# 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): April 29, 2003

# OraSure Technologies, Inc. (Exact name of issuer as specified in charter)

**DELAWARE** 

(State or Other Jurisdiction of **Incorporation or Organization)**  001-16537

(Commission file number)

36-4370966 (I.R.S. Employer Identification Number)

220 East First Street Bethlehem, Pennsylvania 18015-1360 (Address of principal executive offices)

(610) 882-1820

(Registrant's telephone number, including area code)

# Item 7. Financial Statements, Pro Forma Financial Information and Exhibits.

(c) Exhibits

Exhibit No.	Description
99	Press Release dated April 29, 2003, announcing financial results of OraSure Technologies, Inc. for the quarter ended March 31, 2003.

# Item 9. Regulation FD Disclosure.

This Current Report on Form 8-K is being furnished pursuant to Item 12, "Results of Operations and Financial Condition," in accordance with interim procedures promulgated by the Securities and Exchange Commission in Release No. 34-47583 issued March 27, 2003. See Item 12, "Results of Operations and Financial Condition" below, which is incorporated by reference.

#### Item 12. Results of Operations and Financial Condition.

On April 29, 2003, OraSure Technologies, Inc. issued a press release announcing its financial results for the quarter ended March 31, 2003. A copy of the press release is attached as Exhibit 99 to this Form 8-K and is incorporated herein by reference.

# 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: April 30, 2003

By: /s/ JACK E. JERRETT

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

# Index to Exhibits

Exhibit No. Description

Exhibit 99 Press Release dated April 29, 2003, announcing financial results of OraSure Technologies, Inc. for the quarter ended March 1, 2003.

#### [LOGO OF ORASURE TECHNOLOGIES, INC.]

Company Contact:

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

# **OraSure Technologies Announces 2003 First Quarter Results**

**BETHLEHEM, PA** – April 29, 2003 – (BW HealthWire) – OraSure Technologies, Inc. (Nasdaq NM:OSUR), the market leader in oral fluid diagnostics, today announced its financial results for the quarter ended March 31, 2003.

Total revenues for the quarter increased approximately 11% to \$8.6 million, compared to \$7.7 million for the quarter ended March 31, 2002. Product revenues for the first quarter of 2003 increased approximately 12% to \$8.3 million, compared to \$7.5 million in 2002. Both amounts represent record quarterly revenues for the Company.

The Company's net loss was approximately \$1.1 million, or \$(0.03) per share, for the first quarter of 2003, a penny better than street estimates. These results compare to a net loss of approximately \$1.6 million, or \$(0.04) per share, in the first quarter of 2002.

"The first quarter was highlighted by the launch of the OraQuick® Rapid HIV-1 Antibody Test, increased penetration of our Intercept® oral fluid drugs of abuse test, and improved financial performance," said Mike Gausling, President and CEO of OraSure Technologies, Inc. "Additionally, the Company continued to make substantial advances in paving the way for the future with the receipt of a CLIA waiver for OraQuick®, initiation of the oral fluid clinical trials for OraQuick®, the completion of successful pre-clinical trials for the  $UPlink^{TM}$  drug testing system, and the signing of an agreement for expansion of Histofreezer® into the over-the-counter market."

The revenue increase during the first quarter was primarily attributable to increased sales of OraQuick® and Intercept®, partially offset by substantially lower sales of the Histofreezer® wart removal system in the United States and lower urine assay sales in the insurance risk assessment market.

Gross margin in the first quarter decreased to approximately 58% from approximately 63% for the first quarter of 2002, primarily as a result of a \$1.0 million decrease in high-margin Histofreezer\* sales and start-up costs associated with the initial production runs of the OraQuick\* test. The decrease in Histofreezer\* sales accounted for four percentage points of the gross margin reduction.

Operating expenses for the quarter decreased approximately \$300,000 to approximately \$6.2 million, from approximately \$6.5 million in the comparable period in 2002. This decrease was primarily attributable to lower staffing and clinical trial expenses and the absence of severance charges incurred in 2002, partially offset by increased sales and marketing expenses associated with the launch of OraQuick® and additional costs related to the occupancy of the Company's new corporate headquarters in Bethlehem, Pennsylvania.

Cash and short-term investments totaled approximately \$15.3 million and working capital equaled approximately \$19.0 million at March 31, 2003, compared to approximately \$14.9 million in cash, cash equivalents and short-term investments and \$18.9 million of working capital at December 31, 2002.

Cash flow from operations was \$172,000 for the first quarter of 2003, a \$2.2 million improvement from the comparable quarter in 2002. This is the fourth 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,		
	2003	2002		
Results of Operations				
Revenues	\$ 8,611	\$ 7,725		
Cost of products sold	3,580	2,894		
Gross profit	5,031	4,831		
Operating expenses				
Research and development	2,055	2,420		
Sales and marketing	2,235	1,988		
General and administrative	1,865	2,085		
Total operating expenses	6,155	6,493		
Operating loss	(1,124)	(1,662)		
Other income (expense), net	31	69		
Net loss	\$ (1,093)	\$ (1,593)		
Basic and diluted net loss per share	\$ (0.03)	\$ (0.04)		
Shares used in computing basic and diluted net loss per share	38,248	37,434		

	Dol	lars	%	Percentage of Total Revenues	
	2003	2002	Change	2003	2002
Revenues by Principal Markets					
Insurance risk assessment	\$3,000	\$2,792	7%	35%	36%
Infectious disease testing	2,768	1,510	83%	32%	20%
Substance abuse testing	1,598	1,187	35%	19%	15%
Physicians' offices therapies	977	1,979	(51%)	11%	26%
	8,343	7,468	12%	97%	97%
License and product development	268	257	4%	3%	3%
Total revenues	\$8,611	\$7,725	11%	100%	100%

	Mar	March 31, 2003		December 31, 2002	
Balance Sheets					
<u>Assets</u>	\$				
Cash and short-term investments		15,264	\$	14,908	
Accounts receivable, net		5,499		5,198	
Inventories		4,049		4,088	
Other current assets		916		926	
Property and equipment, net		7,321		7,428	
Other non-current assets		3,015		3,189	
Total assets	\$	36,064	\$	35,737	
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Liabilities and Stockholders' Equity					
Current portion of long-term debt		1,098	\$	1,066	
Accounts payable		2,068		1,802	
Accrued expenses		3,539		3,321	
Long-term debt, less current portion		3,215		3,409	
Other liabilities		187		120	
Stockholders' equity		25,957		26,019	
		<u> </u>			
Total liabilities and stockholders' equity	\$	36,064	\$	35,737	

# **Conference Call**

The Company will host a conference call with analysts and simultaneous audio webcast to discuss the Company's first quarter 2003 financial results beginning at 5:00 p.m. Eastern Time (2:00 p.m. Pacific Time) today. On the call will be Mike Gausling, Chief Executive Officer, Ronald H. Spair, Chief Financial Officer, and R. Sam Niedbala, Chief Science Officer. The call will include brief 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), or go to OraSure Technologies' Web site, www.orasure.com, and click on the Investor Information 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 3, 2003, by

dialing 800-642-1687 (Domestic) or 706-645-9291 (International) and entering the Conference ID #9418965.

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, Inc. is the market leader for oral fluid diagnostics. The Company develops, manufactures, and markets medical devices and diagnostic products for use by insurance companies, public health agencies, clinical laboratories, physicians' offices, and workplace sites. For more information on the Company, please visit <a href="https://www.orasure.com">www.orasure.com</a>.

#### **Important Information**

This press release contains certain forward-looking statements, including with respect to sales, markets, products, research and development activities, and regulatory submissions. Actual results could be significantly different. Factors that could affect results include the ability to market products; impact of competitors, competing products and technology changes; ability to develop, commercialize and market new products; market acceptance of oral fluid testing products and other products; ability to fund research and development and other projects and operations; ability to obtain and timing of obtaining necessary regulatory approvals; ability to develop product distribution channels; uncertainty relating to patent protection and potential patent infringement claims; 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; 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 inventory practices and consolidations; equipment failures and ability to obtain needed raw materials and components; the impact of terrorism and civil unrest; and general business, political and economic conditions. These and other factors are discussed more fully in the Securities and Exchange Commission filings of OraSure Technologies, including its registration statements and its Annual Report on Form 10-K for the year ended December 31, 2002. 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