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**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**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): September 17, 2003

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**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)

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**Item 5 – Other Events and Regulation FD Disclosure.**

OraSure Technologies, Inc. (the “Company”) issued a press release announcing that the use of the Company’s OraQuick<sup>®</sup> Rapid HIV-1 Antibody Test at the point of care was found to provide results faster than when the test was used in a laboratory setting, in the Mother Infant Rapid Intervention at Delivery (MIRIAD) study conducted by The Centers for Disease Control and Prevention. The information contained in the press release dated September 16, 2003 is incorporated herein by reference and attached to this Current Report on Form 8-K as Exhibit 99.

**Item 7. Financial Statements and Exhibits**

**(c) Exhibits**

<u>Exhibit Number</u>	<u>Description</u>
99	Press Release dated September 16, 2003, announcing certain findings of the Mother Infant Rapid Intervention at Delivery (MIRIAD) study involving the Company’s OraQuick <sup>®</sup> Rapid HIV-1 Antibody Test, conducted by The Centers for Disease Control and Prevention.



**Index to Exhibits**

**Exhibit  
Number**

**Description**

99

Press Release dated September 16, 2003, announcing certain findings of the Mother Infant Rapid Intervention at Delivery (MIRIAD) study involving the Company's OraQuick® Rapid HIV-1 Antibody Test, conducted by The Centers for Disease Control and Prevention.

**[LOGO OF ORASURE TECHNOLOGIES, INC.]**

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**CDC STUDY FINDS THAT ORAQUICK® TEST  
PROVIDES FAST RESULTS DURING LABOR AND DELIVERY**

**BETHLEHEM, PA** – September 16, 2003 – OraSure Technologies, Inc. (Nasdaq NM:OSUR), the market leader in oral fluid diagnostics, announced today that the use of its OraQuick® Rapid HIV-1 Antibody Test at the point of care was found to provide testing results four-times faster than when the OraQuick® test was used in a laboratory setting. These findings resulted from the Mother Infant Rapid Intervention at Delivery (MIRIAD) study, which was conducted by the Centers for Disease Control and Prevention (“CDC”) in Chicago, Illinois during the first six months of 2002. The use of the OraQuick® test during this period also provided 100 percent accurate HIV-1 testing results. The findings were published in the CDC’s September 12, 2003, Morbidity and Mortality Weekly Report, Vol. 52 / No. 36 (“MMWR”).

The CDC study tested a total of 380 women in four hospitals in Chicago that have the highest rate of HIV infection in that city among women of childbearing age. The study found that rapid HIV-1 testing enables healthcare professionals to determine the HIV status of the mother and administer antiretroviral drugs to both the mother and child more quickly than traditional laboratory testing, thereby reducing the chances of mother-to-child transmission of the HIV-1 virus. Study authors noted that HIV rapid testing is of particular importance in labor and delivery settings, since even small delays can result in a woman not receiving timely drug treatment that can prevent HIV transmission to her baby.

The study found that the average turnaround time for results where the OraQuick® test was administered by the obstetric staff at the point of care was 45 minutes, which was substantially shorter than the average 3.5-hour turnaround time where rapid OraQuick® testing was performed in a laboratory. The findings in the report complement the new CDC initiative aimed at reducing barriers to early diagnosis of HIV infection, which includes a goal of further decreasing perinatal HIV transmission in the United States. According to the CDC, the “FDA’s approval of the OraQuick® rapid test now provides healthcare providers with an opportunity to test for HIV infection and inform patients of their HIV status rapidly. This can have a profound benefit for the care of women who have not been tested for HIV during pregnancy.” (*MMWR, September 12, 2003*)

“The findings of the MIRIAD study indicate that rapid testing results using the OraQuick® test at the point of care are available on average four-times faster than where rapid testing with an OraQuick® device is performed in a laboratory. This demonstrates both the necessity and feasibility of using rapid point-of-care HIV testing in the labor and delivery setting,” said Mike Gausling, President and Chief Executive Officer of OraSure Technologies. “In fact, the CDC reported that three women in the study were found to be HIV-infected, antiretroviral therapy was administered and none of their infants became HIV-infected as of the date of the report. We are obviously pleased with our role in the MIRIAD study, and we look forward to continuing our work with the CDC in an effort to make rapid HIV testing available to all who need it.”

The full report on the MIRIAD study findings, entitled “*Rapid Point-of-Care Testing for HIV-1 During Labor and Delivery — Chicago, Illinois, 2002*,” can be accessed at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5236a4.htm>.

OraQuick® is the first rapid, point-of-care test approved by the FDA to detect antibodies to HIV-1 in fingerstick and venipuncture whole blood specimens within approximately 20 minutes. OraSure received FDA approval of the OraQuick® test for fingerstick whole blood on November 7, 2002, and for venipuncture whole blood on September 5, 2003. On January 31, 2003, OraSure received a CLIA (Clinical Laboratory Improvements Amendments of 1988) waiver for the test, permitting its use by more than 180,000 sites in the United States, including outreach clinics, community-based organizations and physicians’ offices.

### **About OraSure Technologies**

OraSure Technologies develops, manufactures and markets oral fluid specimen collection devices using proprietary oral fluid technologies, diagnostic products including immunoassays and other in vitro diagnostic tests, and other medical devices. These products are sold in the United States as well as internationally to various clinical laboratories, hospitals, clinics, community-based organizations and other public health organizations, distributors, government agencies, physicians’ offices, and commercial and industrial entities.

OraSure Technologies is the leading supplier of oral-fluid collection devices and assays to the life insurance industry and public health markets for the detection of antibodies to HIV-1. In addition, the Company supplies oral-fluid testing solutions for drugs of abuse testing. For more information on the Company, please go to [www.orasure.com](http://www.orasure.com).

### **Important Information**

This press release contains certain forward-looking statements, including with respect to sales, 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; 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, 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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