
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, 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 February 10, 2004, announcing financial results of OraSure Technologies, Inc. for the year and quarter ended December 31, 2003.

Item 12. Results of Operations and Financial Condition.

On February 10, 2004, OraSure Technologies, Inc. issued a press release announcing its financial results for the year and quarter ended December 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: February 10, 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 Record Financial Results

BETHLEHEM, PA – February 10, 2004 (BW HealthWire) – OraSure Technologies, Inc. (Nasdaq NM:OSUR), the market leader in oral fluid diagnostics, today announced record revenues of \$40.5 million and \$11.9 million for the year and quarter ended December 31, 2003, respectively. Full year 2003 revenues represent a 26% increase from the \$32.0 million in revenues recorded for 2002. Revenues for the quarter ended December 31, 2003, were 44% higher than those for the same period of 2002.

The Company also reported a net loss of \$1.1 million, or \$(0.03) per share, for the full year 2003, and a profit of \$435,000, or \$0.01 per share, for the fourth quarter of 2003. These results represent an improvement from the net loss of \$3.3 million, or \$(0.09) per share, for the full year 2002, and the loss of \$82,000, or \$(0.00) per share, for the fourth quarter of 2002.

“2003 was a great year and marks the beginning of what is expected to be a sustainable growth phase for the Company,” said Mike Gausling, President and CEO of OraSure Technologies. “Last year, we had strong revenue growth, generated positive cash flow from operations, improved profitability, strengthened our balance sheet, secured important regulatory approvals, and continued to pursue new products and opportunities for the future. The global visibility around OraQuick® has been an incredible boost for the Company, and we expect to continue to advance OraQuick® to be the most versatile rapid HIV test in the world. These efforts serve as a terrific foundation for the Company for 2004 and beyond.”

The increase in 2003 full year revenues was primarily the result of increased sales of the Company’s OraQuick® rapid HIV-1 antibody test, the successful launch of the Freeze Off™ wart removal product, and higher sales of the Intercept® oral fluid drug testing system. These increases were partially offset by a decline in sales of urine assays in the insurance risk assessment market and lower sales of Histofreezer® in the U.S. professional marketplace. Product revenues were a record \$39.7 million for the full year 2003 and a record \$11.7 million for the quarter ended December 31, 2003, representing increases of 25% and 42%, respectively, over the comparable 2002 periods.

The Company's gross margin was 60% in 2003, which was unchanged from 2002. Gross margin was positively affected by increased Intercept® drug test system sales and the more efficient utilization of the Company's manufacturing capacity resulting in lower scrap and spoilage and better absorption of overhead. Offsetting these contributions to gross margin were lower urine assay sales in the insurance risk assessment market and lower sales of Histofreezer® in the U.S. professional marketplace. For the fourth quarter of 2003, gross margin increased to 61% compared to 58% for the fourth quarter of 2002, largely as a result of significantly lower scrap in 2003.

For the full year 2003, operating expenses increased 13% to \$25.7 million from the \$22.7 million recorded in 2002. Operating expenses for the quarter ended December 31, 2003 increased 39% to \$6.8 million from the \$4.9 million recorded in 2002. The increases for 2003 were the result of significantly higher sales and marketing expenses related to the launch of the OraQuick® and Freeze Off™ products, and higher general and administrative expenses primarily resulting from increased facility related expenses, partially offset by lower compensation costs. Partially offsetting these increases was a slight decrease in research and development expenditures for the full year 2003, primarily as a result of lower staffing costs, offset by increased outside consulting fees.

Cash, cash equivalents and short-term investments were \$64.0 million and working capital was \$67.2 million at December 31, 2003. This compares quite favorably to the cash, cash equivalents and short term investments of \$14.9 million and working capital of \$18.9 million at December 31, 2002, and is primarily the result of the \$47.8 million in net proceeds from the Company's successful public offering of common stock in October 2003. The Company's total debt outstanding at December 31, 2003 amounted to \$3.6 million.

Cash flow from operations in 2003 improved to \$2.7 million from a use of \$0.5 million in 2002, an improvement of \$3.2 million for the year. For the quarter ended December 31, 2003, cash flow from operations amounted to \$1.8 million.

The Company expects 2004 revenues of approximately \$50.0 million, primarily as a result of increasing sales of its OraQuick® rapid HIV-1 antibody test, higher utilization of its Intercept® oral fluid drug testing products, a revitalization of Histofreezer® sales in the U.S. professional marketplace, and increasing sales of the Freeze Off™ wart removal product. The Company also expects revenues in 2004 from the launch of its UPlink® rapid oral fluid drug detection system in Europe with its partner Dräger Safety. Additionally, the Company projects profitability for the whole year.

The Company's ability to achieve the financial results projected for 2004 is dependent on several factors, including the timely receipt of regulatory approvals for both OraQuick® and UPlink®, market acceptance of new products including an OraQuick® test with new claims, the successful deployment of the Company's hospital-based sales force, and the continued performance of the Company's distributors and other business partners.

Internet Audio Broadcast

OraSure Technologies will host a conference call and an audio webcast today to discuss the Company's 2003 fourth quarter and full-year financial results, financial guidance for 2004 and major business objectives, beginning at 5:00 p.m. Eastern Time (2:00 p.m. Pacific Time). On the call will be Mike Gausling, 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, 2004, by dialing 800-642-1687 (Domestic) or 706-645-9291 (International) and entering the Conference ID #4884253.

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, profitability, 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 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 (including the outcome of our dispute with Abbott Laboratories); 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, 2002, 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		%	Percentage of Total Revenues	
	2003	2002		Change	2003
Three Months Ended December 31,					
Product Revenues					
Insurance risk assessment	\$ 1,423	\$ 3,131	(55)%	12%	38%
Infectious disease testing	4,144	1,517	173%	35%	18%
Substance abuse testing	2,061	1,666	24%	17%	20%
Cryosurgical systems	4,110	1,932	113%	35%	24%
	<u>11,738</u>	<u>8,246</u>	42%	99%	100%
Licensing and product development	142	2	N/M	1%	0%
Total revenues	\$ 11,880	\$ 8,248	44%	100%	100%

	Dollars		%	Percentage of Total Revenues	
	2003	2002		Change	2003
Year Ended December 31,					
Product Revenues					
Insurance risk assessment	\$ 9,708	\$ 12,030	(19)%	24%	38%
Infectious disease testing	11,909	6,063	96%	29%	19%
Substance abuse testing	7,295	6,434	13%	18%	20%
Cryosurgical systems	10,828	7,165	51%	27%	22%
	<u>39,740</u>	<u>31,692</u>	25%	98%	99%
Licensing and product development	711	318	124%	2%	1%
Total revenues	\$ 40,451	\$ 32,010	26%	100%	100%

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

Results of Operations

	Three Months Ended December 31,		Year ended December 31,	
	2003	2002	2003	2002
Revenues	\$ 11,880	\$ 8,248	\$ 40,451	\$ 32,010
Cost of products sold	4,658	3,445	16,061	12,889
Gross profit	7,222	4,803	24,390	19,121
Operating expenses:				
Research and development	1,778	1,753	8,000	8,274
Sales and marketing	3,279	1,741	10,765	8,069
General and administrative	1,786	1,432	6,911	6,319
Total operating expenses	6,843	4,926	25,676	22,662
Operating income (loss)	379	(123)	(1,286)	(3,541)
Other income, net	56	41	150	198
Net income (loss)	\$ 435	\$ (82)	\$ (1,136)	\$ (3,343)
Basic and diluted net income (loss) per share	\$ 0.01	\$ (0.00)	\$ (0.03)	\$ (0.09)
Weighted average shares:				
Basic	43,799	37,863	39,794	37,583
Diluted	44,795	37,863	39,794	37,583

Balance Sheets

	December 31, 2003	December 31, 2002
<u>Assets</u>		
Cash, cash equivalents and short-term investments	\$ 64,024	\$ 14,908
Accounts receivable, net	8,234	5,198
Inventories	4,003	4,088
Other current assets	923	926
Property and equipment, net	6,471	7,428
Other non-current assets	2,496	3,189
Total assets	\$ 86,151	\$ 35,737
<u>Liabilities and Stockholders' Equity</u>		
Current portion of long-term debt	\$ 1,126	\$ 1,066
Accounts payable	3,511	1,802
Accrued expenses	5,376	3,321
Long-term debt, less current portion	2,457	3,409
Other liabilities	172	120
Stockholders' equity	73,509	26,019
Total liabilities and stockholders' equity	\$ 86,151	\$ 35,737