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): November 4, 2020

OraSure Technologies, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware	**001-16537**	**36-4370966**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

220 East First Street **Bethlehem, Pennsylvania**	**18015-1360**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's telephone number, including area code: 610-882-1820

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

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the Registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Emerging growth company ☐

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

Item 2.02 – Results of Operations and Financial Condition.

On November 4, 2020, OraSure Technologies, Inc. (the "Company") issued a press release announcing its consolidated financial results for the quarter and nine months ended September 30, 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 November 4, 2020, 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 and nine months ended September 30, 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.

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 November 4, 2020, announcing consolidated financial results of OraSure Technologies, Inc. for the quarter and nine months ended September 30, 2020 and certain other matters.
99.2	Prepared Remarks of Stephen S. Tang, Ph.D. and Roberto Cuca for OraSure Technologies, Inc. Third Quarter 2020 Analyst/ Investor Conference Call Held November 4, 2020.
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: November 4, 2020

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

OraSure Technologies, Inc.

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OraSure Technologies, Inc. Announces Third Quarter 2020 Financial Results and Provides Update on COVID-19 Developments

Net Third Quarter Revenues of $48.0 Million Increased 33% Year-Over-Year, Driven by $18.4 Million in Sales of Oral Fluid Collection Devices for COVID-19 Molecular Testing

Company Has Submitted EUA Application For Its Lab-based Oral Fluid SARS-CoV-2 Antibody Test

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

BETHLEHEM, PA, November 4, 2020 (GLOBE NEWSWIRE) -- OraSure Technologies, Inc. (NASDAQ: OSUR), a leader in point-of-care diagnostic tests, specimen collection devices, and microbiome laboratory and analytical services, today announced its financial results for the three- and nine-month periods ended September 30, 2020.

“We achieved strong top-line results in the third quarter driven by the performance of our Molecular Solutions business unit, which marked its highest quarter ever, with $31.7 million in total revenue. The Company’s ability to quickly respond to the need for increased COVID-19 testing resulted in $18.4 million in sales of sample collection devices for molecular testing in the third quarter, which is more than double the COVID-19 related revenue achieved in the first half of the year,” said Stephen S. Tang, Ph.D., President and Chief Executive Officer. “We are confident in our ability to meet the massive and persistent need for COVID-19 testing and sample collection. We recently submitted an application for Emergency Use Authorization (EUA) to the U.S. Food and Drug Administration (FDA) for our laboratory-based oral fluid SARS-CoV-2 Antibody test. To date there are no oral fluid antibody tests for COVID-19 authorized for sale in the U.S. We continue to make progress on our rapid antigen self-test and have completed studies to confirm the assay’s proprietary chemistry. Additionally, we were pleased to see growth in the quarter from our international HIV business.”

Third Quarter Financial Highlights

- Net revenues for the third quarter of 2020 were $48.0 million, a 33% increase from the third quarter of 2019. Net product and services revenues were $46.7 million, a 32% increase from the third quarter of 2019.

- Total product and service revenues for the Company's Molecular Solutions business unit were $31.2 million during the third quarter of 2020, an increase of 79% from the third quarter of 2019. This increase included $18.4 million in sales of oral fluid sample collection devices for COVID-19 molecular testing, which was partially offset by a decrease in genomics sales.
- International sales of the Company's OraQuick® HIV Self-Test increased 17% compared to the third quarter of 2019.
- Net income for the third quarter of 2020 was $1.0 million, or $0.01 per share on a fully-diluted basis, compared to net income of $13.1 million, or $0.21 per share on a fully-diluted basis, for the third quarter of 2019.
- Cash and investments totaled $263.7 million at September 30, 2020.

COVID-19 Update

Molecular/PCR:

- **In the third quarter, sales of oral fluid collection devices for molecular/PCR COVID-19 testing grew substantially, two of the Company's collection devices received Emergency Use Authorization (EUA), and the Company's collection devices are expected to be part of future customer EUAs.**
    - COVID-19 testing revenue grew to $18.4 million in the third quarter, up 118% from the second quarter of 2020. About half of these sales were to customers not currently holding EUAs.
    - The OMNIgene®•ORAL (OM-505, OME-505) and the ORAcollect®•RNA (OR-100, ORE-100) collection devices were granted EUAs by the FDA for the collection, stabilization and transport of saliva specimens suspected of containing SARS-CoV-2 RNA. The authorizations also allow the products to be used as a component of an authorized or cleared self-collection kit for unsupervised home-use. This means the devices can be part of a kit that is authorized under its own EUA for use by an individual to collect saliva specimens at home.[1] Both devices also have CE marking for in vitro diagnostic use in the European Union.
    - The Company's molecular collection kits have also been included in six EUAs granted by the FDA to DNA Genotek customers for COVID-19 testing.
    - Costco is selling COVID-19 saliva collection kits in conjunction with P23 Labs, which received an FDA EUA for the laboratory test workflow with its PCR test for COVID-19. The workflow includes OMNIgene•ORAL as the saliva collection device.

[1]The ORAcollect•RNA and OMNIgene•ORAL sample collection devices have not been FDA cleared or approved; the devices have been authorized by FDA under an EUA. The ORAcollect•RNA and OMNIgene•ORAL sample collection devices have been authorized only to collect, stabilize, and maintain during transport, saliva specimens suspected of containing SARS-CoV-2 ribonucleic acid (RNA), not for any other viruses or pathogens; and the ORAcollect•RNA and OMNIgene•ORAL sample collection devices are only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in medical devices during the COVID-19 outbreak under Section564(b)(1) of the Federal Food, Drug, and Cosmetic Act,21U.S.C. §360bbb-3(b)(1),unless the authorization is terminated or revoked sooner.

Antibody:

- **OraSure recently submitted an EUA application to the FDA for its laboratory-based oral fluid SARS-CoV-2 Antibody ELISA test. To date, there are no oral fluid antibody tests for COVID-19 authorized for sale in the U.S.**
    - The Company plans to commercialize the laboratory-based test in the fourth quarter, subject to receipt of the EUA.
    - The OraSure SARS-CoV-2 Antibody ELISA is intended for qualitative detection of total antibodies (including IgM/IgA/IgG) to SARS-CoV-2 in human oral fluid specimens collected with the OraSure Oral Antibody Collection Device.
    - Oral sample collection is quick, painless, non-invasive and requires less human contact than a blood draw, minimizing the need for personal protective equipment and reducing exposure to potentially infected patients.
    - 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, and then later 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 recent or prior infection.
    - Antibody tests are well suited for community surveillance and seroprevalence studies to identify people in a population or community who have antibodies against an infectious disease such as COVID-19.

Antigen:

- **The Company continues to make progress on its OraQuick® Coronavirus Rapid Antigen Self-Test and expects to apply for its first EUA in the first quarter of 2021. To date, there are no self-tests authorized in the U.S. to detect active COVID-19 infection that enable individuals to test themselves and read the results at the point of collection with no instrumentation needed**.
    - Between now and the filing of the EUA application OraSure will finalize the device design and complete the EUA studies necessary to demonstrate achievement of the high performance standards the FDA demands of a self-test.
    - Subject to receipt of an EUA, this product would test for active COVID-19 infection using nasal samples self-collected from the lower nostril. Results would be available at the point of collection, with no instrumentation or laboratory analysis needed to interpret results.
    - Subject to regulatory approvals, the Company intends to sequentially introduce its antigen test to the market for three different uses:
        - **Professional Test** for use at drive-through sites, physician offices, public health testing sites, and employer/university health centers. In this instance, a physician would prescribe the test and the patient would conduct a self-swab in the presence of a healthcare provider who would then interpret the results.
        - **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. In this instance, a physician would prescribe the test and the patient would conduct a self-swab at home, or in any location, where they would then interpret their own results.

        - **OTC Self-Test** for use by consumers who would purchase online or at retail without prescription, and conduct the test and receive the results themselves anytime, anywhere.
    - OraSure expects to file for the Professional Test EUA in Q1 2021, with the Prescription Self-Test and OTC Self-Test EUAs to follow as soon as possible thereafter. Although the timing of the EUA receipt is subject to FDA review, the Company will be prepared to launch the test, subject to authorization, without delay.

Manufacturing:

- **OraSure's plans to increase manufacturing capacity to meet demand for COVID-19 sample collection kits and tests continue on schedule.**

Financial Results for the Three Months Ended September 30, 2020

Net revenues for the third quarter of 2020 of $48.0 million increased 33% from the comparable period of 2019, primarily as a result of strong sales of molecular sample collection kits for COVID-19 testing, an increase in international sales of the Company's HIV Self-Test and in laboratory service revenues. These increases were partially offset by lower sales of the Company's genomics, risk assessment, HCV, and domestic HIV products.

Gross profit percentage was 63% and 60% for the three months ended September 30, 2020 and 2019, respectively. Gross profit percentage in the third quarter of 2020 benefited from an improved product mix associated with higher gross profit percentage product sales.

For the three months ended September 30, 2020, operating expenses were $25.9 million, an increase of $17.3 million from the $8.6 million reported for the three months ended September 30, 2019. This increase was due primarily to increased spend associated with COVID-19 product development and the inclusion of expenses incurred by the Company's newly acquired subsidiaries, UrSure and Diversigen, whose results were not included in the third quarter of 2019. In addition, operating expenses in the third quarter of 2019 were reduced by a gain on the sale of the Company's cryosurgical business of $10.1 million and a $2.4 million decrease in the change in the fair value of contingent acquisition consideration.

The Company generated operating income of $4.4 million in the third quarter of 2020 compared to operating income of $13.1 million in the third quarter of 2019.

During the third quarters of 2020 and 2019, the Company recorded income tax expense of $3.7 million and $1.2 million, respectively. Income tax expense in both periods largely consisted of foreign taxes due.

Fourth Quarter 2020 Guidance

The Company expects fourth quarter 2020 net revenues to range from $55 million to $60 million.

Financial Data

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Results of Operations				
Net revenues	$ 48,011	$ 35,989	$ 108,866	$ 104,937
Cost of products and services sold	17,722	14,343	45,182	40,193
Gross profit	30,289	21,646	63,684	64,744
Operating expenses:				
Research and development	8,007	4,619	20,575	13,525
Sales and marketing	7,849	8,955	25,339	23,937
General and administrative	10,108	7,556	30,442	23,748
Change in fair value of acquisition-related contingent consideration	(60)	(2,387)	390	(843)
Gain on sale of business	—	(10,149)	—	(10,149)
Total operating expenses	25,904	8,594	76,746	50,218
Operating income (loss)	4,385	13,052	(13,062)	14,526
Other income	314	1,195	1,960	2,243
Income (loss) before income taxes	4,699	14,247	(11,102)	16,769
Income tax expense	3,659	1,169	5,680	2,551
Net income (loss)	$ 1,040	$ 13,078	$ (16,782)	$ 14,218
Income (loss) per share:				
Basic	$ 0.01	$ 0.21	$ (0.25)	$ 0.23
Diluted	$ 0.01	$ 0.21	$ (0.25)	$ 0.23
Weighted average shares:				
Basic	71,537	61,726	66,088	61,656
Diluted	72,662	62,143	66,088	62,172

	Three Months Ended September 30,				
	Dollars			Percentage of Total Net Revenues	
	2020	2019	% Change	2020	2019
Market					
Infectious disease testing	$ 13,224	$ 13,588	(3) %	28 %	38 %
Risk assessment testing	2,316	3,312	(30)	5	9
Cryosurgical systems	—	961	(100)	—	3
Molecular collection systems	31,209	17,438	79	66	48
Net product and service revenues	46,749	35,299	32	99	98
Royalty income	450	758	(41)	-	2
Other	812	(68)	—	2	-
Net revenues	$ 48,011	$ 35,989	33 %	101 %	100 %

	Nine Months Ended September 30,				
	Dollars			Percentage of Total Net Revenues	
	2020	2019	% Change	2020	2019
Market					
Infectious disease testing	$ 36,625	$ 39,273	(7) %	34 %	37 %
Risk assessment testing	6,848	9,246	(26)	6	9
Cryosurgical systems	—	7,054	(100)	—	7
Molecular collection systems	62,499	45,325	38	58	43
Net product and service revenues	105,972	100,898	5	98	96
Royalty income	1,623	2,956	(45)	1	3
Other	1,271	1,083	17	1	1
Net revenues	$ 108,866	$ 104,937	4 %	100 %	100 %

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2020	2019	% Change	2020	2019	% Change
OraQuick® Revenues						
Domestic HIV	$ 3,909	$ 4,259	(8) %	$ 11,323	$ 13,024	(13) %
International HIV	6,865	5,891	17	17,697	15,313	16
Net HIV revenues	10,774	10,150	6	29,020	28,337	—
Domestic HCV	1,186	1,977	(40)	3,437	5,907	(42)
International HCV	1,033	1,129	(9)	2,772	3,569	(22)
Net HCV revenues	2,219	3,106	(29)	6,209	9,476	(34)
Net product revenues	$ 12,993	$ 13,256	(2) %	$ 35,229	$ 37,813	(7) %

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2020	2019	% Change	2020	2019	% Change
Molecular Collection Systems Revenues						
Genomics	$ 8,519	$ 13,647	(38) %	$ 23,381	$ 35,449	(34) %
Microbiome	1,828	1,878	(3)	4,259	5,325	(20)
COVID-19	18,441	—	N/A	27,307	—	N/A
Laboratory services	2,418	1,618	49	7,472	3,947	89
Other product revenues	3	295	(99)	80	604	(87)
Net product and service revenues	31,209	17,438	79	62,499	45,325	38
Other	488	821	(41)	1,834	3,277	(44)
Net product and service revenues	$ 31,697	$ 18,259	74 %	$ 64,333	$ 48,602	32 %

Condensed Consolidated Balance Sheets (Unaudited)

	September 30, 2020	December 31, 2019
Assets		
Cash and cash equivalents	$ 162,859	$ 75,715
Short-term investments	72,961	80,623
Accounts receivable, net	30,638	36,948
Inventories	30,488	23,155
Other current assets	6,031	8,109
Property, plant and equipment, net	39,056	30,339
Intangible assets, net	18,111	14,674
Goodwill	39,480	36,201
Long-term investments	27,841	33,420
Other non-current assets	8,945	10,111
Total assets	$ 436,410	$ 349,295
Liabilities and Stockholders' Equity		
Accounts payable	$ 14,377	$ 9,567
Deferred revenue	5,311	3,713
Contingent consideration obligation	764	3,500
Other current liabilities	16,775	15,933
Non-current contingent consideration obligation	3,176	112
Other non-current liabilities	8,115	9,325
Stockholders' equity	387,892	307,145
Total liabilities and stockholders' equity	$ 436,410	$ 349,295

Additional Financial Data (Unaudited)

	Nine Months Ended September 30,	
	2020	2019
Capital expenditures	$ 11,234	$ 7,961
Depreciation and amortization	$ 7,051	$ 5,532
Stock-based compensation	$ 5,913	$ 3,283
Cash provided by operating activities	$ 2,196	$ 10,838

Conference Call

The Company will host a conference call and audio webcast for analysts and investors to discuss the Company's 2020 third 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 #9459222 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, November 18, 2020, 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, CoreBiome (now operating under the Diversigen brand), UrSure and Novosanis, OraSure provides its customers with end-to-end solutions that encompass tools, services and diagnostics. The OraSure family of companies is a leader in the development, manufacture, and distribution of rapid diagnostic tests, sample collection and stabilization devices, and molecular services solutions designed to discover and detect critical medical conditions. OraSure's portfolio of products is sold globally to clinical laboratories, hospitals, physician's offices, clinics, public health and community-based organizations, research institutions, government agencies, pharma, commercial entities and direct to consumers. For more information on OraSure Technologies, please visit www.orasure.com.

Important Information

This press release contains certain forward-looking statements, including with respect to expected revenues, 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, 2019, Quarterly Reports on Form 10-Q, and other filings with the SEC. Although forward-looking statements help to provide information about future prospects, readers should keep in mind that forward-looking statements may not be reliable. Readers are cautioned not to place undue reliance on the forward-looking statements. The forward-looking statements are made as of the date of this press release and OraSure Technologies undertakes no duty to update these statements.

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Exhibit 99.2

OraSure Technologies, Inc.
2020 Third Quarter
Analyst-Investor Conference Call
November 4, 2020

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 third quarter 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 with 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, 2019, 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 know last night was a late night for many, so I appreciate your attention and interest this afternoon.

I hope you and your families are faring well during these challenging times. As you will hear today OraSure had a strong quarter. Our molecular sample collection devices are widely used for lab-based COVID-19 molecular tests. We've submitted our lab-based oral fluid SARS-CoV-2 antibody test to the FDA for Emergency Use Authorization (or EUA), and we expect our rapid coronavirus antigen test to be ready for EUA submission in Q1 2021.

Overall, our ability to address the COVID-19 pandemic through sample collection has contributed positively to our business in the third quarter. We generated $48 million in revenue this quarter -- a 33% increase over the prior year.

This performance was driven by our Molecular Solutions business unit. Our products continue to be in demand as the need for COVID-19 testing continues to rise. The Molecular Solutions

business unit generated $18.4 million in COVID-19 related sales in Q3, which is more than double the COVID-19 revenue achieved in the first half of the year.

Globally, we're seeing what appears to be the third wave of the pandemic, as the number of COVID-19 cases surges here in the U.S. and around the world. COVID-19 forecasts are not completely in alignment, but most predict that the current impact will be felt for another year or two years, with COVID-19 existing at some level in perpetuity, as the disease becomes endemic.

While there is hope that a vaccine will be approved by year-end or early 2021, we expect it will take quite some time for a vaccine to be broadly available in the U.S. and internationally. Until then – and beyond – testing will continue to play a critical role in managing the pandemic.

We expect OraSure to continue to play an important and growing role to address the massive and persistent need for COVID-19 testing and sample collection.

During our Q2 Earnings Call, I cited an estimate from the Rockefeller Foundation that called for 1.5 billion COVID-19 tests per year to get the pandemic under control. Since then, the Foundation has increased its estimate to approximately 2.3 billion tests per year, in the U.S. alone.

With this in mind, we expect there will continue to be strong demand for COVID-19 testing for the foreseeable future. And we are prepared to help meet that need with our innovative solutions for testing and sample collection.

All of OraSure's COVID-19 products are centered on the easy self-collection of samples by individuals, an area in which we have long experience. Our products are designed to make it easier to obtain results, either through oral fluid sample collection for PCR and antibody testing, or through a full diagnostic test that consumers can conduct on their own.

I'd like to address our current COVID-19 innovations, beginning with sample collection for molecular, or PCR, testing, which is the gold standard when it comes to detecting active COVID-19 infection. Our experience in innovating devices to facilitate at-home, self-collection of samples

has led to significant interest in our collection devices for molecular COVID-19 testing. Devices made by our DNA Genotek subsidiary support both PCR and sequencing-based COVID-19 tests, and these collection kits are now being used for collection at home by consumers, or by laboratory staff and healthcare providers.

Notably, two of our sample collection devices, ORAcollect®•RNA and OMNIgene®•ORAL received EUAs from the FDA in October.

Both EUAs allow for the collection, stabilization and transport of saliva specimens suspected of containing SARS-CoV-2 RNA. The authorizations also allow the products to be used as a component of an authorized or cleared self-collection kit for unsupervised home-use. This means the devices can be part of a kit that is authorized under its own EUA for the use by an individual to collect saliva specimens at home.

It's important to note that these devices are not COVID tests. They are components of the tests that would be run in a lab. DNA Genotek's customers, which are typically laboratories offering a COVID-19 test pipeline, would use the devices as the saliva sample collection method for their lab-based COVID-19 tests.

OMNIgene ORAL and ORAcollect•RNA are two of three molecular test collection kits that have been included in six EUAs DNA Genotek customers obtained from the FDA.

But the EUAs are only one part of the molecular success story. About half of the third quarter sales of molecular sample collection devices for COVID applications were to customers not currently holding EUAs, with the balance of customers operating their COVID tests as laboratory developed tests, or LDTs.

Use of DNA Genotek collection kits continues to grow in back-to-work settings, back-to-school programs and laboratory testing. For example, 30,000 students were tested at the University of Kansas before returning to campus, using kits from Clinical Reference Laboratory. And 64 State

University of New York campuses are testing students and employees with tests developed by Quadrant Biosciences.

Our OraGene DX saliva collection device is available in Albertsons Companies pharmacies throughout the U.S., as part of Phosphorus Diagnostics' COVID-19 testing program. And, back-to-work programs are integrating COVID-19 testing, monitoring, assessment and access to telemedicine visits for companies, through Azova, Inc.

Additionally, Costco is selling COVID-19 saliva collection kits in conjunction with P23 Labs, which received an FDA EUA for the laboratory test workflow with their PCR test. The workflow includes OMNIgene•ORAL as the saliva collection device.

Easy self-collection of samples is essential to ensuring the safety of workers and students, and their families, by helping to curtail the spread of the virus, as people resume normal aspects of life.

We expect the sales of molecular collection kits for COVID-19 testing to continue to grow, within the U.S. with existing and new customers, but also outside the US as other nations complete their validation work around saliva as a sample type.

Moving on to **antibody testing**, we have submitted an EUA application to the FDA for our oral fluid SARS-CoV-2 Antibody ELISA and are in the review process. To date there are no oral fluid antibody tests for COVID-19 authorized for sale in the U.S. Pending receipt of an EUA from the FDA, we have the potential to be the first.

This lab-based, oral-fluid test is intended for the qualitative detection of total antibodies to SARS-CoV-2. We have a number of interested customers and are prepared to commercialize our antibody test in the fourth quarter of this year, subject to receipt of the EUA.

Oral sample collection is quick, painless, non-invasive and requires less human contact in comparison to a blood draw, both minimizing the need for personal protective equipment, or PPE, and reducing exposure to potentially infected patients.

With OraSure's test, individuals would use a collection pad to self-collect an oral fluid sample under the direction of a healthcare professional. The sample would then be placed into the OraSure Oral Antibody Collection Device buffer for storage and transport. The sample would later be dispensed onto our proprietary ELISA microplate for analysis in a commercial laboratory to determine the presence of antibodies in the oral fluid sample.

Potential locations for sample collection include physician's offices, labs, testing facilities and drive-through testing sites.

We are evaluating whether the EUA subsequently could be amended to permit an unsupervised in-home sample collection option, with samples sent to a central laboratory for testing.

At an epidemiologic level, it is extremely important for public health officials to have an accurate understanding of who has been infected. Antibody tests are well suited for community surveillance and seroprevalence studies, as they can help identify people in a population or community that have mounted antibodies against COVID-19.

According to the Centers for Disease Control and Prevention (CDC), this information could be used to estimate the number of people who have been previously infected with SARS-CoV-2 and were not included in official case counts. This is critical to maintaining an accurate count of infection rates and informing decisions that can advance public health.

Antibody tests could also potentially complement vaccine development and implementation.

Turning to our **antigen test**, OraSure continues to make tangible progress in the development of our OraQuick® Coronavirus rapid antigen self-test.

Subject to receipt of an EUA, this product would test for active COVID-19 infection, using nasal samples self-collected from the lower nostril. Results would be available at the point of collection, with no instrumentation needed to interpret results.

To date, there are no self-tests authorized in the U.S. that enable individuals to test themselves and read the results at the point of collection with no instrumentation needed.

We are highly confident that we can bring to market an accurate test that meets FDA standards for a rapid self-test.

As we disclosed previously, we intend to sequentially introduce our antigen test for three different uses, subject to regulatory authorization.

First, a Professional Test for use at drive-through sites, physician offices, public health testing sites, and employer and university health centers. In this instance, a physician would prescribe the test and the patient would conduct a self-swab in the presence of a healthcare provider who would then interpret the results.

Second, a Prescription Self-Test for use by individual consumers, which could be offered by employers or universities on- or off-site, or by physicians or public health authorities via remote testing or telemedicine. In this instance, a physician would prescribe the test and the consumer would conduct the self-swab at home, or any location, where they would then interpret their own results.

Thirdly, an Over-The-Counter (or OTC) Self-Test for use by consumers who would purchase online or at retail without prescription, and who would conduct the test and receive the results themselves anytime, anywhere.

We expect to file for the Professional Test EUA in Q1 2021, and the Prescription Self-Test and OTC Self-Test EUAs to follow as soon as possible thereafter.

This is a complex process that cannot be rushed. Between now and the filing of the EUA application we will finalize the device design and complete the EUA studies necessary to determine achievement of the high performance standards as the FDA demands of a self-test.

We are committed to delivering a rapid antigen self-test that meets FDA requirements for a self-test – and the needs of the pandemic – as well as our own rigorous standards for quality and performance.

We have made a great amount of progress and have completed important benchmarks. Limits of Detection studies were conducted with live coronavirus at a certified third-party laboratory to evaluate the analytical sensitivity in comparison to an EUA-authorized, instrument-free, rapid antigen test. The results from the comparison provided further confidence that the proprietary chemistries incorporated on OraSure's lateral flow test strip will deliver the sensitivity needed.

In addition, the Company currently has prototypes on the OraQuick platform under evaluation at clinical testing locations, continually providing data on the performance of the design against FDA requirements.

Based on what we know at this time, we believe there will be significant demand for our antigen self-test in 2021 as it puts control of the process in the hands of the user. In the U.S. alone, the Rockefeller Foundation estimates demand at approximately 2.3 billion tests annually. The Rockefeller Foundation and others have identified fast and frequent testing as a key to getting COVID-19 under control. This is exactly what our antigen test will deliver.

The timing of an EUA is subject to FDA review. Once EUA is obtained, we are prepared to launch the test without delay.

Moving on to manufacturing, early on in this pandemic, we understood that increasing our manufacturing capacity would be key. To that end, we are confirming that our plans to increase manufacturing capacity to meet demand for COVID-19 sample collection kits and tests continues on track as outlined last quarter.

With that, I'll hand it over to Roberto for a report on the quarter's financials. Roberto…

Financial Results – Roberto Cuca

Thanks, Steve.

As Steve mentioned earlier, our third quarter net revenues increased 33% to $48.0 million from the $36.0 million reported in the third quarter of 2019, primarily as a result of strong sales of molecular sample collection kits for COVID-19 testing, increased international sales of the Company's HIV Self-Test and higher laboratory services revenues, partially offset by lower sales across all of our other product lines primarily due to the impact of the COVID-19 pandemic. Net product and services revenues were $46.7 million, a 32% increase from the third quarter of 2019.

Total product and services revenues for the Company's molecular business unit were $31.2 million during the third quarter of 2020, an increase of 79% from the third quarter of 2019. This increase included $18.4 million in sales of oral fluid sample collection devices for COVID-19 molecular testing, which was partially offset by a decrease in genomics sales.

International sales of the Company's OraQuick® HIV Self-Test increased 17% compared to the third quarter of 2019 largely due to higher sales into Africa.

Gross profit percentages were 63% and 60% for the three months ended September 30, 2020 and 2019, respectively. Gross profit percentage in the third quarter of 2020 benefited from an improved product mix associated with higher gross profit percentage product sales.

Net income for the third quarter of 2020 was $1.0 million, or $0.01 per share on a fully-diluted basis, compared to net income of $13.1 million, or $0.21 per share on a fully-diluted basis, for the third quarter of 2019. Third quarter 2019 results included two gains associated with the sales of a business and a change in the estimated fair value of our acquisition-related contingent consideration together totaling $12.5 million which accounted for approximately $0.16 per share in 2019.

Cash and investments totaled $263.7 million at September 30, 2020.

As we disclosed in our press release, we expect revenues of $55 million to $60 million in the fourth quarter of 2020. As we discussed on our second quarter earnings call, we expect that as we've just seen with the third quarter, non-COVID revenues will be flat or improved for each business unit in the fourth quarter compared to the second quarter and that COVID-19 product sales will add to this performance. For the full year, we continue to expect that, excluding cryosurgical revenues from 2019, non-COVID-19 revenues in both the infectious disease and molecular collections lines of business will be down in 2020 compared to the year ago period, with molecular collections bearing the greater impact. However, as our revenue guidance for the fourth quarter indicates, we anticipate that the revenue opportunities for our COVID-19 sample collection products and tests will more than offset the year-on-year decrease in our non-COVID-19 lines of business such that our total revenues will be higher in 2020 than in 2019.

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

Steve Tang

Thank you, Roberto. Turning to our legacy businesses, HIV testing remains an important area of global focus for OraSure. Access to testing during the pandemic has been challenging as in-person testing facilities for HIV in the United States have been, in many cases, shut down. Self-testing, which enables social distancing and helps protect healthcare workers and test users alike, is a key strategy in the efforts to help people know their HIV status, especially under the current global pandemic conditions.

Overall, our net HIV test revenues increased 6% over Q3 2019. This was driven by strong International sales of our OraQuick® HIV Self-Test that increased 17% compared to the third quarter of 2019. To put this in perspective, a UNAIDS report noted significant decreases in HIV testing services between January and July in nearly all countries with available data.

CDC and other government agencies have encouraged health departments at all levels to consider HIV self-testing as an additional testing strategy to reach persons most affected, which speaks to the usability and convenience of our at-home tests which allow individuals to test themselves and receive the results at home. To-date, OraSure offers the only over-the-counter self-test for HIV in the United States, and the only World Health Organization (or WHO) prequalified rapid oral fluid HIV self-test globally.

I'd also like to briefly touch on our collection business outside of COVID-19. Although not yet back to pre-COVID levels, we saw increases in our genomics and microbiome kit sales, quarter over quarter. Third quarter kit sales for genomics and microbiome were up 32% and 114% versus the prior quarter respectively, driven by strength in the commercial market. Academic sales also increased quarter over quarter but to a lesser degree.

Our laboratory services revenues showed a slight increase over the previous quarter. We continue to innovate in the microbiome arena adding new products and services. Our DNA Genotek subsidiary has launched a skin microbiome collection kit. OMNIgene•SKIN offers a standard method for collecting skin microbiome samples from sebaceous, dry and wet skin sites, which will aid researchers in obtaining reproducible high-quality samples.

In a great example of how our microbiome services and product teams complement each other, a startup company, Pure Culture Beauty has partnered with DNA Genotek and Diversigen to use data and science to deliver a comprehensive, customized skincare regimen to its customers. DNA Genotek will supply the OMNIgene•SKIN microbiome collection kits and Diversigen will provide full microbiome analytical services, offering a complete understanding of the users' skin microbiome.

We continue to believe in the promise of our microbiome products and services and look forward to continued growth.

In closing, our business momentum is strong and we expect that trend to continue as evidenced by our guidance. We see COVID-19 testing as a robust part of our business for now and the

foreseeable future. With molecular collection devices already driving significant revenue, and our antibody and antigen 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 understand the opportunity for our tests and sample collection kits is substantial and their role in the fight against COVID-19 is vital. We want to reiterate our confidence in OraSure's ability to bring our antibody and antigen tests to market. We believe they will be worthy of joining the list of our other highly regarded OraSure products.

With that, I will open up the call to your 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 collector products and commercialize such products for COVID-19 testing; changes in relationships, including disputes or disagreements, with strategic partners or other parties and reliance on strategic partners for the performance of critical activities under collaborative arrangements; ability to meet increased demand for the Company's products; impact of replacing distributors; inventory levels at distributors and other customers; ability of the Company to achieve its financial and strategic objectives and continue to increase its revenues, including the ability to expand international sales; ability to identify, complete, integrate and realize the full benefits of future acquisitions; impact of competitors, competing products and technology changes; reduction or deferral of public funding available to customers; competition from new or better technology or lower cost products; ability to develop, commercialize and market new products; market acceptance of oral fluid or urine testing, collection or other products; market acceptance and uptake of microbiome informatics, microbial genetics technology and related analytics services; changes in market acceptance of products based on product performance or other factors, including changes in testing guidelines, algorithms or other recommendations by the Centers for Disease Control and Prevention ("CDC") or other agencies; ability to fund research and development and other products and operations; ability to obtain and maintain new or existing product distribution channels; reliance on sole supply sources for critical products and components; availability of related products produced by third parties or products required for use of our products; impact of contracting with the U.S. government; impact of negative economic conditions; ability to maintain sustained profitability; ability to utilize net operating loss carry

forwards or other deferred tax assets; volatility of the Company's stock price; uncertainty relating to patent protection and potential patent infringement claims; uncertainty and costs of litigation relating to patents and other intellectual property; availability of licenses to patents or other technology; ability to enter into international manufacturing agreements; obstacles to international marketing and manufacturing of products; ability to sell products internationally, including the impact of changes in international funding sources and testing algorithms; adverse movements in foreign currency exchange rates; loss or impairment of sources of capital; ability to attract and retain qualified personnel; exposure to product liability and other types of litigation; changes in international, federal or state laws and regulations; customer consolidations and inventory practices; equipment failures and ability to obtain needed raw materials and components; the impact of terrorist attacks and civil unrest; and general political, business and economic conditions. These and other factors that could affect our results are discussed more fully in our Securities and Exchange Commission ("SEC") filings, including our registration statements, Annual Report on Form 10-K for the year ended December 31, 2019, Quarterly Reports on Form 10-Q, and other filings with the SEC. Although forward-looking statements help to provide information about future prospects, readers should keep in mind that forward-looking statements may not be reliable. Readers are cautioned not to place undue reliance on the forward-looking statements. The forward-looking statements are made as of the date of this call and we undertake no duty to update these statements.