# ProSomnus Severe Indication 510(k) Submission Accepted for Review by the FDA

January 30, 2024

PLEASANTON, Calif., Jan. 30, 2024 (GLOBE NEWSWIRE) -- ProSomnus, Inc. (NASDAQ: OSA) (the "Company"), the leading non-CPAP Obstructive Sleep Apnea (OSA) therapy™, announced today that the United States Food and Drug Administration (the "FDA") has accepted, and is in the process of reviewing, the Company's premarket notification for its ProSomnus® EVO® precision medical device for the treatment of patients with severe obstructive sleep apnea.

"The acceptance of our 510(k) submission for substantive review represents a significant step towards expanding access to care for the millions of patients with Obstructive Sleep Apnea who prefer a safe, effective and convenient treatment alternative to CPAP or invasive procedures," commented Len Liptak, ProSomnus Chief Executive Officer. "We look forward to working closely with the FDA throughout this review process as we look to expand the labeling for our precision Oral Appliance Therapy device."

The Company's premarket notification 510(k) submission included a robust clinical data dossier demonstrating the safety and efficacy of its ProSomnus EVO precision medical device relative to the performance goals indicated in pre-submission meetings and reference devices. The clinical data submitted by the Company in support of its 510(k) submission included data on 92 patients with severe OSA from two prospective clinical studies.

- The mean age of patients was 52 (26-77);
- Mean body mass index ("BMI") was 31.4 (19.8-45.9);
- Baseline mean apnea-hypopnea index ("AHI") was 47.5 (30.1-106.9); and
- Mean baseline oxygen desaturation index ("ODI") was 47.1 (16.7-107.9).

When compared to baseline measurements:

- 75% of patients successfully achieved the AHI target of AHI < 20 and a 50% reduction from baseline;
- 91% of patients successfully achieved the ODI target of 25% improvement from the baseline;
- 82% of patients achieved the sleep apnea specific hypoxic burden target of < 60 % min / hr.; and
- 89% of patients achieved a 45% improvement in AHI or improved their OSA severity by at least one strata.

With ProSomnus treatment, compared to baseline, patients experienced:

- a mean AHI improvement of 66%;
- a mean ODI improvement of 60%; and
- a mean improvement in sleep apnea specific hypoxic burden of 69%.

These results were achieved without patient preselection or excluding patients with concentric collapse airway profiles.

"We believe the clinical data from treating patients with severe Obstructive Sleep Apnea combined with an excellent safety profile derived from hundreds of thousands of real-world cases, positions us well for obtaining severe indication clearance from the FDA," noted Dr. John Remmers, MD, ProSomnus Chief Scientist. "FDA clearance for the use of the ProSomnus EVO precision medical device in the treatment of severe OSA patients has the potential to open a new, safer, more effective and less invasive treatment modality for such patients that does not exist today."

Pursuant to Section 510(k), following acceptance, the FDA will conduct its substantive review of the submission, which may include a request for additional information from the Company. FDA guidance indicates that the FDA seeks to complete its review of 510(k) submissions within 90 calendar days of date of receipt, excluding time required by the Company to respond to additional information requests. The time required to respond to any such requests will depend on the nature of the request.

**About ProSomnus**
ProSomnus (NASDAQ: OSA) is the leading non-CPAP therapy for the treatment of Obstructive Sleep Apnea, a serious medical disease affecting over 1 billion people worldwide, that is associated with comorbidities including heart failure, stroke, hypertension, morbid obesity, and type 2 diabetes. ProSomnus intraoral medical devices are engineered to precisely track the treatment plan and anatomy for each patient. Non-invasive, patient preferred and easy to use, ProSomnus devices have demonstrated excellent efficacy, safety, adherence, and overall outcomes in a growing body of clinical investigations. ProSomnus precision intraoral devices are FDA-cleared, patented, and covered by commercial medical insurance, Medicare, TRICARE and many Government-sponsored healthcare plans around the world, representing over 200 million covered lives. 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 timing, outcome and impact of the FDA's review of the Company's 510(k) submission for the severe OSA indication, are forward-looking statements. The words "expect," "believe," "estimate," "intend," "plan" and similar expressions indicate forward-looking statements, although not all forward-looking statements contain these or similar identifying words.

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: changes in the timelines and potential

outcomes of regulatory clearance and/or approval processes; securing and maintain regulatory clearances, approvals and compliance in jurisdiction in which the Company intends to offer its products, competitive industries in which the Company operates and variations in operating performance across competitors; changes in laws and regulations affecting ProSomnus's business; the risk of downturns in the market and ProSomnus's industry; risks related to ProSomnus's limited operating history and history of losses; 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; the understanding and adoption by dentists and other healthcare professionals of ProSomnus oral devices for severe OSA if clearance for such indication be secured from the FDA; 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; 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 adoption of its devices; 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; the extent of patient reimbursement by medical insurance in the United States and internationally; and the outcome of any legal proceedings that may be instituted against the Company. A further list and description of risks and uncertainties can be found in the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (the "SEC") on November 14, 2023. 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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