
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): February 10, 2005

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

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 Securities 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))
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Item 2.02 – Results of Operations and Financial Condition

On February 10, 2005, OraSure Technologies, Inc. issued a press release announcing its financial results for the quarter and year ended December 31, 2004. 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**

<u>Exhibit Number</u>	<u>Description</u>
99	Press Release dated February 10, 2005, announcing financial results of OraSure Technologies, Inc. for the quarter and year ended December 31, 2004.

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: February 10, 2005

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 Record Financial Results

BETHLEHEM, PA – February 10, 2005 (BW HealthWire) – OraSure Technologies, Inc. (NASDAQ:OSUR), the market leader in oral fluid diagnostics, today announced record revenues of \$54.0 million and \$14.2 million for the year and quarter ended December 31, 2004, respectively. Full year 2004 revenues represent a 34% increase from the \$40.5 million in revenues recorded for 2003. Revenues for the quarter ended December 31, 2004 were 20% higher than those for the same period of 2003.

The Company also reported a net loss of \$0.6 million, or \$(0.01) per share, for the full year 2004, and a net loss of \$245,000, or \$(0.01) per share, for the fourth quarter of 2004. This compares to a net loss of \$1.1 million, or \$(0.03) per share and a profit of \$435,000, or \$0.01 per share, for the full year and quarter ended December 31, 2003, respectively.

“We are very pleased with the Company’s fourth quarter results leading to a tenth consecutive quarter of record revenues,” said Douglas A. Michels, President and CEO of OraSure Technologies. “Each of our product lines continued to experience growth in the fourth quarter with notable gains in Substance Abuse Testing and Cryosurgical Systems. Our performance in 2004 has put us in position for great success in 2005 and beyond.”

The increase in 2004 full year revenues was primarily the result of increased sales of the Company’s Freeze Off™ wart removal product, OraQuick® rapid HIV antibody tests, and Intercept® oral fluid drug testing system. These increases were partially offset by a decline in sales of assays in the insurance risk assessment market. Product revenues were a record \$53.6 million for the full year 2004 and a record \$14.1 million for the quarter ended December 31, 2004, representing increases of 35% and 20%, respectively, over the comparable 2003 periods.

The Company’s gross margin was 59% in 2004, down from the 60% gross margin recorded in 2003. Gross margin was positively affected by more efficient utilization of the Company’s manufacturing capacity, offset by higher production costs associated with the Company’s UPlink® rapid oral fluid drug detection system, a less favorable product sales mix and higher scrap. For the fourth quarter of 2004, gross margin decreased to 60% compared to 61% for the fourth quarter of 2003, largely as a result of the more efficient utilization of the Company’s manufacturing capacity, offset by a less favorable product sales mix and higher production costs associated with the Company’s UPlink® rapid oral fluid drug detection system.

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For the full year 2004, operating expenses increased 29% to \$33.2 million from the \$25.7 million recorded in 2003. Operating expenses for the quarter ended December 31, 2004 increased 32% to \$9.0 million from the \$6.8 million recorded in 2003. These increases were primarily attributable to higher promotional expenditures, staffing expenses, including CEO transition-related expenses, legal fees associated with the Schering-Plough patent litigation, and consulting fees, partially offset by a reduction in research and development expenses.

Cash, cash equivalents and short-term investments were \$66.7 million and working capital was \$68.9 million at December 31, 2004. This compares to cash, cash equivalents and short-term investments of \$64.0 million and working capital of \$67.2 million at December 31, 2003. The Company's total debt outstanding at December 31, 2004 amounted to \$2.5 million, a reduction of \$1.1 million from December 31, 2003.

Cash flow from operations in 2004 increased to \$3.5 million from \$2.7 million in 2003, an improvement of \$0.8 million for the year. For the quarter ended December 31, 2004, cash flow from operations amounted to \$1.3 million.

As previously announced, OraSure expects total revenues for 2005 to increase by 25% over 2004 levels, to approximately \$67.5 million. In addition, OraSure expects to achieve full-year profitability for 2005, with net income ranging from \$0.06 to \$0.08 per share.

Internet Audio Broadcast

OraSure Technologies will host a conference call and audio webcast today to discuss the Company's 2004 fourth quarter and full-year 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 Doug Michels, Chief Executive Officer and Ron Spair, 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 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 February 13, 2005, by dialing 800-642-1687 (Domestic) or 706-645-9291 (International) and entering the Conference ID #3409876.

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.

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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 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; 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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Revenue Summary By Principal Markets
(Dollars in thousands)
(Unaudited)

	Dollars		% Change	Percentage of Total Revenues	
	2004	2003		2004	2003
Three Months Ended December 31,					
Product Revenues					
Insurance risk assessment	\$ 1,780	\$ 1,423	25%	12%	12%
Infectious disease testing	4,517	4,144	9%	32%	35%
Substance abuse testing	2,779	2,061	35%	20%	17%
Cryosurgical systems	5,031	4,110	22%	35%	35%
	<u>14,107</u>	<u>11,738</u>	20%	99%	99%
Licensing and product development	102	142	-28%	1%	1%
	<u>14,209</u>	<u>\$11,880</u>	20%	100%	100%

	Dollars		% Change	Percentage of Total Revenues	
	2004	2003		2004	2003
Year Ended December 31,					
Product Revenues					
Insurance risk assessment	\$ 7,777	\$ 9,708	-20%	14%	24%
Infectious disease testing	15,526	11,909	30%	29%	29%
Substance abuse testing	10,108	7,295	39%	19%	18%
Cryosurgical systems	20,193	10,828	86%	37%	27%
	<u>53,604</u>	<u>39,740</u>	35%	99%	98%
Licensing and product development	404	711	-43%	1%	2%
	<u>\$54,008</u>	<u>\$40,451</u>	34%	100%	100%

Condensed Financial Data
(Dollars in thousands, except per-share data)
(Unaudited)

	Three months ended December 31,		Year ended December 31,	
	2004	2003	2004	2003
Results of Operations				
Revenues	\$14,209	\$11,880	\$54,008	\$40,451
Cost of products sold	5,706	4,658	22,143	16,061
Gross profit	8,503	7,222	31,865	24,390
Operating expenses:				
Research and development	1,317	1,778	6,062	8,000
Sales and marketing	3,767	3,279	15,154	10,765
General and administrative	3,919	1,786	12,006	6,911
Total operating expenses	9,003	6,843	33,222	25,676
Operating income (loss)	(500)	379	(1,357)	(1,286)
Other income, net	255	56	797	150
Net income (loss)	\$ (245)	\$ 435	\$ (560)	\$ (1,136)
Basic and diluted net income (loss) per share	\$ (0.01)	\$ 0.01	\$ (0.01)	\$ (0.03)
Weighted average shares:				
Basic	44,578	43,799	44,464	39,794
Diluted	44,578	44,795	44,464	39,794
			December 31, 2004	December 31, 2003
Balance Sheets				
	Assets			
Cash, cash equivalents and short-term investments		\$ 66,723	\$ 64,024	
Accounts receivable, net		7,074	8,234	
Inventories		4,952	4,003	
Other current assets		1,195	923	
Property and equipment, net		5,551	6,471	
Other non-current assets		2,569	2,496	
Total assets		\$ 88,064	\$ 86,151	
	Liabilities and Stockholders' Equity			
Current portion of long-term debt		\$ 1,123	\$ 1,126	
Accounts payable		2,360	3,511	
Accrued expenses		7,552	5,376	
Long-term debt, less current portion		1,334	2,457	
Other liabilities		118	172	
Stockholders' equity		75,577	73,509	
Total liabilities and stockholders' equity		\$ 88,064	\$ 86,151	