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): November 29, 2011

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 November 29, 2011, the Company issued a press release announcing the receipt from the U.S. Food and Drug Administration of a waiver under the Clinical Laboratory Improvement Amendments of 1988 ("CLIA") for the Company's OraQuick® HCV rapid antibody test. A copy of the press release is attached as Exhibit 99 to this Form 8-K and is incorporated herein by reference.

Item 9.01 – Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99	Press Release, dated November 29, 2011, announcing receipt of a CLIA waiver for the Company's OraQuick® HCV rapid 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: November 29, 2011

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

Index to Exhibits

Exhibit No.	Description
99	Press Release, dated November 29, 2011, announcing receipt of a CLIA waiver for the Company's OraQuick® HCV rapid antibody test.

Exhibit 99

Investor Contact:
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Chief Financial Officer
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OraSure Technologies Receives CLIA Waiver for OraQuick® HCV Rapid Test

BETHLEHEM, PA – November 29, 2011 – OraSure Technologies, Inc. (NASDAQ:OSUR) announced today that the U.S. Food and Drug Administration ("FDA") has granted a waiver under the Clinical Laboratory Improvement Amendments of 1988 ("CLIA") for its OraQuick® HCV Rapid Antibody Test for use with fingerstick whole blood and venous whole blood specimens.

The OraQuick® HCV Rapid Antibody Test is the first and only FDA-approved rapid test for the detection of antibodies to the hepatitis C virus ("HCV"). The test, which utilizes the OraQuick® technology platform, provides results in 20 minutes. With this waiver, the OraQuick® HCV test now can be used by more than 180,000 sites in the United States to test persons who are at risk for hepatitis C or have signs or symptoms of hepatitis. These sites now extend to facilities that can perform CLIA-waived tests, such as outreach clinics, community-based organizations and physician offices.

"Today, more than 4 million Americans are infected with hepatitis C and the vast majority do not know it," said Dr. Willis C. Maddrey, President of the Chronic Liver Disease Foundation. "Hepatitis C is a leading cause of chronic liver disease, cirrhosis and liver cancer. However, new therapies are now available that can effectively treat a high percentage of people with HCV infection, making expanded and accessible testing for HCV a critical step in fighting this epidemic."

"A CLIA waiver for our OraQuick® HCV test represents a critical milestone in our quest to make the test available to the widest possible range of at risk individuals in the U.S.," said Douglas A. Michels, President and Chief Executive Officer of OraSure Technologies. "The CLIA waiver will enable healthcare providers, those on the front lines of fighting this devastating disease, to use this simple and accurate test in physician offices and outreach settings so more individuals infected with hepatitis C can be diagnosed and treated."

As previously announced, OraSure has entered into agreements with Merck & Co. (NYSE:MRK) to collaborate on the development and promotion of the OraQuick® HCV test. Under these agreements, Merck will provide detailing and other promotional support for the test in the physicians' office markets in the United States and internationally. The approval of the CLIA waiver will now enable physicians to utilize the test in their office settings.

About OraSure Technologies

OraSure Technologies is a leader in the development, manufacture and distribution of oral fluid diagnostic and collection devices and other technologies designed to detect or diagnose critical medical conditions. Its innovative products include rapid tests for the detection of antibodies to HIV and HCV at the point of care and testing solutions for detecting various drugs of abuse. In addition, through its wholly-owned subsidiary, DNA Genotek Inc., the Company also is a leading provider of oral fluid sample collection, stabilization and preparation products for molecular diagnostic applications. OraSure's portfolio of products is sold globally to various clinical laboratories, hospitals, clinics, community-based organizations and other public health organizations, research and academic institutions, distributors, government agencies, physicians' offices, and commercial and industrial entities. The Company's products enable healthcare providers to deliver critical information to patients, empowering them to make decisions to improve and protect their health. For more information on OraSure Technologies, please visit www.orasure.com.

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