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): July 3, 2012

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** **(Address of Principal Executive Offices)**	**18015-1360** **(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 8.01 – Other Events.

On July 3, 2012, OraSure Technologies, Inc. (the "Company") issued a press release announcing the receipt of U.S. Food and Drug Administration ("FDA") approval of the Company's OraQuick® In-Home HIV Test. A copy of the press release is attached as Exhibit 99.1 to this Form 8-K and is incorporated herein by reference.

Item 9.01 – Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release, dated July 3, 2012, announcing the receipt of FDA approval of the OraQuick® In-Home HIV 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: July 3, 2012

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

Index to Exhibits

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Exhibit 99.1

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OraSure Receives FDA Approval of OraQuick® In-Home HIV Test

First and Only Rapid HIV Test For Over the Counter Use – To be Available in October for Purchase Online and at Retail Stores Nationwide

BETHLEHEM, Pa., July 3, 2012 – OraSure Technologies, Inc. (NASDAQ: OSUR) today announced that the U.S. Food and Drug Administration (FDA) has approved the Company's OraQuick® In-Home HIV Test for sale directly to consumers in the over-the-counter (OTC) market – making it the first and only rapid OTC HIV test approved in the U.S. The OraQuick® In-Home HIV Test can detect antibodies to both HIV-1 and HIV-2 with an oral swab, providing a confidential in-home testing option with results in as little as 20 minutes. It is the first rapid diagnostic test for any infectious disease that has been approved by the FDA for sale over the counter.

"Approval of the OraQuick® In-Home HIV Test represents a major breakthrough in HIV testing," said Douglas A. Michels, President and Chief Executive Officer of OraSure Technologies. "For the first time ever, individuals will have access to an in-home oral test that will empower them to learn their HIV status in the comfort of their home and obtain referral to care if needed. This new in-home rapid test – the same test doctors have used for years – will help individuals at risk for HIV who otherwise may not test in a professional or clinical setting."

The OraQuick® In-Home HIV Test is an over-the-counter version of the Company's OraQuick ADVANCE® HIV 1/2 Antibody Test the market leading rapid HIV test with millions of units sold to hospitals, clinics, community-based organizations and physician offices.

The OraQuick® In-Home HIV Test is expected to be available for purchase this October at more than 30,000 retail outlets throughout the country and online.

OraSure is committed to providing OraQuick® In-Home HIV customers with extensive resources and support. Each test kit includes detailed information on HIV and HIV testing, including step-by-step directions on how to use the OraQuick® In-Home HIV Test. Customers also have access to a "live" toll-free customer support center and comprehensive consumer website. The support center is staffed with bi-lingual (English/Spanish) representatives who are available by telephone (toll free 866-436-6527) to answer questions about HIV/AIDS, describe how to use the test and interpret the results, and to provide direct referral to care if needed. Support center representatives are available 24 hours a day, seven days a week, 365 days a year and will be active starting on Monday, July 9th. In addition to the support center, a comprehensive consumer website will be launched to provide access to resources and referral to follow-up counseling and medical care. The comprehensive website will launch when product is available in October.

According to the Centers for Disease Control and Prevention (CDC), there are approximately 1.2 million people in the U.S. that have HIV and approximately 240,000 of them are unaware of their status. Those who do not know they are HIV positive are disproportionately responsible for the 50,000 new HIV infections that occur each year.

“We set out with a clear purpose – to dramatically impact the number of people getting tested for HIV nationwide,” added Michels. “Today’s FDA approval of OraQuick brings us much closer to accomplishing that goal.”

For information about the OraQuick In-Home HIV Test, visit OraQuick.com.

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, the Company 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.

Important Information

This press release contains certain forward-looking statements, including with respect to products and expected sales and product availability. Forward-looking statements are not guarantees of future performance or results. Known and unknown factors that could cause actual performance or results to be materially different from those expressed or implied in these statements include, but are not limited to: 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; 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; changes in relationships, including disputes or disagreements, with strategic partners or other parties 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; ability to integrate and realize the full benefits of the Company’s acquisition of DNA Genotek; ability to identify, complete, integrate and realize the full benefits of future

acquisitions; impact of competitors, competing products and technology changes; impact of the economic downturn, high unemployment and poor credit conditions; reduction or deferral of public funding available to customers; competition from new or better technology or lower cost products; 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, extended shelf life or other factors; 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; history of losses and ability to achieve sustained profitability; ability to utilize net operating loss carry forwards or other deferred tax assets; volatility of our 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 the impact of changes in international funding sources and testing algorithms; adverse movements in foreign currency exchange rates; loss or impairment of sources of capital; ability to meet financial covenants in agreements with financial institutions; ability to refinance outstanding debt under expiring credit facilities on acceptable terms or at all; ability to retain qualified personnel; exposure to 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; and general political, business and economic conditions. These and other factors are discussed more fully in the Company's Securities and Exchange Commission filings, including its registration statements, Annual Report on Form 10-K for the year ended December 31, 2011, Quarterly Reports on Form 10-Q, and other filings with the SEC. Although forward-looking statements help to provide 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.