# 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, 2014

# 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

ck 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 risions:
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, 2014, OraSure Technologies, Inc. (the "Company") issued a press release providing an update on the Company's substance abuse testing business and updating its second quarter 2014 financial guidance. A copy of this press release is attached as Exhibit 99.1 to this Form 8-K and is incorporated herein by reference.

The information in this Item 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 <u>Number</u>	<u>Description</u>
99.1	Press Release, dated June 25, 2014, providing an update on the Company's substance abuse testing business and updating its second quarter 2014 financial guidance.

#### 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, 2014

By: /s/ Jack E. Jerrett

Jack E. Jerrett

Senior Vice President, General Counsel and Secretary

### **Index to Exhibits**

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Ronald H. Spair Chief Financial Officer 610-882-1820 Investorinfo@orasure.com www.orasure.com Media Contact: Jennifer Moritz Zer0 to 5ive for OraSure Technologies 917-748-4006 jmoritz@0to5.com

#### ORASURE PROVIDES UPDATE ON SUBSTANCE ABUSE TESTING BUSINESS

Company Now Projects Net Profit for Second Quarter

**BETHLEHEM, Pa. – June 25, 2014** – OraSure Technologies (NASDAQ: OSUR), a market leader in point of care diagnostics, announced today continued progress under its agreement with Thermo Fisher Scientific (Thermo Fisher) to develop and supply homogenous fully-automated oral fluid drugs of abuse assays to be used with a new version of the Company's Intercept® oral fluid specimen collection device. The NIDA-5 panel of automated assays developed by Thermo Fisher and the new Intercept oral fluid specimen collection device are expected to launch in the domestic criminal justice and forensics markets in the fourth quarter of 2014.

As a result of this progress, OraSure has issued its final purchase order for fully-automated assays previously developed under its now terminated collaboration with Roche Diagnostics. Under the Roche Diagnostics collaboration, which was terminated in November 2013, OraSure is entitled to receive \$5.5 million as a result of its submission of a final purchase order. Payment is expected to be received during the third quarter.

As a result of the \$5.5 million payment expected from Roche Diagnostics, the Company is reaffirming its projected range of consolidated net revenues of \$26.0 to \$26.5 million and is now projecting consolidated net income of approximately \$.01 to \$.02 per share for the second quarter of 2014. The payment from Roche will be recorded as a reduction of the Company's operating expenses.

"The progress we have made on the development of our new Intercept® collection device and the optimization of this device with the homogenous assays developed by Thermo Fisher, enables us to place our final purchase order with Roche," said Douglas A. Michels, President and Chief Executive Officer of OraSure Technologies. "The anticipated launch of our new device with the Thermo Fisher assays later this year will be an important development for our substance abuse testing business."

OraSure and Thermo Fisher signed an agreement in November 2013 that will enable OraSure to provide its customers with fully-automated oral fluid assays that can be used by laboratories on their existing 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,

which features a volume indicator that activates when a sufficient oral fluid sample has been collected. This new feature is expected to better serve the future needs of OraSure's drug testing customers. Under its agreement with Thermo Fisher, 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's current Intercept<sup>®</sup> 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 increased sample integrity and the accuracy of laboratory-based drug tests.

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 OraSure's Substance Abuse Testing products, please visit <a href="http://www.orasure.com/products-substance/products-substance-abuse.asp">http://www.orasure.com/products-substance/products-substance-abuse.asp</a>.

#### **About OraSure Technologies**

OraSure Technologies is a leader in the development, manufacture and distribution of point of care 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 tests for detecting various drugs of abuse. The Company sells the OraQuick® In-Home HIV Test, the first and only rapid HIV test approved by the U.S. Food and Drug Administration for sale to the consumer over-the-counter market 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.

#### **OraSure Technologies Forward-Looking Statement**

This press release contains certain forward-looking statements, including with respect to expected revenues, net income and product usage. 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 our 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; ability to

effectively resolve warning letters, audit observations and other findings or comments from the FDA or other regulators; 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, historic purchase levels or minimum purchase requirements for the Company's products; impact of replacing distributors; inventory levels at distributors and other customers; ability of DNA Genotek to achieve its financial and strategic objectives and continue to increase its revenues; ability to identify, complete, integrate and realize the full benefits of future acquisitions; impact of competitors, competing products and technology changes; impact of negative economic conditions, 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 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 the Company's 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 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 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, 2013, 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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