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): May 5, 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 **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 May 5, 2021, OraSure Technologies, Inc. (the "Company") issued a press release announcing its consolidated financial results for the quarter ended March 31, 2021 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 May 5, 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 quarter ended March 31, 2021, 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 these Items 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 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 May 5, 2021, announcing consolidated financial results of OraSure Technologies, Inc. for the quarter ended March 31, 2021 and certain other matters.
99.2	Prepared Remarks of Stephen S. Tang, Ph.D. and Roberto Cuca for OraSure Technologies, Inc. First Quarter 2021 Analyst/ Investor Conference Call Held May 5, 2021.
99.3	OraSure Technologies, Inc. Investor Presentation dated May 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: May 5, 2021

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

Exhibit 99.1

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OraSure Technologies, Inc. Announces First Quarter 2021 Financial Results and Provides COVID-19 Update

First Quarter 2021 Net Revenues of $59 Million Increased 85% Over 2020, Driven by $27 Million in Sales of Sample Collection Devices for COVID-19 Molecular Testing

EUA Application Submitted in Q1 to FDA for COVID-19 Rapid Antigen Test for Both Prescription Home Use and Professional Use in Point of Care Settings

Management to Host Analyst/Investor Call and Webcast Today at 5:00 p.m. ET

BETHLEHEM, PA, May 5, 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 ended March 31, 2021.

“OraSure had another strong quarter, as the Company delivered double-digit year-over-year revenue growth for the third quarter in a row. Our sample collection devices for COVID-19 molecular testing continue to make a significant contribution to our revenues. Moreover, we have submitted our COVID-19 rapid antigen test to the US Food and Drug Administration for Emergency Use Authorization, and look forward to bringing a prescription home test and a professional test for point of care use to market,” said Stephen Tang, Ph.D., President and CEO of OraSure Technologies.

Dr. Tang continued, “As coronavirus variants continue to spread, we believe convenient, safe and accurate COVID-19 testing will continue to play a key role in identifying those who are infected and helping to safely reopen workplaces, schools, and other places where people gather. We are confident in the market potential for our COVID products, as well as the resilience of our other business segments as demonstrated by the strong first quarter performance of our commercial genomics, microbiome, and domestic HIV testing business. Given the overall strong financial performance of our business, the EUA applications pending before the FDA and our solid financial foundation, we are confident that OraSure is well positioned for continued success.”

Financial Highlights

- Net revenues for the first quarter of 2021 were $58.6 million, an 85% increase from the first quarter of 2020. Net product and services revenues were $56.6 million, an 83% increase from the first quarter of 2020.

- Total product and service revenues for the Company's molecular business unit were $43.2 million during the first quarter of 2021, an increase of 227% from the first quarter of 2020. This increase included $27.4 million in sales of sample collection devices for COVID-19 molecular testing.
- The Company's genomics business grew 32% year over year, driven by demand in the Disease Risk Management, Companion Animal and Academic Research markets. The Microbiome kits business grew 32% driven by sales to commercial accounts.
- Domestic HIV revenues of $5.3 million grew 26% year over year, driven by HIV OTC test sales.
- International HIV and HCV revenues declined 42% over the prior year, due to several large distributor orders which occurred in Q1 2020 and variations in timing as compared to 2021 ordering.
- Net income for the first quarter of 2021 was $3.8 million, or $0.05 per share on a fully-diluted basis, compared to a net loss of $7.3 million, or $0.12 per share on a fully-diluted basis, for the first quarter of 2020.
- Cash and investments totaled $240.5 million at March 31, 2021.

COVID-19 Update

Antigen:

- **OraSure has submitted an Emergency Use Authorization (EUA) application to the U.S. Food and Drug Administration (FDA) for its COVID-19 rapid antigen test for both Prescription Home Use, and Professional Use in point of care (POC) CLIA-waived settings.**
    - These lateral flow, rapid diagnostic tests are designed to detect active COVID-19 infection with a simple, easy-to-use workflow, using samples self-collected from the lower nostrils. After users swab their lower nostrils, the test stick is swirled in a pre-measured buffer solution. No instrumentation, batteries, smart phone or laboratory analysis is needed to read the result, which appears on the test stick a short time later.
    - Subject to receipt of EUA, the Company intends to market the COVID-19 Prescription Home Test and a Professional Test for use in POC CLIA-waived settings.
    - With a simple design and straightforward workflow, the Company believes its tests are well suited for use by individuals at home, as well as by health care providers, employers, pharmacies, universities, and for deployment into underserved communities when prescribed by a healthcare provider. The simple, user-friendly nature of the test can make testing more accessible and convenient in areas where medical personnel, infrastructure and supplies may be lacking.
    - The Company has started manufacturing the COVID-19 antigen tests as it awaits EUA.
    - The Company also intends to pursue an over-the-counter (OTC) indication for the rapid antigen test.

Molecular/PCR:

- **Sales of sample collection devices for molecular/PCR COVID-19 testing in the first quarter continued to grow sequentially.**
    - Use of DNA Genotek molecular sample collection kits continued to grow in the first quarter of 2021, with demand driven by both high-volume repeat orders from existing customers and

demand from new customers engaged in back-to-work and back-to-school testing programs around the world.

- The ORAcollect®•RNA saliva collection device has been used in more than two million COVID-19 tests developed by DNA Genotek customer Quadrant Biosciences in partnership with SUNY Upstate Medical University, up from the one million administered tests SUNY announced in February 2021. This test has been used extensively by State University of New York campuses since the start of the fall 2020 semester.

Antibody:

- **OraSure has collected all the data necessary to resubmit the two requested EUA applications for its oral fluid antibody test. At the FDA's request, the Company plans to submit separate EUAs for the ELISA microplate assay and the OraSure Oral Antibody Collection Device.**
  - To date, no oral fluid antibody tests have received EUA; OraSure's test has the potential to be the first.
  - 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.
  - OraSure continues to sell its antibody test for research use only.

Manufacturing:

- **OraSure's initiative to increase manufacturing capacity to meet demand for COVID-19 sample collection kits and tests continues.**
  - The Company is expanding installed manufacturing capacity for the rapid antigen test to 70 million tests per year in the third quarter of 2021 (including tests for HIV, HCV and Ebola).
  - OraSure plans additional expansion of 50 million rapid antigen tests, bringing installed 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.
  - Capacity expansion for the Company's molecular sample collection kits has increased beyond its original projections. The Company is expanding installed capacity of its molecular sample collection devices to a rate of approximately 80 million units annually in the second quarter of 2021, ahead of the 75 million annual units previously communicated, and further to 105 million units annually by the end of 2021, including non-COVID kits.
  - Installation of new lines for the oral-fluid antibody test will bring total capacity to 20 million units per year by the end of the year, including existing products.

Financial Results for the Three Months Ended March 31, 2021

Net revenues for the first quarter of 2021 of $58.6 million increased 85% from the comparable period of 2020, primarily as a result of strong sales of molecular sample collection kits for COVID-19 testing, higher genomics product sales and increased sales by the Company's domestic HIV testing business, partially offset by declines in revenues of our international HIV products due to order timing and risk assessment products due to the impact of COVID-19 on the overall risk assessment testing market in the US.

Gross profit percentage was 65% for the three months ended March 31, 2021 compared to 51% for the three months ended March 31, 2020. 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 March 31, 2021, operating expenses were $27.9 million, an increase of $3.7 million from the $24.2 million reported for the three months ended March 31, 2020, largely due to increased investment in the development and sale of the Company's COVID products. Operating expenses were also impacted by a benefit of $806,000 representing the change in the estimated fair value of acquisition-related contingent consideration compared to an expense of $1.1 million recorded the same period of 2020.

The Company generated operating income of $10.4 million in the first quarter of 2021 compared to an operating loss of $8.1 million in the first quarter of 2020.

During the first quarters of 2021 and 2020, the Company recorded income tax expense of $6.5 million and $712,000, respectively.

Second Quarter 2021 Guidance

The Company expects second quarter 2021 net revenues to range from $55 million to $60 million.

Financial Data (Unaudited)

	Three Months Ended March 31,	
	2021	2020
Results of Operations		
Net revenues	$ 58,582	$ 31,596
Cost of products and services sold	20,256	15,465
Gross profit	38,326	16,131
Operating expenses:		
Research and development	8,992	5,644
Sales and marketing	9,530	7,369
General and administrative	10,188	10,054
Change in fair value of acquisition-related contingent consideration	(806)	1,110
Total operating expenses	27,904	24,177
Operating income (loss)	10,422	(8,046)
Other income (expense)	(119)	1,430
Income (loss) before income taxes	10,303	(6,616)
Income tax expense	6,529	712
Net income (loss)	$ 3,774	$ (7,328)
Earnings (loss) per share:		
Basic	$ 0.05	$ (0.12)
Diluted	$ 0.05	$ (0.12)
Weighted average shares:		
Basic	71,878	61,927
Diluted	72,766	61,927

	Three Months Ended March 31,				
	Dollars			Percentage of Total Net Revenues	
	2021	2020	% Change	2021	2020
Market					
Infectious disease testing	$ 11,371	$ 14,664	(22) %	20 %	46 %
Risk assessment testing	1,962	3,000	(35)	3	9
Molecular solutions	43,246	13,222	227	74	43
Net product and service revenues	56,579	30,886	83	97	98
Other	2,003	710	182	3	2
Net revenues	$ 58,582	$ 31,596	85 %	100 %	100 %

	Three Months Ended March 31,		
	2021	2020	% Change
Infectious Disease Testing Revenues			
Domestic HIV	$ 5,293	$ 4,216	26 %
International HIV	3,486	6,949	(50)
Net HIV revenues	8,779	11,165	(21)
Domestic HCV	1,182	1,494	(21)
International HCV	1,184	1,097	8
Net HCV revenues	2,366	2,591	(9)
Other product revenues	226	908	(75)
Net product revenues	$ 11,371	$ 14,664	(22) %

	Three Months Ended March 31,		
	2021	2020	% Change
Molecular Solutions Revenues			
Genomics	$ 11,064	$ 8,393	32 %
Microbiome	2,088	1,577	32
COVID-19	27,389	394	N/A
Laboratory services	2,497	2,415	3
Other product and service revenues	208	443	(53)
Net product and service revenues	43,246	13,222	227
Other	790	582	36
Net revenues	$ 44,036	$ 13,804	219 %

Condensed Consolidated Balance Sheets (Unaudited)

	March 31, 2021	December 31, 2020
Assets		
Cash and cash equivalents	$ 177,676	$ 160,802
Short-term investments	29,080	48,599
Accounts receivable, net	36,391	38,835
Inventories	40,348	31,863
Other current assets	8,913	8,794
Property, plant and equipment, net	64,943	51,860
Intangible assets, net	16,945	17,904
Goodwill	40,493	40,351
Long-term investments	33,706	47,718
Other non-current assets	7,999	7,746
Total assets	$ 456,494	$ 454,472
Liabilities and Stockholders' Equity		
Accounts payable	$ 20,731	$ 17,407
Deferred revenue	4,580	4,811
Contingent consideration obligation	365	402
Other current liabilities	18,967	23,869
Non-current contingent consideration obligation	874	2,049
Other non-current liabilities	7,434	7,363
Stockholders' equity	403,543	398,571
Total liabilities and stockholders' equity	$ 456,494	$ 454,472

Additional Financial Data (Unaudited)

	Three Months Ended March 31,	
	2021	2020
Capital expenditures	$ 11,061	$ 2,595
Depreciation and amortization	$ 2,489	$ 2,165
Stock-based compensation	$ 1,464	$ 1,376
Cash provided by (used in) operating activities	$ (4,393)	$ 2,499

Conference Call

The Company will host a conference call and audio webcast for analysts and investors to discuss the Company's first quarter 2021 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 # 1349536 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 14 days. A replay of the call can also be accessed until midnight, May 19, 2021, by dialing 855-859-2056 (Domestic) or 404-537-3406 (International) and entering the Conference ID # 1349536.

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. OraSure, together with its wholly-owned subsidiaries, DNA Genotek, Diversigen, and Novosanis, 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.

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OraSure Technologies, Inc.
First Quarter 2021
Analyst-Investor Conference Call
May 5, 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 first quarter 2021 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.

I am pleased to report another record quarter for OraSure. Our 85% growth in first quarter net revenues represents the third quarter in a row of year-over-year double-digit revenue growth. Our sample collection devices for COVID-19 molecular testing continue to make a significant contribution to our revenues, and our genomics, microbiome, and domestic HIV diagnostic businesses showed strong performance as well.

We achieved a significant milestone in March when we submitted our COVID-19 rapid antigen test to the US Food and Drug Administration (FDA) for Emergency Use Authorization (EUA), and look forward to bringing both a prescription home test and a professional test for point of care use to market. We are confident in the market potential for our COVID-19 products, as well as the resilience of our non-COVID businesses.

Total net revenues of $58.6 million for the first quarter were driven by strong revenue performance of $43.2 million from the Molecular Solutions Business Unit. We recorded $27.4 million in revenue from our sample collection kits for COVID-19 molecular testing and expect our molecular sample collection kits to continue to meaningfully contribute to our business as testing remains a key strategy to combat the pandemic.

Top of mind for investors is the outlook for COVID-19 testing given the downward trend in testing numbers. Before providing further detail on our activities, I'd like to offer our perspective on the global COVID-19 testing landscape.

Here in the U.S., vaccines are readily available and the number of cases in the U.S. has dropped meaningfully since the start of the year. However, as variants continue to spread, testing will continue to play a crucial part in mitigating the spread of the virus and helping to safely reopen workplaces, schools, and other places where people gather. A recent McKinsey report notes that rapid, accurate testing will play a key role as the transition back to pre-pandemic routines continues.

The emergence of new, more contagious variants of the coronavirus underscores the importance of testing to detect infection even as vaccination campaigns continue. Scientists are particularly concerned about the rising prevalence of variants, which they say could prolong the pandemic. When you factor in vaccine hesitancy, it becomes apparent that achieving herd immunity may take longer than hoped for – or even be elusive. Experts estimate that 70-85% of the population must be vaccinated to stop the spread of COVID-19. Yet, a quarter of Americans say they probably or definitely will not get vaccinated. In some states supply is now higher than demand.

Outside the U.S., however, the vaccine rollout is slower. Bloomberg projects it will take years to achieve significant global herd immunity, while McKinsey notes that herd immunity may look different across the world, with some areas achieving it, others moving in and out of it, and some failing to achieve it due to vaccine hesitancy.

Market research reports forecast a robust testing market with estimates of total global volumes for molecular and antigen tests in the range of two to four billion tests in 2021.

Consequently, we believe the need for convenient, safe and accurate testing will continue alongside vaccination rollouts, and our tests and molecular sample collection kits will be critical to this effort.

OraSure is dedicated to simplifying COVID-19 testing. Our tests and collection kits are all centered on the convenient, pain-free self-collection of samples, making it easier for people to know if they have COVID-19. This simplicity and ease of use can help increase access to testing, alleviate the burden on the healthcare system, minimize exposure risks, and conserve personal protective equipment (PPE).

Our molecular sample collection kits made by our DNA Genotek subsidiary continue to drive performance showing continued sequential quarterly growth. Demand has been driven by both high-volume repeat orders from existing customers and from new customers engaged in back-to-work and back-to-school testing programs around the world.

As a reminder, our OMNIgene®•ORAL and ORAcollect®•RNA collection devices have received EUAs from the FDA allowing 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. They are also included in eight EUAs received by DNA Genotek's customers.

ORAcollect®•RNA saliva collection devices have been used in more than two million COVID-19 tests developed by DNA Genotek customer Quadrant Biosciences in partnership with SUNY Upstate Medical University, up from the one million administered tests SUNY announced in February of 2021. This test has been used extensively by State University of New York campuses since the start of the fall 2020 semester.

Turning to our COVID-19 rapid antigen test, we were delighted to announce in March that we had submitted an EUA application to the FDA for our COVID-19 rapid antigen test for both Prescription Home Use and Professional Use at point of care (POC) settings. The concurrent

submission for both products represented an acceleration of the Prescription Home Test use product and reflects our continued focus on the home testing market.

This easy and intuitive ‘swab, swirl and see’ test detects active COVID-19 infection with no instrumentation, batteries or smartphone needed to read the results. Users simply swab their lower nostrils, swirl the swab in buffer solution and see the result right on the test stick a short time later. It’s that simple.

With just a few steps to follow, we believe our test would be one of the simplest COVID-19 tests on the market. We expect that its simplicity will give users peace of mind that they performed the test correctly and can be confident in the result.

Our rapid antigen tests are well suited for use by individuals at home, as well as health care providers, employers, pharmacies and universities. Because they do not rely on batteries, electricity, cell service or WiFi, our tests could be administered wherever testing is needed, such as in underserved communities where vaccinations are low and COVID incidence is high.

We have begun manufacturing our antigen test as we await Emergency Use Authorization.

We also plan to pursue an over-the-counter indication for our rapid antigen test. Given our experience selling our HIV test over the counter for close to 10 years, we are well suited to capitalize on this opportunity once authorized by the FDA.

Turning to our oral fluid antibody test, we have collected the data requested by the FDA and plan to submit separate EUA applications for the ELISA microplate assay and the OraSure Oral Antibody Collection Device. This lab-based antibody test can aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating prior infection.

Our test has the potential to be the first oral fluid antibody test to receive FDA Emergency Use Authorization. To date, all of the FDA authorized antibody tests require a venous blood draw or finger stick. Antibody tests can play a role in community surveillance efforts and seroprevalence

studies. We continue to sell this pioneering product for research use only and it has been validated by numerous laboratories.

With this qualitative test, individuals would self-collect an oral fluid sample using the OraSure Oral Antibody Collection Device, under the observation of a healthcare professional. The sample would be placed into a buffer vial for storage and transport, and later dispensed onto the OraSure Sars-CoV-2 ELISA microplate for testing in a laboratory.

Each of OraSure's accurate, easy-to-administer testing and collection methods, in conjunction with vaccination efforts, can play a key role in identifying COVID-19 cases, isolating the infected, controlling outbreaks and helping the world get back to "normal."

We are confident in the sustained market potential for our COVID-19 solutions. As the recent surges around the world have shown, COVID-19 is still having a significant impact worldwide.

We are prepared to address this global opportunity. Our molecular collection sample kits are already authorized in Europe and in Canada. We are actively working on the requirements for international regulatory approvals for our rapid antigen test and plan to leverage our existing infrastructure of teams and distributors.

If we capture just a small percentage of the global COVID-19 testing market, it will have a meaningful impact on the company.

With that, I'll turn it over to Roberto for a report on our financials and an update on our COVID-19 manufacturing capacity expansion. Roberto?

Financial Results – Roberto Cuca

Thank you, Steve.

Our first quarter net revenues increased 85% to $58.6 million from the $31.6 million reported in the first quarter of 2020, primarily as a result of strong sales of molecular sample collection kits for COVID-19 testing, higher genomics product sales, and increased sales of our over the counter OraQuick® In-Home HIV test. This was partially offset by lower sales of our HIV and HCV professional products and risk assessment products. Net product and services revenues were $56.6 million, an 83% increase from the first quarter of 2020.

Total product and service revenues for the Company's molecular business unit were $44.0 million during the first quarter of 2021, an increase of 219% from the first quarter of 2020. This increase included $27.4 million in sales of oral fluid sample collection devices for COVID-19 molecular testing.

Domestic sales of the Company's OraQuick® HIV tests increased 26% compared to the first quarter of the prior year largely due to higher sales of the over-the-counter OraQuick® In-Home HIV test. International HIV and HCV revenues declined 42% over the prior year, due to several large distributor orders which occurred in the first quarter of 2020 and variations in timing as compared to 2021 ordering. Overall, the underlying international growth in HIV and HCV testing is still strong vs. prior year outside of the single-quarter timing impact of these distributor orders.

Gross profit percentage was 65% for the three months ended March 31, 2021 compared to 51% in the same period of 2020 due to an improved product mix of higher gross profit percentage product sales.

Net income for the first quarter of 2021 was $3.8 million, or $0.05 per share on a fully-diluted basis, compared to a net loss of $7.3 million, or $0.12 per share on a fully-diluted basis, for the first quarter of 2020. First quarter 2021 results included a benefit of $806,000 for the change in the estimated fair value of our acquisition-related contingent consideration compared to a charge recorded in the first quarter of 2020 of $1.1 million. 2021 results also reflect the additional product development and sales and marketing costs incurred for our COVID-19 tests as well as increased tax expense associated with the improved results of the Company.

Cash and investments totaled $240.5 million at March 31, 2021.

As we disclosed in our press release, we expect revenues of $55.0 million to $60.0 million in the second 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.

I'll now turn to our manufacturing capacity expansion efforts for our COVID-19 products, starting with our rapid antigen test. As of the end of the first quarter, all the equipment needed to achieve the previously communicated planned capacity of 55 million units annually is on-site and either installed or in the process of being installed. More specifically, lines capable of manufacturing 44 million units a year are in place with the remainder to be finished by the end of May. Plans are on-track to achieve 70 million units annually of installed capacity in the third quarter and 120 million units by the second quarter of 2022 as previously disclosed. These are annualized numbers of installed capacity and include our existing tests for HIV, HCV and Ebola, and will require some ramp up time for validation and new employee training.

For our oral fluid antibody test, we currently have installed capacity of 10 million units per year, including existing products, as we have previously communicated. We remain on track to expand this capacity to 20 million units a year by the end of 2021.

Capacity expansion for our molecular sample collection kits exceeds our original projections. We are expanding installed capacity of our molecular sample collection devices to a rate of approximately 80 million units annually in the second quarter of 2021, ahead of the 75 million annual units previously communicated, and further to 105 million units annually by the end of 2021. Of this capacity we expect that 7-8 million units annually will go to non-COVID-19 applications.

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

Steve Tang

Thank you, Roberto. I'd now like to provide some brief updates on our non-COVID-19 businesses, which have shown not only resiliency, but in some cases, indications of a return to pre-pandemic levels. In fact, our molecular non-COVID-19 business rebounded beyond first quarter 2020's pre-COVID levels, signaling that COVID-19 headwinds in the molecular market may be subsiding.

Non-COVID molecular product revenue in the first quarter grew 32% over the prior year. Our total genomics business was up 32% for the quarter, with signals of recovery driven by momentum in the Disease Risk Management, Ancestry and Companion Animal markets. Our academic market for genomics is also showing signs of resilience with 9% growth over prior year quarter.

Our microbiome collection kits business rebounded in the first quarter with a 32% growth over the same quarter a year ago, driven by demand from our commercial customers. We expect our commercial microbiome business will continue to recover as investment continues in the microbiome industry, driving growth potential for both Diversigen services and DNA Genotek kits.

Turning to our Diagnostics Business Unit, overall domestic diagnostics revenue was on par with first quarter 2020, despite COVID-19 headwinds. Sales of our over the counter HIV In-Home test grew by triple digits over the prior year as public health HIV testing programs in the U.S. continue to use our over-the-counter product. For example, the Centers for Disease Control and Prevention (CDC) is distributing our OraQuick In-Home HIV Tests via a partnership with Insignia, Building Healthy Online Communities and Emory University. CDC's *Let's Stop HIV Together* campaign is leading the marketing efforts and sending consumers to a unique website link to order tests. This large-scale and targeted distribution of self-test kits to populations disproportionately impacted by HIV/AIDS will assist CDC in future efforts related to in-home testing strategies and contribute to the Ending the HIV Epidemic (EHE) initiative.

International diagnostics revenue was down from the year prior largely due to unusually large orders from initial program stocking in first quarter 2020 and variable timing associated with re-stocking. The underlying growth in Q1, outside of these stocking orders, is still strong and we expect international diagnostics revenue in the first half of 2021 to show strong growth vs. 2020.

Finally, before we move to the Q&A session, I'd like to share with you a few summarizing thoughts.

Our business is strong and we expect our momentum to continue in a balanced manner. As you've seen, our non-COVID revenue is beginning to return to pre-pandemic levels and our COVID-19 related revenue remains robust. We believe the collective contributions from our rapid antigen test and oral fluid antibody test will be substantial subject to receipt of EUAs for these products, and we're confident we'll continue to make significant commercial strides with our molecular sample collection kits. Lastly, we will leverage our strong balance sheet, with more than $3 per share in cash, to maximize the COVID-19 tailwinds, fund R&D in our non-COVID businesses, and fuel our business development activities. For these reasons, we think we are in an excellent position to capitalize on multiple fronts and drive further growth in the coming quarters.

With that, operator, please open the call up 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

MAY 2021

DNAgenotek™ Diversigen® novosanis

Forward-Looking Statements Disclaimer

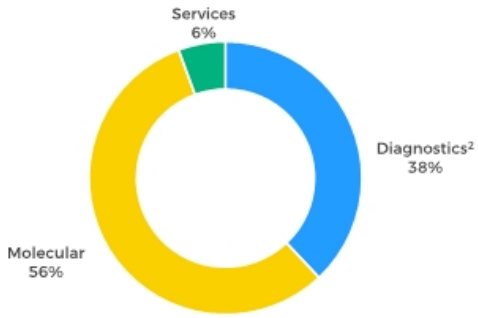
This presentation contains certain forward-looking statements, including with respect to expected revenues and earnings/loss per share. Forward-looking statements are not guarantees of future performance or results. Known and unknown factors that could cause actual performance or results to be materially 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, **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
- **$240 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 March 31,** 2020

[2] Infectious Disease and Risk Assessment Testing

Investment Rationale

Multiple Near-term COVID-19 Opportunities andLong-term Growth Drivers

- Well positioned to simplify global COVID-19 testing:
  - Two self-collection devices for molecular testing received EUAs + CE-IVD marks and are in wide use
  - EUA application submitted for COVID-19 rapid antigen test for Prescription home use and Professional use in point-of-care settings with plans to pursue OTC indication
  - Data collected for lab-based oral fluid antibody test 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
- $240 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 March 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 for healthcare professionals and consumers

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**

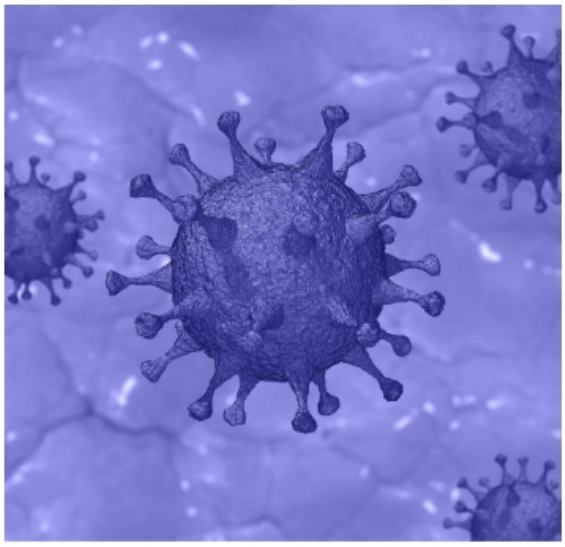
- **Our unique platform for HIV and HCV provides accurate and easy-to-administer testing methods**

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 **home** 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

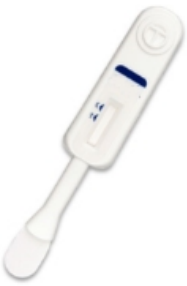
ORAgene·Dx

OM-505**
OGD-500

*As of 5/4/21

**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 **Home** Test



Simple "swab, swirl, see" process using samples collected from lower nostrils

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

Swab is fully integrated into the test stick eliminating dependence on scarce NP swabs

Enables testing scale

- EUA submitted in Q1 2021 for Prescription home test and Professional POC test
- Simple, easy-to-use test to detect active COVID-19 infection **anytime, anywhere** with direct results available a short time later on the test stick
- No instrumentation or laboratory analysis needed to interpret results
- Based on proven OraQuick® platform (HIV, HCV, Ebola) with over 80 million tests sold
- Expanding manufacturing capacity to meet anticipated demand, ahead of EUA

Image shows OraQuick lateral flow platform

OraSure's COVID-19 Rapid Antigen **Home** 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
- Data requested by FDA collected; plan to resubmit as two separate EUAs, per FDA request
- Product currently sold as Research Use Only (RUO) and in use by customers

*As of 5/3/21

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

OraQuick Coronavirus Rapid AntigenHome Test

Today	Q2 2021	Q3 2021	Q2 2022
Current capacity for **44 million** OraQuick tests 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 in Q2**	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	Q4 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 80 million** units per year	Further expansion will allow **105 million** total kits per year including non-COVID kits

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

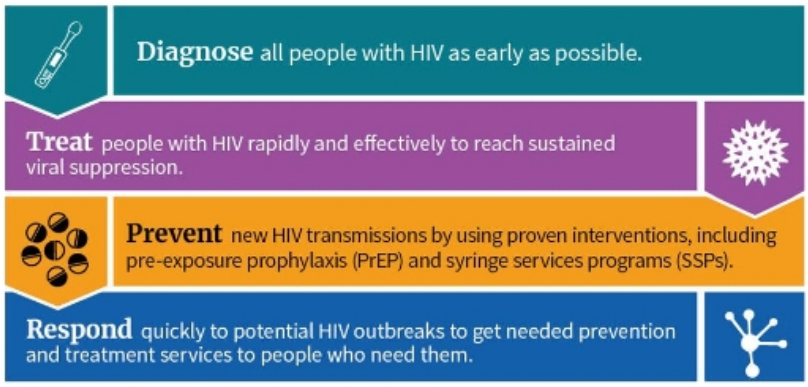
First and only rapid HIV OTC test approved by FDA
First and only WHO-prequalified rapid oral HIV self-test

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

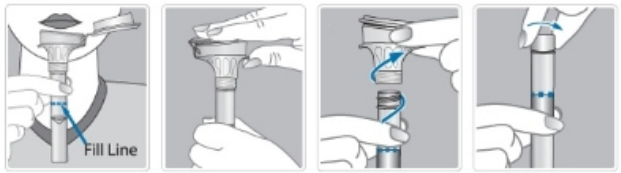
Opportunities in Substance Abuse Testing

- 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

DNAgenotek™



- 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

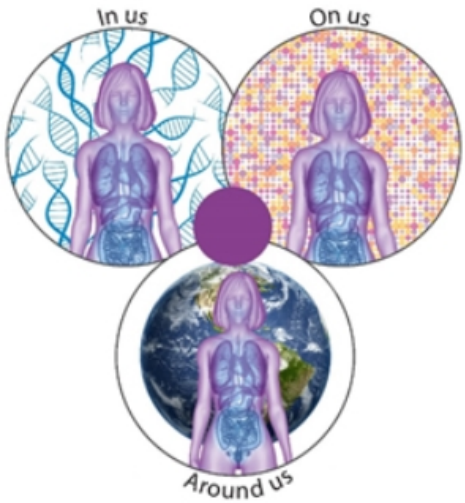
The microbiome is believed to influence many diseases and biological processes

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

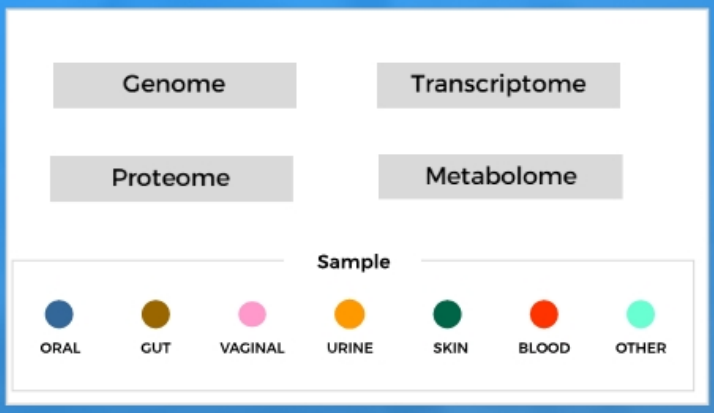
Multiple research reports project mid-teens growth for the microbiome market from 2019-2024



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
- **$240** 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 March 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
- Non-COVID business is showing resiliency
- 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