
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 27, 2004

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 5 – Other Events and Required Reg FD Disclosures.

R. Sam Niedbala, the Company's Executive Vice President and Chief Science Officer, has advised the Company that he will retire from the Company on May 21, 2004. Following his retirement, Dr. Niedbala is expected to enter into a consulting agreement with the Company pursuant to which he will be engaged to assist the Company in seeking U.S. Food and Drug Administration clearance of the *UPlink*[®] Oral Fluid Rapid Drug Detection System, expanding the Company's patent portfolio and other matters. P. Michael Formica, the Company's Executive Vice President, Operations, will oversee the Company's research and development activities until a new Chief Science Officer is appointed.

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

(c) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99	Press Release dated April 27, 2004, announcing financial results of OraSure Technologies, Inc. for the quarter ended March 31, 2004.

Item 12. Results of Operations and Financial Condition.

On April 27, 2004, OraSure Technologies, Inc. issued a press release announcing its financial results for the quarter ended March 31, 2004. 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 27, 2004

By: /s/ Jack E. Jerrett

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

Index to Exhibits

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**OraSure Technologies, Inc.**

diagnostic solutions for the new millennium

Company Contact:

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Chief Financial Officer
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www.orasure.com

OraSure Technologies Announces 2004 First Quarter Results*- Revenues Increase 44% to \$12.4 Million -*

BETHLEHEM, PA – April 27, 2004 – (BW HealthWire) – OraSure Technologies, Inc. (Nasdaq NM:OSUR), a market leader in oral fluid diagnostics, today announced record revenues of \$12.4 million for the quarter ended March 31, 2004, representing a 44% increase over the \$8.6 million in revenues recorded for the comparable period in 2003. Product revenues for the quarter were \$12.3 million, a 47% increase over the first quarter of 2003.

The Company's net loss was approximately \$162,000, or \$(0.00) per share, for the first quarter of 2004. These results compare to a net loss of approximately \$1.1 million, or \$(0.03) per share, in the first quarter of 2003.

"We had another great quarter," said Mike Gausling, President and Chief Executive Officer of OraSure Technologies. "It was highlighted by record revenues, positive cash flow from operations, and the achievement of several important and historically significant regulatory approvals. We also made major advances in our efforts to consolidate manufacturing in Bethlehem, which we expect to generate future operating efficiencies. However, undoubtedly the highlight for the quarter and a truly defining moment for the Company was the FDA's approval of our OraQuick® oral fluid claim, which was based on clinical data indicating an accuracy of greater than 99%. This approval further confirms our leadership position in the oral fluid diagnostics market."

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

Gross margin in the first quarter was approximately 58%, which was unchanged from the first quarter of 2003. Gross margin was positively affected by more efficient utilization of the Company's manufacturing capacity, offset by increased currency exchange costs associated with the purchase of cryosurgery products. The Company's Freeze Off™ and Histofreezer® products are purchased from a contract manufacturer in The Netherlands and are paid for in Euros.

Operating expenses for the first quarter of 2004 increased approximately \$1.4 million to \$7.5 million from approximately \$6.2 million in the comparable period in 2003. This increase was primarily attributable to increased sales and marketing expenses due to reimbursement of advertising expenses incurred by MedTech Holdings, the distributor of the Freeze Off™ product, higher fees incurred for the recruitment of a hospital sales team, and higher staffing and travel expenses. General and administrative costs also increased as a result of higher legal fees related to patent prosecution matters and the Company's arbitration proceeding with Abbott Laboratories. Partially offsetting these increases was a reduction in research and development expenses resulting from the absence of costs associated with the transfer of manufacturing operations from Oregon to Bethlehem, PA and significant clinical trial expenditures, which were incurred during the first quarter of 2003.

Cash, cash equivalents and short-term investments totaled approximately \$63.8 million and working capital equaled approximately \$67.3 million at March 31, 2004, compared to approximately \$64.0 million and \$67.2 million, respectively, at December 31, 2003.

Cash flow from operations was \$139,000 for the first quarter of 2004, which is comparable to the level achieved during the first quarter of 2003. This was the eighth 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,	
	2004	2003
Results of Operations		
Revenues	\$12,409	\$ 8,611
Cost of products sold	5,191	3,580
Gross profit	7,218	5,031
Operating expenses:		
Research and development	1,767	2,055
Sales and marketing	3,651	2,235
General and administrative	2,126	1,865
Total operating expenses	7,544	6,155
Operating loss	(326)	(1,124)
Other income (expense), net	164	31
Net loss	\$ (162)	\$ (1,093)
Basic and diluted net loss per share	\$ (0.00)	\$ (0.03)
Shares used in computing basic and diluted net loss per share	44,271	38,248

	Dollars		% Change	Percentage of Total Revenues	
	2004	2003		2004	2003
Revenues by Principal Markets					
Insurance risk assessment	\$ 2,284	\$ 3,000	(24)%	18%	35%
Infectious disease testing	3,338	2,768	21%	27%	32%
Substance abuse testing	2,194	1,598	37%	18%	19%
Cryosurgical markets	4,473	977	358%	36%	11%
	12,289	8,343	47%	99%	97%
License and product development	120	268	(55)%	1%	3%
Total revenues	\$ 12,409	\$ 8,611	44%	100%	100%

	<u>March 31, 2004</u>	<u>December 31, 2003</u>
Balance Sheets		
<u>Assets</u>		
Cash, cash equivalents and short-term investments	\$ 63,754	\$ 64,024
Accounts receivable, net	7,430	8,234
Inventories	4,327	4,003
Other current assets	1,069	923
Property and equipment, net	6,412	6,471
Other non-current assets	2,322	2,496
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Total assets	\$ 85,314	\$ 86,151
<u>Liabilities and Stockholders' Equity</u>		
Current portion of long-term debt	\$ 1,129	\$ 1,126
Accounts payable	2,576	3,511
Accrued expenses	5,549	5,376
Long-term debt, less current portion	2,172	2,457
Other liabilities	259	172
Stockholders' equity	73,629	73,509
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Total liabilities and stockholders' equity	\$ 85,314	\$ 86,151

Conference Call

The Company will host a conference call with analysts and simultaneous audio webcast to discuss the Company's first quarter 2004 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 and Ronald H. Spair, Chief Financial 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 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 April 30, 2004, by dialing 800-642-1687 (Domestic) or 706-645-9291 (International) and entering the Conference ID #6819394.

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 (www.streetevents.com).

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, expenses, operating efficiencies, markets and products. 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 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 (including our ability to successfully implement a direct sales effort or other alternative distribution for OraQuick[®]); 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, 2003, 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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