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): April 6, 2020

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.000001 par value per share	OSUR	The NASDAQ Stock Market LLC

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))

Indicate by a check mark whether the Registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the Registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 – Regulation FD Disclosure.

On April 6, 2020, OraSure Technologies, Inc. (the "Company") issued a press release in which it announced that it has entered into a contract with the Biomedical Advanced Research and Development Authority to develop a pan-SARS-coronavirus antigen rapid in-home self-test for use with oral fluid samples. A copy of the press release is attached as Exhibit 99.1 to this Form 8-K and is incorporated herein by reference.

In addition to the rapid coronavirus antigen self-test disclosed in the press release, we are evaluating the development of antibody tests, including a lab-based oral fluid microplate coronavirus antibody enzyme-linked immunosorbent assay (ELISA).

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 Number	Description
99.1	Press Release dated April 6, 2020,announcing the award of a contract from the Biomedical Advanced Research and Development Authority to develop a pan-SARS-coronavirus antigen rapid in-home self-test for use with oral fluid samples.

EX-104 Cover Page Interactive Data File (embedded within the Inline XBRL document).

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: April 6, 2020

By: */s/ Jack E. Jerrett*
Jack E. Jerrett

EXHIBIT 99.1

Company contacts:

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OraSure Technologies Receives BARDA Contract for Rapid Oral Fluid Pan-SARS-Coronavirus In-home Self-test

BETHLEHEM, PA, April 6, 2020 (GLOBE NEWSWIRE) -- OraSure Technologies, Inc. (NASDAQ: OSUR), a leader in point-of-care diagnostic tests, specimen collection devices and microbiome laboratory and analytical services, today announced it has been awarded a $710,310 contract from the Biomedical Advanced Research and Development Authority (BARDA), part of the Department of Health and Human Services (HHS), to develop a pan-SARS-coronavirus antigen rapid in-home self-test that uses oral fluid samples. This support from BARDA will enable OraSure to file for FDA Emergency Use Authorization (EUA) allowing for an in-home self-test to debut into the U.S. market.

Built on OraSure's OraQuick® platform, the rapid test would allow for in-home self-testing by lay users as well as by medical professionals. OraSure's portable rapid test platform uses an oral fluid sample and provides results in 20 minutes. No instrumentation or trained personnel would be needed to administer the test or to read the results. OraSure has a well-documented history of success with in-home infectious disease testing; the Company's oral fluid self-test for HIV has been used to diagnose millions of people around the world and connect them to life-saving care.

Once developed and the necessary approvals are obtained, an in-home self-test for SARS-coronavirus would help alleviate the pressure on over-burdened healthcare systems. Healthcare providers, retailers, and online vendors could ship tests directly to an individual's home, eliminating unnecessary trips to hospitals, doctors' offices, and testing facilities. This would help maintain social distancing and curb the spread of coronavirus through symptomatic and asymptomatic transmission. Rapid in-home testing could also ease the burden on lab-based testing.

Most current coronavirus tests require a nasopharyngeal or oropharyngeal sample, which can be painful to collect and difficult to attain through self-sampling. An effective test based on an oral sample that can be used in home would enable an easier and pain-free sample collection, as well as much wider access to testing.

A rapid antigen test would also aid in screening initiatives to identify individuals with acute COVID-19 infection with or without symptoms, allowing immediate follow-up access to the patient for further testing and/or quarantine and treatment if necessary.

OraSure envisions a rapid development cycle of approximately 4-6 months prior to seeking Emergency Use Authorization (EUA).

“Lives and global economies are at stake. It’s crucial that we understand just how many people are infected with SARS-coronavirus,” said OraSure President and Chief Executive Officer Stephen S. Tang, Ph.D. “In-home self-testing will dramatically increase the capacity for SARS-coronavirus testing and give our healthcare systems and labs some much-needed breathing room. We believe that the development of an easy-to-use device that delivers accurate results to individuals in their homes can play a significant role in impacting infection rates. We are proud to bring our expertise with quality, rapid, oral fluid self-tests to the battle against the COVID-19 pandemic.”

“We need to put tests into people’s hands to know their infection status and protect their loved ones. At BARDA, we are continually looking for transformative technologies to combat public health threats, and rapid at-home coronavirus testing would be a game-changer,” said BARDA Director Rick Bright, Ph.D. “We know that people can spread COVID-19 without showing any symptoms, and with rapid at-home testing people could take immediate action to prevent the spread of the virus.”

The pan-SARS-coronavirus antigen rapid in-home self-test project has been funded in whole or in part with Federal funds from the Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, under Contract No. 75A50120C00061.

About OraSure Technologies

OraSure Technologies empowers the global community to improve health and wellness by providing access to accurate, essential information. Together with its wholly-owned subsidiaries (DNA Genotek, CoreBiome, Diversigen and Novosanis), OraSure provides its customers with end-to-end solutions that encompass tools, services and diagnostics. The OraSure family of companies is a leader in the development, manufacture, and distribution of rapid diagnostic tests, sample collection and stabilization devices, and molecular services solutions designed to discover and detect critical medical conditions. OraSure’s portfolio of products is sold globally to clinical laboratories, hospitals, physician’s offices, clinics, public health and community-based organizations, research institutions, government agencies, pharma, commercial entities and direct to consumers. 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 expected revenues and earnings/loss per share. 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 successfully manage and integrate acquisitions of other companies in a manner that complements or leverages our existing business, or otherwise expands or enhances our portfolio of products and our end-to-end service offerings, and the diversion of management’s attention from our ongoing business and regular business responsibilities to effect such integration; the expected economic benefits of acquisitions (and increased returns for our stockholders), including that the anticipated synergies, revenue enhancement strategies and other benefits from the acquisitions may not be fully realized or may take longer to realize than expected and our actual integration costs may exceed our estimates; impact of increased or different risks arising from the acquisition of companies located in foreign countries; ability to market and sell products, whether through our internal, direct sales force or third parties; impact of significant customer concentration in the genomics business; failure of distributors or other customers to meet purchase forecasts, historic purchase levels or minimum purchase requirements for our products; 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 U.S. Food and Drug Administration ("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; ability to meet increased demand for the Company's products; impact of replacing distributors; inventory levels at distributors and other customers; ability of the Company to achieve its financial and strategic objectives and continue to increase its revenues, including the ability to expand international sales; ability to identify, complete, integrate and realize the full benefits of future acquisitions; impact of competitors, competing products and technology changes; 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 or urine testing, collection or other products; market acceptance and uptake of microbiome informatics, microbial genetics technology and related analytics services; changes in market acceptance of products based on product performance or other factors, including changes in testing guidelines, algorithms or other recommendations by the Centers for Disease Control and Prevention ("CDC") or other agencies; 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; impact of contracting with the U.S. government; impact of negative economic conditions; ability to maintain 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 attract and 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 that could affect our results are discussed more fully in our Securities and Exchange Commission ("SEC") filings, including our registration statements, Annual Report on Form 10-K for the year ended December 31, 2019, 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. Readers are cautioned not to place undue reliance on the forward-looking statements. The forward-looking statements are made as of the date of this press release and we undertake no duty to update these statements.

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