
**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 21, 2013

OraSure Technologies, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-16537
(Commission
File Number)

36-4370966
(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))
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Item 1.01 – Entry Into a Material Definitive Agreement.

On November 20, 2013, OraSure Technologies, Inc. (the “Company”) entered into a Settlement and Restated Supply Agreement (the “Settlement Agreement”) with F. Hoffman – La Roche Ltd, Roche Diagnostics GmbH and Roche Diagnostics, Inc. (collectively, “Roche”), pursuant to which the Company and Roche terminated their collaboration for the development and commercialization of fully-automated high throughput oral fluid drugs of abuse assays. Under the Settlement Agreement, Roche will make an initial payment of \$8.3 million to the Company and will continue to supply five FDA 510-k cleared assays developed under the collaboration to the Company on a transitional basis for a period of up to five years. The Company has the right to stop the supply of assays prior to the end of the five year period and could receive an additional payment from Roche depending on how early in that five-year period the supply obligation is ended. On November 21, 2013, the Company issued a press release announcing the Settlement Agreement and describing its principal terms. A copy of this press release is attached as Exhibit 99.1 to this Form 8-K and is incorporated herein by reference.

Item 7.01 – Regulation FD Disclosure.

On November 21, 2013, the Company issued a press release announcing that it has entered into an agreement with Thermo Fisher Scientific to develop and supply up to 12 homogenous fully automated oral fluid drugs of abuse assays to be used with the Company’s new Intercept® oral fluid specimen collection device. The Company will have the right to purchase and resell the assays in the U.S. and in certain foreign countries, subject to completion of development activities and receipt of applicable regulatory approvals. A copy of this press release is attached as Exhibit 99.2 to this Form 8-K and is incorporated herein by reference.

Item 9.01 – Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release, dated November 21, 2013, announcing the termination of the Company’s oral fluid drugs of abuse collaboration with Roche Diagnostics.
99.2	Press Release, dated November 21, 2013, announcing the Company’s agreement with Thermo Fisher Scientific for the development and distribution of fully automated oral fluid drugs of abuse assays.

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.

Date: November 21, 2013

ORASURE TECHNOLOGIES, INC.

By: /s/ Jack E. Jerrett

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

Index to Exhibits

**Exhibit
No.**

Description

- | | |
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**OraSure Technologies Terminates Oral Fluid Drugs of Abuse Assay Collaboration
 with Roche Diagnostics**

– Updated Financial Guidance Announced for Fourth Quarter –

BETHLEHEM, Pa. – November 21, 2013 – OraSure Technologies, Inc. (NASDAQ:OSUR) announced today that its assay collaboration agreement with Roche Diagnostics has been terminated. As part of the termination, Roche will continue to supply certain of the assays developed under that collaboration on a transitional basis for use with OraSure's existing Intercept® collection device.

Under the termination agreement, Roche will make an initial payment of \$8.3 million to OraSure, will provide certain transitional product support services and will continue to supply the five FDA-cleared assays for a period of up to five years. OraSure has the right to stop the supply of assays prior to the end of the five-year period and could receive payment of up to an additional \$5.5 million from Roche depending on how early in that five-year period the supply obligation is ended.

OraSure also announced today (<http://phoenix.corporate-ir.net/phoenix.zhtml?c=99740&p=irol-newsarticle&ID=1878751>) that it has reached an agreement with another party to develop and supply up to 12 homogenous fully automated oral fluid drugs of abuse assays to be used with a new Intercept® oral fluid specimen collection device. This new agreement will replace the terminated collaboration with Roche.

Updated Financial Guidance

As a result of the termination agreement announced today, the Company has updated its financial guidance to reflect the initial payment expected from Roche and is now projecting net income of \$0.07 - \$0.08 per share for the fourth quarter of 2013.

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 July 2012, the Company received approval from the U.S. Food and Drug Administration for 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. 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 product supply, certain payments and the Company's revenues and net loss. 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; inventory levels at distributors and other customers; ability to integrate and realize the full benefits of the Company's acquisition of DNA Genotek; ability of DNA Genotek to achieve its financial and strategic objectives; 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, including the OraQuick® In-Home HIV test; 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 products and 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 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, 2012, 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.

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**OraSure Technologies Announces New Agreement with Thermo Fisher Scientific for
Development and Distribution of Fully Automated
Oral Fluid Drugs of Abuse Assays**

OraSure Transitions From Prior Oral Fluid Assay Collaboration

BETHLEHEM, Pa. – November 21, 2013 – OraSure Technologies, Inc. (NASDAQ:OSUR) announced today that it has reached an agreement with Thermo Fisher Scientific (Thermo Fisher), to develop and supply up to 12 homogenous fully automated oral fluid drugs of abuse assays to be used with a new Intercept® oral fluid specimen collection device. OraSure will have the right to purchase and resell the assays in the U.S. and in certain foreign countries, subject to receipt of applicable regulatory approvals.

OraSure also announced today (<http://phoenix.corporate-ir.net/phoenix.zhtml?c=99740&p=irol-newsarticle&ID=1878747>) that although its prior assay collaboration agreement has been terminated, certain assays developed under that collaboration will remain available on a transitional basis for use with OraSure's existing Intercept® collection device.

Under this new agreement with Thermo Fisher, a NIDA-5 panel of assays is expected to be initially sold with the next generation Intercept device in the domestic criminal justice and forensics markets beginning in the second half of 2014. Eventually, the parties expect to complete development of several more assays and obtain FDA 510(k) clearance and approvals in certain foreign countries. The assays will be optimized as needed to comply with new oral fluid guidelines expected to be issued by the Substance Abuse and Mental Health Services Administration (SAMHSA) for the federally regulated market and certain other markets that follow Federal drug testing guidelines, none of which are currently served by OraSure.

The new agreement will enable OraSure to provide its customers with a comprehensive menu of automated oral fluid assays that can be used by laboratories on their established base of clinical chemistry automated analyzers, allowing oral fluid samples to be processed with the same efficiency as current fully automated urine-based drug tests. These assays will be used with OraSure's new Intercept® collector (expected to be available in 2014), which features a volume indicator that activates when a 1mL sample of oral fluid has been collected. This new feature is expected to meet anticipated new SAMHSA oral fluid drug testing guidelines and better serve the future needs of OraSure's drug testing customers.

“The new agreement with Thermo Fisher is an important strategic development for our Substance Abuse Testing business,” said Douglas A. Michels, President and Chief Executive Officer of OraSure Technologies. “Combined with our new Intercept® collector, we look forward to adding a complete menu of fully automated oral fluid drug assays to our customer offerings beginning in 2014.”

OraSure’s current Intercept® Oral Fluid Drug Testing System was the first FDA-cleared in-vitro diagnostic laboratory-based oral fluid drug testing system, and is the only one that is FDA cleared for detection of nine commonly abused drugs, including marijuana, cocaine, opiates, PCP, amphetamines, methamphetamine, barbiturates, methadone and benzodiazepines. It combines the ease, efficiency, and cost savings of oral fluid collection with significantly increased sample integrity and the accuracy of lab-reliable, proven results.

The Intercept® Oral Fluid Drug Testing System is primarily being used in the workplace, drug treatment and criminal justice drug testing markets. To learn more about the OraSure’s Substance Abuse Testing products, please visit <http://www.orasure.com/products-substance/products-substance-abuse.asp>.

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 July 2012, the Company received approval from the U.S. Food and Drug Administration for 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. 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.

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Important Information

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