OraSure Technologies Announces Actions to Enhance Stockholder Value

January 5, 2022

Provides Preliminary 4Q21 Financial Outlook

Commences Review of Strategic Alternatives

Announces Transition of CEO and Organizational Changes

BETHLEHEM, Pa., Jan. 05, 2022 (GLOBE NEWSWIRE) -- OraSure Technologies, Inc. (NASDAQ: OSUR), a global leader in point-of-care and home diagnostic testing and sample collection technologies, today announced preliminary Q4 2021 results, organizational changes, and a Board-level review of strategic alternatives to enhance stockholder value.

InteliSwab™ Update and 4Q21 Financial Outlook

OraSure expects to deliver total revenue in the fiscal fourth quarter at the low end of the Company's guidance range of approximately $60 million, driven by lower than anticipated InteliSwab™ sales coupled with outperformance in the Company's Molecular Solutions business unit.

The Company anticipates total InteliSwab™ revenue of approximately $12 million for the quarter and $20 million for the full year. During the fiscal fourth quarter OraSure made material progress in resolving the technology transfer issues and is now in the process of normal scale-up. Given the time involved to resolve those issues and the impact of additional hiring, training, and global supply chain challenges experienced by OraSure in the fourth quarter, the Company did not achieve its InteliSwab™ guidance for the fiscal year. The Company anticipates continued scaling of its InteliSwab™ production from 4Q21 levels and will provide an additional update on its 4Q21 earnings call. The Company is also in the process of hiring staff for additional shifts and installing additional automated equipment to further increase production.

"The Board and executive leadership team are taking action to ensure that we are in the best position to drive long-term value for our stockholders," said OraSure President and Chief Executive Officer Stephen Tang, Ph.D. "Despite the slower scale-up in InteliSwab™ revenue in 2021, we are encouraged by our potential in 2022 for a significant step up in InteliSwab™ revenue given the strong demand environment and our United States government procurement contract. In addition, we are very pleased with the continued strong performance in our Molecular Solutions business unit, which has grown at over a 30% CAGR the last two calendar years including double-digit growth in our core molecular kits and services businesses."

OraSure can also confirm that InteliSwab™ detects the Omicron variant when tested by an outside third-party laboratory with live viral samples. In addition, as previously confirmed, InteliSwab™ also detects the Delta variant and other variants of concern so consumers and caregivers can be confident in the results.

The estimated preliminary revenue results presented above are based on the information available to OraSure as of the date of this press release. OraSure has not yet completed its quarter-end closing. Actual results for the fourth quarter and year ended December 31, 2021 may vary from these estimated preliminary results and will not be finalized until after the date of this press release.

Evaluation of Strategic Alternatives

The COVID-19 pandemic has provided OraSure an opportunity to fundamentally transform into a higher growth, more innovative and efficient organization with broader customer reach, both within and outside the United States. The Company believes it is well positioned to address current public health challenges and capitalize on diagnostic trends in the market and enhance its operational and competitive profile. Against this backdrop, the OraSure Board of Directors intends to explore and evaluate a broad range of strategic alternatives with the goal of maximizing value for stockholders.

There can be no assurance that the exploration of strategic alternatives will result in any agreements or transactions, or that, if completed, any agreements or transactions will be successful or on attractive terms. OraSure does not intend to make any further public comment regarding the review until it has been completed or the Company determines that disclosure is required or appropriate. Evercore is serving as OraSure's financial advisor and Troutman Pepper is serving as the Company's legal advisor in this evaluation.

Leadership Changes

OraSure also announced that Stephen Tang Ph.D., President and CEO, will be the leaving the Company as of March 31, 2022. In the interim, Dr. Tang will focus primarily on assisting the Board in its strategic review process and helping to ensure an orderly transition of the CEO role. Under Dr. Tang's four years as CEO, OraSure acquired four companies and launched several COVID-19 products, including InteliSwab™. As a member of the Board, he will have served for 11 years, including Chairman.

The Board has initiated a search for his successor as CEO. During this transition, while the CEO search is in process, the Board of Directors will be taking a more active role. For this purpose, the Board has appointed Director Eamonn Hobbs to serve as point person for the Board. Mr. Hobbs will not be a candidate for the permanent CEO position.

Organizational Changes

The Company is also making certain organizational changes to focus priorities, resources, expertise, and drive improved operational performance. Under the new vertically integrated business unit structure, operations, R&D and manufacturing will now report to each of the respective business unit leaders. Key to these changes, Lisa Nibauer will become President of Diagnostics and Kathleen Weber will become President of Molecular Solutions.

Ms. Nibauer joined OraSure as Executive Vice President, Business Unit Leader, Diagnostics, in May 2020. She previously spent eight years at Becton Dickinson, Inc. (“BD”), most recently as Vice President & General Manager, Global Medication Delivery Solutions, where she had complete operational and strategic responsibility for $1.6 billion in annual revenue globally and was also accountable for the largest business within BD. Prior to joining BD, she held general management, sales and marketing positions at several large healthcare companies.

Ms. Weber has served as the Executive Vice President, Business Unit Leader for Molecular Solutions, since January 2019 and previously held various senior executive leadership roles at OraSure since joining the Company in 2012. She is responsible for establishing the strong foundation of both our HIV self-testing and emerging disease programs. Prior to joining OraSure, Ms. Weber held several executive leadership positions at Pfizer, Johnson and Johnson and Schering–Plough leading and accountable for multi-billion dollar business units.

“The focus of the Board of Directors continues to be on ensuring OraSure can execute at a high level. We believe the organizational changes and other actions we are undertaking will best position the Company as it scales up with InteliSwab™ and delivers on its significant potential in key, high growth areas of healthcare. We appreciate Steve Tang’s years of service to OraSure and look forward to his continued leadership as we evaluate available strategic alternatives to maximize stockholder value,” said OraSure Chairman of the Board, Michael Celano.

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.

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.

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.

Important Information

This press release contains certain forward-looking statements, including with respect to our expectations regarding the exploration of strategic alternatives, expected revenues and production estimates, 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 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 our operating results, business or investor perceptions; the diversion of management’s attention from our ongoing business and regular business responsibilities; whether actual financial results for the fourth quarter and year ending December 31, 2021 will differ materially from the preliminary results reported above; ability to resolve our 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 our business and our ability to successfully develop new products, validate the expanded use of existing collector products, receive necessary regulatory approvals and authorizations and commercialize such products for COVID-19 testing; changes in relationships, including disputes or disagreements, with strategic partners or other parties and reliance on strategic partners for the performance of critical activities under collaborative arrangements; ability to meet increased demand for the Company’s products; impact of replacing distributors; inventory levels at distributors and other customers; ability of the Company to achieve its financial and strategic objectives and continue to increase its revenues, including the ability to expand international sales; 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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