# 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): December 21, 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<br>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.**

Product Update

On December 21, 2020, OraSure Technologies, Inc. (the "Company") issued a press release announcing an update regarding its application to the U.S. Food and Drug Administration for Emergency Use Authorization ("EUA") of the Company's oral fluid SARS-CoV-2 Antibody ELISA. A copy of the press release is attached as Exhibit 99.1 to this Form 8-K and is incorporated herein by reference. Additional information regarding the Company's EUA application is set forth in the "Questions and Answers" attached as Exhibit 99.2 hereto and is also incorporated herein by reference.

Updated Investor Presentation

The Company hereby furnishes an updated Investor Presentation the Company will present to analysts and investors on or after the date hereof. The presentation is attached as Exhibit 99.3 to this Form 8-K, is incorporated herein by reference and will be available on the Company's website at www.orasure.com. The information contained in the Investor Presentation is summary information that is intended to be considered in the context of the Company's Securities and Exchange Commission ("SEC") filings and other public announcements that the Company may make, by press release or otherwise, from time to time.

The information in this Item and attached Exhibits 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 Exhibits 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 Exhibits 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 Exhibits.

**Item 9.01 – Financial Statements and Exhibits.**

**(d) Exhibits**

| Exhibit Number | Description |
|---|---|
| 99.1 | Press Release, dated December 21, 2020, announcing update on the Company's Emergency Use Authorization application for oral fluid SARS-CoV-2 Antibody ELISA. |
| 99.2 | Questions and Answers, dated December 21, 2020, regarding the Company's Emergency Use Authorization application for oral fluid SARS-CoV-2 Antibody ELISA. |
| 99.3 | OraSure Technologies, Inc. Investor Presentation dated December 21, 2020. |
| 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: December 21, 2020

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

**Exhibit 99.1**

Investor Contact: Media Contact:
Sam Martin Jeanne Mell
Argot Partners VP Corporate Communications
212-600-1902 484-353-1575
orasure@argotpartners.com media@orasure.com

**OraSure Technologies Provides Update on Its Emergency Use Authorization Application for Its Lab-based Oral Fluid SARS-CoV-2 Antibody Test**

BETHLEHEM, Pa., December 21, 2020 - OraSure Technologies, Inc. (NASDAQ: OSUR), a leader in point-of-care diagnostic tests and specimen collection devices, today disclosed that the U.S. Food and Drug Administration (FDA) has requested additional information as part of its review of the Company's application for Emergency Use Authorization (EUA) for its laboratory-based oral fluid SARS-CoV-2 antibody test. The OraSure SARS-CoV-2 Antibody ELISA is intended for qualitative detection of total antibodies to SARS-CoV-2 in human oral fluid specimens collected with the OraSure Oral Antibody Collection Device. At the FDA's request, the Company intends to resubmit two separate EUAs for the ELISA and the oral specimen collection device. In addition, the FDA has requested that additional analytical studies be conducted on sample collection and stability.

"To date, there are no oral fluid antibody tests for COVID-19 authorized for sale in the U.S. As such, FDA's guidance on EUA submissions for COVID-19 antibody tests focuses on blood samples for tests; the Agency did not outline specific requirements for an oral fluid test. Consequently, we were unable to completely anticipate all of the data that would be required for a first-of-its-kind oral fluid antibody test," said OraSure President and CEO Stephen S. Tang, Ph.D. "This request is within the normal course of an FDA review and we are confident that we'll be able to provide the requested data, and resubmit our EUA application for this pioneering product promptly."
Antibody tests are well suited for community surveillance and seroprevalence studies to identify people who have antibodies against COVID-19. Oral sample collection is quick, painless, non-invasive and requires less human contact than a blood draw, minimizing the need for personal protective equipment and reducing exposure to potentially infected patients.

**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, Diversigen, CoreBiome (now operating under the Diversigen brand), UrSure 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; 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 our results are discussed more fully in our SEC filings, including our registration statements, Annual Report on Form 10-K for the year ended December 31, 2019, Quarterly Report on Form 10-Q for the quarter ended September 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. 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 OraSure Technologies undertakes no duty to update these statements.

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Exhibit 99.2

**Questions and Answers Regarding OraSure Technologies, Inc. EUA Application for Lab-based Oral Fluid SARS-CoV-2 Update – December 2020**

***1. What additional information has FDA requested?***

- The FDA requested that OraSure perform additional analytical studies related to collection and stability in support of the use of oral fluid as a sample matrix.
- The FDA also requested that the Company submit separate EUA requests for the ELISA and the oral specimen collector ("Collector").

***2. Will you amend the existing application?***

- FDA's COVID-19 Emergency Use Authorization ("EUA") process departs significantly from the "traditional" 510(k) submission process; there is no procedural way to amend a submission or "stop the clock" before authorization to allow for additional requests for data as there is with a 510(k) submission.
- OraSure plans to collect the requested data and resubmit its application for EUA for its lab-based oral fluid antibody test once the studies have been completed.
- Per the FDA's request, the Company will submit separate EUA requests for the ELISA and the Collector rather than a single EUA request for both components of this product, as previously submitted by the Company.

***3. Does a resubmission, rather than an amendment, mean you will lose valuable time? When do you now expect authorization and launch?***

- No. The time needed for the Company to resubmit its application does not differ from the time that would have been needed for an amendment, had an amendment been possible in the EUA process. The timing of the review and authorizations of EUA submissions is at the discretion of the FDA.
- We are working as expeditiously as possible to provide the resubmission to the FDA with the additional data requested. We are confident that the need for antibody testing will continue, as it is a valuable tool for community surveillance and seroprevalence, and has demonstrated benefits to public health.

***4. Were you surprised by this FDA request?***

- It is not unusual for the FDA to request additional data during the review of a regulatory submission, especially one involving a pioneering product such as the Company's oral fluid SARS-CoV-2 antibody test, which could be the first oral fluid SARS-CoV-2antibody test to receive EUA.
- Because the FDA's guidance to date on the requirements for COVID-19 EUA submissions focused on serological or blood tests, the agency did not outline specific requirements for an oral fluid test. Consequently, the Company could not have completely anticipated all of the data that would be required for an oral fluid antibody test EUA vs. what is typically required for 510(k) clearance.

5. ***Do you expect to receive the EUA based upon the additional information that you will be submitting? Will it be enough?***
    - We cannot speculate about the FDA's response to our application. Our intent is to work closely and expeditiously with the agency to ensure it has the data it needs.
    - We are confident in the value of our oral fluid antibody test. Oral fluid testing is particularly well-suited to the COVID-19 pandemic. Oral sample collection is quick, painless, non-invasive and requires less human contact than a blood draw, minimizing the need for personal protective equipment and reducing exposure to potentially infectious individuals.

6. ***Will there still be a market for OraSure's antibody test if and when you receive the EUA?***
    - We believe that the need for antibody testing is durable. Antibody tests are sparking renewed interest as vaccine development continues and public health officials seek to understand just how many people have been previously infected with SARS-CoV-2 and are not included in official case counts.
    - Antibody tests are well suited for community surveillance and seroprevalence studies to help identify people in a population or community that have mounted antibodies against COVID-19.
    - Antibody tests could also be used to determine durability of antibodies in those who have been vaccinated.
    - It's important to note that to date, there are no oral fluid antibody tests for SARS-CoV-2 authorized for sale in the U.S. Ours could be the first.
    - We've seen demand from a wide spectrum of our customers including clinical and research labs, public health and clinics, all of whom are currently offering blood-based antibody tests and see oral fluid as a preferred method as it eliminates the need for a phlebotomist and reduces employee exposure.

7. ***Do you have any customer contracts waiting on this test?***
    - Yes. In the meantime, several customers are purchasing our oral fluid antibody test for Research Use Only (RUO). The FDA's request does not impede our ability to continue to sell the test for RUO.

8. ***Were there any concerns from the FDA that oral fluids are not a suitable sample type for SARS-CoV-2 antibody testing? If necessary, would you consider developing a test with different sample type, similar to the approach you took with the antigen test development?***
    - The FDA has not expressed concerns about oral fluid as a sample type in their communications with us.
    - We believe that oral fluid is an appropriate sample type for our antibody test. Antibody titers in oral fluid are a reflection of the antibody titer found in an individual's blood.
    - We are committed to working as expeditiously as possible to collect the requested data and resubmit our EUA applications for the ELISA and Collector.

**Important Information**

This report contains certain forward-looking statements with respect to products and regulatory submissions. 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 our performance are discussed more fully in our 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 report and OraSure Technologies undertakes no duty to update these statements.

Exhibit 99.3

# OraSure Technologies

INVESTOR PRESENTATION
DECEMBER 2020

DNAgenotek™ Diversigen® novosanis UrSure

# Forward-Looking Statements Disclaimer

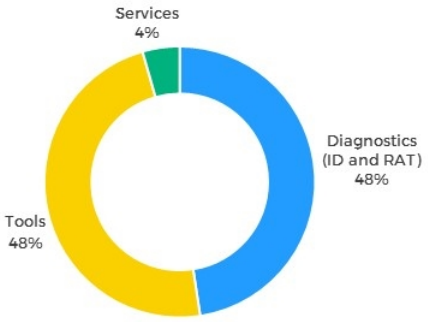
This presentation contains certain forward-looking statements, including with respect to expected revenues and earnings/loss per share. Forward-looking statements are not guarantees of future performance or results. Known and unknown factors that could cause actual performance or results to be materially 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, June 30, 2020, and September 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.

# Company Snapshot

## Sampling tools, services and diagnostics to understand what's in us, on us, and around us.

- $148 million in net revenue in 2019[1]
- 470 employees
- Offices in U.S., Canada and Belgium
- Active business development program
- $263.7 million in cash[2] on balance sheet; no debt
- Products registered in 89 countries

**2019 Revenue by segment[1]**




[1] Excludes net revenue of cryosurgical business, which was divested in August 2019
[2] Cash and cash equivalents, short-term investments, and long-term investments as of September 30, 2020

# Investment Rationale

## Multiple Near-term COVID-19 Opportunities and Long-term Growth Drivers

- Well positioned for global COVID-19 response: two oral fluid self-collection devices for molecular testing received EUAs + CE-IVD marks and are in wide use; **EUA being pursued for lab-based oral fluid antibody test; rapid** antigen self-test under development
- Investment in manufacturing capacity and improved production efficiency continues
- Continued expansion in global markets with OraQuick HIV Self-Test and OraQuick HCV test
- Market leading microbiome products and services offer tremendous growth potential
- $263.7 million in cash[1] on balance sheet and no debt supports ongoing business development activities that have generated four acquisitions and one divesture since January '19

[1] Cash and cash equivalents, short-term investments, and long-term investments as of September 30, 2020

# Improving Global Access to Accurate Healthcare Information

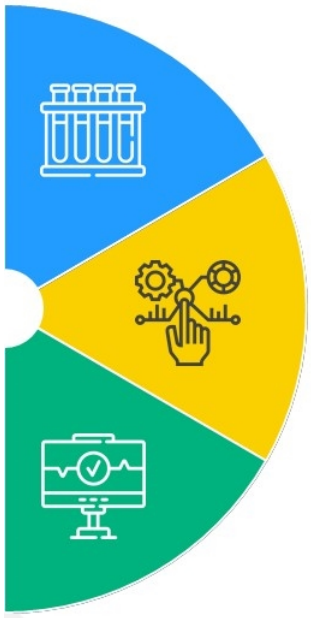
## Experts in sample collection, preservation and diagnostics

- Over 20 years of proprietary knowledge in oral fluid testing enables self collection and rapid in-home results
- Broad, well-established channels of distribution across global public health, academic and research institutions, laboratories, employers, hospitals, physician offices, pharmacies and direct-to-consumer
- Leadership in infectious disease, genomics and emerging microbiome fields
- Innovative technologies to collect and analyze molecular samples

# Capitalizing on Next-generation Health and Wellness Technologies

- Innovative sampling tools, services and diagnostics help people understand what's in us, on us, and around us
- Unlocking access to accurate essential information that advances global health and well-being
- Driving access to multiple layers of information and data to understand health, wellness and disease states
- Differentiated products with competitive profiles in large attractive markets - many in their early days

# OraSure Solutions



## Sampling

Sample collection & stabilization devices to drive discovery and access

DNAgenotek™ novosanis

- Best-in-class tools and chemistries
- Multiple samples/analytes

## Services

Data analytics and AI, multiomic view to health & wellness

Diversigen®

- Study design
- Customization
- Single-order fulfillment
- Wet lab & sequencing
- Analysis
- Consulting

## Diagnostics

Selection of high value/ actionable testing

OraSure Technologies, Inc. UrSure

- Infectious disease
- Substance abuse testing

# Innovation and Expertise in Infectious Disease Diagnostics

- **Our technologies are the ideal platform for the emerging trends in diagnostic testing**

- **Directly suited for the current COVID-19 testing dynamic**

  Leveraging our proven experience with HIV Self-Test and Rapid Ebola Antigen Test to develop a Coronavirus Antigen Rapid Self-test

- **Our unique platform for HIV and HCV provides accurate and easy-to-administer testing methods**

Bringing our innovation and expertise in infectious disease diagnostics and sample collection to the fight against COVID-19 and the global eradication of HIV

# Three Distinct COVID-19 Opportunities

- **Oral Fluid Collection Devices for COVID-19 Molecular Testing**
  - Sample collection products included in multiple EUAs and lab validated workflows; incorporated into diverse range of back to school and back to work programs nationwide
  - ORAcollect®·RNA and OMNIgene®·ORAL have received EUAs and are CE-IVD marked
  - $27M in revenue recorded through Q3 2020
- **COVID-19 ELISA Antibody Test**
  - Potential to be the first COVID-19 antibody test to use oral fluid samples
  - EUA application submitted; will be resubmitted as separate EUAs for assay and collector with additional data requested by FDA
  - Oral fluid collection is quick, painless, and non-invasive, and requires less human contact in comparison to blood draw, minimizing exposure to potentially infected individuals
- **OraQuick Coronavirus Rapid Antigen Self-test**
  - Would use a nasal sample easily collected from the lower nostril to maximize accuracy and convenience
  - Initial launch expected to be Professional Test; second phase expected to be Prescription Self-test; third phase expected to be for Over-The-Counter use in asymptomatic individuals
  - Expected EUA submission for Professional Test in Q1 2021, with launch to follow authorization
  - Prescription Self-Test and OTC Self-Test EUA submissions to follow as soon as possible thereafter

# 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
- ORAcollect®·RNA and OMNIgene®·ORAL have received EUAs and are CE-IVD marked
- Six customers to date* have received EUAs incorporating our sample collection products
- OMNIgene·ORAL named one of TIME magazine's best inventions of 2020

**VALIDATING WITH PARTNERS**

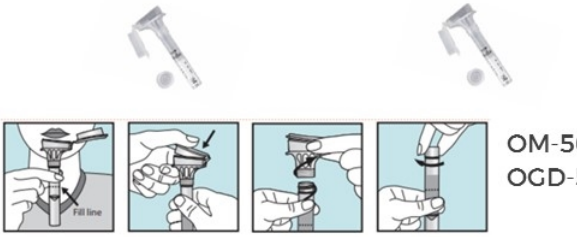
ORAcollect·RNA


OR-100**

**VALIDATING WITH PARTNERS**

OMNIgene·ORAL

ORAgene·Dx




OM-505**
OGD-500

*As of 12/18/20
**OR-100/OM-505 are the formats for the US market. Outside of the US, we use the ORE-100/OME-505 formats.

# Sars-Cov-2 Oral Fluid Antibody Test

- No oral fluid COVID-19 antibody tests authorized for sale in U.S. to date*
- Easy and non-invasive self-collection
- ELISA Microplate lab-based oral fluid test
- Short turn-around time and high-throughput
- Ideal for surveillance data
- BARDA contract to develop
- EUA application submitted; will be resubmitted as separate EUAs for assay and collector with additional data requested by FDA
- Research Use Only (RUO) product available for sale currently with numerous labs in validation

**EUA SUBMITTED**

**Collect Sample with OraSure Device**

**Insert the device into the buffer**

**Sample sent to lab where ELISA test is run**

*As of 12/18/20

# OraQuick Coronavirus Rapid Antigen Self-Test

- Game-changing test to detect active COVID-19 infection **anytime, anywhere** with direct results available a short time later at point of collection
- No instrumentation or laboratory analysis needed to interpret results
- Based on proven OraQuick® platform (HIV, HCV, Ebola)
- Targeting EUA submission in Q1 2021 for Professional Test
- Expanding manufacturing capacity to meet anticipated demand, ahead of EUA

**IN DEVELOPMENT**

**Coronavirus Rapid Antigen Self-Test**

Ideal for in-home testing to prevent the spread of COVID-19

Enables testing scale

*Image shows OraQuick lateral flow platform*

# OraQuick Coronavirus Rapid Antigen Self-Test: Three Products Covering Various Use-Cases

**Professional Test**

Rx
Self-Swab
Healthcare practitioner reads result

*Drive-Thru Sites*

*Physician offices, Employer/University Health Centers, Pharmacy clinics*


**Rx Self-test**

Rx
Self-Swab
Consumer reads result

*Consumer Home Use via Pharmacy Rx*

*Employers for Home or Off-site Testing*

*Education*

*Nursing Homes*

*Travel / Entertainment*

**Over-the-counter Test**

OTC
Self-Swab
Consumer reads result

*Consumer Home Testing*

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

## OraQuick Coronavirus Rapid Antigen Self-Test

| Today | Q1 2021 | Q3 2021 |
|---|---|---|
| Current capacity for **35 million** OraQuick test per year including HIV, HCV and Ebola tests+ | Installation of new lines will expand total capacity for all tests to **55 million** tests per year | Further expansion will allow **70 million total** tests per year including HIV, HCV and Ebola |

## COVID-19 Molecular Sample Collection

| Today | Q2 2021 | Q3 2021 |
|---|---|---|
| Current capacity for **35 million** units per year including non-COVID kits* | Installation of new lines will increase total capacity for all kits to **75 million** units per year | Further expansion will allow **80 million** total kits per year including non-COVID |

## Sars-Cov-2 Oral Antibody Collection Device

| Today | Q4 2021 |
|---|---|
| Current capacity for **10 million** units per year including existing products++ | Installation of new lines will expand total capacity to **20 million** tests per year including existing products |





+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
++ Approximately 3 million for existing products

# Trailblazer in HIV Self-Testing

ORAQUICK®
HIV SELF-TEST

- 21% of the 38 million people with HIV do not know their status
- Safe, accurate, convenient point-of-care and in-home HIV tests key to identifying HIV positive patients and linking them to care
- OraSure is International HIV Self-Test market share leader with oral fluid self-collection and in-home result
- Opportunities in Africa with UNITAID STAR program expansion, Europe, Eastern Europe, Central Asia and Latin America

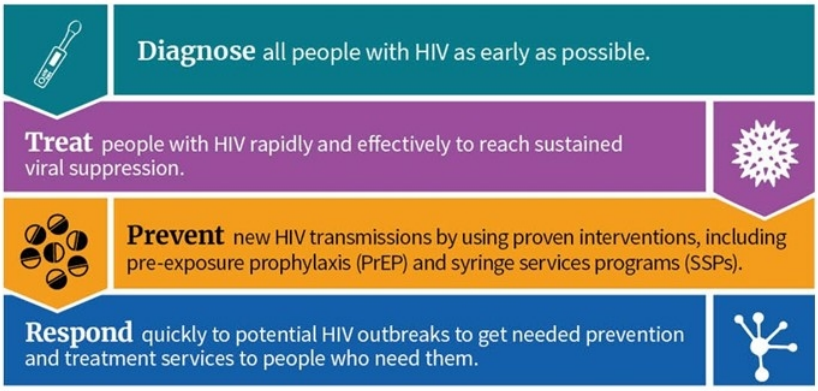
First and only rapid HIV in-home test approved by FDA
First and only WHO-prequalified rapid oral HIV self-test

Source: WHO/UNITAID/UNAIDS

# Well-Positioned to Play an Important Role in the Eradication of HIV in the U.S.

ENDING THE HIV EPIDEMIC: THE PLAN FOR AMERICA

- The Plan for America continues with $267 million in FY 2020 funding and meaningful increase proposed for FY 2021
- Reaching the difficult to reach is key to achieving plan goals
- Rapid testing is an important tool
- OraSure has the only FDA-approved OTC self-test for HIV in the U.S.
- UrSure acquisition adds PrEP adherence testing to portfolio




COVID-19 IMPACT

- CDC is encouraging funded sites to use in-home self-testing for HIV in order to continue testing while complying with COVID-19 safety restrictions.
- Public health departments are increasing purchases of our FDA approved in-home HIV test

# Hepatitis C

OraQuick® Rapid Antibody Test HCV

- 81% of the estimated 71 million people with chronic Hepatitis C do not know their status
- Antiviral medications can now cure 95%+ of those infected but access to diagnosis and treatment is low
- Opioid crisis is fueling the Hepatitis C epidemic
- OraSure makes the first and only FDA-approved, CLIA-waived rapid HCV test*
- $10 million in FY 2020 funding to diagnose infectious disease from the opioid epidemic. The opioid and infectious diseases program authorized by Congress for up to $40 million; the administration has requested additional funding for FY 2021.
- $341 million for CDC's viral hepatitis surveillance & prevention awards, including testing, being issued to states and major jurisdictions
- OraSure's HCV POC test will play an important role in reaching the hard-to-reach people who are driving a majority of the infections
- Anticipate an eventual return to more normal levels of revenue after COVID-19 begins to resolve

Source: WHO & CDC

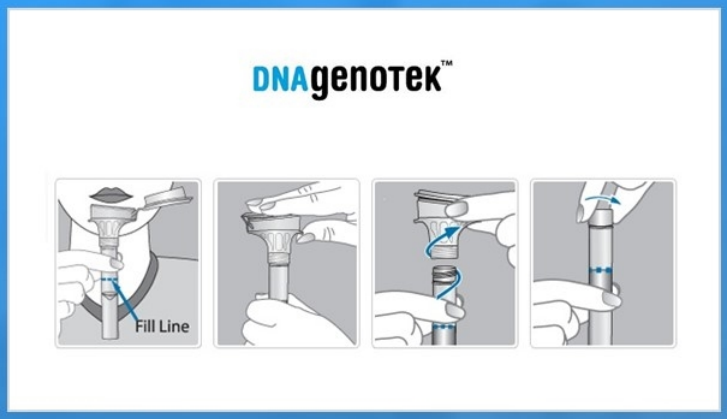
* VWB and FSWB only

# Opportunities in Substance Abuse Testing


- New federal guidelines permit oral fluid drug testing
- SAMHSA estimates oral fluid testing will grow to 25% of total testing by 2025
- OraSure pioneered oral fluid testing for substance abuse
- Socially distanced, easier, less costly and more efficient sample collection

*Product shown is under development to meet SAMHSA guidelines.*
*Currently for Forensic Use Only.*

# DNA Genotek: The Magic Behind Human Genomics




- Pioneer in DNA/RNA sample collection, stabilization and preparation products
- Technology stabilizes DNA for long periods of time at ambient temperatures
- Increased interest in sample collection due to COVID-19

DNA Genotek "has done for DNA collection what Google did for Web searches: made it ridiculously simple and efficient." – TIME Magazine

Illustration depicts Oragene self-collection kit

# Microbiome Impact on Healthcare

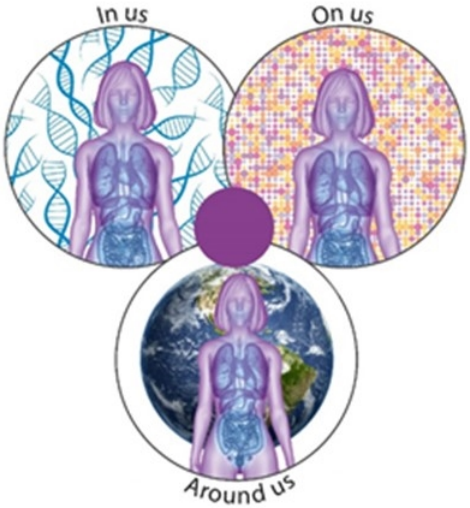
**The microbiome is believed to influence many diseases and biological processes**

Gastrointestinal diseases, Type 1&2 Diabetes, skin conditions, the urinary tract, women's health and neonatal health

**It provides a means of intercepting disease and personalizing treatments**

Diagnostics, therapeutics and preventive medicine are all enabled with this new perspective

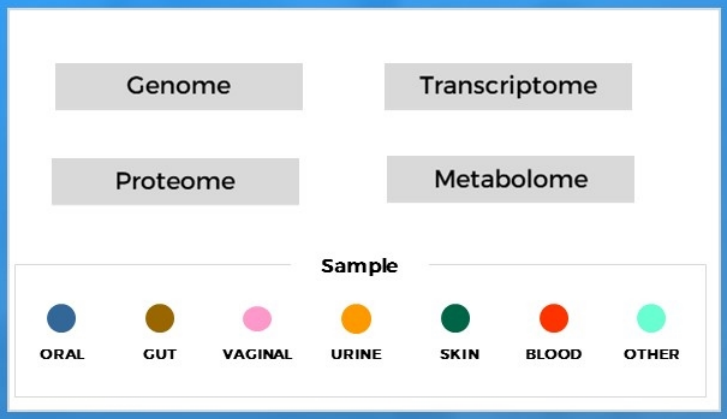
**Multiple research reports project mid-teens growth for the microbiome market** from 2019-2024



# Services: Unmatched Offering From Sample to Answer

- Blue-chip customer base and technical innovation in microbiome analysis and DNA Genotek's microbiome sampling kits
- Consolidated CoreBiome and Diversigen services under Diversigen brand
- Combined operation offers science-driven, customized solutions for metagenomics sequencing, bioinformatics, and statistical analysis for the study of the microbiome
- Diversigen represents experts with 100+ years of microbiome experience and 300+ scientific publications with ~100,000 citations
- Integrating lab operations in Minnesota

# Multiomics: New Health Paradigm




- Multifactorial examination of an individual's health
- Informing health, wellness, infectious disease, chronic disease and cancer
- Introduced first and only commercially available device for in-home, self-collection of fecal samples for metabolomics

End-to-end quality in sampling, services, and bioinformatics

# Business Development

- Using robust balance sheet to create revenue and shareholder value
- $263.7 million in cash on balance sheet[1] with no debt
- Four completed acquisitions 2019-2020
- Continue to seek acquisitions that are accretive to our innovation-based growth strategy
- Considering infectious disease possibilities as well as molecular
- Target rich environment
- Committed to doing the right deal, for the right price, at the right time

[1] Cash and cash equivalents, short-term investments, and long-term investments as of September 30, 2020