

OraSure Technologies Acquires Sherlock Biosciences

December 19, 2024

BETHLEHEM, Pa., Dec. 19, 2024 (GLOBE NEWSWIRE) -- OraSure Technologies, Inc. ("OTI") (NASDAQ: OSUR), a leader in point-of-need and home diagnostic tests and sample management solutions, today announced the acquisition of Sherlock Biosciences, Inc., a global health company bringing next-generation diagnostics to consumers and healthcare providers.

This acquisition expands OraSure's innovation pipeline with the addition of Sherlock's molecular diagnostics platform, which is able to provide rapid results with strong sensitivity and specificity in a disposable format that is well-suited for over-the-counter usage. Sherlock's first molecular self-test is for Chlamydia Trachomatis (CT) and Neisseria Gonorrhoeae (NG) which will expand OraSure's portfolio of rapid diagnostics for sexually transmitted infections (STIs), subject to regulatory approvals. Test results are expected to be provided in under 30 minutes by analyzing DNA and RNA from self-collected swabs using isothermal amplification. In addition, Sherlock has been developing a pipeline of other molecular tests, along with several next-generation technology platforms, including Ambient Temperature Amplification and CRISPR-based technologies that have the potential to further reduce costs and improve performance of its platforms.

Sherlock's CT/NG self-test is in clinical studies and is expected to be submitted to the FDA by the end of 2025 for review. Subject to regulatory approvals, revenue from Sherlock's CT/NG test is expected to contribute to OTI's growth beginning in 2026, benefitting from OraSure's existing infrastructure, commercial capabilities, and strong customer relationships.

OTI estimates that testing for CT/NG represents a total addressable market of more than \$1.5 billion. The vast majority of CT/NG tests in the U.S. are processed in a centralized lab, and the introduction of an affordable, rapid self-test has the potential to drive significant incremental market expansion. Additionally, public health channels play a key role in STI screening, which is an area where OraSure has a strong presence.

"The acquisition of Sherlock represents the next step in OTI's innovation strategy," said Carrie Eglinton Manner, President and CEO of OraSure. "Sherlock brings valuable capabilities with an advanced molecular platform that aims to deliver lab-like accuracy in a format that expands access to diagnostic insights through convenient, effortless tests. We are excited to welcome Sherlock's talented team to OTI and believe that Sherlock's unique capabilities will contribute significantly to the expansion of our pipeline of diagnostic tests in infectious disease, sexual health, and beyond."

Conference Call Information

OraSure will host a conference call to discuss the acquisition of Sherlock Biosciences at 5:00 p.m. ET on Thursday, Dec. 19, 2024. A webcast of the conference call will be available on the investor relations page of OraSure's website at https://orasure.gcs-web.com/events-and-presentations. Please click on the webcast link and follow the prompts for registration and access at least 10 minutes prior to the call. The webcast will be archived on OraSure's website shortly after the call has ended and will be available for approximately 90 days.

To participate in the live conference call, please follow the link below to pre-register. After registering, you will be provided with access details via email.

https://register.vevent.com/register/BIb938f5bae2a442d9acdb83f4bdd9286d

About OraSure Technologies, Inc.

OraSure Technologies, Inc. ("OraSure") transforms health through actionable insight and powers the shift that connects people to healthcare wherever they are. OraSure improves access, quality, and value of healthcare with innovation in effortless tests and sample management solutions. OraSure, together with its wholly-owned subsidiary, DNA Genotek Inc., is a leader in the development, manufacture, and distribution of rapid diagnostic tests and sample collection and stabilization devices 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, pharmaceutical companies, and direct to consumers. For more information on OraSure Technologies, please visit www.orasure.com

Forward Looking Statements

This press release contains certain "forward-looking statements" within the meaning of the Federal securities laws, including with respect to products, product development and manufacturing activities, the Company's acquisition of Sherlock, revenue growth, cash flow, increasing margins and other matters. Words such as "expects," "estimates," "forecasts," "intends," "plans," "projects," "could," "may," "should," "will" or other similar words and expressions are intended to identify these forward-looking statements. 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: the Company's ability to integrate Sherlock's business and achieve the intended benefits of the acquisition on the timeline expected or at all; Sherlock's ability to seek and obtain regulatory approval for products in development; the Company's ability to satisfy customer demand; ability to reduce the Company's spending rate, capitalize on manufacturing efficiencies and drive profitable growth; ability to achieve the anticipated cost savings as a result of the Company's business restructuring, including from insourcing third party manufacturing and exiting microbiome services; ability to market and sell products, whether through the Company's 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 the Company's products; ability to manufacture or have manufactured 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 FDA or other regulators; the impact of the novel coronavirus ("COVID-19") pandemic on the Company's business, supply chain, labor force, 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, and demand for the Company's COVID-19 testing products; 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 and the ability to continue to reduce costs; 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 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 the Company's 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; cybersecurity breaches or other attacks involving the Company's systems or those of the Company's third-party contractors and IT service providers; the impact of terrorist attacks, civil unrest, hostilities and war; and general political, business and economic conditions, including inflationary pressures and banking stability. These and other factors that could affect the Company's results are discussed more fully in the Company's filings with the Securities and Exchange Commission (the "SEC"), including the Company's registration statements, Annual Report on Form 10-K for the year ended December 31, 2023, 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 the Company undertakes no duty to update these statements.

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