## **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, 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

ck 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 isions:
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))

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

On August 5, 2008, OraSure Technologies, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended June 30, 2008 and providing an update on certain financial guidance. A copy of the press release is attached as Exhibit 99.1 to this Form 8-K and is incorporated herein by reference.

# Item 5.02 – Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

Joseph E. Zack, the Company's Executive Vice President, Marketing and Sales, will retire from the Company on August 29, 2008. Following his retirement, Mr. Zack will provide consulting services for the Company. Although the terms of a consulting agreement have not yet been completely finalized, it is expected that Mr. Zack will provide service for a twelve-month period following his retirement for compensation equal to his current annual base salary.

P. Michael Formica, the Company's Executive Vice President, Operations, will be appointed as Executive Vice President and General Manager, Cryosurgery Systems. In this capacity, Mr. Formica will oversee the Company's professional and over-the-counter cryosurgical product lines. Mr. Formica will continue to oversee operations until a successor for that position is found.

#### Item 8.01 - Other Events.

On August 5, 2008, the Company issued a press release announcing that its Board of Directors has authorized a stock repurchase program for up to a total of \$25 million of the Company's outstanding common stock. A copy of the press release is attached as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference.

#### Item 9.01 – Financial Statements and Exhibits.

### (d) Exhibits

Exhibit <u>Number</u>	<u>Description</u>
99.1	Press Release, dated August 5, 2008, announcing financial results of OraSure Technologies, Inc. for the quarter ended June 30, 2008 and providing an update on certain financial guidance.
99.2	Press Release, dated August 5, 2008, announcing a stock repurchase program.

## 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, 2008

By: /s/ Jack E. Jerrett

Jack E. Jerrett

Senior Vice President, General Counsel and Secretary

## **Exhibit Index**

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Company Contact:

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

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

- Significant Milestones Achieved in Clinical Development Programs -

**BETHLEHEM, PA** – August 5, 2008 – (BW HealthWire) – OraSure Technologies, Inc. (NASDAQ:OSUR), a market leader in oral fluid diagnostics, today announced quarterly revenues of \$18.9 million for the three months ended June 30, 2008, compared to \$21.4 million in revenues for the three months ended June 30, 2007. Increased sales of the Company's OraQuick *ADVANCE®* rapid HIV-1/2 antibody test and insurance risk assessment products, as well as increased licensing and product development revenue during the second quarter 2008, were offset by expected decreased sales of the Company's cryosurgical wart removal products and substance abuse testing products.

The Company's net loss was \$2.2 million, or \$0.05 per share for the second quarter of 2008, compared to net income of \$955,000, or \$0.02 per share on a fully-diluted basis for the second quarter of 2007. This decrease is primarily the result of higher research and development expenses associated with the Company's OraQuick® HIV OTC and OraQuick® HCV clinical development programs, coupled with lower sales primarily of cryosurgical products.

For the six months ended June 30, 2008, the Company recorded revenues of \$37.0 million, a decrease of 11% when compared to revenues of \$41.5 million for the six months ended June 30, 2007. The Company recorded a net loss of \$242,000 or \$0.01 per share, for the six months ended June 30, 2008, compared to net income of \$2.4 million, or \$0.05 per share on a fully-diluted basis, during the six months ended June 30, 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 first 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 second quarter and the six months ended June 30, 2008 was 59% compared with 63% in the second quarter and six months ended June 30, 2007. Margins in the current periods were primarily impacted by an unfavorable product mix.

Operating expenses for the second quarter of 2008 increased \$2.1 million to \$15.0 million, from \$12.9 million in the comparable period in 2007. Operating expenses for the six months ended June 30, 2008 were \$28.6 million, compared to \$24.8 million for the comparable period in 2007. These increases are attributable to higher research and development costs associated with the Company's OraQuick® HIV OTC and OraQuick® HCV clinical development programs.

"The ongoing clinical work to obtain FDA approval for an OraQuick® rapid HIV OTC test continues to go extremely well," said Douglas A. Michels, President and Chief Executive Officer of OraSure Technologies. "This study was initiated in April, and I am happy to report that we recently completed testing for the first 1,000 subjects, and believe we have met the stopping criteria under our protocol. We have also continued to make good progress in our clinical trials to support a PMA submission for our OraQuick® rapid HCV test to the FDA."

Cash, cash equivalents and short-term investments were \$91.0 million and working capital was \$104.4 million at June 30, 2008, compared to \$95.6 million and \$105.6 million, respectively, at December 31, 2007. Cash flow used in operating activities for the six months ended June 30, 2008 was \$1.9 million compared to \$2.7 million provided by operations for the comparable period in 2007.

## Third Quarter 2008 Outlook

With respect to the third quarter, the Company expects that revenues will be in the range of \$16.0 and \$16.5 million and its loss per share will approximate \$0.09.

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

## <u>Unaudited</u>

		Three months ended June 30,		Six months ended June 30,	
	2008	2007	2008	2007	
Results of Operations					
Revenues	\$18,946	\$21,352	\$37,035	\$41,461	
Cost of products sold	7,803	7,889	15,249	15,474	
Gross profit	11,143	13,463	21,786	25,987	
Operating expenses:					
Research and development	6,099	3,304	10,697	6,224	
Sales and marketing	4,962	5,249	10,178	10,020	
General and administrative	3,890	4,325	7,731	8,562	
Total operating expenses	14,951	12,878	28,606	24,806	
Operating income (loss)	(3,808)	585	(6,820)	1,181	
Other income, net	745	969	6,490	3,358	
Income tax provision (benefit)	(820)	599	(88)	2,098	
Net income (loss)	\$ (2,243)	\$ 955	\$ (242)	\$ 2,441	
Earnings (loss) per share:	<del></del>				
Basic and Diluted	\$ (0.05)	\$ 0.02	\$ (0.01)	\$ 0.05	
Weighted average shares:		·		· <u> </u>	
Basic	46,847	46,215	46,815	46,165	
Diluted	46,847	46,629	46,815	46,592	

		Three months ended June 30,			
		ollars 2007	% Change	Percenta Total Re- 2008	
Market Revenues					
Infectious disease testing	\$10,033	\$ 9,185	9%	53%	43%
Substance abuse testing	3,697	4,396	(16)	20	21
Cryosurgical systems	2,719	5,772	(53)	14	27
Insurance risk assessment	1,693	1,350	25	9	6
Product revenues	18,142	20,703	(12)	96	97
Licensing and product development	804	649	24	4	3
Total revenues	\$18,946	\$21,352	(11)%	100%	100%

		Dollars		Percentage of Total Revenu		
		2008	2007	Change	2008	2007
Market Revenues						
Infectious disease testing		\$19,512	\$18,117	8%	53%	44%
Substance abuse testing		6,974	8,325	(16)	19	20
Cryosurgical systems		6,055	11,452	(47)	16	28
Insurance risk assessment		3,236	2,239	45	9	5
Product revenues		35,777	40,133	(11)	97	97
Licensing and product development		1,258	1,328	(5)	3	3
Total revenues		\$37,035	\$41,461	(11)%	100%	100%
		onths ended ne 30,	% Change	Six mont June 2008		% Change
OraQuick® Revenues	2008	2007	Change	2000	2007	Change
Direct to U.S. Public Health	\$ 6,899	\$ 5,502	25%	\$13,183	\$ 9,846	34%
Abbott	1,698	1,778	(4)	3,622	3,928	(8)
SAMHSA/CDC		485	N/A		1,434	N/A
International	701	514	36	1,347	1,260	7
Total OraQuick® revenues	\$ 9,298	\$ 8,279	12%	\$18,152	\$16,468	10%
		onths ended		Six mont		
	<u>Jui</u> 2008	1e 30, 2007	% Change	June 2008	2007	% Change
Intercept® Revenues						
Workplace testing	\$ 1,272	\$ 1,977	(36)%	\$ 2,287	\$ 3,523	(35)%
Criminal Justice	708	661	7	1,327	1,306	2
International	564	633	(11)	1,089	1,233	(12)
Direct	330	264	25	601	466	29
Total Intercept® revenues	<u>\$ 2,874</u>	\$ 3,535	(19)%	\$ 5,304	\$ 6,528	(19)%
		Three months ended		Six mont		
		1e 30, 2007	% Change	2008	2007	% Change
Cryosurgical Systems Revenues						
Professional domestic	\$ 1,004	\$ 1,360	(26)%	\$ 2,037	\$ 2,413	(16)%
Professional international	665	510	30	1,404	977	44
OTC domestic	_	983	N/A	_	3,133	N/A
OTC international	1,050	2,919	(64)	2,614	4,929	(47)
Total cryosurgical systems revenues	\$ 2,719	\$ 5,772	(53)%	\$ 6,055	\$11,452	(47)%

Six months ended June 30,

		udited
	June 30, 2008	December 31, 2007
Balance Sheets		2007
Assets		
Cash, cash equivalents and short-term investments	\$ 91,047	\$ 95,566
Accounts receivable, net	12,780	11,296
Inventories	10,286	9,410
Current portion of deferred income taxes	2,384	5,061
Other current assets	1,717	2,456
Property and equipment, net	21,276	20,911
Deferred income taxes	20,060	17,266
Other non-current assets	4,870	5,387
Total assets	\$164,420	\$ 167,353
Liabilities and Stockholders' Equity		
Current portion of long-term debt	\$ 557	\$ 557
Accounts payable	4,210	5,616
Accrued expenses	9,090	11,995
Long-term debt	8,581	8,818
Other liabilities	7	312
Stockholders' equity	_141,975	140,055
Total liabilities and stockholders' equity	\$164,420	\$ 167,353
	As of	June 30,
	2008	2007
Additional Financial Data		
Capital expenditures	\$ 1,314	\$ 2,597
Depreciation and amortization	\$ 1,387	\$ 1,321
Accounts receivable – days sales outstanding	61 days	63 days

## **Conference Call**

The Company will host a conference call and audio webcast today to discuss the Company's 2008 second quarter financial results, business developments and the Company's 2008 third quarter 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 56781070 or go to OraSure Technologies' web site, <a href="https://www.orasure.com">www.orasure.com</a>, 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, 2008, by dialing 800-642-1687 (Domestic) or 706-645-9291 (International) and entering the Conference ID #56781070.

#### **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; impact of replacing distributors; inventory levels at distributors and other customers; impact of replacing distributors; 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 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.



Company Contact:

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#### OraSure Technologies Announces \$25 Million Share Repurchase Program

**BETHLEHEM, PA** – August 5, 2008 – (BW HealthWire) – OraSure Technologies, Inc. (NASDAQ: OSUR), a market leader in oral fluid diagnostics, today announced that its Board of Directors has approved a share repurchase program to acquire up to \$25 million of its outstanding common shares.

Purchases under the program will be made at the Company's discretion, subject to market conditions, in the open market, in privately-negotiated transactions or otherwise, including pursuant to a 10b5-1 plan, and will be made in accordance with the regulations of the U.S. Securities and Exchange Commission. The Company has made no commitment to purchase any shares, and purchases may be discontinued at any time.

## **About OraSure Technologies**

OraSure Technologies develops, manufactures and markets oral fluid specimen collection devices using proprietary oral fluid technologies, diagnostic products including immunoassays and other in vitro diagnostic tests, and other medical devices. These products are sold in the United States as well as internationally to various clinical laboratories, hospitals, clinics, community-based organizations and other public health organizations, distributors, government agencies, physicians' offices, and commercial and industrial entities.

OraSure Technologies is the leading supplier of oral-fluid collection devices and assays to the life insurance industry and public health markets for the detection of antibodies to HIV. In addition, the Company supplies oral-fluid testing solutions for drugs of abuse testing. For more information on the Company, please go to www.orasure.com.