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 3, 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 November 3, 2021, OraSure Technologies, Inc. (the "Company") issued a press release announcing its consolidated financial results for the quarter ended September 30, 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 November 3, 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 Scott Gleason, the Company's Interim Chief Financial Officer and Senior Vice President, Investor Relations and Corporate Communications, discussed the Company's consolidated financial results for the quarter ended September 30, 2021, and described certain business developments. A copy of the prepared remarks of Dr. Tang and Mr. Gleason is attached as Exhibit 99.2 to this Form 8-K and is incorporated herein by reference. A copy of a slide presentation used during the webcast conference call is attached as Exhibit 99.3 to this Form 8-K, is incorporated herein by reference and will be posted on the Company's website at www.orasure.com.

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 November 3, 2021, announcing consolidated financial results of OraSure Technologies, Inc. for the quarter ended September 30, 2021 and certain other matters.
99.2	Prepared Remarks of Stephen S. Tang, Ph.D. and Scott Gleason for OraSure Technologies, Inc. Third Quarter 2021 Analyst/ Investor Conference Call Held November 3, 2021.
99.3	Slide Presentation for OraSure Technologies, Inc. Third Quarter 2021 Analyst/Investor Conference Call Held August 3, 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: November 3, 2021

By: */s/ Jack E. Jerrett*

Jack E. Jerrett

Senior Vice President, General Counsel and Chief Compliance Officer

OraSure Technologies, Inc.

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OraSure Technologies Reports 3Q21 Revenue of $53.9 Million, Signs Three Major U.S. Government Contracts Positioning the Company for Significant InteliSwab™ Growth in FY22

- Third quarter revenue of $53.9 million grew 12% year-over-year; excluding COVID-19 product revenues, revenues for the quarter grew 37% from the prior year, demonstrating strong growth
- OraSure signs three major U.S. government contracts providing $205 million in government InteliSwab™ procurement, $109 million for InteliSwab™ manufacturing capacity build out, and $13.6 million to pursue full FDA 510(k) clearance and CLIA waiver for InteliSwab™
- Company increases financial guidance range for fiscal year 2021 and is now expecting revenues of $230-$233 million
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Management to Host Analyst/Investor Call and Webcast Today at 5:00 p.m. ET

BETHLEHEM, PA, November 3, 2021 (GLOBE NEWSWIRE) -- OraSure Technologies, Inc. (NASDAQ: OSUR), a leader in point-of-care and home diagnostic tests, specimen collection devices, and microbiome laboratory and analytical services, today announced its financial results for the three months ended September 30, 2021.

“OraSure demonstrated strong revenue growth and laid the foundation to dramatically scale the size of the Company in fiscal year 2022. Importantly, we signed three major contracts this quarter with the U.S. government: $205 million for InteliSwab™ COVID-19 Rapid Test procurement, $109 million for InteliSwab™ manufacturing capacity build out, and $13.6 million to pursue full FDA 510(k) clearance for InteliSwab™. These contracts position OraSure as an important part of the government’s global pandemic response and will lower our cost per product and broaden our customer reach.”

Dr. Tang continued, “We continue to view InteliSwab™ as an integral part of our long-term growth strategy, as an entrance into the respiratory rapid test market--the largest point-of-care testing market in the world. This provides an unprecedented opportunity to strategically transform our company and improve our long-term growth profile. Given the strong growth we anticipate in 2022, we are highly focused on execution and ramping our manufacturing production to meet demand. We are also actively working to bolster innovation both through internal research and development and external M&A which we believe will drive long-term sustained growth and value for our stockholders.”

Financial Highlights

- Net revenues for the third quarter of 2021 were $53.9 million, a 12% increase from the third quarter of 2020. Excluding COVID-19 product revenues, revenues for the quarter increased 37% year-over-year representing a continued recovery in the Company's core business.
- Total revenues from the Company's Diagnostic business unit were $23.5 million during the third quarter of 2021 and grew 44% relative to the same period last year. Revenue growth was driven predominantly by the addition of InteliSwab™ along with higher global HCV and risk assessment revenues.
- Total product and service revenues for the Company's Molecular Solutions business unit were $30.4 million during the third quarter of 2021, a decline of 4% from the third quarter of 2020. The decline was driven primarily by lower sales of the Company's COVID-19 molecular collection kits. Excluding these COVID-19 revenues, the molecular solutions business grew 87% year-over-year.
- Gross margin percentage in the third quarter was 39.8% compared to 63.1% in the prior year. Gross margins were negatively impacted by the build out of manufacturing capacity to support the InteliSwab™ COVID-19 Rapid Test launch, along with production inefficiencies and higher scrap rates as the Company worked through the scale-up process. Additionally, gross margins were negatively impacted by the expiration of the Bill and Melinda Gates Foundation subsidy for international OraQuick® HIV self-tests and a less favorable product mix.
- Operating loss in the third quarter was ($13.0) million compared to operating income of $4.4 million in the third quarter of last year. OraSure's operating loss in the quarter was driven by a ramp in investments to support the InteliSwab™ launch and higher sales projected for 2022, along with lower gross margins as described above.
- Net loss for the third quarter of 2021 was ($15.0) million, or ($0.21) per share on a fully-diluted basis, compared to a net income of $1.0 million, or $0.01 per share on a fully-diluted basis, for the third quarter of 2020.
- Cash flow used in operations in the quarter was ($22.6) million. Cash and investments totaled $202.3 million at September 30, 2021.

Recent Business Highlights

InteliSwab™ COVID-19 Testing

- Awarded a procurement contract from the Defense Logistics Agency (DLA) for the Company's InteliSwab™ COVID-19 Rapid Test for over-the-counter use, which the DLA estimated to have a value of $205 million. Under the terms of the contract, OraSure will provide its InteliSwab™ COVID-19 Rapid Test to up to 25,000 sites throughout the United States with the test purchases funded by the U.S. government. The contract will run from October 2021 through September 2022.
- Awarded a $109 million contract from the U.S. Department of Defense (DOD), in coordination with the Department of Health and Human Services, to build additional manufacturing capacity in the United States for InteliSwab™ COVID-19 rapid tests as part of the nation's pandemic preparedness plan. The federal funding will be used to expand OraSure's production capacity by 100 million tests annually, by March 2024.
- Announced that the Biomedical Advanced Research Development Authority (BARDA), part of the office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services, will provide up to $13.6 million in funding for the Company to obtain 510(k) clearance and Clinical Laboratory Improvement Amendments (CLIA) waiver for the InteliSwab™ COVID-19 Rapid Test

from the U.S. Food and Drug Administration (FDA). These authorizations will help ensure the continued availability of InteliSwab™ products long after the pandemic is declared over.

- OraSure has been scaling its weekly manufacturing production for InteliSwab™ and the Company believes it has isolated the scale-up challenges to variability in certain incoming raw materials and processing steps. We are currently working with vendors and third-party experts to work toward resolution. Importantly, as we look to January of next year, we believe we are on track to scale to approximately four million tests a month, our current installed capacity, assuming resolution of our manufacturing process.
- Received U.S. FDA authorization to amend the over-the-counter InteliSwab™ emergency use authorization to revise the indication for use such that those with symptoms only need to test once and serial testing is only required for those without symptoms and to create a new single-test over-the-counter product with this new indication.
- Submitted data from pediatric-specific usability and clinical studies to the U.S. FDA to expand the age range enabling use of InteliSwab™ with individuals two and older, and to revise our instructions to include the new InteliSwab™ Connect application for reporting of results.
- Confirmed that InteliSwab™ detects all variants of concern, including the Delta variant, via testing in third party laboratories with live virus.

Infectious Disease and Risk Assessment Testing

- Global OraQuick® HIV sales in the third quarter were $10.0 million versus $10.8 million in the prior year period. Despite global test volume growth, revenue declined year-over year due to the expected expiration of the Bill and Melinda Gates Foundation test subsidy when the Company's four year contract with the Foundation ended in the second quarter of 2021, as well as order timing changes between the second and third quarters.
- InteliSwab™ revenue in the third quarter was $7.7 million, limited by supply as production is scaling up.
- Global OraQuick® HCV sales grew 22% to $2.7 million in the third quarter compared to $2.2 million in the third quarter of 2020 as a result of the recovery in testing programs following the pandemic and new marketing initiatives.
- Risk assessment testing revenue grew 19% in the third quarter to $2.7 million compared to $2.3 million in 2020 primarily due to increased workplace drugs-of-abuse testing and insurance testing as economic conditions and hiring have improved.

Molecular Solutions

- Genomics collection kit revenue of $19.0 million for the third quarter of 2021 grew 125% year-over-year. The growth was driven predominantly by higher sales in the key markets of consumer genomics, disease risk management, companion animal and research as well as accelerated ordering patterns of certain consumer facing customers anticipating strong holiday sales.
- Sales of OraSure's sample collection devices for molecular/PCR COVID-19 testing decreased year-over-year to $6.3 million in the third quarter of 2021 compared to $18.8 million in the prior year period. The decline in revenue is attributable to lower testing volumes with core customers, as high vaccination rates and the increasing availability of rapid antigen tests impact lab-based PCR workplace and back to school testing programs.
- Total microbiome revenue, including kits and services, was $4.1 million in the quarter and grew 8% relative to the third quarter of last year. OraSure's Diversigen business now supports over 50 commercial customers including over 30 biopharmaceutical customers with 20 ongoing clinical trials.

- Announced plans to launch a new gut metatranscriptome collection kit and metatranscriptome service offering to our microbiome customers through our Diversigen subsidiary by the first quarter of fiscal year 2022.
- The Company has developed and submitted for FDA approval a new collection kit for gut microbiome which the company plans to launch commercially in the first half of fiscal year 2022.

Fiscal Year 2021 and Fourth Quarter 2021 Guidance

The Company is increasing its financial guidance range for 2021 and is now calling for revenues of $230 to $233 million compared to previous guidance which called for total revenues of approximately $230 million. For the fourth quarter of 2021, this translates to total revenue of $60 to $63 million. The Company continues to expect total InteliSwab™ revenue of approximately $30 million for the fiscal year.

Financial Data (Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Results of Operations				
Net revenues	$ 53,917	$ 48,011	$ 170,106	$ 108,866
Cost of products and services sold	32,449	17,722	79,639	45,182
Gross profit	21,468	30,289	90,467	63,684
Operating expenses:				
Research and development	8,596	8,007	25,270	20,575
Sales and marketing	13,886	7,849	33,836	25,339
General and administrative	12,499	10,108	33,680	30,442
Change in fair value of acquisition-related contingent consideration	(500)	(60)	(1,526)	390
Total operating expenses	34,481	25,904	91,260	76,746
Operating income (loss)	(13,013)	4,385	(793)	(13,062)
Other income	100	314	429	1,960
Income (loss) before income taxes	(12,913)	4,699	(364)	(11,102)
Income tax expense	2,102	3,659	12,241	5,680
Net income (loss)	$ (15,015)	$ 1,040	$ (12,605)	$ (16,782)
Earnings (loss) per share:				
Basic	$ (0.21)	$ 0.01	$ (0.18)	$ (0.25)
Diluted	$ (0.21)	$ 0.01	$ (0.18)	$ (0.25)
Weighted average shares:				
Basic	72,023	71,537	71,962	66,088
Diluted	72,023	72,662	71,962	66,088

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2021	2020	% Change	2021	2020	% Change
DIAGNOSTICS						
Infectious Disease Testing Revenues						
Domestic HIV	$ 3,440	$ 3,909	(12) %	$ 12,490	$ 11,323	10 %
International HIV	6,582	6,865	(4)	17,255	17,697	(2)
Net HIV revenues	10,022	10,774	(7)	29,745	29,020	2
Domestic HCV	1,827	1,186	54	5,580	3,437	62
International HCV	888	1,033	(14)	3,802	2,772	37
Net HCV revenues	2,715	2,219	22	9,382	6,209	51
Net OraQuick® revenues	12,737	12,993	(2)	39,127	35,229	11
COVID-19	7,675	63	NM	7,938	63	NM
Other infectious disease revenues	195	231	(16)	537	1,396	(62)
Total Infectious Disease	20,607	13,287	55	47,602	36,688	30
Risk Assessment	2,674	2,253	19	7,265	6,786	7
Other non-product revenues	230	774	(70)	2,501	1,060	136
TOTAL DIAGNOSTIC NET REVENUE	23,511	16,314	44	57,368	44,534	29
MOLECULAR SOLUTIONS						
Genomics	$ 19,018	$ 8,454	125	$ 49,333	$ 23,224	112
Microbiome	1,693	1,530	11	5,888	3,869	52
COVID-19	6,255	18,804	(67)	46,209	27,855	66
Laboratory services	2,406	2,280	6	8,017	6,798	18
Other product and services revenues	576	141	309	1,235	752	64
Net product and service revenues	29,948	31,209	(4)	110,682	62,498	77
Other non-product and service revenues	458	488	(6)	2,056	1,834	12
TOTAL MOLECULAR SOLUTIONS NET REVENUE	30,406	31,697	(4)	112,738	64,332	75
TOTAL NET REVENUES	$ 53,917	$ 48,011	12 %	$ 170,106	$ 108,866	56 %

	September 30, 2021	December 31, 2020
Assets		
Cash and cash equivalents	$ 134,962	$ 160,802
Short-term investments	50,065	48,599
Accounts receivable, net	40,075	38,835
Inventories	53,583	31,863
Other current assets	10,542	8,794
Property, plant and equipment, net	77,586	51,860
Intangible assets, net	15,221	17,904
Goodwill	40,264	40,351
Long-term investments	17,271	47,718
Other non-current assets	16,188	7,746
Total assets	$ 455,757	$ 454,472
Liabilities and Stockholders' Equity		
Accounts payable	$ 23,778	$ 17,407
Deferred revenue	3,488	4,811
Contingent consideration obligation	201	402
Other current liabilities	26,700	23,869
Non-current contingent consideration obligation	318	2,049
Other non-current liabilities	13,452	7,363
Stockholders' equity	387,820	398,571
Total liabilities and stockholders' equity	$ 455,757	$ 454,472

Additional Financial Date (Unaudited)	**Nine Months Ended September 30,**	
	2021	**2020**
Capital expenditures	$ 27,508	$ 11,234
Depreciation and amortization	$ 8,479	$ 6,880
Stock-based compensation	$ 5,155	$ 5,913
Cash (used in) provided by operating activities	$ (22,598)	$ 2,196

Conference Call

The Company will host a conference call and audio webcast for analysts and investors to discuss the Company's third quarter 2021 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 Scott Gleason, Interim 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 (888) 771-4371 (Domestic) or (847) 585-4405 (International) and reference Conference ID # 50214426 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, November 17, 2021, by dialing 855-859-2056 (Domestic) or 404-537-3406 (International) and entering the Conference ID # 50214426.

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.

Multiple government agencies, including the DOD and HHS are working to address COVID-19 testing needs. Development of the InteliSwab™ COVID-19 Rapid Test has been funded in whole or in part with federal funds

from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, Division of Research, Innovation and Ventures under contract number 75A50120C00061, utilizing Health Care Enhancement Act (HCEA) funding. The DoD's Defense Assisted Acquisition (DA2) Cell led the manufacturing expansion effort for the InteliSwab™ COVID-19 rapid test in coordination with the Department of the Air Force's Acquisition COVID-19 Task Force (DAF ACT). This effort was funded through the American Rescue Plan Act (ARPA) to enable and support domestic industrial base expansion for critical medical resources.

About InteliSwab™

OraSure has received Emergency Use Authorizations (EUA) from the U.S. Food and Drug Administration (FDA) for its InteliSwab™ COVID-19 rapid tests. The FDA has authorized the InteliSwab™ COVID-19 Rapid Test for Over-the-Counter (OTC) use without a prescription. FDA has also authorized the InteliSwab™ COVID-19 Rapid Test Pro for professional use in point of care (POC) CLIA-waived settings, and InteliSwab™ COVID-19 Rapid Test Rx for Prescription Home Use. These remarkably simple COVID-19 lateral flow tests use samples self-collected from the lower nostrils. InteliSwab™'s unique design incorporates a built-in swab fully integrated into the test stick. After users swab their lower nostrils, the test stick is swirled in a pre-measured buffer solution, and the result appears right on the test stick within 30 minutes, with no instruments, batteries, smartphone or laboratory analysis needed to see the result. With less than one minute of "hands-on time," it is as simple as Swab, Swirl, and See.

This product has not been FDA cleared or approved; but authorized by the FDA under an EUA; This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens; and, This product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb- 3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

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 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 of the Company to manufacture sufficient quantities of the InteliSwab COVID-19 rapid test and resolve manufacturing challenges and the expected timeframe for doing so; 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.

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EXHIBIT 99.2

OraSure Technologies, Inc.

Third Quarter 2021

Analyst-Investor Conference Call

November 3, 2021

Prepared Remarks of Dr. Stephen S. Tang and Scott Gleason

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

Operator Remarks

Good afternoon everyone and welcome to the OraSure Technologies third 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 Scott Gleason, Interim CFO and Senior Vice President of Investor Relations and Corporate Communications for OraSure. Scott?

Slide – 1

Scott Gleason –Interim CFO & SVP of IR and Corp. Communications

Good afternoon and welcome to OraSure Technologies' third-quarter 2021 earnings call. I am Scott Gleason, the Interim CFO and SVP of Investor Relations and Communications. Presenting with me today for OraSure is Dr. Stephen Tang, our President and Chief Executive Officer. As a reminder, today's webcast is being recorded and the recording along with a slide presentation accompanying the webcast can be found on our investor relations website.

Slide – 2

Before we begin, 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 am pleased to turn the call over to Dr. Stephen Tang.

Slide – 3

Dr. Stephen Tang, President and CEO of OraSure Technologies

Thanks Scott, and thank you to everyone for joining us on the call today. This quarter, OraSure once again delivered strong topline performance with sales of our core products growing 37% year-over-year. As an organization, we began setting the stage for even more rapid growth, as we look forward to fiscal year 2022. The global pandemic is providing the impetus to fundamentally transform our company into a higher growth and more innovative organization with broader customer reach, both within and outside the United States. Perhaps as importantly, what we call effortless diagnostics, which are diagnostic products and collection kits that are so simple in design they can be used in any setting, are having a watershed moment. Consumers, healthcare workers, and regulators are seeing the power these tests can have on addressing our greatest public health challenges. We see significant opportunity to capitalize on these trends, and utilize InteliSwab growth to permanently enhance our operational profile and our competitive positioning through investments in automation and efficiency. We will increasingly talk about these plans as we transition into fiscal year 2022.

Slide – 4

We remain highly focused on executing on our strategic priorities which include capitalizing on the COVID-19 testing opportunity, expanding our sample collection and molecular services businesses further in support of multi-omic discovery and diagnostics, expanding our global reach, and driving innovation with a focus on achieving higher growth through both internal R&D and M&A. I would now like to discuss our progress in each of these areas.

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First, as we look at the COVID-19 testing opportunity, we are convinced that COVID-19 testing will be an integral part of our business over the long term. Internal and external market models project testing demand based upon vaccination rates and epidemiology, and forecast a slow taper in disease incidence and testing over the next five years. Coupled with recent discussions with the federal government and Fortune 500 employers, we are increasingly convinced of the durability of InteliSwab™ as a product for the Company. As you can see on slide 5, our epidemiology based model forecasts a global testing market of approximately 1.1 billion rapid antigen tests by 2025.

Rapid COVID antigen tests, especially extremely easy to use tests such as InteliSwab™, are having a breakthrough moment in the United States. The ability to rapidly assess disease status outside of the healthcare setting by an untrained user is proving to be a critical tool in countering the pandemic and this is an area where OraSure has a long history and expertise. In this quarter alone, we received over $400 million in customer orders, including those from major commercial retailers such as Walgreens and Walmart and many other major retail customers, which we had to turn away due to manufacturing constraints. We also have received orders and inquiries from multiple Fortune 500 companies, major healthcare systems, and numerous entertainment and hospitality customers. You may have even noticed singer Sheryl Crow tweeted about using InteliSwab™, with her touring team. We are currently in a position where we can sell every test we can manufacture, and we believe this paradigm will persist into at least fiscal year 2022.

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This quarter we also signed three major U.S. government contracts that are transformational for the Company, as we look to the future. The first is a $205 million procurement contract from the Defense Logistics Agency for InteliSwab™ over-the-counter tests. This contract is strategically important for the Company, and we bid aggressively to ensure we would win a significant portion of this business for several reasons. First, this contract will essentially fill the factory for OraSure in fiscal year 2022, providing meaningful fixed cost absorption and ensuring we generate significant free cash flow which we can reinvest in growth and utilize to further expand our war chest for strategic M&A. Importantly, given this fixed cost absorption, the contribution margin on additional testing beyond the government contract will be higher. Second, as part of the contract, we will ship product to up to 25,000 customers across the United States, expanding our customer interactions and enabling even more consumers to experience the simplicity of testing that only InteliSwab™ can provide.

The second major contract we received was a $109 million contract with the Department of Defense to expand our manufacturing capacity for InteliSwab™. This contract further integrates us as part of the government's pandemic response program and will increase our annual capacity for InteliSwab™ test production to 200 million tests by early 2024. Under this contract, the capital equipment investments, installation, and validation work will be funded by the government, thereby increasing our ability to supply InteliSwab™ tests and improving our longer-term cost structure.

Finally, we will receive up to $13.6 million from the Biomedical Advanced Research Development Authority to fund our additional clinical studies and application for FDA 510k clearance and CLIA waiver for InteliSwab™. Once received, these full regulatory clearances will ensure that InteliSwab™ remains commercially available long-term even after the pandemic is declared over and Emergency Use Authorizations are no longer allowed.

We also recently received a label claim expansion from the FDA as it pertains to our InteliSwab™ COVID-19 rapid test where the FDA to revise the over-the-counter indication, enabling anyone with symptoms to only use one test to determine if they have COVID-19. Those without symptoms will still be directed to test twice within 24-36 hours if their first test is negative.

In addition, we have submitted to the FDA to expand our age range across all of our EUAs to include children ages 2-14 in addition to our prior authorizations for ages 15 and up. Per FDA agreed upon protocols, we conducted both pediatric specific usability and clinical studies to ensure acceptability and performance in this population. We are now awaiting FDA review of this data. We also submitted for authorization of our new reporting app, InteliSwab™ Connect, which can be used by communities, schools, and businesses to record, save and report their results to public health. Finally, we conducted studies with live Delta and Lambda variants in two independent labs and detected both variants in addition to Alpha, Beta, and Gamma variants from prior studies.

While we believe the preponderance of our InteliSwab™ revenue in fiscal year 2022 will be domestic, our long-range plan has an increasing contribution from international markets over time. In fiscal year 2022, we are planning to conduct studies to support the CE Mark for InteliSwab™ with a configuration most appropriate for countries outside the United States.

Finally, we have continued to make progress on our manufacturing scale-up for InteliSwab™, but are behind where we would hope to be from a test production standpoint. Despite the challenges we are facing, we continue to believe we are on track to generate approximately $30 million in total InteliSwab™ revenue this year. We believe we have isolated the scale-up challenges to be primarily caused by variability in certain raw materials and processing steps. We are currently working with vendors and third-party experts to achieve a resolution. Importantly, as we look to January of next year, we believe we are on track to scale to greater than 4 million InteliSwab™ tests a month, which is our

current installed capacity assuming resolution of the manufacturing process. However, given timelines to pack tests into finished OTC two-pack kits, our sales run rate will likely be below this level in the first quarter. We also continue to anticipate being at annual production levels of approximately 8 million InteliSwab™ tests per month by June, and are looking at ways to more rapidly scale and supply the significant market demand that currently exists.

Slide – 7

Next, I would like to discuss some of our recent internal innovation and highlight our work on expanding sample coverage and analytical services as part of our multi-omic vision. In the first quarter of next year, we expect to launch a new gut metatranscriptome collection kit and related service offering through our Diversigen subsidiary. For those that don't know, the metatranscriptome looks at gene expression levels across the genome, and in this case, the metagenome. Our pharmaceutical and research customers have been highly interested in this technology which we believe will expand our current microbiome offerings and provide a new avenue for growth in both collection kits and services. We continually evaluate new opportunities to introduce new collection kits and services in support of our vision of enabling multi-omic discovery and diagnostics.

On that note, in the first half of fiscal year 2022 we plan to take a step forward in our microbiome program and launch the first FDA cleared collection kit for gut microbiome. We have submitted our application for this product to the FDA and are awaiting regulatory approval. This innovation will support our commercial customers as they seek to launch clinical assays based on the microbiome or want the reliability of an FDA cleared device in their therapeutic development programs. Additionally, looking at our Collipee first-void urine collection device, we have seen commercial interest following the

publication of our data demonstrating similar sensitivity and specificity with Collipee to clinician-collected cervical samples using the Abbott's RealTime High Risk HPV assay for the detection of neoplasia. We plan to present and publish additional data sets with other major global HPV test manufacturers in the first half of fiscal year 2022. To support further applications of Collipee, we are launching a new research use only chemistry to stabilize analytes in urine critical to oncology applications such as liquid biopsy. This will allow us to access additional high growth segments of the oncology market.

Slide – 8

Moving on to our strategy to expand our global reach and presence, we continue to see strong adoption of our OraQuick® HIV tests internationally driven by the double-digit annual growth since 2016 of our HIV self-test, the only CE Marked and World Health Organization Pre-Qualified oral fluid self-test for HIV in the world. And, as we look forward to 2023, InteliSwab™ could quickly become our largest international product, and could provide the impetus for further international expansion and new customer relationships outside the United States. For our legacy business, we continue to expand our global reach and now have over 445 product registrations in 98 countries. These efforts were aided this quarter with the receipt of our Thailand Free Sales Certificate for our OraQuick® HIV Self-Test. This was an important certification which now enables us to obtain registrations and sell our tests in a number of Latin American and Asian countries.

With our molecular collection kits business we have identified eight target countries, predominantly in Europe and Asia, where we see an ongoing demand for PCR testing and an opportunity for expanding the use of our products. We plan to make broader inroads internationally with our collection kit business in the coming years.

Slide – 9

Finally, I would like to discuss our strategic priority of driving innovation with a focus on higher growth spaces through internal R&D and M&A. Now that we have successfully launched InteliSwab™, which was a major R&D undertaking, we are planning on investing more heavily in research and development to build out our internal product development capabilities. We have a number of products we have publicly spoken about including novel new point-of-care tests to determine medication adherence for PrEP and anti-retroviral drugs from our UrSure acquisition last summer, the launch of a CE Marked HIV oral fluid self-test in Europe, our Collipee research collaborations with major diagnostic manufacturers in HPV and other STDs, and our upcoming gut metatranscriptome collection kit and Diversigen service launch. Beyond these initiatives we have other pipeline development projects we will look to showcase at future investor events.

From an external business development standpoint, we are highly focused and currently engaged in evaluating a number of potential opportunities. One area of strategic interest is to find a next generation platform for our broader expansion into what we call effortless diagnostics. We have seen the market increasingly transition to point-of-care testing and these trends have only been accelerated by the pandemic. We are currently in discussions with a number of companies which we believe could increase the customer value proposition around our diagnostic products and facilitate broader test menu expansion. We also continue to evaluate technology and product adjacencies that would complement our molecular solutions business and facilitate our strategy of enabling multi-omics through expanded kit, service and data integration offerings.

The global pandemic has provided OraSure with the opportunity to fundamentally transform the Company, spur innovation, invest for growth, and increase our efficiency as an organization. We have now updated our strategic plan and we believe our plan will position OraSure to unlock shareholder value in coming years. We look forward to sharing key elements of this plan with the investment community in the first half of 2022.

With that I would like to turn the call over to Scott to discuss our financial results and outlook.

Scott Gleason – Interim Chief Financial Officer of OraSure Technologies

Thanks Steve, I am pleased to discuss our financial results for the third quarter and provide updates on our financial outlook.

First, from a top line perspective we delivered total revenue of $53.9 million in the third quarter of 2021 compared to $48.0 million in the prior year, representing year-over-year growth of 12%. Excluding COVID-19 revenue, our core business grew 37% in the quarter to over $40 million, reflecting a continuation of the strong growth trends we saw last quarter.

Slide – 10

This quarter we had record diagnostic revenue which was $23.5 million vs. $16.3 million in the previous year reflecting 44% growth. This growth was driven primarily by InteliSwab™. Our HIV business was relatively flat year-over-year for two reasons. First, the Bill and Melinda Gates Foundation subsidy for our international HIV Self-Test business expired in the second quarter which negatively impacted revenue despite test volume growth on a year-over-year basis. Secondly, we continued to see logistical issues with shipping and with our NGO partners in Africa which impacted international HIV sales, as COVID-19 spiked in much of Africa and Asia this quarter. We anticipate some improvement on this front in the fourth quarter. In terms of domestic HIV testing, there was a recent publication with results from the Center for Disease Control's "Take Me Home" program where our OraQuick® HIV self-tests were shipped directly to consumers. The study found that 37% of the high risk consumers receiving a test had never been tested at all in the past and 56% had not been tested for HIV in the last year. This data was very positively received, and we are optimistic that it could lead to further utilization of home HIV self-testing. As a reminder, our OraQuick® oral fluid HIV test is the only over-the-counter self-test for HIV in the United States, and required significant studies to gain its PMA approval.

This quarter we also continued to see strong growth in our HCV and drugs of abuse testing businesses based predominantly on a recovery in testing from the impact of the pandemic.

Finally, we had stronger than anticipated InteliSwab™ revenue in the quarter of $7.7 million predominantly based upon better than forecasted test pricing. As we stated last quarter, we have seen exceptionally strong customer demand for InteliSwab™ and can sell every test we can manufacture, so our performance depends on our ability to produce tests. As Steve mentioned earlier in the call, we are ramping production on a weekly basis but remain constrained due to raw material variability and

processing issues. For the year, we are anticipating approximately $30 million in InteliSwab™ revenue and our goal is to have our production capacity match our installed capacity early in the first quarter. Given demand levels, we are also evaluating ways to further accelerate our production capacity.

Slide - 11

Looking at the molecular solutions business, total third quarter revenue was $30.4 million and declined 4% from the same period last year. The decline was entirely driven by lower sales of molecular collection kits for COVID-19 testing of $6.3 million in the quarter vs. $18.8 million in the same period of the prior year as customers experienced lower PCR testing levels due to vaccination rates and an increasing availability of rapid point of care antigen tests. Excluding COVID-19 testing, molecular solutions revenue grew 87% year-over-year driven by an ongoing rebound in research and clinical markets as well as accelerated ordering patterns of seasonal customers, seeking to ensure product availability for holiday promotions. We continue to take a conservative outlook for the COVID-19 molecular collection kit business, but it is possible we could see a step up in revenue in the fourth quarter as some of our core customers resume back to school and workplace testing programs.

Microbiome services revenue in the quarter was $2.4 million and grew 6% year-over-year. Revenue this quarter was negatively impacted by the timing of our pharmaceutical partner contracts, however, we are anticipating a strong fourth quarter.

Slide – 12

Turning to gross margin, our gross margin percentage in the third quarter was 39.8% compared to 63.1% in the same period last year. The decline in overall gross margin this quarter was primarily due to our

production scale up for InteliSwab™ as our equipment and labor was utilized inefficiently relative to the revenue base this quarter for InteliSwab™. We also had material scrap rates higher than we anticipate in the future as we streamline our production process, and we are seeing a negative impact on all our products, including InteliSwab™, from the higher shipping costs associated with the global supply chain crisis. We also saw a detrimental gross margin impact in the quarter on a year-over-year basis from product and customer mix and the expiration of the Bill and Melinda Gates subsidy. We also had a $1.8 million reserve on inventory this quarter related to our oral fluid antibody test where we had built inventory in anticipation of an EUA and have withdrawn that application to focus on research use sales given the antibody testing market for COVID-19.

Looking forward to 2022, our gross margins and operating margins will be impacted by the large government procurement contract for InteliSwab™. We priced the government contract to have an attractive operating margin but the gross margin on this business will be significantly below our historical gross margins for the Company. These gross margins include our incremental shipping costs which will be significant under the contract due to the fact that it requires potential shipment of low volumes to up to 25,000 customers in the U.S. This was done strategically to ensure we would be well positioned to win a significant part of the contract and knowing that from an operating profit standpoint, we will not incur significant additional expenses beyond our manufacturing and shipping costs. Importantly, this contract fills our factory for next year and makes the contribution margin on the remaining business higher.

From an expense standpoint, total operating expenses in the quarter were $34.5 million compared to $25.9 million in the third quarter of last year. Higher expenses in the quarter were predominantly attributable to higher sales and marketing costs with our InteliSwab™ launch and expenses associated with our strategic review. In the quarter, we had an operating loss of ($13.0) million compared to an operating profit of $4.4 million in the third quarter of 2020. We expect to once again generate negative

operating income in the fiscal fourth quarter due to production inefficiencies and our scaling of the InteliSwab™ business and then transition to meaningful operating profit in fiscal year 2022. Moving to the bottom line, we generated a loss per share of ($0.21) in the third quarter of this year compared to a net profit of $0.01 per share in the same quarter last year.

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Moving on to our financial outlook, we are raising our financial outlook for the year and are now anticipating total revenue of $230 to $233 million versus our previous guidance which called for full year revenues of approximately $230 million. This implies fourth quarter revenue of $60 to $63 million.

Looking at our 4Q revenues, we are expecting lower sales of molecular collection kits due to the timing of orders from some of our larger consumer testing customers.

From an expense perspective we expect gross margins to once again be similar to what we saw in the 3rd quarter due to a continuation of the issues we previously discussed. We are also anticipating higher operating expenses. Several of our ongoing and completed InteliSwab™ post marketing and clinical studies will lead to higher R&D expenses in the fourth quarter. We also expect higher SG&A expenses as we prepare for the significant commercial ramp of our business in fiscal year 2022.

While we are in a transitory period here, we are well positioned as we look to next year to significantly scale our revenue base which will facilitate further investment by the Company in growth initiatives. With that, I am pleased to turn the call back over to Steve.

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Dr. Stephen Tang, President and CEO of OraSure Technologies

Thanks Scott, our goal all along has been to emerge from the pandemic as a larger and faster growing company. We strongly believe that the tailwind behind InteliSwab™ revenue is longer than most investors give us credit for, and will facilitate significant growth investment in the organization in coming years. We also see additional tangible benefits such as growing our customer base, expanding our global reach into new markets, and demonstrating the significant clinical importance of effortless diagnostics that empower consumers and health care workers. Our expertise in this area positions us exceptionally well for the healthcare markets of the future.

With that, I would like to turn the call back over to Scott for Q&A.

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Scott Gleason – Interim Chief Financial Officer

Thanks, Steve. Operator we are now ready to begin the Q&A portion of the call. We would ask that you limit your questions to one question and one follow up to ensure broad participation.

Final Conclusion - Dr. Stephen Tang, President and CEO of OraSure Technologies

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 of the Company to manufacture sufficient quantities of the InteliSwab COVID-19 rapid test and resolve manufacturing challenges and the expected timeframe for doing so; 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.

About InteliSwab™™

OraSure has received Emergency Use Authorizations (EUA) from the U.S. Food and Drug Administration (FDA) for its InteliSwab™™ COVID-19 rapid tests. The FDA has authorized the InteliSwab™™ COVID-19 Rapid Test for Over-the-Counter (OTC) use without a prescription. FDA has also authorized the InteliSwab™™ COVID-19 Rapid Test Pro for professional use in point of care (POC) CLIA-waived settings, and InteliSwab™™ COVID-19 Rapid Test Rx for Prescription Home Use. These remarkably simple COVID-19 lateral flow tests use samples self-collected from the lower nostrils. InteliSwab™™'s unique design incorporates a built-in swab fully integrated into the test stick. After users swab their lower nostrils, the test stick is swirled in a pre-measured buffer solution, and the result appears right on the test stick within 30 minutes, with no instruments, batteries, smartphone or laboratory analysis needed to see the result. With less than one minute of "hands-on time," it is as simple as Swab, Swirl, and See.

This product has not been FDA cleared or approved; but authorized by the FDA under an EUA; This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens; and, This product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb- 3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

Multiple government agencies, including the DOD and HHS are working to address COVID-19 testing needs. Development of the InteliSwab™™ COVID-19 Rapid Test has been funded in whole or in part with federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, Division of Research, Innovation and Ventures under contract number 75A50120C00061, utilizing Health Care Enhancement Act (HCEA) funding. The DoD's Defense Assisted Acquisition (DA2) Cell led the manufacturing expansion effort for the InteliSwab™™ COVID-19 rapid test in coordination with the Department of the Air Force’s Acquisition COVID-19 Task Force (DAF ACT). This effort was funded through the American Rescue Plan Act (ARPA) to enable and support domestic industrial base expansion for critical medical resources.

EXHIBIT 99.3

OraSure 3Q21 Earnings

November 3, 2021

OraSure Technologies

DNAgenotek™ Diversigen® novosanis

Forward-Looking Statements Disclaimer

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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.

3Q21 Financial Results

FINANCIAL METRIC	3Q21 RESULTS	3Q20 RESULTS	YEAR-OVER-YEAR GROWTH RATE
3Q21 Total Revenue	$53.9 million	$48.0 million	12%
3Q21 Total Revenue Excluding COVID-19 Product Revenue	$40.0 million	$29.1 million	37%
3Q21 COVID-19 Product Revenue	$13.9 million	$18.9 million	-26%

Key Focus Areas to Drive Shareholder Value

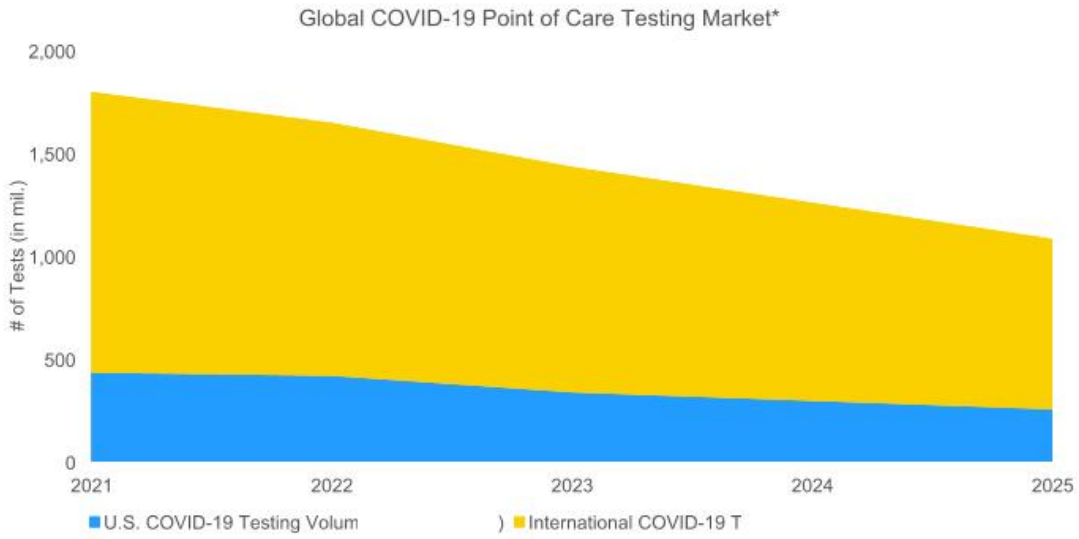
Capitalize on COVID-19 Testing Opportunity To Fund Future Growth

Expand Into New Sample Types and New Testing Modalities in Molecular Solutions

Expand Global Commercial Capabilities and Reach

Drive Higher Growth Through Expanded R&D and M&A

Epidemiology Based Market Model Shows Longer COVID-19 Revenue Tail



*Source: Epidemiology data, OSUR estimates

OraSure Signs Three Major Government Contracts in Quarter

$205 Million Department of Defense Procurement Contract

$109 Million Department of Defense Contract To Expand InteliSwab™ Manufacturing Capacity

$13.6 Million From BARDA To Get 510k Clearance and CLIA Waiver for InteliSwab™

Innovation in Molecular Solutions As Part of Multi-Omics Strategy

Diversigen®

Meta-transcriptome Launch

OMNIgene·GUT

FDA Clearance for Gut Kit

Colli-Pee™

Colli-Pee™ studies in HPV

Colli-Pee™

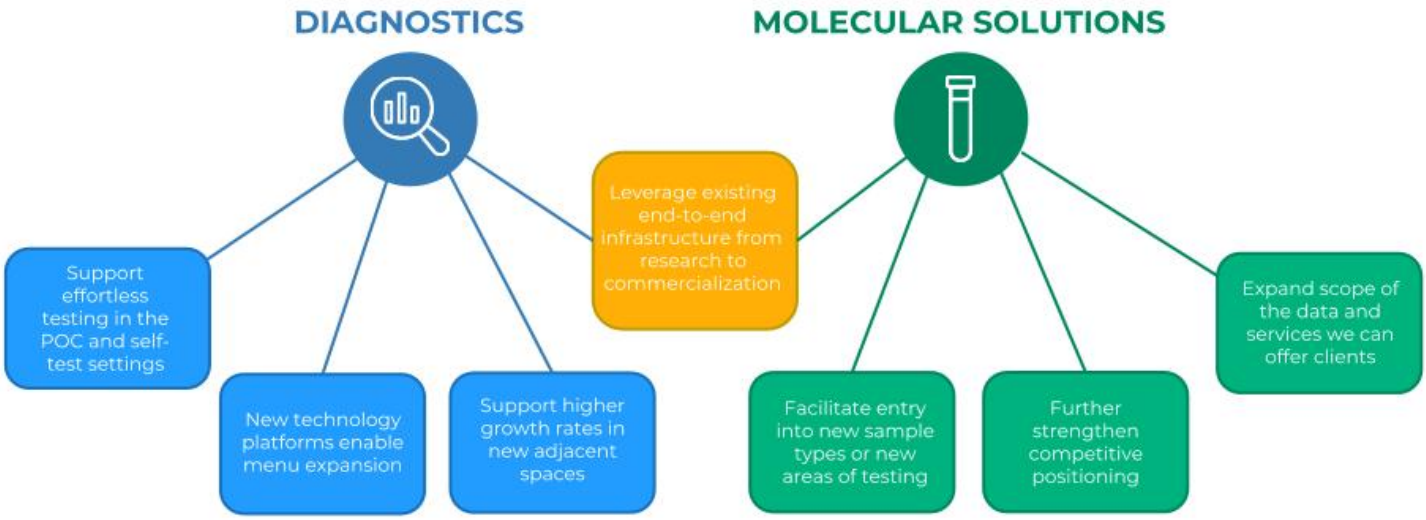
New Cancer Chemistry

Expanding Global Reach To Broaden Market Access

We now have over **445** product registrations in **98** countries globally

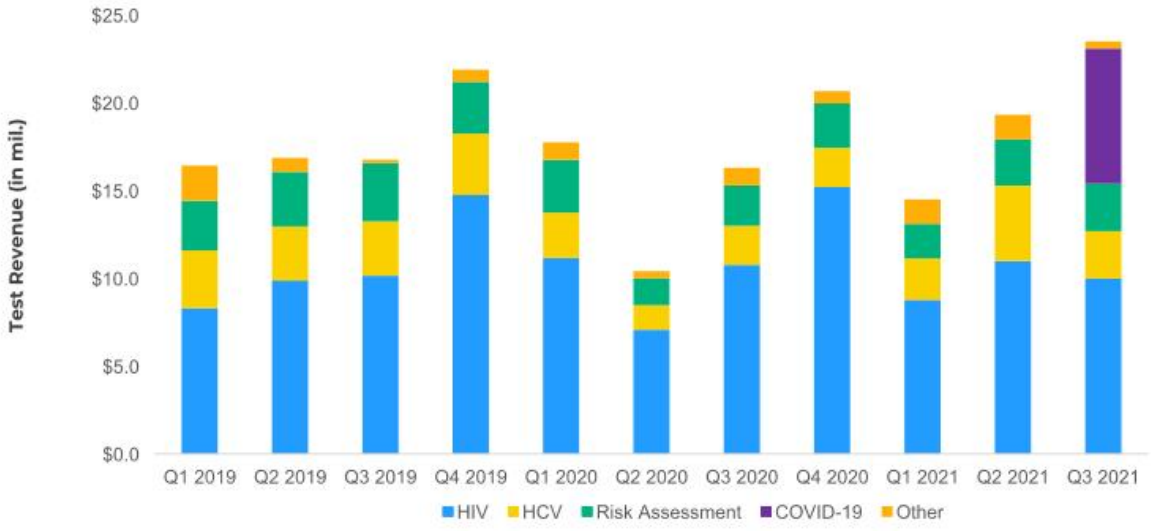
- Pursuing CE Mark for InteliSwab™
- Thailand Free Sales Certification and CE Mark for OraQuick® HIV Self Test
- Targeted 8 country launch for collection kits globally

Actively Evaluating Strategically Sound M&A Opportunities



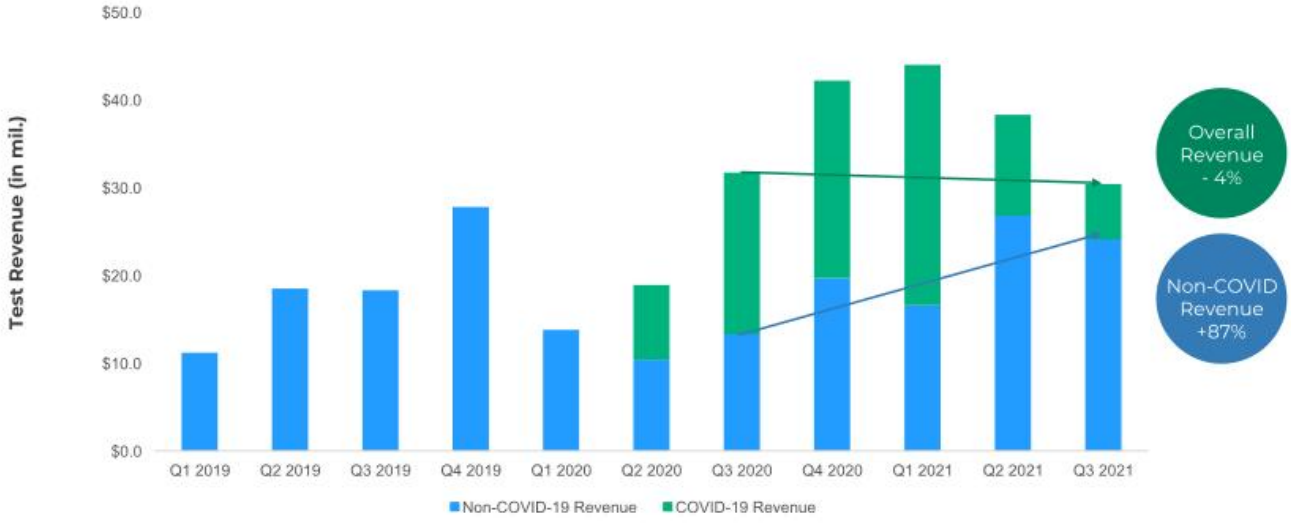
Revenue in Key Diagnostic Testing Categories

Record DiagnosticTesting Revenue for the Company



Strong Core Growth in Molecular Solutions

Continued Strong Core Growth in Molecular Kits and Services



Financial Results

	Three Months Ended September 30,	
	2021	2020
Results of Operations		
Net revenues	$ 53,917	$ 48,011
Cost of products and services sold	32,449	17,722
Gross profit	21,468	30,289
Operating expenses:		
Research and development	8,596	8,007
Sales and marketing	13,886	7,849
General and administrative	12,499	10,108
Change in fair value of acquisition-related contingent consideration	(500)	(60)
Total operating expenses	34,481	25,904
Operating income (loss)	(13,013)	4,385
Other income	100	314
Income (loss) before income taxes	(12,913)	4,699
Income tax expense	2,102	3,659
Net income (loss)	$ (15,015)	$ 1,040
Earnings (loss) per share:		
Basic	$ (0.21)	$ 0.01
Diluted	$ (0.21)	$ 0.01
Weighted average shares:		
Basic	72,023	71,537
Diluted	72,023	72,662

Financial Guidance

GUIDANCE METRIC	FINANCIAL GUIDANCE
4Q21 Total Revenue	$60 - $63 million
FY21 InteliSwab™ Revenue	≈$30 million
FY21 Total Revenue	$230 - $233 million

Summary

- Commercially tied to high growth areas of healthcare such as consumer/clinical genomics and shift to direct-to-patient/near patient testing
- Increased investment in internal R&D pipeline and reinvigorating innovation
- Significant opportunity with InteliSwab™ to drive growth and fund additional investment
- Strong balance sheet with focus on deploying capital to drive growth and leverage infrastructure

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Q&A

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