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ORASURE TECHNOLOGIES INC

Form 8-K

February 19, 2002

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 15, 2002

ORASURE TECHNOLOGIES, INC.  
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(Exact name of issuer as specified in charter)

|                     |             |                  |
|---------------------|-------------|------------------|
| DELAWARE            | 1-10492     | 36-4370966       |
| (State or Other     | (Commission | (I.R.S. Employer |
| Jurisdiction        | file        | Identification   |
| of Incorporation or | number)     | Number)          |
| Organization)       |             |                  |

150 Webster Street  
Bethlehem, Pennsylvania 18015  
(Address of principal executive offices)

(610) 882-1820  
(Registrant's telephone number, including area code)

Item 5 - Other Events.

On February 15, 2002, OraSure Technologies, Inc. (the "Company" or "OraSure Technologies") announced that it would report revenues of \$32.6 million for the full year 2001 and \$8.1 million for the quarter ended December 31, 2001. After excluding revenues in 2000 from the discontinued Serum Western Blot product, these amounts represent increases of 20 percent and 9 percent, respectively, over revenues reported for the same periods a year ago.

The Company's net loss was approximately \$3.7 million or \$(0.10) per share for the full year 2001 and \$2.3 million or \$(0.06) per share for the fourth quarter. These results represent an improvement from the net loss of \$12.7 million or \$(0.36) per share for the full year 2000 and the net loss of \$3.7 million or \$(0.10) per share in the fourth quarter of 2000, which included merger-related charges of \$7.6 million and \$1.7 million, respectively.

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The increase in revenues was primarily the result of increased market penetration of the Company's oral fluid substance abuse and infectious disease testing products and increased license and product development revenue. These increases were partially offset by a decline in revenues in the insurance risk assessment market due to customer inventory consolidation and increased efficiencies at certain customers as well as declines in other product lines due to generally soft market conditions.

The Company's gross margin for the full year 2001 improved from 61% to 62%, as a result of lower material costs, productivity gains and higher license and development revenues, which were partially offset by the recognition of an inventory reserve in the fourth quarter of \$0.6 million related to OraQuick(R) HIV tests manufactured for sale to the Company's African distributor. For the fourth quarter of 2001, the Company's gross margin declined from 63% to 53%, primarily as a result of the OraQuick(R) inventory reserve established during that period. Because of the repeated failure by the Company's African distributor to meet its contractually-required minimum purchase commitments, the Company recently reevaluated its international strategy for OraQuick(R) distribution and terminated its agreement with this distributor. The resulting inventory reserve was required in light of this action and serious concerns surrounding the product's remaining shelf-life in relation to the Company's ability to rapidly establish a new distribution channel in Africa to sell the product.

Operating expenses for the fourth quarter, excluding merger-related charges in 2000, declined 4% from a year ago to approximately \$6.8 million. For the full year ended December 31, 2001, operating expenses, excluding merger-related charges, remained flat at approximately \$24 million.

### Item 9 - Regulation FD Disclosure.

On February 15, 2002, the Company announced that it continues to target revenue growth of up to 30% for 2002 to approximately \$42 million, and profitability in the second half of 2002 and for the year as a whole. However, the Company's ability to achieve these results is dependent on several factors, including the timely receipt of regulatory approvals, market acceptance of new products and the timely startup of several new distributors for its products.

The foregoing discussion contains certain forward-looking statements with respect to revenues, earnings, products, regulatory filings and markets. 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 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 terrorist attacks and civil unrest; and general

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business, political and economic conditions. These and other factors are discussed more fully in the Securities and Exchange Commission (the "SEC") filings of OraSure Technologies, including its registration statements, its Annual Report on Form 10-K for the year ended December 31, 2000, 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 Report and OraSure Technologies undertakes no duty to update these statements.

### 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 19, 2002

By: /s/ Michael G. Gausling

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Michael G. Gausling  
President and Chief Executive Officer