ProSomnus® Enrolls First Participant in Study Evaluating Safety and Efficacy of ProSomnus EVO™ in Treating Severe Obstructive Sleep Apnea

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SAN FRANCISCO, Dec. 19, 2022 (GLOBE NEWSWIRE) -- ProSomnus, Inc. ("the Company") (NASDAQ: OSA), a pioneer in precision medical devices for the treatment of Obstructive Sleep Apnea (OSA), today announced the enrollment of the first patient in its Severe Obstructive Sleep Apnea (SOS) study. The SOS study is a prospective, FDA-reviewed, multi-center, single-arm study evaluating the safety and efficacy of precision oral appliance therapy (OAT) with the ProSomnus EVO Sleep and Snore device in individuals with severe OSA. ProSomnus intends to use data from the SOS study to apply for an expanded indication for use with the FDA. If successful, the ProSomnus EVO would be the first intraoral medical device cleared for the treatment of patients with Severe OSA.

Efficacy and safety are the two primary endpoints for the study. Researchers in the study will assess the ProSomnus EVO's efficacy by measuring participants' apnea-hypopnea index (AHI) and oxygen desaturation index (ODI) six months after initiation of precision OAT. Investigators will evaluate the safety of the ProSomnus EVO by reviewing all reported adverse events, dental examinations, and safety evaluations.

"Many patients with severe OSA are in dire need of treatment, and previous research suggests that ProSomnus' precision OAT devices could successfully treat most patients' OSA," said John E. Remmers, MD, Chief Scientist of ProSomnus. "Further establishing the efficacy and safety of precision OAT in this study could lead to the wider adoption of a much-needed alternative to CPAP, which many patients cannot adhere to because of the discomfort it can cause."

The ProSomnus EVO is an alternative to legacy dental products and CPAP machines, and can result in more effective treatment and superior patient compliance. Fully customized based on the anatomy and treatment plan for each patient, the ProSomnus EVO precisely repositions and stabilizes the jaw during sleep, improving airflow through a patient's pharyngeal space. The ProSomnus EVO consists of maxillary and mandibular aligners that are precision-manufactured with twin-mated posts, and is digitally manufactured to be patient-specific. Prescribed advancements can be achieved by removing the current upper- or lower-device arch and inserting the next arch in the mandibular advancement series.

Participants in the study will receive a custom ProSomnus EVO and be tested using a Type II home sleep apnea test (HSAT) to determine if they have achieved an AHI of less than 15 h^{-1} with the device in place. Researchers will administer HSATs at predetermined intervals. To determine the ProSomnus EVO's efficacy, participants will complete a set device advancement and testing protocol and a final HSAT six months after precision OAT begins. During each visit after precision OAT begins, researchers will conduct safety evaluations which, along with dental examinations and adverse event reports, will be used to determine the ProSomnus EVO's safety. After collecting data for the study's primary endpoints for six months after precision OAT begins, researchers will monitor participants for six more months.

"OSA is a health issue of global proportions with dire health and economic consequences if not properly treated. Physicians must be able to provide severe OSA patients with a treatment option that they will use every night, all night," said Len Liptak, Co-Founder and Chief Executive Officer of ProSomnus. "This study is designed to validate the ProSomnus EVO as a safe and efficacious treatment option for the millions of people with OSA, giving healthcare providers a patient-preferred alternative to CPAP and Hypoglossal Nerve Stimulation implants."

More information about the SOS study can be found at www.clinicaltrials.gov using the identifier NCT05445869.

About OSA
OSA is the recurring collapse of the airway during sleep, resulting in oxygen shortages and abrupt awakenings accompanied by gasping or choking. In addition to daytime sleepiness, OSA is associated with serious comorbidities, including heart failure, stroke, hypertension, morbid obesity and type 2 diabetes. Patients with untreated OSA are 23 times more likely to suffer a heart attack and four times more likely to have a stroke. It is estimated that more than one billion people worldwide and over 74 million people in North America suffer from OSA. Approximately 56 million of those 74 million people in North America are undiagnosed.

About ProSomnus
ProSomnus (NASDAQ: OSA) is the first manufacturer of precision, mass-customized Precision Oral Appliance Therapy devices to treat OSA, which affects over 74 million Americans and is associated with serious comorbidities, including heart failure, stroke, hypertension, morbid obesity and type 2 diabetes. ProSomnus' patented devices are a more comfortable and less invasive alternative to Continuous Positive Airway Pressure (CPAP) therapy, and lead to more effective and patient-preferred outcomes. With more than 150,000 patients treated, ProSomnus' devices are the most prescribed Precision Oral Appliance Therapy in the U.S. To learn more, visit www.ProSomnus.com.

Important Notice Regarding Forward-Looking Statements
This Press Release contains certain "forward-looking statements" within the meaning of the Securities Act of 1933 and the Securities Exchange Act of 1934, both as amended. Statements that are not historical facts, including statements about the parties' perspectives and expectations, are forward-looking statements. The words "expect," "believe," "estimate," "intend," "plan" and similar expressions indicate forward-looking statements. These forward-looking statements are not guarantees of future performance and are subject to various risks and uncertainties, assumptions (including assumptions about general economic, market, industry and operational factors), known or unknown, which could cause the actual results to vary materially from those indicated or anticipated.

Such risks and uncertainties include, but are not limited to: (i) the effect of the announcement or the business combination on ProSomnus's business relationships, operating results and business generally; (ii) risks that the business combination disrupts current plans and operations of ProSomnus; (iii) the outcome of any legal proceedings that may be instituted against ProSomnus or Purchaser related to the business combination; (iv) changes in the competitive industries in which ProSomnus operates, variations in operating performance across competitors, changes in laws and regulations affecting ProSomnus's business and changes in the combined capital structure; (v) the ability to implement business plans, forecasts and other expectations after the completion of the business combination, and identify and realize additional opportunities; (vi) the risk of downturns in the market

and ProSomnus's industry including, but not limited to, as a result of the COVID-19 pandemic; (vii) costs related to the transaction and the failure to realize anticipated benefits of the transaction or to realize estimated pro forma results and underlying assumptions, including with respect to estimated stockholder redemptions; (viii) the risk of potential future significant dilution to stockholders resulting from lender conversions under the convertible debt financing; and (ix) risks and uncertainties related to ProSomnus's business, including, but not limited to, risks relating to the uncertainty of the projected financial information with respect to ProSomnus; risks related to ProSomnus's limited operating history, the roll-out of ProSomnus's business and the timing of expected business milestones; ProSomnus's ability to implement its business plan and scale its business, which includes the recruitment of healthcare professionals to prescribe and dentists to deliver ProSomnus oral devices; the understanding and adoption by dentists and other healthcare professionals of ProSomnus oral devices for mild-to-moderate OSA; expectations concerning the effectiveness of OSA treatment using ProSomnus oral devices and the potential for patient relapse after completion of treatment; the potential financial benefits to dentists and other healthcare professionals from treating patients with ProSomnus oral devices and using ProSomnus's monitoring tools; ProSomnus's potential profit margin from sales of ProSomnus oral devices; ProSomnus's ability to properly train dentists in the use of the ProSomnus oral devices and other services it offers in their dental practices; ProSomnus's ability to formulate, implement and modify as necessary effective sales, marketing, and strategic initiatives to drive revenue growth; ProSomnus's ability to expand internationally; the viability of ProSomnus's intellectual property and intellectual property created in the future; acceptance by the marketplace of the products and services that ProSomnus markets; government regulations and ProSomnus's ability to obtain applicable regulatory approvals and comply with government regulations, including under healthcare laws and the rules and regulations of the U.S. Food and Drug Administration; and the extent of patient reimbursement by medical insurance in the United States and internationally. A further list and description of risks and uncertainties can be found in Lakeshore's initial public offering prospectus dated June 10, 2021 and in the Company's quarterly reports on Form 10-Q and annual reports on Form 10-K filed with the Securities and Exchange Commission (the "SEC") subsequent thereto and in the Registration Statement on Form S-4 and proxy statement that has been filed with the SEC by Lakeshore in connection with the business combination, and other documents that the parties may file or furnish with the SEC, which you are encouraged to read. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those indicated or anticipated by such forward-looking statements. Accordingly, you are cautioned not to place undue reliance on these forward-looking statements. Forward-looking statements relate only to the date they were made, and the Company and its subsidiaries undertake no obligation to update forward-looking statements to reflect events or circumstances after the date they were made except as required by law or applicable regulation.

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