



## Data Presented at the 2023 SLEEP Annual Meeting Strengthens Evidence for ProSomnus Precision Oral Appliance Therapy for the Treatment of Obstructive Sleep Apnea

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PLEASANTON, Calif., June 08, 2023 (GLOBE NEWSWIRE) -- ProSomnus, Inc. (NASDAQ: [OSA](#)), a leading CPAP alternative for the treatment of Obstructive Sleep Apnea (OSA), announced the presentation of three abstracts at the 2023 SLEEP Annual Meeting, hosted jointly by the Associated Professional Sleep Societies, LLC (APSS), the American Academy of Sleep Medicine (AASM), and the Sleep Research Society (SRS), held June 3-7 in Indianapolis, Indiana.

"The collective research demonstrates that ProSomnus's Precision Oral Appliance Therapy (OAT) devices are associated with significantly fewer adverse event reports than other OATs, CPAP and hypoglossal nerve stimulation treatments," stated John E. Remmers, MD, Chief Scientist of ProSomnus. "Furthermore, the data show that Precision OAT can efficaciously treat all severities of OSA, making a strong case for the widespread adoption of this less invasive, patient-preferred treatment modality."

- *Assessing precision oral appliance efficacy using frequency- and risk-based indices; abstract 0513*
  - This investigation is one of the first to demonstrate the efficacy of precision OAT, or any OSA treatment for that matter, using a risk-based (sleep apnea specific hypoxic burden "SASHB") index.
  - Prior research importantly demonstrates that SASHB is predictive of mortality, cardiovascular events, and overall health outcomes, whereas the frequency-based index (apnea hypopnea index "AHI") is not.
  - In this retrospective analysis of 48 patients, precision OAT demonstrated 90% therapeutic efficacy using the risk based SASHB index.
- *Adverse Event Reports for CPAP, HNS and Oral Devices: An FDA MAUDE Database Analysis; abstract 0509*
  - This analysis of the FDA MAUDE database reports significantly fewer AERs for OAT than for CPAP and hypoglossal nerve stimulation (HNS).
  - From January 1, 2022 to September 2022, there were 72,251 AERs for CPAP, 11,867 for HNS and just 30 for OAT.
  - From January 2017 to September 2022, the annual count of AERs for CPAP increased by 245% and in HNS by 252%, while the annual count of AERs for OATs decreased by 1.3%.
- *OAT Device Designs are Not the Same When It Comes to FDA Adverse Event Reports; abstract 0539*
  - This analysis of the FDA Manufacturer and User Facility Device Experience (MAUDE) database demonstrates that Precision OAT devices using precision-engineered materials, monolithic structures, 90-degree twin posts and precision-engineered liner-less designs are associated with fewer adverse event reports (AERs).
  - Materials: 98.5% of AERs involved OATs made from dental lab materials, while just 1.5% involved devices made from engineered medical grade materials, such as Medical-grade Class VI polymers.
  - Structure: 98% of AERs involved OATs with metal, elastomeric or nylon components, while just 2% involved monolithic structures.
  - Liners: 98.5% of AERs involved lab-formed OATs with and without liners, while just 1.5% of AERs involved precision-engineered liner-less devices.

"ProSomnus is proud to contribute research, in the form of these three abstracts, toward some of the most important topics in sleep medicine," explained Len Liptak, Chief Executive Officer of ProSomnus. "As the CPAP recall persists, two abstracts investigate FDA adverse event reports and the safety of precision OAT. As the field of sleep medicine moves beyond the AHI scale, our third abstract evaluates the efficacy of precision OAT using the risk-based index SASHB. This research further establishes ProSomnus precision OAT as a safe and efficacious treatment for OSA."

### About ProSomnus

ProSomnus (NASDAQ: [OSA](#)) is a leading CPAP alternative 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](http://www.ProSomnus.com).

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