

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): August 25, 2020

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

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 August 25, 2020, OraSure Technologies, Inc. (the “Company”) issued a summary of the Company’s recent COVID-19 communications (the “COVID Summary”). A copy of the COVID Summary 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 Number	Description
99.1	OraSure Technologies, Inc. Summary of Recent COVID-19 Communications
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: August 25, 2020

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



OraSure Technologies

SUMMARY OF RECENT COVID-19 COMMUNICATIONS

AUGUST 25, 2020

DNAgenotek™  **Diversigen®**  **novosanis**  **UrSure**



Forward-Looking Statements Disclaimer



This presentation 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; the impact of the novel coronavirus ("COVID-19") pandemic on our business and our ability to successfully develop new products, validate the expanded use of existing collector products and commercialize such products for COVID-19 testing; 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 the Company's results are discussed more fully in the Company's 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 for the quarters ended March 31, 2020 and June 30, 2020, 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 presentation and OraSure Technologies undertakes no duty to update these statements.

Three Distinct COVID-19 Opportunities: Current Progress⁺



▪ OraQuick Coronavirus Rapid Antigen Self-test

- Would use a nasal sample easily collected from the lower nostril to maximize accuracy and convenience
- Currently in clinical testing with human subjects
- Expected launch in Q4 2020 following EUA
- Initial launch will be Professional Test for symptomatic individuals; second phase will be Prescription Self-test; third phase for Over-The-Counter use in asymptomatic individuals. EUA for first two phases expected in Q4 2020

▪ COVID-19 ELISA Antibody Test

- Potential to be the first COVID-19 antibody test to use oral fluid samples
- Expected launch in Q4 2020 following EUA

▪ Oral Fluid Collection Devices for COVID-19 Molecular Testing

- Sample collection devices already included in four* customer EUAs (CRL; Biocerna; P23 Labs; and Phosphorous), with more expected
- \$8.5M in revenue recorded in 2Q 2020

⁺As of 8/5/20
^{*}As of 8/1/20.

Confidential

© 2020 OraSure Technologies, Inc.

3

OraQuick Coronavirus Rapid Antigen Self-Test: Three Parallel Pathways to Launch



▪ Phased approach to EUA

To bring the product to market as quickly as possible

1

EUA for Phases 1 and 2 in Q4 2020

2

3

Professional Test:

Professional market for testing symptomatic individuals with suspected COVID-19 infection

Prescription-use self-test:

Prescription-use self-test for symptomatic individuals with suspected COVID-19 infection

OTC Self-Test:

Self-test for symptomatic and asymptomatic individuals

▪ Clinical Trial Pathway

- Rapid antigen self-test is currently in human clinical testing
- This will provide the necessary, real-use data to file for FDA EUA and enable OraSure to bring the test widely to market

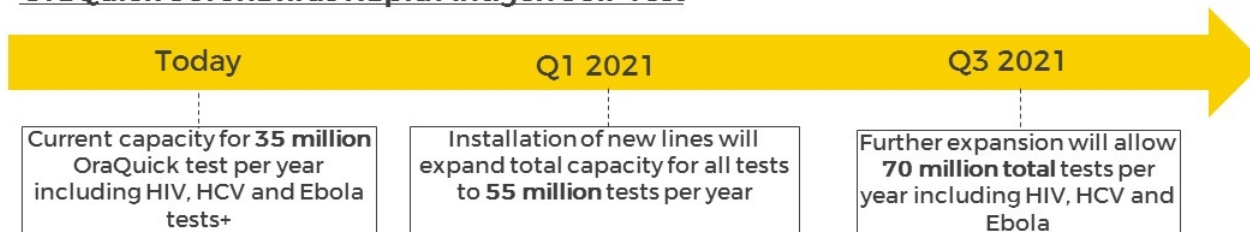
▪ Manufacturing to Scale

- Expanding manufacturing capacity to meet anticipated demand, ahead of EUA

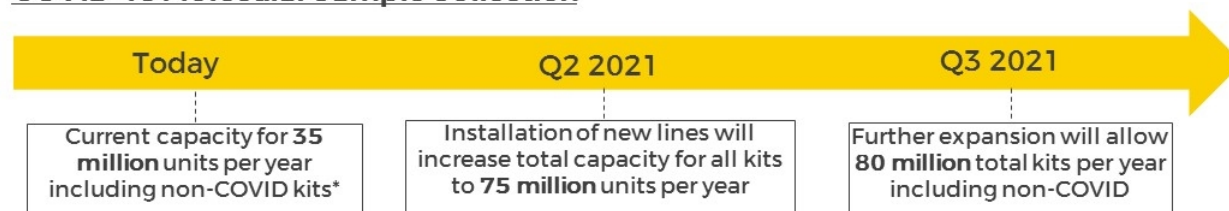
Expansion of Manufacturing Capacity to Meet Anticipated Demand for COVID-19 Opportunities



OraQuick Coronavirus Rapid Antigen Self-Test



COVID-19 Molecular Sample Collection



Confidential

+Approximately half of this capacity is devoted to HIV, HCV, and Ebola testing *Approximately 7 to 8 million units expected to be used for non-COVID applications

© 2020 OraSure Technologies, Inc.

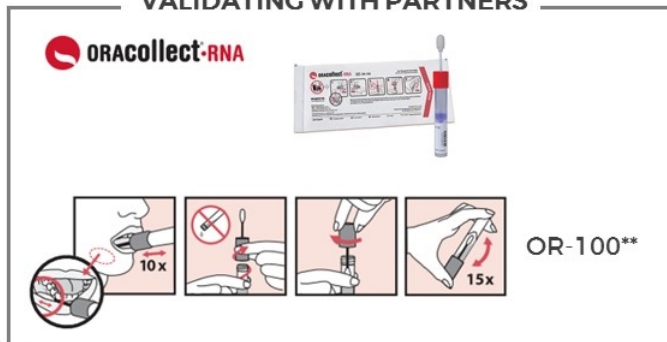
5

All-in-one solutions for self-collection of samples for molecular COVID-19 testing



- All-in-one, easy, reliable and non-invasive self-collection
- High quality DNA and RNA
- Ambient temperature stability
- Compatible with high throughput processing
- Four customers to date* have received EUAs incorporating our sample collection products with more expected to follow

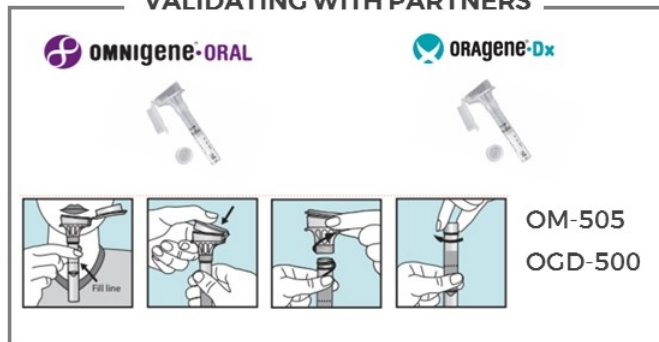
VALIDATING WITH PARTNERS



*As of 8/1/20

**OR-100 is the format for the US market. Outside of the US, it is the ORE-100 format.

VALIDATING WITH PARTNERS



Confidential

© 2020 OraSure Technologies, Inc.

6

