# 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): March 1, 2021**

# 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 2.02 – Results of Operations and Financial Condition.**

On March 1, 2021, OraSure Technologies, Inc. (the "Company") issued a press release announcing its consolidated financial results for full year and quarter ended December 31, 2020 and certain other matters. A copy of the 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 7.01 – Regulation FD Disclosure.**

On March 1, 2021, the Company held a webcast conference call with analysts and investors, during which Stephen S. Tang, Ph.D., the Company's President and Chief Executive Officer, and Roberto Cuca, the Company's Chief Financial Officer, discussed the Company's consolidated financial results for the full year and quarter ended December 31, 2020, and described certain business developments. A copy of the prepared remarks of Dr. Tang and Mr. Cuca is attached as Exhibit 99.2 to this Form 8-K and is incorporated herein by reference.

In addition, the Company hereby furnishes the Investor Presentation the Company will present to analysts and investors on or after the date hereof, which is attached as Exhibit 99.3 to this Current Report, 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 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 March 1, 2021, announcing consolidated financial results of OraSure Technologies, Inc. for the full year and quarter ended December 31, 2020 and certain other matters. |
| 99.2 | Prepared Remarks of Stephen S. Tang, Ph.D. and Roberto Cuca for OraSure Technologies, Inc. Full Year and Fourth Quarter 2020 Analyst/ Investor Conference Call Held March 1, 2021. |
| 99.3 | OraSure Technologies, Inc. Investor Presentation dated March 2021. |
| Exhibit 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: March 1, 2021

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

**EXHIBIT 99.1**

Investor contact:
Sam Martin
Argot Partners
212-600-1902
orasure@argotpartners.com

Media contact:
Jeanne Mell
OraSure Technologies
484-353-1575
media@orasure.com

**OraSure Technologies, Inc. Announces 2020 Full-Year and Fourth Quarter Financial Results and Provides COVID-19 Update**

*Full-Year 2020 Net Revenues of $172 Million Increased 11% Year-Over-Year, Driven by $50 Million in Sales of Oral Fluid Collection Devices for COVID-19 Molecular Testing*

*COVID-19 Rapid Antigen Test clinical trials complete; OraSure plans to submit both a Prescription Self-Test and a Professional Test for EUA in Q1*

*Management to Host Conference Call and Webcast Today at 5:00 p.m. ET*

BETHLEHEM, PA, March 1, 2021 (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 its financial results for the three months and year ended December 31, 2020.

“OraSure continues to successfully navigate the pandemic, with a record-breaking fourth quarter and double-digit full-year revenue growth driven by a strong sequential quarterly increase in sales of our molecular sample collection kits for COVID-19 testing. We expect this strong sustained performance to persist as testing continues to be a key strategy to combat the ongoing pandemic. Our base business was resilient, with demonstrated strength in international HIV testing,” said Stephen S. Tang, Ph.D., President and Chief Executive Officer.

Dr. Tang continued, “Importantly, we have made substantial progress on our COVID-19 Rapid Antigen Self-Test and oral fluid antibody test. We expect that OraSure’s COVID-19 activities will continue to accelerate the Company’s growth and significantly outweigh any negative impact of the pandemic on other parts of our business. We have locked the proprietary assay chemistry and completed development and clinical testing of our rapid antigen test for COVID-19. We accelerated the Prescription Self-Test trials and now plan to submit for both the Professional and Prescription Self-Test for Emergency Use Authorization (EUA) by the end of this month. We are also planning to resubmit two separate EUAs for our lab-based oral fluid antibody test, including additional analytical study data, as requested by the FDA, and look forward to bringing this important product to market as soon as possible.”

**Financial Highlights**

- Net revenues for the fourth quarter of 2020 were $62.9 million, a 27% increase from the fourth quarter of 2019. Net product and services revenues were $60.4 million, a 28% increase from the fourth quarter of 2019.
- Net revenues for the full year 2020 were $171.7 million, an 11% increase over 2019.
- Total product and service revenues for the Company's molecular business unit were $40.3 million during the fourth quarter of 2020, an increase of 58% from the fourth quarter of 2019. This increase included $22.5 million in sales of sample collection devices for COVID-19 molecular testing.
- Total product and service revenues for the Company's molecular business unit were $102.8 million for the full year 2020, an increase of 45% from the full year 2019. The increase included $49.8 million in sales of sample collection devices for COVID-19 molecular testing.
- Full year 2020 international sales of the Company's HIV products grew 16% over the prior year driven by a 21% increase in HIV Self-Test sales in Africa. For the fourth quarter, HIV international revenue was $11.3 million, a 16% increase from the fourth quarter of 2019. This was a record quarter and year for sales of OraSure's HIV self-tests internationally.
- Net income for the fourth quarter of 2020 was $1.9 million, or $0.03 per share on a fully-diluted basis, compared to net income of $2.4 million, or $0.04 per share on a fully-diluted basis, for the fourth quarter of 2019.
- Cash and investments totaled $257.1 million at December 31, 2020.

**COVID-19 Update**

*Molecular/PCR:*

- **Sales of sample collection devices for molecular/PCR COVID-19 testing in the fourth quarter showed sequential quarterly growth and persistence of commercial opportunity; the Company's sample collection kits continued to be included in Emergency Use Authorizations (EUAs) granted to customers.**
    - Use of DNA Genotek molecular sample collection kits continued to grow in back-to-work settings, back-to-school programs, laboratory testing and direct-to-consumer offerings. OraSure continues to build its customer base, with high-volume repeat orders from existing customers and demand from new customers.
        - The Company's molecular collection kits are now included in eight EUAs granted by the U.S. Food and Drug Administration (FDA) to DNA Genotek customers for COVID-19 testing.
        - The Company's ORAcollect® •RNA saliva collection device has been used in the more than one million COVID-19 tests administered by State University of New York campuses since the start of the 2020-2021 academic year. These tests were developed by DNA Genotek customer Quadrant Biosciences.
        - The Company's OMNIgene•ORAL and ORAcollect® •RNA saliva collection devices have received interim authorization for use in COVID-19 testing from Health Canada.
        - Through OraSure's customer Chronomics, the OMNIgene•ORAL is being utilized as a collection device for the UK Government's "Test to Release for International Travel" COVID-19 testing program.

*Antigen:*

- **OraSure has finalized all product development and completed clinical studies for its COVID-19 Rapid Antigen Self-Test and now plans FDA EUA submission for <u>both</u> Professional and Prescription Self-Test in the first quarter.**
    - OraSure has locked the proprietary assay chemistry and completed development of its COVID-19 Rapid Antigen Self-Test and has collected all clinical study data to now submit both the Professional version and Prescription Self-Test version for EUA in the first quarter of 2021.
    - Subject to receipt of EUA, this product would test for active COVID-19 infection using nasal samples self-collected from the lower nostrils. The COVID-19 Rapid Antigen Self-Test is designed to be performed anytime, anywhere, with no instrumentation, batteries or laboratory analysis needed to interpret results.
    - Subject to regulatory approvals, the Company intends to market its **Prescription Self-Test** for use by individual consumers (with prescription) at home, or in any location by employers/universities on- or off-site, or by physicians, or public health via remote testing, and its **Professional Test** for use at drive-through sites, physician offices, public health testing sites, and employer/university health centers.
    - After the Company submits the Professional Test and Prescription Self-Test for EUA, it intends to continue plans to pursue an OTC claim.
    - The Company will be manufacturing at risk and intends to launch the tests without delay, subject to authorization.

*Antibody:*

- **OraSure is working with the FDA to secure Emergency Use Authorization for its lab-based OraSure SARS-CoV-2 Antibody ELISA. Currently no COVID-19 antibody tests that use oral fluid samples have received Emergency Use Authorization. OraSure's test could be the first. Oral fluid samples minimize healthcare professionals' need for personal protective equipment and reduces their exposure to potentially infected patients as compared to blood draws; the test could aid health officials in community surveillance efforts and seroprevalence studies.**

    - With this test, individuals would use the OraSure Oral Antibody Collection Device to self-collect an oral fluid sample under the observation of a healthcare professional. The sample would then be placed into the buffer vial for storage and transport, and then later dispensed onto the OraSure SARS-CoV-2 ELISA microplate for testing in a laboratory. This lab-based antibody test can aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating prior infection.
    - At the request of the FDA, the Company plans to resubmit two separate EUAs for the test, one covering the oral fluid specimen collector and one for the microplate assay. In addition, the FDA has requested that additional analytical studies be conducted on sample collection and stability.
    - OraSure continues to sell its antibody test for research use only, which has led to interest from several companies and labs regarding seroprevalence studies in cities or university populations.

*Manufacturing:*

- **OraSure's initiative to increase manufacturing capacity to meet demand for COVID-19 sample collection kits and tests continues on schedule. Additional expansion planned to support Rapid Antigen Self-Test.**
    - Previously the Company had disclosed that it was expanding manufacturing capacity for the Rapid Antigen Self-Test to 70 million tests per year in the third quarter of 2021 (including tests for HIV, HCV and Ebola).
    - OraSure now plans additional expansion of 50 million Rapid Antigen Self-Tests, bringing capacity to 120 million tests per year (including tests for HIV, HCV and Ebola) by the second quarter of 2022. The Company expects this additional capacity to support sales outside of the U.S.
    - As previously disclosed, the Company is expanding capacity of its molecular sample collection devices to a rate of approximately 75 million units annually in the second quarter of 2021 and further to 80 million units in the third quarter, including non-COVID kits.
    - Also as previously disclosed, installation of new lines for the oral-fluid antibody test will bring total capacity to 20 million units per year by the fourth quarter, including existing products.

**Financial Results for the Three Months Ended December 31, 2020**

Net revenues for the fourth quarter of 2020 of $62.9 million increased 27% from the comparable period of 2019, primarily as a result of strong sales of molecular sample collection kits for COVID-19 testing and increased international sales of the Company's HIV Self-Test partially offset by declines in revenues of our other product lines largely due to the impact of COVID-19.

Gross profit percentage was 61% for the three months ended December 31, 2020 compared to 60% for the three months ended December 31, 2019. Gross profit in the current quarter benefited from an improved product mix associated with higher gross profit percentage product sales.

For the three months ended December 31, 2020, operating expenses were $30.3 million, an increase of $4.1 million from the $25.8 million reported for the three months ended December 31, 2019, largely due to increased investment in the development of the Company's COVID products.

The Company generated operating income of $7.9 million in the fourth quarter of 2020 compared to operating income of $4.1 million in the fourth quarter of 2019.

During the fourth quarters of 2020 and 2019, the Company recorded income tax expense of $5.7 million and $2.1 million, respectively. Income tax expense in both periods largely consisted of foreign taxes due related to our Canadian subsidiary.

**First Quarter 2021 Guidance**

The Company expects first quarter 2021 net revenues to range from $55.0 million to $60.0 million.

**Financial Data (Unaudited)**

| | Three Months Ended December 31, | | Year Ended December 31, | |
|---|---|---|---|---|
| | 2020 | 2019 | 2020 | 2019 |
| **Results of Operations** | | | | |
| Net revenues | $ 62,855 | $ 49,668 | $ 171,721 | $ 154,605 |
| Cost of products and services sold | 24,671 | 19,829 | 69,853 | 60,022 |
| Gross profit | 38,184 | 29,839 | 101,868 | 94,583 |
| Operating expenses: | | | | |
| Research and development | 10,457 | 6,104 | 31,032 | 19,629 |
| Sales and marketing | 9,120 | 7,932 | 34,459 | 31,869 |
| General and administrative | 12,211 | 11,539 | 42,653 | 35,287 |
| Change in fair value of acquisition-related contingent consideration | (1,489) | 179 | (1,099) | (664) |
| Gain on sale of business | — | — | — | (10,149) |
| Total operating expenses | 30,299 | 25,754 | 107,045 | 75,972 |
| Operating income (loss) | 7,885 | 4,085 | (5,177) | 18,611 |
| Other income (expense) | (307) | 477 | 1,653 | 2,720 |
| Income (loss) before income taxes | 7,578 | 4,562 | (3,524) | 21,331 |
| Income tax expense | 5,718 | 2,124 | 11,398 | 4,675 |
| Net income (loss) | $ 1,860 | $ 2,438 | $ (14,922) | $ 16,656 |
| Earnings (loss) per share: | | | | |
| Basic | $ 0.03 | $ 0.04 | $ (0.22) | $ 0.27 |
| Diluted | $ 0.03 | $ 0.04 | $ (0.22) | $ 0.27 |
| | | | | |
| Weighted average shares: | | | | |
| Basic | 71,723 | 61,729 | 67,505 | 61,675 |
| Diluted | 72,817 | 62,199 | 67,505 | 62,170 |

| | Three Months Ended December 31, | | | | |
|---|---|---|---|---|---|
| | Dollars | | | Percentage of Total Net Revenues | |
| | 2020 | 2019 | % Change | 2020 | 2019 |
| **Market** | | | | | |
| Infectious disease testing | $ 17,602 | $ 18,743 | (6) % | 28 % | 38 % |
| Risk assessment testing | 2,526 | 2,944 | (14) | 4 | 6 |
| Molecular solutions | 40,281 | 25,487 | 58 | 64 | 51 |
| Net product and service revenues | 60,409 | 47,174 | 28 | 96 | 95 |
| Royalty income | 1,809 | 2,160 | (16) | 3 | 4 |
| Other | 637 | 334 | 91 | 1 | 1 |
| Net revenues | $ 62,855 | $ 49,668 | 27 % | 100 % | 100 % |

| | Year Ended December 31, | | | | |
|---|---|---|---|---|---|
| | Dollars | | | Percentage of Total Net Revenues | |
| | 2020 | 2019 | % Change | 2020 | 2019 |
| **Market** | | | | | |
| Infectious disease testing | $ 54,227 | $ 58,016 | (7) % | 32 % | 38 % |
| Risk assessment testing | 9,374 | 12,189 | (23) | 5 | 8 |
| Cryosurgical systems | — | 7,054 | (100) | — | 5 |
| Molecular solutions | 102,780 | 70,814 | 45 | 60 | 45 |
| Net product and service revenues | 166,381 | 148,073 | 12 | 97 | 96 |
| Royalty income | 3,432 | 5,116 | (33) | 2 | 3 |
| Other | 1,908 | 1,416 | 35 | 1 | 1 |
| Net revenues | $ 171,721 | $ 154,605 | 11 % | 100 % | 100 % |

| | Three Months Ended December 31, | | | Year Ended December 31, | | |
|---|---|---|---|---|---|---|
| | 2020 | 2019 | % Change | 2020 | 2019 | % Change |
| **OraQuick® Revenues** | | | | | | |
| Domestic HIV | $ 3,861 | $ 4,960 | (22) % | $ 15,184 | $ 17,984 | (16) % |
| International HIV | 11,343 | 9,795 | 16 | 29,040 | 25,108 | 16 |
| Net HIV revenues | 15,204 | 14,755 | 3 | 44,224 | 43,092 | 3 |
| Domestic HCV | 1,356 | 2,202 | (38) | 4,793 | 8,108 | (41) |
| International HCV | 884 | 1,295 | (32) | 3,655 | 4,864 | (25) |
| Net HCV revenues | 2,240 | 3,497 | (36) | 8,448 | 12,972 | (35) |
| Net product revenues | $ 17,444 | $ 18,252 | (4) % | $ 52,672 | $ 56,064 | (6) % |

| | Three Months Ended December 31, | | | Year Ended December 31, | | |
|---|---|---|---|---|---|---|
| | 2020 | 2019 | % Change | 2020 | 2019 | % Change |
| **Molecular Solutions Revenues** | | | | | | |
| Genomics | $ 13,760 | $ 20,761 | (34) % | $ 37,141 | $ 56,212 | (34) % |
| Microbiome | 1,898 | 1,847 | 3 | 6,156 | 7,172 | (14) |
| COVID-19 | 22,494 | — | N/A | 49,802 | — | N/A |
| Laboratory services | 2,093 | 2,820 | (26) | 9,564 | 6,767 | 41 |
| Other product revenues | 36 | 59 | (39) | 117 | 663 | (82) |
| Net product and service revenues | 40,281 | 25,487 | 58 | 102,780 | 70,814 | 45 |
| Other | 1,866 | 2,289 | (18) | 3,701 | 5,566 | (34) |
| Net revenues | $ 42,147 | $ 27,776 | 52 % | $ 106,481 | $ 76,380 | 39 % |

**Condensed Consolidated Balance Sheets (Unaudited)**

| | December 31, 2020 | December 31, 2019 |
|---|---|---|
| Assets | | |
| Cash and cash equivalents | $ 160,802 | $ 75,715 |
| Short-term investments | 48,599 | 80,623 |
| Accounts receivable, net | 38,835 | 36,948 |
| Inventories | 31,863 | 23,155 |
| Other current assets | 8,794 | 8,109 |
| Property, plant and equipment, net | 51,860 | 30,339 |
| Intangible assets, net | 17,904 | 14,674 |
| Goodwill | 40,351 | 36,201 |
| Long-term investments | 47,718 | 33,420 |
| Other non-current assets | 7,746 | 10,111 |
| Total assets | $ 454,472 | $ 349,295 |
| | | |
| Liabilities and Stockholders' Equity | | |
| Accounts payable | $ 17,407 | $ 9,567 |
| Deferred revenue | 4,811 | 3,713 |
| Contingent consideration obligation | 402 | 3,500 |
| Other current liabilities | 23,869 | 15,933 |
| Non-current contingent consideration obligation | 2,049 | 112 |
| Other non-current liabilities | 7,363 | 9,325 |
| Stockholders' equity | 398,571 | 307,145 |
| Total liabilities and stockholders' equity | $ 454,472 | $ 349,295 |

**Additional Financial Data (Unaudited)**

| | Year Ended December 31, | |
|---|---|---|
| | 2020 | 2019 |
| Capital expenditures | $ 26,674 | $ 9,314 |
| Depreciation and amortization | $ 9,714 | $ 7,730 |
| Stock-based compensation | $ 7,139 | $ 4,057 |
| Cash provided by operating activities | $ 5,807 | $ 9,804 |

**Conference Call**

The Company will host a conference call and audio webcast for analysts and investors to discuss the Company's 2020 full year and fourth quarter results and certain business developments, beginning today at 5:00 p.m. Eastern Time (2:00 p.m. Pacific Time). On the call will be Dr. Stephen S. Tang, President and Chief Executive Officer, and Roberto Cuca, Chief Financial Officer. The call will include prepared remarks by management and a question and answer session.

In order to listen to the conference call, please dial 844-831-3030 (Domestic) or 315-625-6887 (International) and reference Conference ID # 8168847 or go to OraSure Technologies' web site, www.orasure.com, and click on the Investor Relations page. Please click on the webcast link and follow the prompts for registration and access 10 minutes prior to the call. A replay of the call will be archived on OraSure Technologies' web site shortly after the call has ended and will be available for seven days. A replay of the call can also be accessed until midnight, March 15, 2021, by dialing 855-859-2056 (Domestic) or (404) 537-3406 (International) and entering the Conference ID #9459222.

It is recommended to dial-in at most 15 to 20 minutes prior to the call start to reduce waiting times. If a participant will be listen-only, they are encouraged to listen via the webcast on OraSure's Investor Relations page.

**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 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, products, product development activities, regulatory submissions and authorizations and other matters. 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, receive necessary regulatory approvals and authorizations 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, 2020, 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 OraSure Technologies undertakes no duty to update these statements.

###

**EXHIBIT 99.2**

**OraSure Technologies, Inc.**
**2020 Fourth Quarter and Full Year**
**Analyst-Investor Conference Call**
**March 1, 2021**

**Prepared Remarks of Dr. Stephen S. Tang and Roberto Cuca**

***Please see "Important Information" at the conclusion of the following prepared remarks***

***Operator Remarks***

Good afternoon everyone and welcome to the OraSure Technologies 2020 fourth quarter and full year financial results conference call and simultaneous webcast. As a reminder, today's conference is being recorded. All lines have been placed on mute to prevent any background noise. After the speaker's remarks, there will be a question and answer period. If you would like to ask a question during this time, simply press "star" then the number 1 on your telephone keypad. If you would like to withdraw your question, press the # key. To allow time for as many questions as possible, questioners are asked to limit themselves to only a single question with no more than one follow-up question related to the same topic. Once the follow-up is completed, a questioner can rejoin the queue for further questions.

I would now like to turn the call over to Jeanne Mell, Vice President of Corporate Communications for OraSure. Jeanne?

***Jeanne Mell, VP Corporate Communications***

Thank you, Operator. With us today are Dr. Stephen Tang, President and Chief Executive Officer, and Mr. Roberto Cuca, Chief Financial Officer. Dr. Tang and Mr. Cuca will begin with opening statements, which will be followed by the question and answer session.

Before I turn the call over to Dr. Tang, you should know that this call may contain certain forward-looking statements, including statements with respect to revenues, expenses, profitability, earnings or loss per share and other financial performance, product development, performance, shipments and markets, business plans, regulatory filings and approvals, expectations and strategies. Actual results could be significantly different. Factors that could affect results are discussed more fully in the Company's SEC filings, including its registration statements, its Annual Report on Form 10-K for the year ended December 31, 2020, its quarterly reports on Form 10-Q, and its other SEC filings. Although forward-looking statements help to provide complete information about future prospects, listeners should keep in mind that forward-looking statements are based solely on information available to management as of today. The Company undertakes no obligation to update any forward-looking statements to reflect events or circumstances after this call.

With that, I will turn the call over to Dr. Stephen Tang.

***Introduction – Stephen Tang, President and Chief Executive Officer***

Thank you, Jeanne, and thank you everyone for joining us today. I hope you and your families are safe and well.

As you will hear today, OraSure continues to successfully navigate the COVID-19 pandemic. Today we reported a record-breaking fourth quarter and double-digit full-year revenue growth, driven by our sales of our molecular sample collection kits for COVID-19 testing. In addition, our base business was resilient, with demonstrated strength in sales of our international HIV testing products, which also grew by double digits year over year, and strong genomics growth in key customers in our Disease Risk Management and Companion Animal segments.
We expect our role in COVID-19 detection to only grow in importance as we have made substantial progress in our rapid antigen self-test for COVID-19. We have locked the proprietary assay chemistry and completed development and completed clinical testing. I'm delighted that we were able to accelerate the clinical trials for the Prescription Self-Test and now plan to submit for Emergency Use Authorization (or EUA) for both a Prescription Self-Test and a Professional Test by the end of the month. We also remain on track to resubmit two separate EUAs for our lab-based

oral fluid antibody test and look forward to bringing this pioneering product to market as soon as possible.
Revenue from our sample collection kits for COVID-19 molecular testing continues to meaningfully contribute to our business, with full-year revenue from these kits totaling $50 million. In the fourth quarter, net revenues of $62.9 million represent the highest quarterly revenue performance in OraSure's history, driven by $22.5 million in sales of our COVID-19 molecular sample collection kits in that quarter.

We expect this strong, sustained performance to persist, as testing remains a key strategy to combat the pandemic. Here in the U.S., the Biden Administration has called for more broad testing to turn the tide of the pandemic and proposes dedicating $50 billion in spending to testing.

A December Rockefeller Foundation report calls for 300 million tests per month – and that's just to safely reopen America's public schools and keep them open. Globally, this number will likely be much larger, because vaccines will not be widely available in much of the world. Multiple tests from multiple manufacturers will be required to meet the massive global need.

The emergence of new, more contagious variants of the coronavirus underscores the importance of testing as a means to detect infection -- especially as the rollout of vaccines encounters logistical hurdles. Dr. Anthony Fauci has said that we will reach herd immunity when 70-85% of the population is vaccinated. Currently, less than 10% of the U.S. population is fully vaccinated. Globally the number is far less.

And as COVID-19 moves from a pandemic to an endemic disease, we believe people will still need to know their status and test regularly, making testing an important part of overall disease management. Also, as the virus mutates, surveillance, or the genetic sequencing of samples for variant identification, will become an increasingly important part of our global COVID-19 response plan. We join our industry peers and public officials who believe that testing will remain a key part of our return to "normal" life of unrestricted gathering and travel, even with widespread vaccination.

Against that backdrop, OraSure continues to advance its three distinct COVID-19 opportunities: sample collection for molecular testing and surveillance, an easy-to-use rapid antigen self-test, and a lab-based oral fluid antibody test, each of which will help accelerate OraSure's growth.

Our portfolio of COVID-19 tests and collection kits all feature convenient, pain-free self-collection, and can help improve access to testing, alleviate the burden on the healthcare system, minimize exposure risks, and conserve personal protective equipment, or PPE.

The momentum we've seen from our molecular COVID-19 sales significantly outweighs the challenges that the pandemic presents to other areas of our business, and we expect that, once commercialized, our antigen and antibody tests will accelerate our record-breaking growth.

Use of DNA Genotek molecular sample collection kits continues to grow in back-to-work settings, back-to-school programs, laboratory testing and direct-to-consumer offerings. We are encouraged by the high-volume repeat orders from existing customers, as well as demand from new customers. To date, our molecular collection kits are now included in eight EUAs granted by the U.S. Food and Drug Administration to DNA Genotek's customers.

We have also received our own FDA EUAs for the use of our OMNIgene®•ORAL and ORAcollect® •RNA collection devices in COVID-19 testing, which allows for the unsupervised use of these devices at home or in healthcare settings when used as part of an approved or validated at-home test kit.

In February, State University of New York announced that their campuses have administered more than one million COVID-19 tests since the start of the 2020-2021 academic year. These tests were developed by DNA Genotek customer Quadrant Biosciences and use our ORAcollect® •RNA collection device.

And Clinical Reference Laboratory has announced that their CRL Rapid Response COVID-19 Saliva Test, which uses the OMNIgene•Oral collection device, is now available through Walgreens Find Care® digital health platform.

Internationally, the OMNIgene•ORAL is being utilized as a collection device by Chronomics for the UK Government's "Test to Release for International Travel" COVID-19 testing program, which was announced in January.

In addition, both the OMNIgene•ORAL and ORAcollect•RNA saliva collection devices received interim authorization for use in COVID-19 testing from Health Canada in January. This enables diagnostic labs, health authorities, and COVID-19 test kit providers across Canada to offer self-collection both at-home and via healthcare professionals. These authorizations could be transformative for public health efforts in Canada by adding important tools to increase access to testing.

Also of note, OMNIgene•ORAL was included in TIME Magazine's round up of the Best Inventions of 2020.

Turning to our diagnostic tests for COVID-19, OraSure continues to make substantial progress on the development of our COVID-19 Rapid Antigen Self-Test. Subject to regulatory authorization, our rapid antigen self-test would detect COVID-19 infection using nasal samples self-collected from the lower nostril.

As we've learned from our HIV self-test, simplicity and ease of use are paramount when it comes to self-tests. Our COVID-19 rapid antigen test requires no instrumentation, batteries or smart phone. Users would simply swab their nostrils, swirl the swab in buffer solution, and see the result.

As I noted earlier, we have finalized product development and completed the clinical studies necessary to submit both the Professional version and the Prescription Self-Test version in Q1. We are pleased that the clinical trial results validate our commitment to meeting the high standards we have set for ourselves. The self-test market represents a significant opportunity for COVID-19 testing, and as of Friday only three self-tests have been authorized by the FDA.

Subject to regulatory approvals, we intend to market the **Prescription Self-Test** for use by individual consumers (with a prescription) at home, or in any location by employers and universities on- or off-site, or by physicians, or public health authorities via remote testing; and

the **Professional Test** for use at drive-through sites, physician offices, public health testing sites, and employer or university health centers. In addition, we intend to continue our plans to pursue an over-the-counter claim with the additional clinical testing required.
We are also planning to launch our Rapid Antigen test outside of the U.S. as we anticipate the COVID-19 diagnostic testing market will shift to international markets as U.S. vaccination advances.

Moving on to our third COVID-19 opportunity, our lab-based, oral fluid antibody ELISA test. Antibody tests are becoming more important as vaccines roll out and the focus on herd immunity increases. Our test has the potential to be the first antibody test authorized by the FDA that uses oral fluid samples. This is an important distinction. Oral fluid samples are easy for individuals to collect. They minimize healthcare professionals' need for PPE and reduce the exposure to potentially infected patients as compared to blood draws.

OraSure's test has been shown in a peer-reviewed clinical study to increase the ability to antibody test by 25-fold versus blood-based testing. In addition, in this study the OraSure Oral Fluid Sars-CoV-2 Antibody test was shown to have a 90.9 Positive Percent Agreement and 100% Negative Percent Agreement versus serology.

With this test, individuals would use a collection pad to self-collect an oral fluid sample under the observation of a healthcare professional. The sample would then be placed into the OraSure Oral Antibody Collection Device buffer for storage and transport. It would then later be dispensed onto the OraSure ELISA microplate for testing in a laboratory. This lab-based antibody test can aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating prior infection. The test could also aid health officials in community surveillance efforts and seroprevalence studies.

At the request of the FDA, we plan to resubmit two separate EUAs for the test, one covering the oral fluid specimen collector and one for the microplate assay. In addition, the FDA has requested that additional analytical studies be conducted on sample collection and stability. These studies

are in process, and we plan to file the EUAs for this pioneering product as soon as the studies are completed.

Meanwhile, we continue to sell our antibody test for research use only. This has led to interest from several companies and labs that are conducting seroprevalence studies. In addition, our antibody test is being used in studies that are looking at vaccine response. We expect that antibody testing will become more important as the vaccine roll-out continues, both to determine vaccine longevity and measure progress towards herd immunity.

I'd also like to touch on our ongoing manufacturing capacity expansion efforts, which continue on schedule for all of our COVID-19 activities. In addition, we now plan to add capacity for an additional 50 million Rapid Antigen Self-Tests, bringing capacity to 120 million tests per year by the second quarter of 2022. This additional capacity is intended to support sales outside the U.S. Included in these numbers are approximately 17 million of our existing tests for HIV, HCV and Ebola.

Before I turn the call over to Roberto for a report on our fourth quarter and year-end financials, I'd like to note that we are encouraged by the Biden Administration's stated commitment to a scientific, organized and centralized approach to COVID-19 testing in the U.S. We especially welcome the Administration's focus on rapid tests and the proposed $50 billion investment to increase the nation's testing capacity. This underscores the durability of our COVID-19 testing opportunities and aligns with our motivation to ensure simple, safe and rapid testing is widely available.

With that, I'll hand it over to Roberto for a report on our financials. Roberto?

***Financial Results – Roberto Cuca***

Thank you, Steve.

As Steve mentioned earlier, our fourth quarter net revenues increased 27% to $62.9 million from the $49.7 million reported in the fourth quarter of 2019, primarily as a result of strong sales of molecular sample collection kits for COVID-19 testing and increased international sales of the Company's HIV Self-Test. This was partially offset by lower sales across all our other product lines primarily due to the impact of the COVID-19 pandemic as well as a shift in the ordering patterns of a large genomics customer. Net product and services revenues were $60.4 million, a 28% increase from the fourth quarter of 2019.

Total product and service revenues for the Company's molecular business unit were $40.3 million during the fourth quarter of 2020, an increase of 58% from the fourth quarter of 2019. This increase included $22.5 million in sales of oral fluid sample collection devices for COVID-19 molecular testing, which was partially offset by a decrease in genomics and laboratory services sales.

International sales of the Company's OraQuick® HIV tests increased 16% compared to the fourth quarter of 2019 largely due to higher sales of our HIV Self-Test into Africa.

Gross profit percentage was 61% for the three months ended December 31, 2020 compared to 60% in the same period of 2019 due to an improved product mix of higher gross profit percentage product sales.

Net income for the fourth quarter of 2020 was $1.9 million, or $0.03 per share on a fully-diluted basis, compared to net income of $2.4 million, or $0.04 per share on a fully-diluted basis, for the fourth quarter of 2019. Fourth quarter 2020 results included a benefit of $1.5 million for the change in the estimated fair value of our acquisition-related contingent consideration compared to a charge recorded in the fourth quarter of 2019 of $179,000. 2020 results also reflect the additional product development costs incurred for our COVID-19 tests as well as increased foreign tax expense associated with the improved results of our Canadian subsidiary.

Cash and investments totaled $257.1 million at December 31, 2020.

As we disclosed in our press release, we expect revenues of $55.0 million to $60.0 million in the first quarter of 2021. We are not providing full year guidance at this time, but will revisit that option as we get greater clarity on the regulatory status of our COVID-19 antigen and antibody tests.

With that, I will turn the call back to Steve.

***Steve Tang***

Thank you, Roberto. I would now like to provide some brief updates on our legacy businesses, which continued to show resiliency in the face of the challenges of the pandemic.

Access to HIV testing continues to be challenging in this pandemic, and self-testing is a convenient solution that enables social distancing and helps minimize COVID-19 exposure. This past quarter, we ensured continued access to rapid, convenient HIV testing both domestically and internationally.

HIV OTC and self-tests continued to show strength and offset declines in professional testing due to the COVID-19 related clinic closures, which were seen across the U.S., Korea and the European Union.

We were encouraged by robust international HIV self-test sales, which increased 16% over the same quarter in 2019 and for the full year. In Q4, OraSure sold over 4 million HIV Self-Tests outside the U.S., as compared to 2.9 million Self-Tests in the fourth quarter of 2019. We expect this trend to continue.

Total Diagnostic revenues were down 7% for the fourth quarter vs the fourth quarter of 2019 and down 8% for the full-year period. However, it is important to note that the testing markets for HIV, HCV, and Risk Assessment, which represent the vast majority of the Diagnostics Business Unit, have been stated by various sources as being down by as much as 50%. Comparatively, OraSure's

Diagnostic business unit showed strength, a testament to OraSure's legacy of providing easy, accurate answers to critical health questions.

On the Molecular side, outside of COVID-19, we have expanded the scope and applications of our genomics collection products through new regulatory clearances. The Oragene®•Dx saliva collection device was included as a component in the De Novo FDA authorization granted to Helix for their whole exome sequencing platform. This is the first exome sequencing-based platform authorized by the FDA. Oragene•Dx was also included as a component in the 510(k) clearance Helix received for its Helix® Genetic Health Risk App for late-onset Alzheimer's Disease for over-the-counter use, the first test to be cleared on the Helix® Laboratory Platform.

As noted earlier, we saw growth with customers in Disease Risk Management as saliva collection enabled ongoing genetic testing, when blood collection became more difficult due to COVID-19 closures. Additionally, the companion animal testing segment saw growth as pet adoptions rose double digits during the quarantine.

Our microbiome business held steady in Q4 with 3% growth over Q4 2019, driven by strong repeat business from our customers.

And as I announced on the third quarter call, we continued to build our multiomics strategy with new product introductions such as OMNImet®•GUT and OMNIgene®•SKIN, the first combined product/service offering with Diversigen.

Finally, before we move to Q&A, I'd like to provide some summarizing thoughts.

Over the past year we have seen further evidence that infectious disease testing and sample collection must meet customers wherever they are. OraSure is steadfastly focused on making COVID-19 detection simpler, faster and smarter, putting the control in the hands of the individual.

The results of this past quarter make it clear that OraSure is well positioned to assist in the battle against COVID-19, and the best is yet to come. Expected continued growth in COVID-19

molecular revenues into 2021, the planned introduction of our new rapid antigen and antibody tests, and the ongoing expansion of capacity to meet demand solidify our confidence that COVID-19 is a long-term, substantial and sustainable opportunity.

Meanwhile, we remain optimistic for the resilience and the future of our legacy businesses, as well as our journey towards multiomics.

Our strong balance sheet, bolstered by COVID-19 revenues will afford us the opportunity to maximize the COVID-19 market opportunity, fund our legacy businesses and seek transformative and accretive business development opportunities.

We are confident that we will emerge from the pandemic a larger, stronger and more innovative company able to effectively compete in key burgeoning markets in diagnostics and molecular solutions

With that, Operator, I'll turn the call over for questions.

***[Q&A SESSION]***

***Final Conclusion – Steve Tang***

Thank you for participating in today's call and for your continued interest in OraSure. Have a good afternoon and evening. Stay safe and be well.

**Important Information**

This document 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 collection 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 Securities and Exchange Commission ("SEC") filings, including our registration statements, Annual Report on Form 10-K for the year ended December 31, 2020, 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 call and we undertake no duty to update these statements.

Exhibit 99.3

# OraSure Technologies

INVESTOR PRESENTATION

MARCH 2021

DNAgenotek™ Diversigen® novosanis

# Forward-Looking Statements Disclaimer

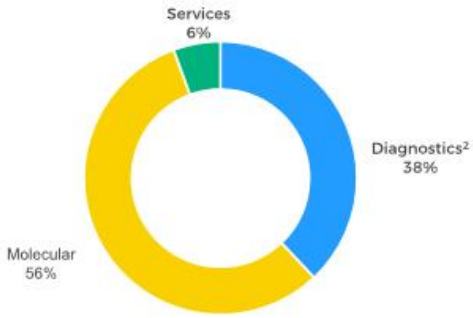
This presentation contains certain forward-looking statements, including with respect to expected revenues and earnings/loss per share. Forward-looking statements are not guarantees of future performance or results. Known and unknown factors that could cause actual performance or results to be materially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

- **$172 million** in net revenue in 2020
- **570** employees
- Offices in U.S., Canada and Belgium
- Active business development program
- **$257 million** in cash[1] on balance sheet; no debt
- Products registered in 89 countries

**2020 Revenue by segment**




[1] Cash and cash equivalents, short-term investments, and long-term investments as of December 31, 2020

[2] Infectious Disease and Risk Assessment Testing

# Investment Rationale

## Multiple Near-term COVID-19 Opportunities andLong-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; rapid antigen self-test development and clinical studies completed, preparing for Q1 EUA submission; lab-based oral fluid antibody test clinical study completed, finishing additional studies for EUA resubmission**
- 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
- **$257 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 December 31, 2020

# Improving Global Access to Accurate Healthcare Information

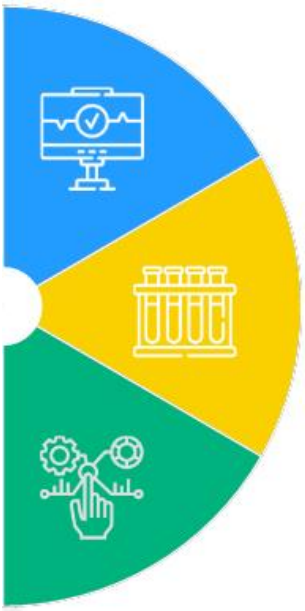
## Experts in sample collection, preservation and diagnostics

- 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



## Diagnostics

Selection of high value/ actionable testing

OraSure Technologies, Inc.

- Infectious disease
- Substance abuse testing

## 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

# 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**

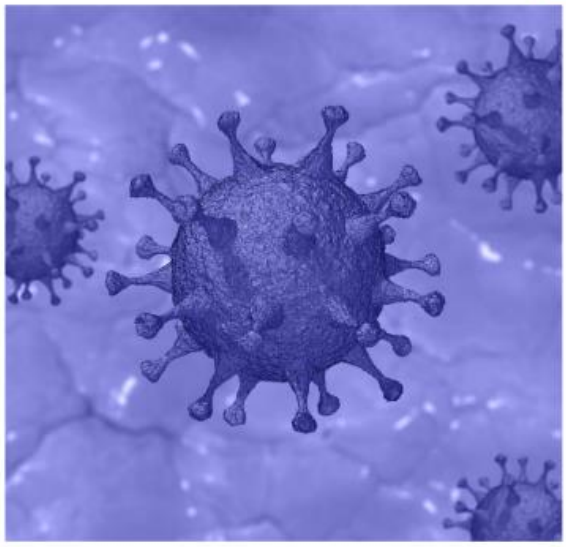
- **Our unique platform for HIV and HCV provides accurate and easy-to-administer testing methods**

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

- Sample Collection Devices for COVID-19 Molecular Testing
- COVID-19 Rapid Antigen Self-test
- COVID-19 Oral Fluid AntibodyELISA

  - ✓ Convenient, pain-free self-collection
  - ✓ Increased access to testing
  - ✓ Less burden on healthcare systems
  - ✓ Minimized exposure risks to healthcare workers
  - ✓ Conserve much-needed PPE



# All-in-one Solutions for Self-collection of Samples for Molecular COVID-19 Testing

- All-in-one, easy, reliable and non-invasive self-collection of high quality DNA and RNA
- Ambient temperature stability
- Compatible with high throughput processing
- ORAcollect® ·RNA and OMNIgene® ·ORAL have received EUAs, interim authorization from Health Canada, and are CE-IVD marked
- Eight 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

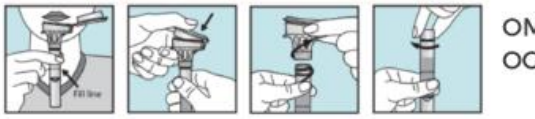
ORAcollect·RNA


OR-100**

VALIDATING WITH PARTNERS

OMNIgene·ORAL

ORAgene·Dx



OM-505**
OGD-500

*As of 2/28/21
**OR-100/OM-505 are the formats for the US market. Outside of the US, we use the ORE-100/OME-505 formats.

# COVID-19 Rapid Antigen Self-Test

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

Lower nasal collection not dependent on scarce NP swabs

Simple collection method, "lab on a swab"

Enables testing scale

- Simple, easy-to-use 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) with over 80 million tests sold
- Targeting EUA submission in Q1 2021
- Expanding manufacturing capacity to meet anticipated demand, ahead of EUA

*Image shows OraQuick lateral flow platform*

# OraSure's COVID-19 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*

# Sars-Cov-2 Oral Fluid AntibodyTest

Collect Sample with OraSure Device

Insert the device into the buffer

Sample sent to lab where ELISA test is run

- No oral fluid COVID-19 antibody tests have received Emergency Use Authorization 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
- On track to resubmit as two separate EUAs, with additional data as requested by FDA
- Product currently sold as Research Use Only (RUO) and in use by customers

*As of 2/28/21

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

## OraQuick Coronavirus Rapid Antigen Self-Test

| Today | Q1 2021 | Q3 2021 | Q2 2022 |
|---|---|---|---|
| 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 by the end of Q1 | Further expansion will allow **70 million** total tests per year | Further expansion will allow **120 million** total tests per year |

## 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 OTC 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

- FY 2021 federal budget includes $386 million for EHE implementation, up from $267 million in FY 2020.
- 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

- OraSure makes the first and only FDA-approved, CLIA-waived rapid HCV test*
- 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
- $39.5 million for the Division of Viral Hepatitis at CDC, an increase of $500,000 over FY 2020
- $13 million for Infectious Diseases and the Opioid Epidemic at CDC, an increase of $3 million over FY 2020
- 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

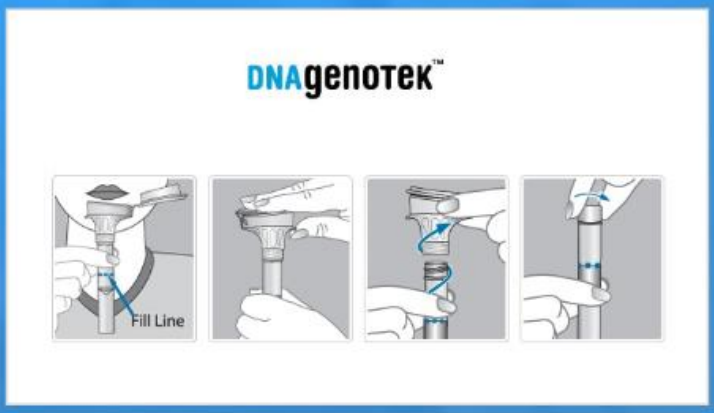
* VWB and FSWB only

# 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

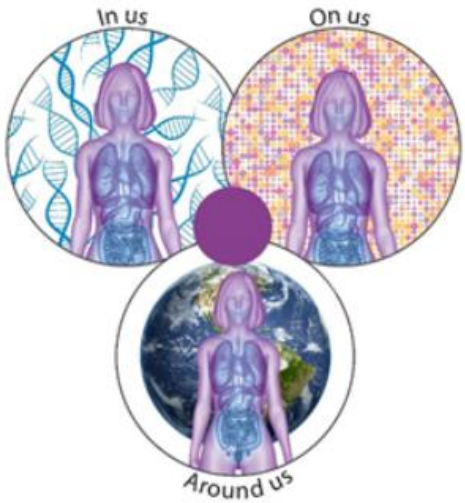
**The microbiome is believed to influence many diseases and biological processes**

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

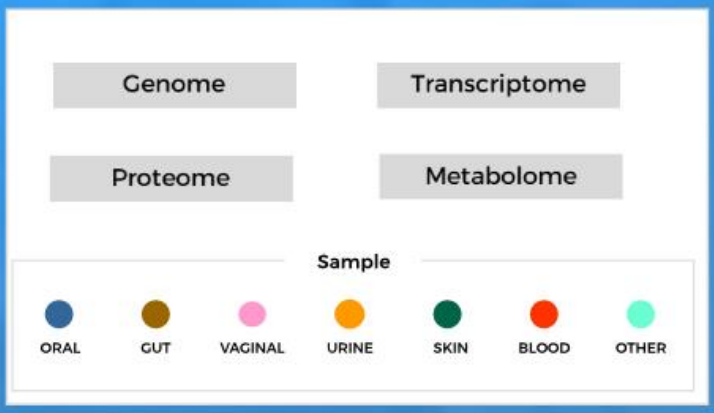
**Multiple research reports project mid-teens growth for the microbiome market** from 2019-2024



# 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
- Integrated 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
- **$257** 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 diagnostic possibilities as well as molecular

[1] Cash and cash equivalents, short-term investments, and long-term investments as of December 31, 2020

# Summary

- Business momentum is strong
- Significant COVID-19 opportunity is robust part of our business for now and the foreseeable future
- Molecular collection devices driving significant revenue
- COVID-19 Antigen and Antibody tests on the road to commercialization
- OraSure is poised for continued and sustained growth
- Our work with COVID-19 will help accelerate our growth significantly

We expect to emerge from the pandemic a stronger and larger company