# 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 12, 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 February 12, 2008, OraSure Technologies, Inc. issued a press release announcing its financial results for the quarter and full year ended December 31, 2007 and providing an update on financial guidance for the first 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.

Description

(d) Exhibits

Exhibit <u>Number</u> 99

Press Release, dated February 12, 2008, announcing financial results of OraSure Technologies, Inc. for the quarter and full year ended December 31, 2007 and providing an update on financial guidance for the first 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.

Date: February 12, 2008

By: /s/ Jack E. Jerrett

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

### Index to Exhibits

<u>Exhibit No.</u> 99

Description
Press Release, dated February 12, 2008, announcing financial results of OraSure Technologies, Inc. for the quarter and full year ended December 31, 2007 and providing an update on financial guidance for the first quarter and full year 2008.



**Company Contact:** 

Ronald H. Spair Chief Financial Officer 610-882-1820 <u>Investorinfo@orasure.com</u> <u>www.orasure.com</u>

### OraSure Announces Fourth Quarter and Full Year 2007 Financial Results

- Annual Revenues Reach Record Level With 21% Growth Over 2006 -

**BETHLEHEM, PA** – February 12, 2008 – (BW HealthWire) – OraSure Technologies, Inc. (NASDAQ: OSUR), a market leader in oral fluid diagnostics, today announced revenues of \$82.7 million and \$19.8 million for the year and quarter ended December 31, 2007, respectively. This compares to revenues of \$68.2 million and \$17.7 million for the year and quarter ended December 31, 2006, respectively.

The Company reported net income of \$2.5 million, or \$0.05 per share on a fully-diluted basis, for the full year 2007. These results compare to net income of \$5.3 million, or \$0.11 per share on a fully-diluted basis, for the full year 2006. Net income for the full year 2007 included a \$1.4 million pre-tax gain on sale of an investment in a privately-held nonaffiliated company.

For the quarter ended December 31, 2007, the Company reported net income of \$27,000 representing break-even earnings per share on a fully-diluted basis. These results compare to net income of \$1.0 million, or \$0.02 per share on a fully-diluted basis, for the quarter ended December 31, 2006.

For the year ended December 31, 2007, increased sales of the Company's OraQuick<sup>®</sup> rapid HIV-1/2 antibody tests and over-the-counter ("OTC") cryosurgery products, together with an increase in funded research and development related to the Company's rapid Hepatitis C ("HCV") test, contributed to the 21% increase in total revenue. Revenue for the quarter ended December 31, 2007 increased 12%, also as a result of increased sales of the Company's OraQuick<sup>®</sup> tests and OTC cryosurgery products, as well as increased sales in the insurance risk assessment market. These increases for the quarter were partially offset by a decrease in sales of the Company's Intercept<sup>®</sup> oral fluid drug testing product compared to 2006.

"We are pleased with the robust revenue increase delivered in 2007, and in particular with the continued growth of our infectious disease business," said Douglas A. Michels, President and Chief Executive Officer of OraSure Technologies. "We believe the OraQuick<sup>®</sup> rapid HIV test will continue to drive significant growth in the future. During 2007, we also expanded our international business and continued to build the groundwork for our future success by making significant progress in the clinical development of a rapid HIV test for home use and a rapid Hepatitis C test for professional use."

The Company's gross margins were 61% and 58% for the full year 2007 and quarter ended December 31, 2007, respectively. Gross margins decreased from 64% for the full year 2006 and from 65% for the quarter ended December 31, 2006. The decrease in gross margin for the year was largely due to an increase in inventory scrap expenses, higher product support costs and a less favorable product mix. The decrease for the fourth quarter was largely due to a less favorable product mix and a higher unit cost associated with the introduction of a new cryosurgical device in the European OTC Market. The 2006 fourth quarter and full year margins also benefited from a favorable adjustment to royalty expense as the result of a re-negotiated patent license.

For the full year 2007, operating expenses increased to \$51.5 million from \$37.9 million in 2006. Operating expenses for the quarter ended December 31, 2007 were \$13.0 million, compared to \$10.7 million for the comparable period in 2006. These increases were primarily attributable to higher research and development costs associated with the development and clinical work for an OraQuick<sup>®</sup> rapid HIV test for home use and an OraQuick<sup>®</sup> hepatitis C test for professional use, higher staffing related costs and increased advertising reimbursement expense related to the Company's international OTC cryosurgical product. Operating expenses for the full year 2007 were also higher due to increased legal expenses related to the dispute with Prestige Brands, which was resolved in the fourth quarter of 2007.

Cash flow from operating activities was \$11.5 million in 2007, compared to \$16.9 million reported in 2006. The decrease was primarily the result of lower net income and increases in inventories and accounts receivable, partially offset by an increase in accounts payable and accrued expenses.

Cash, cash equivalents and short-term investments totaled \$95.6 million and working capital was \$105.6 million at December 31, 2007, compared to \$91.0 million and \$96.0 million, respectively, at December 31, 2006.

### Full Year and First Quarter 2008 Outlook

The Company expects total revenues for 2008 to range from approximately \$90.0 to \$92.0 million. This projection does not include the amount payable under the Schering-Plough settlement for past sales which will be recorded as other income, nor does it include

any contribution in 2008 from the reintroduction of a cryosurgical wart treatment product in the U.S. OTC market or launch of an OTC cryosurgical product line extension for which the Company is seeking FDA 510(k) clearance. The timing and potential magnitude of any revenues from these cryosurgical products are not predictable at this time. The Company does not include items in its guidance unless it believes the related revenues are likely to be achieved.

The Company expects to increase its Research and Development expenditures for 2008 to approximately \$21.0 million, representing an increase of \$7.0 million or approximately \$0.08 per share over 2007. As a result, the Company expects to achieve fully diluted earnings per share for 2008 of approximately \$0.05 to \$0.07.

For the first quarter of 2008, revenues are expected to range from approximately \$18.0 to \$18.5 million with sequential growth in infectious disease and substance abuse testing revenues compared to the fourth quarter of 2007, offset by lower cryosurgical revenues as a result of seasonality and the absence of U.S. OTC cryosurgical sales. The Company is currently projecting fully-diluted earnings per share for the first quarter of 2008 of approximately \$0.03 to \$0.04.

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

<u>Unaudited</u>

<u>Ollaudieu</u>	Three months ended December 31,	Year ended December 31,	
	2007 2006	2007	2006
Results of Operations			
Revenues	\$19,809 \$17,734	\$82,686	\$68,155
Cost of products sold	8,281 6,240	32,403	24,756
Gross profit	11,528 11,494	50,283	43,399
Operating expenses:			
Research and development	4,240 2,898	14,136	8,648
Sales and marketing	5,063 3,945	20,062	15,921
General and administrative	3,668 3,885	17,304	13,367
Total operating expenses	12,971 10,728	51,502	37,936
Operating income (loss)	(1,443) 766	(1,219)	5,463
Other income, net	1,070 1,020	5,513	3,599
Pre-tax income (loss)	(373) 1,786	4,294	9,062
Income tax provision (benefit)	(400) 761	1,821	3,794
Net income	<u>\$ 27</u> <u>\$ 1,025</u>	\$ 2,473	\$ 5,268
Earnings per share			
Basic	<u>\$ </u> <u>\$ 0.02</u>	\$ 0.05	\$ 0.11
Diluted	\$	\$ 0.05	\$ 0.11
Weighted average shares:			
Basic	46,625 45,974	46,325	45,910
Diluted	47,336 46,440	46,878	46,580

		Three months ended December 31,			
		Dollars		Percentage of Total Revenues	
Market Revenues		2006	<u>Change</u>	2007	2006
Infectious disease testing	\$ 9,444	\$ 7,943	19%	48%	45%
Substance abuse testing	3,390	4,058	(16)	17	23
Cryosurgical systems	5,343	4,269	25	27	24
Insurance risk assessment	1,605	1,437	12	8	8
Product revenues	19,782	17,707	12	100	100
Licensing and product development	27	27			_
Total revenues	\$19,809	\$17,734	12%	100%	100%

			Year	ended Decembe			
		n	ollars	%		Percentage of Total Revenues	
		2007	2006	Change	2007	2006	
Market Revenues							
Infectious disease testing		\$35,791	\$29,180	23%		43%	
Substance abuse testing		15,789	15,752		19	23	
Cryosurgical systems		23,533	17,333	36	28	25	
Insurance risk assessment		5,464	5,565	(2)	7	8	
Product revenues		80,577	67,830	19	97	99	
Licensing and product development		2,109	325	549%	3	1	
Total revenues		\$82,686	\$68,155	21%	100%	100%	
		Three months ended December 31, %		Year ended December 31,		%	
	2007	2006	Change	2007	2006	Change	
OraQuick <sup>®</sup> Revenues							
Direct to U.S. Public Health	\$ 5,460	\$ 4,475	22%	\$19,799	\$15,268	30%	
Abbott	2,018	1,674	21	8,103	6,897	17	
SAMHSA		150	N/A	339	406	(17)	
CDC		282	N/A	1,125	1,291	(13)	
International	1,181	509	132%	3,291	1,694	94	
Total OraQuick <sup>®</sup> revenues	\$ 8,659	\$ 7,090	22%	\$32,657	\$25,556	28%	
		Three months ended December 31, %		Year ended December 31,		%	
	2007	2006	Change	2007	2006	70 Change	
Intercept <sup>®</sup> Revenues							
Workplace testing	\$ 1,282	\$ 1,871	(31)%	\$ 6,650	\$ 6,616	1%	
Criminal Justice	622	600	4	2,570	2,398	7	
International	431	636	(32)	2,188	2,314	(5)	
Direct	264	200	32	1,003	728	38	
Total Intercept <sup>®</sup> revenues	\$ 2,599	\$ 3,307	(21)%	\$12,411	\$12,056	3%	
		Three months ended		Year ended			
	<u>December 31,</u> 2007 2006 C		% Change	%         December 31,           hange         2007         2006		% Change	
Cryosurgery Revenues							
Professional domestic	\$ 1,806	\$ 1,203	50%	\$ 5,247	\$ 5,360	(2)%	
Professional international	798	788	1	2,349	2,284	3	
OTC domestic	650	1,216	(47)	6,237	5,174	21	
OTC international	2,089	1,062	97	9,700	4,515	115%	
Total cryosurgery revenues	\$ 5,343	\$ 4,269	25%	\$23,533	\$17,333	36%	

	Dece	December 31, 2007		December 31, 2006	
Balance Sheets					
Assets					
Cash, cash equivalents and short-term investments	\$	95,566	\$	91,001	
Accounts receivable, net		11,296		10,357	
Inventories		9,410		5,534	
Current deferred income taxes		5,061		3,676	
Other current assets		2,744		1,990	
Property and equipment, net		20,911		17,375	
Deferred income taxes		17,266		19,846	
Other non-current assets		5,387		6,786	
Total assets	\$	167,641	\$	156,565	
Liabilities and Stockholders' Equity					
Current portion of long-term debt	\$	557	\$	609	
Accounts payable		5,905		3,312	
Accrued expenses		11,996		12,658	
Long-term debt		8,818		10,031	
Other liabilities		311		451	
Stockholders' equity		140,054		129,504	
Total liabilities and stockholders' equity	\$	167,641	\$	156,565	
			Year ended D	ecember 31.	
			2007	2006	

Additional Financial Data		
Capital expenditures	\$ 5,372	\$ 12,643
Depreciation and amortization	\$ 2,736	\$ 1,923
Accounts receivable – days sales outstanding	50 days	55 days

### **Conference Call**

The Company will host a conference call and audio webcast to discuss the Company's 2007 fourth quarter and full-year financial results, business developments and 2008 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 #32848688, 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 February 19, 2008, by dialing 800-642-1687 (Domestic) or 706-645-9291 (International) and entering the Conference ID #32848688.

### **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 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; impact of competitors, competing products and technology changes; ability to develop, commercialize and market new products; market acceptance of oral fluid testing, rapid point-of-care 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 and legal requirements; history of losses and ability to achieve sustained profitability; volatility of our stock price; uncertainty relating to patent protection; 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; loss or impairment of sources of capital or investments; 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, 2006, 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.