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

November 3, 2021

- 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

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

BETHLEHEM, Pa., Nov. 03, 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 %

Condensed Consolidated Balance Sheets (Unaudited)

	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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