



ProSomnus® Announces Medicare Reimbursement for ProSomnus EVO® [PH] Sleep Apnea and Snoring Device

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Additional reimbursement coverage further expands the market for ProSomnus as the Company seeks to make precision oral appliance therapy a first-line treatment for obstructive sleep apnea

SAN FRANCISCO, Dec. 15, 2022 (GLOBE NEWSWIRE) -- ProSomnus, Inc. ("the Company") (NASDAQ: OSA), a pioneer in precision oral appliance therapy (OAT) for the treatment of Obstructive Sleep Apnea (OSA), today announced that its ProSomnus EVO® [PH] Sleep and Snore Device now qualifies for Medicare reimbursement. The Pricing, Data Analysis, and Coding (PDAC) Contractor has reviewed and verified the device for the Healthcare Common Procedure Coding System (HCPCS) code E0486. Medicare beneficiaries account for an estimated 20% of people in the United States with OSA.

The ProSomnus EVO [PH] is a precision OAT medical device specifically engineered to meet Centers for Medicare Services coding guidelines, offering Medicare beneficiaries a non-invasive, comfortable, easy-to-use, and effective alternative to CPAP machines, surgical procedures, and legacy dental products. Per Medicare coding guidelines, the ProSomnus EVO [PH] device repositions and stabilizes the patient's jaw during sleep, increasing pharyngeal space and reducing the risk of upper airway collapse. The device is approximately 32% smaller than predicate devices and features unique comfort bumps around key components. The device has unique advancement markings and visual indicators to make it easier for beneficiaries to use the device and to communicate with their healthcare providers throughout treatment.

Every ProSomnus EVO [PH] device is personalized and digitally manufactured based upon the patient's unique anatomy and healthcare provider's treatment plan for each patient. The ProSomnus EVO [PH] is the only Medicare coding verified device for OSA made from engineered, Medical Grade Class VI-rated material, the highest material quality grade offered by US Pharmacopeia. In November, ProSomnus [announced](#) that it had received 510(k) clearance from the United States Food and Drug Administration (FDA) for the ProSomnus EVO [PH].

In a multi-center IRB-controlled preference study, 91% of patients strongly preferred ProSomnus EVO [PH] to their prior dental products therapy. 94% of patients reported that EVO [PH] felt smaller, more natural, and more comfortable than their prior therapy. 100% of providers who participated in the study said they would prescribe the device again, and 100% said that they would recommend it to their colleagues.

"With Medicare coding verification, the ProSomnus EVO [PH] offers healthcare providers and their Medicare beneficiary patients a comfortable, effective and reimbursable treatment option for OSA that addresses many of the limitations of dental product and CPAP therapies," said Len Liptak, Co-Founder and Chief Executive Officer of ProSomnus. "Achieving Medicare coding verification for the ProSomnus EVO [PH] enhances our momentum as we expand availability of precision OAT to even more patients, thereby increasing adoption and creating better patient outcomes when treating OSA, a disease state impacting 74 million Americans today."

"The ProSomnus EVO [PH] addresses some of providers' and patients' biggest concerns regarding legacy dental product therapies, including flexibility, durability, stain resistance and maintaining form," said Sung Kim, Co-Founder and Chief Technology Officer of ProSomnus. "Designing a user-friendly yet high-performance device with high-quality materials is key as we continue to raise awareness of precision OAT as a patient-preferred OSA treatment, and in turn addressing this global health emergency."

Patients interested in learning more about ProSomnus' Precision OAT devices for the treatment of OSA can visit www.ProSomnus.com or speak with their [local ProSomnus sleep dentist](#).

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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