
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 3, 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 7 – Financial Statements, Pro Forma Financial Information and Exhibits.

(c) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99	Press Release dated August 3, 2004, announcing financial results of OraSure Technologies, Inc. for the quarter ended June 30, 2004.

Item 12. Results of Operations and Financial Condition.

On August 3, 2004, OraSure Technologies, Inc. issued a press release announcing its financial results for the quarter ended June 30, 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: August 3, 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 Announces 2004 Second Quarter Results

- Company Reports Net Profit for the Quarter -

- Increases Full Year Revenue Guidance -

BETHLEHEM, PA – August 3, 2004 – (BW HealthWire) – OraSure Technologies, Inc. (Nasdaq NM:OSUR), a market leader in oral fluid diagnostics, today announced its financial results for the quarter and six months ended June 30, 2004.

Total revenues for the second quarter of 2004 increased 37% to \$13.2 million, compared to \$9.6 million for the quarter ended June 30, 2003. Product revenues for the second quarter increased 39% to \$13.1 million, compared to \$9.4 million in 2003. Both amounts represent record quarterly revenues for the Company. The Company also recorded a net profit for the quarter of \$142,000, or \$0.00 per share, compared to a net loss of \$530,000, or \$(0.01) per share, in the second quarter of 2003.

For the six months ended June 30, 2004, the Company had total revenues of \$25.6 million, a 40% increase over revenues of \$18.2 million for the six months ended June 30, 2003. Product revenues for the six months ended June 30, 2004 were \$25.4 million, or 43% higher than the \$17.8 million in product revenues recorded during the comparable period in 2003. The Company recorded a net loss of \$20,000, or \$(0.00) per share, for the six months ended June 30, 2004, compared to a net loss of \$1.6 million, or \$(0.04) per share, for the comparable period in 2003.

“We are certainly very pleased with the Company’s financial results during the second quarter of 2004,” said Douglas A. Michels, President and CEO of OraSure Technologies. “This is the sixth consecutive quarter of record revenues and most of the Company’s product lines contributed with strong performances. We believe we are on track to achieve 2004 full year revenues of between \$51.5 and \$52.5 million, although our ability to turn a profit for the year as a whole is now a bit more uncertain. Specifically, the additional expenses associated with the change in CEO and the patent litigation we recently commenced against Schering-Plough will make it difficult to achieve full-year profitability in 2004.”

The revenue increase during the second 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 increases were partially offset by lower revenues in the insurance risk assessment market.

Gross margin in the second quarter was approximately 58%, which was a decrease from the 60% gross margin recorded during the second quarter of 2003. Gross margin was positively affected by more efficient utilization of the Company's manufacturing capacity, offset by a less favorable product sales mix and higher startup production costs associated with both of the products transferred to the Company's Bethlehem, Pennsylvania manufacturing facilities and the recently launched UPlink® rapid point of care oral fluid drug detection system.

Operating expenses for the second quarter of 2004 increased to approximately \$7.7 million from approximately \$6.4 million in the comparable period in 2003. This increase was primarily attributable to higher advertising expenditures, higher staffing expenses, including CEO transition-related expenses, and higher legal fees, partially offset by a reduction in research and development expenses. Operating expenses for the six months ended June 30, 2004 were \$15.3 million, compared to \$12.5 million for the comparable period in 2003.

Cash, cash equivalents and short-term investments totaled approximately \$66.0 million and working capital equaled approximately \$67.9 million at June 30, 2004, compared to approximately \$64.0 million and \$67.2 million, respectively, at December 31, 2003.

Cash flow from operations was approximately \$1.7 million for the second quarter of 2004. This is the ninth consecutive quarter of positive cash flow from operations. Cash flow from operations for the six months ended June 30, 2004 was \$1.9 million.

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

Results of Operations

	Three months ended June 30,		Six months ended June 30,	
	2004	2003	2004	2003
Revenues	\$ 13,215	\$ 9,629	\$ 25,623	\$ 18,240
Cost of products sold	5,525	3,821	10,715	7,401
Gross profit	7,690	5,808	14,908	10,839
Operating expenses:				
Research and development	1,514	1,965	3,281	4,020
Sales and marketing	3,781	2,738	7,431	4,973
General and administrative	2,446	1,657	4,572	3,523
Total operating expenses	7,741	6,360	15,284	12,516
Operating loss	(51)	(552)	(376)	(1,677)
Other income, net	193	22	356	54
Net income (loss)	\$ 142	\$ (530)	\$ (20)	\$ (1,623)
Basic and diluted net income (loss) per share	\$ 0.00	\$ (0.01)	\$ (0.00)	\$ (0.04)
Weighted average shares:				
Basic	44,465	38,412	44,368	38,331
Diluted	45,334	38,412	44,368	38,331

Market Revenues

	Three months ended June 30,				
	Dollars		% Change	Percentage of Total Revenues	
	2004	2003		2004	2003
Insurance risk assessment	\$ 1,905	\$ 2,458	(22)%	14%	26%
Infectious disease testing	3,970	2,703	47	30	28
Substance abuse testing	2,389	1,835	30	18	19
Cryosurgical systems	4,858	2,442	99	37	25
Product revenues	13,122	9,438	39	99	98
Licensing and product development	93	191	(51)	1	2
Total revenues	\$ 13,215	\$ 9,629	37%	100%	100%

Market Revenues

Six months ended June 30,

	Dollars		% Change	Percentage of Total Revenues	
	2004	2003		2004	2003
Insurance risk assessment	\$ 4,190	\$ 5,460	(23)%	16%	30%
Infectious disease testing	7,307	5,472	34	29	30
Substance abuse testing	4,583	3,429	34	18	19
Cryosurgical systems	9,331	3,419	173	36	19
Product revenues	25,411	17,780	43	99	98
Licensing and product development	212	459	(54)	1	2
Total revenues	\$ 25,623	\$ 18,239	40%	100%	100%

Balance Sheets

	June 30, 2004	December 31, 2003
<u>Assets</u>		
Cash, cash equivalents and short-term investments	\$ 66,040	\$ 64,024
Accounts receivable, net	6,809	8,234
Inventories	4,763	4,003
Other current assets	987	923
Property and equipment, net	6,140	6,471
Other non-current assets	3,044	2,496
Total assets	\$ 87,783	\$ 86,151
<u>Liabilities and Stockholders' Equity</u>		
Current portion of long-term debt	\$ 1,130	\$ 1,126
Accounts payable	1,843	3,511
Accrued expenses	7,693	5,376
Long-term debt, less current portion	1,889	2,457
Other liabilities	238	172
Stockholders' equity	74,990	73,509
Total liabilities and stockholders' equity	\$ 87,783	\$ 86,151

Conference Call

The Company will host a conference call with analysts and simultaneous audio webcast to discuss the Company's second quarter 2004 financial results and the status of the Company's launch of its new oral fluid OraQuick[®] rapid HIV antibody test, beginning at 5:00 p.m. Eastern Time (2:00 p.m. Pacific Time) today. On the call will be Douglas A. Michels, President and 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 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 August 6, 2004, by dialing 800-642-1687 (Domestic) or 706-645-9291 (International) and entering the Conference ID #8121210.

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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