# 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): May 6, 2008

# **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)

Dere-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

Dere-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

### Item 2.02 – Results of Operations and Financial Condition.

On May 6, 2008, OraSure Technologies, Inc. issued a press release announcing its financial results for the quarter ended March 31, 2008 and providing an update on financial guidance for the second quarter and full year 2008. 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

Exhibit <u>Number</u> Description 99 Press Rele

Press Release, dated May 6, 2008, announcing financial results of OraSure Technologies, Inc. for the quarter ended March 31, 2008 and providing an update on financial guidance for the second quarter and full year 2008.

### 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.

By: /s/ Jack E. Jerrett

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

Date: May 6, 2008

## Index to Exhibits



Description
Press Release, dated May 6, 2008, announcing financial results of OraSure Technologies, Inc. for the quarter ended March 31, 2008 and providing
an update on financial guidance for the second quarter and full year 2008.



# OraSure Technologies, Inc. diagnostic solutions for the new millennium

Company Contact: Ronald H. Spair Chief Financial Officer 610-882-1820 Investorinfo@orasure.com www.orasure.com

### **OraSure Technologies Announces 2008 First Quarter Results**

**BETHLEHEM, PA** – May 6, 2008 – (BW HealthWire) – OraSure Technologies, Inc. (NASDAQ:OSUR), a market leader in oral fluid diagnostics, today announced quarterly revenues of \$18.1 million for the three months ended March 31, 2008, compared to \$20.1 million in revenues recorded for the three months ended March 31, 2007. Increased sales of the Company's OraQuick *ADVANCE*<sup>®</sup> rapid HIV-1/2 antibody test, professional cryosurgical products and insurance risk assessment products during the first quarter 2008, were offset by decreased sales of the Company's over-the-counter ("OTC") cryosurgical wart removal products and substance abuse testing products and lower licensing and product development revenue.

The Company's net income increased 35% to \$2.0 million, or \$0.04 per share on a fully-diluted basis, for the first quarter of 2008, compared to net income of \$1.5 million, or \$0.03 per share on a fully-diluted basis, for the first quarter of 2007. The 2008 results include a previously-announced \$4.9 million pre-tax gain related to a settlement and licensing agreement entered into during the quarter with Schering-Plough Healthcare Products, Inc. The 2007 results include a \$1.4 million pre-tax gain from the sale of the Company's equity interest in a foreign distributor.

Gross margin in the first quarter of 2008 was 59% compared with 62% in the first quarter of 2007. Gross margin was affected by a less favorable product mix, increased scrap and spoilage expense, and higher unabsorbed overhead.

Operating expenses for the first quarter of 2008 increased \$1.7 million to \$13.6 million, from \$11.9 million in the comparable period in 2007. This increase was primarily attributable to higher research and development costs associated with the Company's OraQuick<sup>®</sup> HIV OTC and OraQuick<sup>®</sup> HCV clinical development programs.

"Our first quarter financial performance was in line with our most recent guidance, and we continue to make very good progress against our strategic initiatives," said Douglas A. Michels, President and Chief Executive Officer of OraSure Technologies. "Our clinical trials for FDA and European approval of an OraQuick<sup>®</sup> HCV test are on schedule and progressing well, and we have initiated the observed use study for our OraQuick<sup>®</sup> OTC test. We have also continued to advance the development of fully automated homogeneous oral fluid drug assays for use with our Intercept<sup>®</sup> collector under our collaboration with Roche Diagnostics. Despite these positive developments, however, we are also facing a number of challenges to our business, against which we will intensify our efforts during the remainder of the year."

Cash, cash equivalents and short-term investments were \$90.4 million and working capital was \$106.0 million at March 31, 2008, compared to \$95.6 million and \$105.6 million, respectively, at December 31, 2007. Cash flow used in operating activities was \$3.7 million in the first quarter of 2008 compared to \$1.0 million in the first quarter of 2007. First quarter 2008 net operating cash out-flows included a \$5.6 million decrease in accounts payable and accrued expenses reflecting reductions in year-end royalty and legal accruals and an increase in accounts receivable balances.

### Full Year and Second Quarter 2008 Outlook

As previously announced, a patent infringement lawsuit against the Company was recently filed by Inverness Medical and Church & Dwight, which will result in an unexpected increase in legal costs during 2008. In addition, there was an unanticipated inventory buildup at the Company's OTC cryosurgical distributor in Mexico and a recent change in funding sources for the purchase of OraQuick<sup>®</sup> HIV tests in Africa, both of which are impacting the Company's business. In the U.S., the Company is experiencing lower than expected growth of OraQuick ADVANCE<sup>®</sup> sales in the U.S. hospital market, and the slowing economy continues to impact hiring and workplace drug testing. In view of these developments, the Company has decided to lower its financial guidance for 2008.

The Company expects total revenues for second quarter 2008 to range from approximately \$18.5 to \$19.0 million and a second quarter loss per share to be between \$0.06 and \$0.07. Full year 2008 revenues are projected to be approximately \$83.0 million with a loss per share ranging from approximately \$0.10 to \$0.11.

### **Financial Data**

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

	 Three months end 2008		<i>,</i>
Results of Operations	 2008		2007
Revenues	\$ 18,089	\$	20,109
Cost of products sold	7,446		7,584
Gross profit	10,643		12,525
Operating expenses:			
Research and development	4,598		2,920
Sales and marketing	5,216		4,771
General and administrative	 3,841		4,237
Total operating expenses	13,655		11,928
Operating income (loss)	(3,012)		597
Other income, net	5,746		2,389
Pre-tax income	2,734		2,986
Income tax provision	732		1,499
Net income	\$ 2,002	\$	1,487
Earnings per share			
Basic	\$ 0.04	\$	0.03
Diluted	\$ 0.04	\$	0.03
Weighted average shares:	 		
Basic	46,784		46,114
Diluted	 47,268		46,554

		Three months ended March 31,	
	2008	2007	Change
Market Revenues			
Infectious disease testing	\$ 9,480	\$ 8,932	6%
Substance abuse testing	3,277	3,929	(17)
Cryosurgical systems	3,336	5,680	(41)
Insurance risk assessment	1,538	889	73
Product revenues	17,631	19,430	(9)
Licensing and product development	458	679	(33)
Total revenues	\$18,089	\$20,109	(10)%

		Three months ended March 31,	
	2008	2007	Change
OraQuick <sup>®</sup> Revenues			
Direct to U.S. Public Health	\$ 6,282	\$ 4,342	45%
Abbott	1,925	2,151	(11)
SAMHSA	_	329	(100)
CDC		620	(100)
International	646	747	(14)
Total OraQuick <sup>®</sup> revenues	\$ 8,853	\$ 8,189	8%

		Three months ended March 31,	
	2008	2007	Change
Intercept <sup>®</sup> Revenues			
Workplace testing	\$ 1,016	\$ 1,545	(34)%
Criminal justice	619	645	(4)
International	525	600	(13)
Direct	271	202	34
Total Intercept <sup>®</sup> revenues	\$ 2,431	\$ 2,992	(19)%

		Three months ended March 31,	
	2008	2007	Change
Cryosurgery Revenues			
Professional domestic	\$ 1,034	\$ 1,053	(2)%
Professional international	737	467	58
OTC domestic		2,150	(100)
OTC international	1,565	2,010	(22)
Total cryosurgery revenues	\$ 3,336	\$ 5,680	(41)%

Ma			December 31, 2007 udited)	
		<b>,</b>	,	
\$	90,396		\$	95,566
	13,729			11,296
	9,929			9,410
	2,200			5,061
	2,433			2,456
	21,172			20,911
	19,328			17,266
	5,113			5,387
\$	164,300		\$	167,353
\$	557		\$	557
	3,654			5,616
	8,440			11,996
	8,720			8,818
	69			312
	142,860			140,054
\$	164,300		\$	167,353
	Three months ended March 31,		arch 31, 2007	
		<u>,                                    </u>		2007
	\$	755	\$	898
	\$	691	\$	656
	69 days			66 days
	\$ \$ \$	13,729 9,929 2,200 2,433 21,172 19,328 5,113 \$ 164,300 \$ 164,300 \$ 164,300 \$ 164,300 \$ 164,300 \$ 164,300 \$ 164,300 \$ 164,300	(Unaudi \$ 90,396 13,729 9,929 2,200 2,433 21,172 19,328 5,113 \$ 164,300 \$ 557 3,654 8,440 8,720 69 142,860 \$ 164,300 <b>Three months</b> 2008	(Unaudited) (Unau

### **Conference Call**

The Company will host a conference call and audio webcast today to discuss the Company's 2008 first quarter financial results, business developments and the Company's 2008 outlook, beginning 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 Operating Officer and Chief Financial Officer. The call will include remarks by management and a question and answer session.

In order to listen to the conference call, please dial 888-742-2024 (Domestic) or 706-643-0033 (International) and reference 43942293 or go to OraSure Technologies' web site, <u>www.orasure.com</u>, 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 May 13, 2008, by dialing 800-642-1687 (Domestic) or 706-645-9291 (International) and entering the Conference ID #43942293.

#### **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, 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; 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; 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; 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; 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 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 complete consolidation or restructuring activities; 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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