



OraSure Technologies, Inc.

OraSure Technologies Reports 4Q21 Revenue of \$63.6 Million; InteliSwab® Production Scales Up

February 23, 2022

Total 2021 revenue of \$233.7 million, up 36% year-over year

InteliSwab® receives emergency use authorization expansion and demonstrates accurate detection of Omicron variant

InteliSwab® revenue of \$14.7 million in Q4, up 92% sequentially

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

BETHLEHEM, Pa., Feb. 23, 2022 (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 December 31, 2021 and fiscal year 2021.

"We are pleased to have delivered record revenue from both our Diagnostics and Molecular Solutions business units in our 2021 fiscal year," said OraSure President and CEO Stephen Tang, Ph.D. "InteliSwab® is an outstanding product in terms of its combination of simplicity and accuracy, and we are excited about its growth potential. OraSure has confirmed through an outside independent laboratory that InteliSwab® detects the live Omicron variant at the same level as other variants of concern. Furthermore, we received FDA Emergency Use Authorization for our pediatric claim and for the InteliSwab® Connect reporting app which further enhance the value proposition of the product."

Dr. Tang continued, "We continue to scale up InteliSwab® production which includes plans for commissioning additional production sites. We continue to address the many typical challenges associated with scale up which will take time to fully implement. Even so, we expect InteliSwab® to scale modestly in the first quarter and then more meaningfully throughout the year. In addition, we continue to execute our multi-omic strategy which drove 35% year-over-year growth in Molecular Solutions, and have aggressive plans to continue expanding our product offerings in the coming years. As we look ahead, I remain confident in our team's ability to deliver strong growth and improving operating performance."

Financial Highlights

- Net revenues for the fourth quarter of 2021 were \$63.6 million, a 1% increase from the fourth quarter of 2020. Excluding COVID-19 product revenues, revenues for the quarter increased 3% year-over-year.
- Total revenues from the Company's Diagnostic business unit were \$32.7 million during the fourth quarter of 2021 and grew 58% relative to the same period last year. Revenue growth was driven entirely by the increase in InteliSwab® revenue on a year-over-year basis.
- Total product and service revenues for the Company's Molecular Solutions business unit were \$30.9 million during the fourth quarter of 2021, a decline of 27% from the fourth quarter of 2020. The decline was driven entirely by lower sales of the Company's COVID-19 molecular collection kits. Excluding these COVID-19 revenues, the molecular solutions business grew 19% year-over-year despite changes in ordering patterns from the Company's direct-to-consumer customers.
- Gross margin percentage in the fourth quarter was 42.7% compared to 60.7% in the prior year. Gross margins were negatively impacted by inefficiencies in the InteliSwab® manufacturing process as the Company worked through initial process automation start up and scale up. 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. Gross margins were positively impacted from the impact of the employee retention credit under the CARES Act in the quarter.
- Operating loss in the fourth quarter was (\$9.4) million compared to operating income of \$7.9 million in the fourth quarter of last year. OraSure's operating loss in the quarter was driven by a ramp in investments to support the InteliSwab® launch, along with lower gross margins as described above. On a sequential basis, operating profit improved by \$3.6 million.
- Net loss for the fourth quarter of 2021 was (\$10.4) million, or (\$0.14) per share on a fully diluted basis, compared to a net income of \$1.9 million, or \$0.03 per share on a fully-diluted basis, for the fourth quarter of 2020.
- Cash flow used in operations in the quarter was (\$12.8) million. Cash and investments totaled \$170.0 million at December 31, 2021. As of December 31, 2021, the Company also had \$10.9 million in funds committed to the capacity expansion build out associated with the Department of Defense contract which should be reimbursed in the first quarter of fiscal year 2022.

Recent Business Highlights

InteliSwab® COVID-19 Testing

- InteliSwab® revenue in the quarter grew to \$14.7 million representing 92% sequential growth relative to the third quarter.
- OraSure has been scaling its weekly manufacturing production for InteliSwab®. At the end of the fourth-quarter, OraSure

restructured its business units to vertically integrate operations within them, and appointed a President with a track record of successful leadership of large-scale manufacturing operations.

- To accelerate production scale up, OraSure has hired an operations consulting firm used by NIH RADx with deep expertise in manufacturing scale up in med tech and diagnostics.
- OraSure announced that its InteliSwab[®] COVID-19 rapid tests have been authorized by the U.S. Food and Drug Administration (FDA) for use in children ages 2 to 14. InteliSwab[®] was previously authorized for self-testing use in adults and in children 15 to 17 when administered by an adult.
- The Company launched a new reporting app, InteliSwab[®] Connect, which will allow people to easily save their test results and report them to public health authorities, helping communities with COVID-19 prevalence surveillance efforts. It can also help employers track prevalence in the workplace. The app will be available on the Apple App Store and via Google Play.
- OraSure announced that the InteliSwab[®] COVID-19 rapid tests detect the Omicron variant as effectively as they detect the original SARS-CoV-2 strain and other previous variants of concern, including Delta, Alpha, Beta and Gamma.

Infectious Disease and Risk Assessment Testing

- Global OraQuick[®] HIV sales in the fourth quarter were \$12.4 million versus \$15.2 million in the prior year period. The decline in revenue was predominantly attributable to the international market which was impacted by two factors. First, international HIV revenue was negatively impacted by the expiration of the Bill and Melinda Gates Foundation test subsidy which occurred in June 2021. Second, the global coronavirus pandemic created logistic delays in shipping our HIV self-tests into numerous countries.
- The Company launched the OraQuick[®] HIV Self-Test, an oral swab in-home test for HIV-1 and HIV-2, into Europe. The test will be available in six European countries: United Kingdom, Germany, France, Italy, Spain and Portugal.
- Global OraQuick[®] HCV sales increased 7% to \$2.4 million in the fourth quarter compared to \$2.2 million in the fourth quarter of 2020.
- Risk assessment testing revenue was flat year-over-year at \$2.4 million primarily due to increased workplace drugs-of-abuse testing offset by continued challenges in insurance testing given the COVID-19 pandemic.

Molecular Solutions

- Genomics collection kit revenue of \$14.0 million for the fourth quarter of 2021 grew 3% year-over-year despite changes in ordering patterns with many direct-to-consumer companies purchasing larger kit quantities in the third quarter prior to the fourth quarter promotional season. For the full year, genomic kit revenue grew 72% to \$63.4 million demonstrating strong growth from existing customers, new customer expansion, and a recovery in clinical and academic markets following global pandemic.
- Sales of OraSure's sample collection devices for molecular/PCR COVID-19 testing decreased year-over-year to \$8.0 million in the fourth quarter of 2021 compared to \$22.9 million in the prior year period. The decline in revenue is attributable to lower testing volumes with core customers as the market transitions to point-of-care solutions such as rapid antigen tests.
- Total microbiome revenue, including kits and services, was \$5.9 million in the quarter and grew 65% relative to the fourth quarter of last year.
 - OraSure's Diversigen business now supports over 50 commercial customers including over 30 biopharmaceutical customers with 20 ongoing clinical trials.
 - The Company announced the planned launch of a new gut metatranscriptome collection kit in first half 2022, to complement the gut metatranscriptome service offering from our Diversigen business launched in the fourth quarter of 2021.
 - OraSure received the first and only U.S. FDA clearance of a new collection kit for gut microbiome which the company plans to launch commercially in the first half of fiscal year 2022.

Strategic Alternatives Review and Fiscal Year 2022 and First Quarter 2022 Financial Guidance

On January 5, 2022, the Company announced it is exploring strategic alternatives. The review is ongoing, and no decision has been made. Accordingly, the Company is not providing fiscal year 2022 or first-quarter 2022 financial guidance at this time.

Financial Data (Unaudited)

	Three Months Ended		Year Ended	
	December 31,		December 31,	
	2021	2020	2021	2020
Results of Operations				
Net revenues	\$ 63,568	\$ 62,855	\$ 233,674	\$ 171,721
Cost of products and services sold	36,435	24,671	116,074	69,853
Gross profit	27,133	38,184	117,600	101,868

Operating expenses:				
Research and development	8,900	10,457	34,170	31,032
Sales and marketing	10,915	9,120	44,751	34,459
General and administrative	16,648	12,211	50,328	42,653
Change in fair value of acquisition-related contingent consideration	41	(1,489)	(1,485)	(1,099)
Total operating expenses	36,504	30,299	127,764	107,045
Operating income (loss)	(9,371)	7,885	(10,164)	(5,177)
Other income	443	(307)	872	1,653
Income (loss) before income taxes	(8,928)	7,578	(9,292)	(3,524)
Income tax expense	1,465	5,718	13,706	11,398
Net income (loss)	\$ (10,393)	\$ 1,860	\$ (22,998)	\$ (14,922)
Earnings (loss) per share:				
Basic	\$ (0.14)	\$ 0.03	\$ (0.32)	\$ (0.22)
Diluted	\$ (0.14)	\$ 0.03	\$ (0.32)	\$ (0.22)
Weighted average shares:				
Basic	72,040	71,723	71,981	67,505
Diluted	72,040	72,817	71,981	67,505

	Three Months Ended December 31,			Year Ended December 31,		
	2021	2020	% Change	2021	2020	% Change
DIAGNOSTICS						
Infectious Disease Testing Revenues						
Domestic HIV	\$ 3,773	\$ 3,861	(2) %	\$ 16,641	\$ 15,184	10 %
International HIV	8,626	11,343	(24)	25,503	29,040	(12)
Net HIV revenues	12,399	15,204	(18)	42,144	44,224	(5)
Domestic HCV	1,301	1,356	(4)	6,881	4,793	44
International HCV	1,100	884	24	4,902	3,655	34
Net HCV revenues	2,401	2,240	7	11,783	8,448	39
Net OraQuick® revenues	14,800	17,444	(15)	53,927	52,672	2
COVID-19	14,770	118	NM	22,707	180	NM
Other infectious disease revenues	183	158	16	718	1,555	(54)
Total Infectious Disease	29,753	17,720	68	77,352	54,407	42
Risk Assessment	2,406	2,408	—	9,678	9,194	5
Other non-product revenues	509	580	(12)	3,010	1,639	84
TOTAL DIAGNOSTIC NET REVENUE	32,668	20,708	58	90,040	65,240	38
MOLECULAR SOLUTIONS						
Genomics	\$ 14,017	\$ 13,655	3	\$ 63,350	\$ 36,878	72
Microbiome	2,050	1,605	28	7,944	5,474	45
COVID-19	7,964	22,892	(65)	54,167	50,747	7
Laboratory services	3,824	1,949	96	11,840	8,746	35
Other product and services revenues	1,334	180	641	2,566	935	174
Net product and service revenues	29,189	40,281	(28)	139,867	102,780	36
Other non-product and service revenues	1,711	1,866	(8)	3,767	3,701	2
TOTAL MOLECULAR SOLUTIONS NET REVENUE	30,900	42,147	(27)	143,634	106,481	35
TOTAL NET REVENUES	\$ 63,568	\$ 62,855	1 %	\$ 233,674	\$ 171,721	36 %

Condensed Consolidated Balance Sheets (Unaudited)

	<u>December 31,</u> <u>2021</u>	<u>December 31,</u> <u>2020</u>
<u>Assets</u>		
Cash and cash equivalents	\$ 116,762	\$ 160,802
Short-term investments	36,279	48,599
Accounts receivable, net	64,952	38,835
Inventories	53,138	31,863
Other current assets	17,300	8,794
Property, plant and equipment, net	88,164	51,860
Intangible assets, net	14,343	17,904
Goodwill	40,279	40,351
Long-term investments	17,009	47,718
Other non-current assets	12,764	7,746
Total assets	<u>\$ 460,990</u>	<u>\$ 454,472</u>

<u>Liabilities and Stockholders' Equity</u>		
Accounts payable	\$ 28,024	\$ 17,407
Deferred revenue	2,936	4,811
Contingent consideration obligation	206	402
Other current liabilities	36,898	23,869
Non-current contingent consideration obligation	354	2,049
Other non-current liabilities	12,039	7,363
Stockholders' equity	380,533	398,571
Total liabilities and stockholders' equity	<u>\$ 460,990</u>	<u>\$ 454,472</u>

Additional Financial Data (Unaudited)

	<u>Year Ended</u> <u>December 31,</u>	
	<u>2021</u>	<u>2020</u>
Capital expenditures	\$ 48,117	\$ 26,674
Depreciation and amortization	\$ 11,658	\$ 9,387
Stock-based compensation	\$ 7,807	\$ 7,139
Cash (used in) provided by operating activities	\$ (35,382)	\$ 5,807

Conference Call

The Company will host a conference call and audio webcast for analysts and investors to discuss the Company's fourth 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, Lisa Nibauer, President Diagnostics, Kathleen Weber, President Molecular Solutions, 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 # 50277718 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, March 9, 2022, by dialing 855-859-2056 (Domestic) or 404-537-3406 (International) and entering the Conference ID # 50277718.

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

About IntelliSwab[®]

OraSure has received Emergency Use Authorizations (EUA) from the FDA for its IntelliSwab[®] COVID-19 rapid tests. The FDA has authorized the IntelliSwab[®] COVID-19 Rapid Test for Over-the-Counter (OTC) use without a prescription. The FDA has also authorized the IntelliSwab[®] COVID-19 Rapid Test Pro for professional use in point of care (POC) CLIA-waived settings, and the IntelliSwab[®] 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. IntelliSwab[®]'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 it has been authorized by the FDA under an EUA. The emergency use of this product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. 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 U.S. Department of Defense (DoD) and Department of Health and Human Services (HHS) are working to

address COVID-19 testing needs. Development of the IntelliSwab[®] COVID-19 Rapid Test has been funded in whole or in part with federal funds from the HHS; the Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, Division of Research, Innovation and Ventures under contract numbers 75A50120C00061 and 75A50121C00078, utilizing Health Care Enhancement Act (HCEA) funding. The DoD's Defense Assisted Acquisition (DA2) Cell led the manufacturing expansion effort for the IntelliSwab[®] COVID-19 rapid test in coordination with the Department of the Air Force's Acquisition COVID-19 Task Force (DAF ACT). The manufacturing effort was funded through the American Rescue Plan Act (ARPA) to enable and support domestic industrial base expansion for critical medical resources.

About OraSure Technologies

OraSure Technologies empowers the global community to improve health and wellness by providing access to accurate, essential information. OraSure, together with its wholly-owned subsidiaries, DNA Genotek, Diversigen, and Novosanis, provides its customers with end-to-end solutions that encompass tools, services and diagnostics. The OraSure family of companies is a leader in the development, manufacture, and distribution of rapid diagnostic tests, sample collection and stabilization devices, and molecular services solutions designed to discover and detect critical medical conditions. OraSure's portfolio of products is sold globally to clinical laboratories, hospitals, physician's offices, clinics, public health and community-based organizations, research institutions, government agencies, pharma, commercial entities and direct to consumers. For more information on OraSure Technologies, please visit www.orasure.com.

Important Information

This press release contains certain forward-looking statements, including with respect to products, product development activities, regulatory submissions and authorizations and other matters. Forward-looking statements are not guarantees of future performance or results. Known and unknown factors that could cause actual performance or results to be materially different from those expressed or implied in these statements include, but are not limited to: risk that the Company's exploration of strategic alternatives may not result in any definitive transaction or enhance stockholder value and may create a distraction or uncertainty that may adversely affect operating results, business or investor perceptions; the diversion of management's attention from the Company's ongoing business and regular business responsibilities due to the Company's exploration of strategic alternatives; ability to resolve the Company's ongoing manufacturing challenges and satisfy customer demand; 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 the Company's business and ability to successfully develop new products, validate the expanded use of existing collector products, receive necessary regulatory approvals and authorizations and commercialize such products for COVID-19 testing; changes in relationships, including disputes or disagreements, with strategic partners or other parties and reliance on strategic partners for the performance of critical activities under collaborative arrangements; ability to meet increased demand for the Company's products; impact of replacing distributors; inventory levels at distributors and other customers; ability of the Company to achieve its financial and strategic objectives and continue to increase its revenues, including the ability to expand international sales; impact of competitors, competing products and technology changes; reduction or deferral of public funding available to customers; competition from new or better technology or lower cost products; ability to develop, commercialize and market new products; market acceptance of oral fluid or urine testing, collection or other products; market acceptance and uptake of microbiome informatics, microbial genetics technology and related analytics services; changes in market acceptance of products based on product performance or other factors, including changes in testing guidelines, algorithms or other recommendations by the Centers for Disease Control and Prevention ("CDC") or other agencies; ability to fund research and development and other products and operations; ability to obtain and maintain new or existing product distribution channels; reliance on sole supply sources for critical products and components; availability of related products produced by third parties or products required for use of our products; impact of contracting with the U.S. government; impact of negative economic conditions; ability to maintain sustained profitability; ability to utilize net operating loss carry forwards or other deferred tax assets; volatility of the Company's stock price; uncertainty relating to patent protection and potential patent infringement claims; uncertainty and costs of litigation relating to patents and other intellectual property; availability of licenses to patents or other technology; ability to enter into international manufacturing agreements; obstacles to international marketing and manufacturing of products; ability to sell products internationally, including the impact of changes in international funding sources and testing algorithms; adverse movements in foreign currency exchange rates; loss or impairment of sources of capital; ability to attract and retain qualified personnel; exposure to product liability and other types of litigation; changes in international, federal or state laws and regulations; customer consolidations and inventory practices; equipment failures and ability to obtain needed raw materials and components; the impact of terrorist attacks and civil unrest; and general political, business and economic conditions. These and other factors that could affect our results are discussed more fully in our SEC filings, including our registration statements, Annual Report on Form 10-K for the year ended December 31, 2020, Quarterly Reports on Form 10-Q, and other filings with the SEC. Although forward-looking statements help to provide information about future prospects, readers should keep in mind that forward-looking statements may not be reliable. Readers are cautioned not to place undue reliance on the forward-looking statements. The forward-looking statements are made as of the date of this press release and OraSure Technologies undertakes no duty to update these statements.

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