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ORASURE TECHNOLOGIES INC

Form 8-K

February 06, 2003

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 5, 2003

OraSure Technologies, Inc.

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(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.

On February 5, 2003, OraSure Technologies, Inc. (the "Company" or "OraSure") announced total revenues of \$32.0 million for the full year 2002 and \$8.25 million for the quarter ended December 31, 2002. Full year 2002 revenues reflect a 2% decline from the \$32.6 million in revenues recorded for 2001. Revenues for the quarter ended December 31, 2002, were 2% higher than those for the same period of 2001.

The Company's net loss was \$3.3 million, or \$(0.09) per share, for the full year 2002 and \$82,000, or \$(0.00) per share, for the fourth quarter of 2002, a penny better than street estimates. These results represent an improvement from the net loss of \$3.7 million, or \$(0.10) per share, for the full year 2001 and the net loss of \$2.3 million, or \$(0.06) per share, for the fourth quarter of 2001.

The decline in 2002 full year revenues was primarily the result of a \$1.2 million decrease in license and product development revenues, partially offset by higher product revenues. Product revenues were \$31.7 million for the full year 2002 and \$8.25 million for the quarter ended December 31, 2002, representing increases of 2% and 5%, respectively, over the comparable 2001

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periods.

The Company's gross margin for the full year 2002 decreased from 62% to 60% compared to 2001, primarily as a result of lower license and development revenues. This was partially offset by a more favorable product mix and the impact of the Company's ongoing cost savings efforts. For the fourth quarter of 2002, the Company's gross margin increased from 53% to 58% as compared to the fourth quarter of 2001. The gross margin in 2001 was negatively impacted by a \$600,000 inventory reserve recorded in the fourth quarter of that year.

For the full year 2002, operating expenses declined 8% from the \$24.6 million recorded in 2001, which included \$450,000 in restructuring charges. Operating expenses for the quarter ended December 31, 2002 declined 28% from a year ago to \$4.9 million. These declines were the result of cost savings generated by workforce reductions, and lower relocation, travel, legal and consulting expenses.

Cash and short-term investments were \$14.9 million and working capital was \$18.9 million at December 31, 2002. The Company's total debt outstanding at December 31, 2002 amounted to \$4.5 million. Cash flow from operations improved from a use of \$5.3 million in 2001 to a use of \$0.5 million in 2002, an improvement of \$4.8 million for the year.

"During 2002, we achieved an historic milestone for the Company with the approval of the OraQuick(R) HIV-1 test in the fourth quarter which, when combined with the recent CLIA waiver, establishes this product as a significant commercial opportunity for years to come," said Mike Gausling, President and CEO of OraSure Technologies. "On the infrastructure side, we focused on streamlining our cost structure and lowering our operating expense levels. This led to a \$4.8 million improvement in our cash flow from operations over 2001 and positive cash flow from operations for the final three quarters of 2002. At December 31, 2002, our balance sheet was strong and we are well positioned to support our product initiatives in 2003."

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

	Three months ended December 31,		Y De
	2002	2001	2002
	----	----	----
Results of Operations			
Revenues	\$ 8,248	\$ 8,063	\$ 32,01
Cost of products sold	3,445	3,754	12,88
	-----	-----	-----
Gross margin	4,803	4,309	19,12
Operating expenses	4,926	6,802	22,66
Restructuring - related costs	-	-	
	-----	-----	-----
Operating loss	(123)	(2,493)	(3,54
Other income (expense), net	41	190	19
	-----	-----	-----
Net loss	\$ (82)	\$ (2,303)	\$ (3,34
	=====	=====	=====
Net loss per common share:			

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Basic and diluted	\$ (0.00)	\$ (0.06)	\$ (0.00)
=====			
Weighted average number of common shares outstanding:			
Basic and diluted	37,863	37,246	37,580
=====			

Balance Sheets	12/31/02	12/31/01	
	-----	-----	
Assets			
-----			
Cash and short-term investments	\$ 14,908	\$ 15,191	
Accounts receivable, net	5,198	6,058	
Inventories	4,088	4,445	
Other current assets	926	1,114	
Property and equipment, net	7,428	7,800	
Other non-current assets	3,137	2,625	
-----			
Total assets	\$ 35,685	\$ 37,233	
=====			
Liabilities and Stockholders' Equity			
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Current portion of long-term debt	\$ 1,066	\$ 1,058	
Accounts payable	1,802	2,874	
Accrued expenses	3,321	3,112	
Long-term debt, less current portion	3,409	3,586	
Other liabilities	68	62	
Stockholders' equity	26,019	26,541	
-----			
Total liabilities and stockholders' equity	\$ 35,685	\$ 37,233	
=====			

Revenue Summary By Principal Markets  
(Dollars in thousands, unaudited)

	Dollars		%
	2002	2001	Change
Three Months Ended December 31,	----	----	
Product Revenues			
Insurance risk assessment	\$ 3,131	\$ 2,333	34%
Infectious disease testing	1,517	1,569	(3)%
Substance abuse testing	1,666	2,043	(18)%
Physicians' office therapies	1,932	1,944	(1)%
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	8,246	7,889	5%
License and product development	2	174	(99)%
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Total revenues	\$ 8,248	\$ 8,063	2%
=====			

Dollars	%
Change	Change
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Year Ended December 31,	2002 ----	2001 ----	
Product Revenues			
Insurance risk assessment	\$ 12,030	\$ 11,713	3%
Infectious disease testing	6,063	5,754	5%
Substance abuse testing	6,434	6,955	(7)%
Physicians' office therapies	7,165	6,674	7%
	-----	-----	
	31,692	31,096	2%
License and product development	318	1,477	(79)%
	-----	-----	
Total revenues	\$ 32,010	\$ 32,573	(2)%
	=====	=====	

### Item 9 - Regulation FD Disclosure.

On February 5, 2003, the Company announced that it expects 2003 revenues to grow approximately 25% over 2002, primarily as a result of the introduction of the OraQuick(R) HIV-1 test, expansion of Intercept(R) drug testing, and broader distribution of Histofreezer(R), and expects to fill the Company's product pipeline further as a result of the FDA submission of the ULink(TM) drugs of abuse panel. Additionally, the Company projects profitability in the second half of 2003 and for the year as a whole.

The Company's ability to achieve the financial results projected for 2003 is dependent on several factors, including the timely receipt of regulatory approvals, market acceptance of new products such as OraQuick(R), and the continued performance of the Company's distributors and other business partners.

The foregoing discussion contains certain forward-looking statements, including with respect to revenues, earnings, markets, regulatory submissions 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 or 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, its Annual Report on Form 10-K for the year ended December 31, 2001, and its most recent Quarterly Report on Form 10-Q. 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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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 6, 2003

By: /s/ Jack E. Jerrett

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