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): September 8, 2004

OraSure Technologies, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware	**001-16537**	**36-4370966**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

220 East First Street **Bethlehem, Pennsylvania**	**18015-1360**
(Address of Principal Executive Offices)	**(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))

Item 8.01 – Other Events.

As previously disclosed, OraSure Technologies, Inc. (the "Company") was recently notified of results from an isolated clinical trial of its new OraQuick® Rapid HIV-1/2 Antibody Test that indicated a higher rate of unconfirmed positive results for oral fluid. These results were in direct contrast to the clinical data compiled by the Company in support of its U.S. Food and Drug Administration ("FDA") approval for oral fluid, which included data from larger Company-sponsored trials as well as data from independent studies by the Centers for Disease Control and Prevention ("CDC"). Nevertheless, the Company elected to delay the launch of its new OraQuick® HIV-1/2 test until the Company could complete its assessment of this matter.

As part of the assessment, the Company has worked diligently to narrow the list of potential causes and, if possible, eliminate factors which may have contributed to the results in question. It is important to note that the specific trial in which this issue arose, included more than 2,000 tests which were successfully performed with an accuracy of greater than 99%. Other large ongoing clinical studies being conducted by the CDC using the OraQuick® test on oral fluid also continue to indicate similar accuracy.

Based on the work performed to date, the Company does not currently believe that its manufacturing processes, the raw materials used to make OraQuick®, or the shelf life of the device are contributing factors. Consequently, this issue may be limited to how the test results were being evaluated in the specific study.

In order to complete the final phase of the assessment, the Company is now performing an additional study to confirm further the foregoing. The Company expects this final phase to be largely complete by the end of October. Assuming no further issues are raised in this study, the Company would expect to launch its new OraQuick® Rapid HIV-1/2 Antibody Test shortly thereafter.

Important Information

This Report contains certain forward-looking statements, including with respect to products, product launches, and clinical studies. 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 successfully 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; 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.

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: September 8, 2004

By: /s/ Jack E. Jerrett

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