# 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 3, 2005

# OraSure Technologies, Inc.

(Exact Name of Registrant as Specified in Charter)

**Delaware** (State or Other Jurisdiction of Incorporation) 001-16537 (Commission File Number)

Registrant's telephone number, including area code: 610-882-1820

36-4370966 (I.R.S. Employer Identification No.)

220 East First Street
Bethlehem, Pennsylvania
(Address of Principal Executive Offices)

18015-1360 (Zip Code)

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))

# Item 2.02 – Results of Operations and Financial Condition

On May 3, 2005, OraSure Technologies, Inc. issued a press release announcing its financial results for the quarter ended March 31, 2005. 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

### (c) Exhibits

Exhibit Number	Description
99	Press Release dated May 3, 2005, announcing financial results of OraSure Technologies, Inc. for the quarter ended March 31, 2005.

#### Signatures

Date: May 3, 2005

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

# **Index to Exhibits**

Exhibit No. Description

99 Press Release dated May 3, 2005, announcing financial results of OraSure Technologies, Inc. for the quarter ended March 31, 2005.



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

#### **OraSure Technologies Announces 2005 First Quarter Results**

- Record Quarterly Revenues of \$15.8 Million and Net Income of \$1.6 Million - Increases Guidance for 2005 Net Income

**BETHLEHEM, PA** – May 3, 2005 – (BW HealthWire) – OraSure Technologies, Inc. (Nasdaq NM:OSUR), a market leader in oral fluid diagnostics, today announced record revenues of \$15.8 million for the quarter ended March 31, 2005, representing a 28% increase over the \$12.4 million in revenues recorded for the comparable period in 2004. Product revenues for the quarter were \$15.7 million, also a 28% increase over the first quarter of 2004.

The Company's net income was approximately \$1.6 million, or \$0.03 per share on a basic and fully-diluted basis, for the first quarter of 2005. These results compare to a net loss of approximately \$162,000, or \$(0.00) per share on a basic and fully-diluted basis, in the first quarter of 2004.

"The first quarter of 2005 represents a big step toward our stated goal of sustainable profitability," said Douglas A. Michels, President and Chief Executive Officer of OraSure Technologies. "It was highlighted by record revenues and an improved gross margin together with cost containment initiatives, resulting in our most profitable quarter to date. Additionally, we continue to make significant progress in expanding our base business, growing internationally and pursuing our long-term strategic objectives. Based on this solid start for the year, and the recent deferral by the SEC of the requirement for the expensing of stock options until calendar year 2006, we now expect profitability for 2005 to be in the range of \$0.10 to \$0.12 per fully-diluted share."

The revenue increase during the first quarter was primarily attributable to increased sales of the Company's OraQuick®  $ADVANCE^{TM}$  rapid HIV-1/2 antibody test, Freeze Off<sup>TM</sup> and Histofreezer® cryosurgical wart removal products, and Intercept® oral fluid drug test. These revenue increases were partially offset by slightly lower revenues in the insurance risk assessment market.

Gross margin in the first quarter of 2005 improved to 60% from 58% in the first quarter of 2004. Gross margin was positively affected by a decrease in production costs for the Freeze Off<sup>™</sup> OTC cryosurgical wart removal product and more efficient utilization of the Company's manufacturing capacity, partially offset by a less favorable sales mix and higher scrap and spoilage.

Operating expenses for the first quarter of 2005 increased approximately \$700,000 to \$8.2 million, from approximately \$7.5 million in the comparable period in 2004. This increase was primarily attributable to increased legal fees associated with the Company's ongoing prosecution of its patent infringement lawsuit against Schering Plough together with increased charges for stock-based compensation and higher staffing related charges in both the sales and marketing and general and administrative areas. Partially offsetting these increases were lower research and development expenses resulting from reduced staffing and the absence in the first quarter of 2005 of costs associated with the transfer of products from the Company's former manufacturing facilities in Oregon to Bethlehem, Pennsylvania.

Cash, cash equivalents and short-term investments totaled approximately \$66.8 million and working capital equaled approximately \$71.2 million at March 31, 2005, compared to approximately \$66.7 million and \$68.9 million, respectively, at December 31, 2004.

Cash flow from operations was \$521,000 for the first quarter of 2005, up substantially from the \$139,000 achieved during the first quarter of 2004. This was the twelfth consecutive quarter of positive cash flow from operations.

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

				Three months ended March 31,				
				2005		2005		
Results of Operations								
Revenues				\$	15,828	\$	12,409	
Cost of products sold					6,370		5,191	
				_		_		
Gross profit					9,458		7,218	
Operating expenses:								
Research and development					1,199		1,767	
Sales and marketing					3,867		3,651	
General and administrative					3,177		2,126	
Total approxing appares				<del></del>	0 242		7 5 4 4	
Total operating expenses					8,243		7,544	
Operating income (loss)					1,215		(326)	
Other income (expense), net					346		164	
Net income (loss)				\$	1,561	\$	(162)	
Basic and diluted earnings (loss) per share				\$	0.03	\$	(0.00)	
				_		_		
Weighted average shares:								
Basic					44,645		44,271	
Diluted					45,046		44,271	
		Dol	Dollars			Percentage of Total Revenues		
	<del></del>	2005	2004	% Change	200	15	2004	
Revenues by Principal Markets		_			_	_	<del></del>	
Insurance risk assessment	\$	2,115	\$ 2,284	(7)	1% 1	3%	18%	
Infectious disease testing		5,126	3,338	54		32	27	
Substance abuse testing		2,925	2,194	33		.9	18	
							36	
Cryosurgical systems		5,578	2,194 4,473	25		.9 85		

License and product development

Total revenues

15,744

\$15,828

84

12,289

\$12,409

120

28

(30)

28%

99

1

100%

99

1

100%

Balance Sheets					
	March 31, 2005		Dece	December 31, 2004	
<u>Assets</u>					
Cash, cash equivalents and short-term investments		66,804	\$	66,723	
Accounts receivable, net		8,742		7,074	
Inventories		4,804		4,952	
Other current assets		1,178		1,195	
Property and equipment, net		5,313		5,551	
Other non-current assets		2,348		2,569	
Total assets	\$	89,189	\$	88,064	
			_		
<u>Liabilities and Stockholders' Equity</u>					
Current portion of long-term debt		1,120	\$	1,123	
Accounts payable		2,726		2,360	
Accrued expenses		6,444		7,552	
Long-term debt, less current portion		1,057		1,334	
Other liabilities		271		118	
Stockholders' equity		77,571		75,577	

#### **Internet Audio Broadcast**

Total liabilities and stockholders' equity

OraSure Technologies will host a conference call and audio webcast today to discuss the Company's 2005 first quarter financial results, financial guidance for 2005 and major business objectives, 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 Financial Officer. The call will include remarks by management and a question and answer session.

89,189

88,064

In order to listen to the conference call, please either dial 888-742-2024 (Domestic) or 706-643-0033 (International) 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 May 6, 2005, by dialing 800-642-1687 (Domestic) or 706-645-9291 (International) and entering the Conference ID #5552177.

The webcast will also be distributed over the CCBN (Corporate Communications Broadcast Network) Investor Distribution Network. Institutional investors can access the call via CCBN's password protected event management site, StreetEvents (<a href="https://www.streetevents.com">www.streetevents.com</a>).

#### **About OraSure Technologies**

OraSure Technologies develops, manufactures and markets oral fluid specimen collection devices and tests and other diagnostic products using its 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 products; impact of competing products and technology changes; ability to develop, commercialize and market new products; market acceptance of oral fluid testing products and up-converting phosphor technology products; ability to fund research and development and other projects and operations; ability to maintain new or existing product distribution channels; reliance on sole supply sources for critical product components; availability of related products produced by third parties; ability to obtain, and timing of obtaining, necessary regulatory approvals; 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; 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; ability to meet financial covenants in agreements with financial institutions; ability to retain qualified personnel; exposure to product liability and other types of litigation; changes in international, federal or state laws and regulations; changes in relationships with strategic partners and reliance on strategic partners for the performance of critical activities under collaborative arrangements; changes in accounting practices or interpretation of accounting requirements; 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, 2004, 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.