
	Unaudited			
	Three months ended June 30,		Six months ended June 30,	
	2009	2008	2009	2008
Results of Operations				
Revenues	\$17,274	\$18,946	\$34,530	\$37,035
Cost of products sold	7,394	7,803	13,678	15,249
Gross profit	<u>9,880</u>	<u>11,143</u>	<u>20,852</u>	<u>21,786</u>
Operating expenses:				
Research and development	2,433	6,099	5,785	10,697
Sales and marketing	5,289	4,962	10,312	10,178
General and administrative	4,435	3,890	8,892	7,731
Impairment of patent and product rights	3,028	—	3,028	—
Total operating expenses	<u>15,185</u>	<u>14,951</u>	<u>28,017</u>	<u>28,606</u>
Operating loss	<u>(5,305)</u>	<u>(3,808)</u>	<u>(7,165)</u>	<u>(6,820)</u>
Other income, net	145	744	387	6,490
Loss before income taxes	<u>(5,160)</u>	<u>(3,064)</u>	<u>(6,778)</u>	<u>(330)</u>
Income tax benefit	—	(821)	—	(88)
Net loss	<u>\$ (5,160)</u>	<u>\$ (2,243)</u>	<u>\$ (6,778)</u>	<u>\$ (242)</u>
Loss per share:				
Basic and Diluted	<u>\$ (0.11)</u>	<u>\$ (0.05)</u>	<u>\$ (0.15)</u>	<u>\$ (0.01)</u>
Weighted average shares:				
Basic and Diluted	<u>45,871</u>	<u>46,847</u>	<u>45,854</u>	<u>46,815</u>

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 settlement and license agreement entered into during the first quarter of 2008, since such significant or comparable transactions did not occur during the comparative period.

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 June 30,		Change
	2009	2008	
Loss before income taxes, as reported under GAAP	<u>\$(5,160)</u>	<u>\$(3,064)</u>	<u>\$(2,096)</u>
Pre-tax impairment charge adjustment	<u>3,028</u>	<u>—</u>	<u>3,028</u>
Loss before income taxes, non-GAAP	<u>\$(2,132)</u>	<u>\$(3,064)</u>	<u>\$ 932</u>
	Six months ended June 30,		Change
	2009	2008	
Loss before income taxes, as reported under GAAP	<u>\$(6,778)</u>	<u>\$ (330)</u>	<u>\$(6,448)</u>
Pre-tax impairment charge adjustment	<u>3,028</u>	<u>—</u>	<u>3,028</u>
Pre-tax gain adjustment	<u>—</u>	<u>(4,884)</u>	<u>4,884</u>
Loss before income taxes, non-GAAP	<u>\$(3,750)</u>	<u>\$(5,214)</u>	<u>\$ 1,464</u>

	Three months ended June 30,				
	Dollars		% Change	Percentage of Total Revenues	
	2009	2008		2009	2008
Market Revenues					
Infectious disease testing	\$ 9,417	\$10,033	(6)%	54%	53%
Substance abuse testing	2,932	3,697	(21)	17	20
Cryosurgical systems	2,901	2,719	7	17	14
Insurance risk assessment	1,499	1,693	(11)	9	9
Product revenues	16,749	18,142	(8)	97	96
Licensing and product development	525	804	(35)	3	4
Total revenues	<u>\$17,274</u>	<u>\$18,946</u>	(9)%	<u>100%</u>	<u>100%</u>

	Six months ended June 30,				
	Dollars		% Change	Percentage of Total Revenues	
	2009	2008		2009	2008
Market Revenues					
Infectious disease testing	\$19,867	\$19,512	2%	58%	53%
Substance abuse testing	5,622	6,974	(19)	16	19
Cryosurgical systems	5,046	6,055	(17)	15	16
Insurance risk assessment	3,134	3,236	(3)	9	9
Product revenues	33,669	35,777	(6)	98	97
Licensing and product development	861	1,258	(32)	2	3
Total revenues	<u>\$34,530</u>	<u>\$37,035</u>	(7)%	<u>100%</u>	<u>100%</u>

	Three months ended June 30,			Six months ended June 30,		
	2009	2008	% Change	2009	2008	% Change
	OraQuick® Revenues					
Direct to U.S. Public Health	\$ 5,790	\$ 6,899	(16)%	\$12,346	\$13,183	(6)%
Hospital Market	2,501	1,698	47	5,245	3,622	45
International	496	701	(29)	953	1,347	(29)
Total OraQuick® revenues	<u>\$ 8,787</u>	<u>\$ 9,298</u>	(5)%	<u>\$18,544</u>	<u>\$18,152</u>	2%

	Three months ended June 30,			Six months ended June 30,		
	2009	2008	% Change	2009	2008	% Change
	Intercept® Revenues					
Workplace testing	\$ 946	\$ 1,272	(26)%	\$1,803	\$2,287	(21)%
Criminal Justice	630	708	(11)	1,182	1,327	(11)
International	523	564	(7)	1,045	1,089	(4)
Direct	195	330	(41)	363	601	(40)
Total Intercept® revenues	<u>\$ 2,294</u>	<u>\$ 2,874</u>	(20)%	<u>\$4,393</u>	<u>\$5,304</u>	(17)%

	Three months ended June 30,		% Change	Six months ended June 30,		% Change
	2009	2008		2009	2008	
Cryosurgical Systems Revenues						
Professional domestic	\$ 807	\$ 1,004	(20)%	\$ 1,749	\$ 2,037	(14)%
Professional international	636	665	(4)	1,265	1,404	(10)
OTC domestic	122	—	100	179	—	100
OTC international	1,336	1,050	27	1,853	2,614	(29)
Total cryosurgical systems revenues	<u>\$ 2,901</u>	<u>\$ 2,719</u>	7%	<u>\$ 5,046</u>	<u>\$ 6,055</u>	(17)%

		June 30, 2009	December 31, 2008
Balance Sheets			
<u>Assets</u>			
Cash, cash equivalents and short-term investments		\$ 79,162	\$ 82,523
Accounts receivable, net		11,071	11,571
Inventories		8,663	10,704
Other current assets		1,273	1,418
Property and equipment, net		20,775	21,235
Other non-current assets		1,036	4,467
Total assets		<u>\$ 121,980</u>	<u>\$ 131,918</u>
<u>Liabilities and Stockholders' Equity</u>			
Current portion of long-term debt		\$ 539	\$ 558
Accounts payable		2,086	3,926
Accrued expenses		8,223	10,796
Long-term debt		8,042	8,301
Other liabilities		5	12
Stockholders' equity		103,085	108,325
Total liabilities and stockholders' equity		<u>\$ 121,980</u>	<u>\$ 131,918</u>

	Six months ended June 30,	
	2009	2008
Additional Financial Data		
Capital expenditures	\$ 741	\$ 1,314
Depreciation and amortization	\$ 1,673	\$ 1,387
Purchase and retirement of common stock	\$ 309	—
Cash flows used in operating activities	\$ 1,641	\$ 1,915
Accounts receivable – days sales outstanding	58 days	62 days

Conference Call

The Company will host a conference call and audio webcast to discuss the Company's 2009 second quarter financial results, business developments and third 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 877-419-6597 (Domestic) or 719-325-4848 (International) and reference Conference ID #4031205, 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 12, 2009, by dialing 888-203-1112 (Domestic) or 719-457-0820 (International) and entering the Conference ID #4031205.

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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