UNITED STATES
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): June 25, 2009

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 Exchange 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 7.01 – Regulation FD Disclosure.

On June 25, 2009, OraSure Technologies, Inc. (the "Company") issued a press release providing an update on clinical development programs and manufacturing issues recently experienced with respect to the OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test. A copy of this press release is attached to this Current Report as Exhibit 99.1.

The information in this Current Report and attached Exhibit shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that section, nor shall such information and Exhibit be deemed incorporated by reference in any filing under the Securities Act of 1933, except as shall be expressly set forth by specific reference in such a filing. The fact that the information and Exhibit are being furnished should not be deemed an admission as to the materiality of any information contained therein. The Company undertakes no duty or obligation to publicly update or revise the information contained in this Current Report or attached Exhibit.

Item 9.01 – Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release, dated June 25, 2009, providing an update on clinical development programs and manufacturing issues recently experienced with respect to the OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test.

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: June 25, 2009

By: */s/ Jack E. Jerrett*
Jack E. Jerrett
Senior Vice President, General Counsel and Secretary

Exhibit Index

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Exhibit 99.1

OraSure Technologies, Inc.

Company contact:

Ronald H. Spair
Chief Financial Officer
610-882-1820
Investorinfo@orasure.com
www.orasure.com

ORASURE TECHNOLOGIES PROVIDES UPDATE ON CLINICAL DEVELOPMENT PROGRAMS AND ORAQUICK® MANUFACTURING

Bethlehem, PA. (June 24, 2009) – OraSure Technologies, Inc. (NASDAQ: OSUR) today announced an update regarding the status of its application for U.S. Food and Drug Administration ("FDA") approval of an OraQuick® Hepatitis C ("HCV") test for professional use and its clinical program for an OraQuick® HIV-1/2 test for sale in the consumer or over-the-counter ("OTC") market. In addition, the Company announced its efforts to address manufacturing challenges recently experienced with respect to its OraQuick ADVANCE® rapid HIV-1/2 antibody test.

OraQuick® HCV Test

During the fourth quarter of 2008, the Company filed a premarket approval application ("PMA") with the FDA for approval of an OraQuick® HCV test for use in the professional market. The application sought approval for use of the product with multiple specimen types, including venous whole blood, fingerstick whole blood, oral fluid and other sample types. The clinical study data submitted in the PMA showed a high degree of correlation to the comparator assay conducted at a central laboratory.

Since filing its PMA, the Company has been in frequent communications with the FDA and has received a number of questions and requests for additional information from the agency. During its review of the PMA, the FDA indicated that the Company's clinical data could potentially have been affected by bias because the same operators performed the test and interpreted the results on multiple specimen types derived from the same patient. The FDA had previously reviewed and concurred with the Company's original clinical trial protocol, which had stated that the study would not be blinded to prevent an operator from seeing the results of multiple devices used on the same patient, but would be blinded as to central laboratory results using an FDA-approved comparator assay.

When the agency later raised concerns during the PMA review regarding potential interpretation bias, the Company reasonably expected to be able to address these concerns without material impact to the clinical program because the Company executed the clinical program as designed. However, the FDA recently concluded that additional clinical testing will be required to obtain approval of the PMA for a venous whole blood claim, and that a new clinical study will be required for approval of claims for oral fluid and other sample types.

Although the Company believes the clinical data originally submitted to the FDA is sufficient to support approval of its PMA, the Company has agreed to conduct the additional

clinical testing and study mandated by the FDA in order to obtain approved claims for oral fluid, venous whole blood, and fingerstick whole blood. The exact timing and costs associated with this work will not be fully determined until after protocols are submitted and reviewed by the FDA, which should occur in the next several weeks. The Company expects first to complete the additional testing required for a venous whole blood claim and submit that data to the FDA for review and approval, while the additional study for the other specimen types is completed. The Company believes that it has adequately responded to all other questions and requests for information received to date from the FDA with respect to the OraQuick® HCV PMA submission.

The Company also plans to submit its application for CE mark approval for the OraQuick® HCV test shortly. A CE mark is required in order to sell the product in Europe.

The Company expects to record a non-cash impairment charge of $3.0 million related to a portion of the milestone payments previously made under a license for certain HCV patents. These milestone payments were initially recorded as capital assets. The Company believes that, in light of the absence of sales in the international marketplace of a rapid HCV test that is subject to that license, coupled with expected delays in FDA approval of the Company's OraQuick® HCV test as described above, such a non-cash charge should be taken. The charge is expected to be reflected in the financial results for the second quarter as an operating expense and was not previously included in the Company's financial guidance for this period.

OraQuick® HIV OTC Test

In August 2008, the Company submitted the results of its observed use study to the FDA as part of its efforts to obtain approval for an OraQuick® rapid HIV OTC test. The observed use study was designed to assess an individual's ability to interact with the product packaging, comprehend the instructions for use, take the test and interpret the results while a trained professional observed those activities. The observed use study was stopped after testing was completed for the first 1,000 subjects, because data from the study met the success criteria initially established in the study protocol for this phase of the trials.

The FDA recently reviewed the data from the observed use study at a meeting of its senior management. Following this meeting, the FDA contacted the Company and indicated that both the results of the observed use study and the Company's remaining clinical activities should also be reviewed and approved by the Blood Products Advisory Committee ("BPAC"), an advisory committee to the FDA, before proceeding.

The Company will meet with the FDA to discuss plans for the upcoming BPAC meeting. The Company intends to gain alignment with the FDA on the next steps required to complete and file a PMA application, before presenting a proposal at the BPAC's meeting scheduled for November 2009.

OraQuick *ADVANCE*® HIV Manufacturing

The Company recently has been experiencing an intermittent difficulty in manufacturing a component required for its OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test that meets the Company's internal quality requirements. This issue initially resulted in lower production yields, but the Company was able to manufacture sufficient product to meet existing customer demand. More recently, however, the Company has experienced additional difficulty in manufacturing this component. A multi-functional team has been working aggressively with the assistance of outside consultants to resolve this manufacturing issue. Because this issue has not yet been satisfactorily resolved, inventory levels have been reduced and the Company has been allocating available product among its customers. In addition, until this issue is satisfactorily resolved, the Company will be assisting customers in meeting their HIV testing needs.

The Company's priority has been and continues to be to provide the highest quality product to its customers in compliance with all applicable legal and regulatory requirements. Only OraQuick *ADVANCE*® devices that meet the Company's stringent quality standards have been and will be released into the field.

If the Company is unable to resume full-scale production of its OraQuick® HIV test this week, its revenues for the second quarter of 2009 will be negatively impacted. In addition, in view of the foregoing, the Company expects gross margin for the second quarter to be negatively impacted due primarily to higher unabsorbed production costs and scrap expenses.

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 to the life insurance industry and public health markets for the detection of antibodies to HIV. 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.

Important Information

This press release contains certain forward-looking statements, including with respect to revenues, expenses, products, clinical testing and regulatory filings. Actual results could be significantly different. Factors that could affect results include the ability to market and sell products, whether through an internal, direct sales force or third parties; ability to manufacture products in accordance with applicable specifications, performance standards and quality requirements; changes in relationships, including disputes or disagreements, with strategic partners and reliance on strategic partners for the performance of critical activities under collaborative arrangements; failure of distributors or other customers to meet purchase forecasts or minimum purchase requirements for the Company's products; impact of replacing distributors and success of direct sales efforts; inventory levels at distributors and other customers; 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; changes in market acceptance of products based on product performance and extended shelf life; continued bulk purchases by customers, including governmental agencies, and the ability to fully deploy those purchases in a timely manner; ability to fund research and development and other products and operations; ability to obtain and maintain new or existing product distribution channels; reliance on sole supply sources for critical product components; availability of related products produced by third parties or products required for use of our products; ability to obtain, and timing and cost of obtaining, necessary regulatory approvals for new products or new indications or applications for existing products; ability to comply with applicable regulatory requirements; history of losses and ability to achieve sustained profitability and ability to utilize net operating loss carryforwards or other deferred tax assets; volatility of the Company's stock price; uncertainty relating to patent protection and potential patent infringement claims; uncertainty and costs of litigation relating to patents and other intellectual property; 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, including changes in international funding sources; loss or impairment of sources of capital; ability to meet financial covenants in agreements with financial institutions; ability to retain qualified personnel; exposure to patent infringement, product liability, and other types of litigation; changes in international, federal or state laws and regulations; 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 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, 2008, 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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