



ProSomnus® Announces Significant Progress on Strategic Programs

SAN FRANCISCO, August 11, 2025 — ProSomnus Sleep Technologies (“the Company”), the leading non-CPAP Obstructive Sleep Apnea (OSA) therapy®, today announced significant progress on strategic programs. The key feature is the successful FDA registration of the company’s HWO₂ buccal mucosal wellness oximeter. The ProSomnus HWO₂ Device enables patients to monitor their nightly health and wellness during sleep, specifically, blood oxygen saturation, pulse rate and overall use time, from their smartphones. In a controlled desaturation study, the HWO₂ Device demonstrated a root mean squared error (RMSE) of 2.94% over the range of 70-100% SaO₂ collected from 325 matched SpO₂/SaO₂ data pairs. Performed at the University of Calgary’s Cumming School of Medicine, the test also confirmed pulse rate accuracy with a RMSE of 2.08 bpm collected from 346 matched pulse rate/electrocardiogram data pairs (Snow et al. Med Devices (Auckl). 2025 Jul 11:18:387-395. doi: 10.2147/MDER.S527510). Testing provided initial confirmation that intraoral oximetry may offer several meaningful benefits as the buccal mucosal region has qualities that mitigate known confounding variables for oximetry. The buccal mucosal region is highly vascular, not prone to contamination from ambient light, temperature stable, and appears to contain less melanin than skin.

“The HWO₂ Device makes it easy, comfortable, and economical to monitor nightly health and wellness. The user simply wears the device, as one might wear a retainer or orthodontic aligner. Upon removal, the device transfers the nightly data to the user’s smartphone app, where the patient can monitor and visualize their nightly health and sleep,” commented Edward T. Sall, MD, DDS, MBA.

HWO₂ comes on the heels of introducing ProSomnus EVO® Guided, the only device bioengineered to dilate the velopharynx and the oropharynx. Unlike traditional oral devices that are built around prefabricated items, each EVO Guided device is custom-fabricated directly from the prescribing provider’s digital records—without prefabricated elements or alterations to the original prescription. This enables EVO Guided to offer more room for the tongue to stay forward; a novel titration mechanism to stabilize the mandible and prevent jaw drop; and an optimized, minimalistic, anatomical design to minimize tooth separation, facilitate mouth closure, and encourage nasal breathing. The company’s post-market surveillance data indicates high levels of patient and provider satisfaction.

“We have been waiting years for a truly accurate SpO₂ monitor embedded in an oral device, and after months of wearing the ProSomnus HWO₂ Device, I believe we are finally here. It is comfortable, reliable, and consistently delivers actionable data—I am sold. Likewise, when we first began using the ProSomnus EVO Guided Device in early 2025, its thinner design and extended mandibular post gave me pause. After delivering more than 1,000 devices, my concerns are gone. EVO Guided is now my oral appliance of choice,” stated Kent Smith, DDS, D-ABDSM, ASBA.

The Company is pleased to also announce that it has secured additional growth capital to support EVO Guided, the HWO₂ program, and other strategic initiatives. The financing was led by existing investors Spring Mountain Capital, LP, Littlejohn & Co. and Masters Special Situations. The Company is also pleased to welcome Jason Orchard as Chief Financial Officer. Jason brings over two decades of investment, financial, and operating expertise to the role, including investing in and successfully building novel healthcare companies.



"I am excited to join the team in such a pivotal time in the Company's evolution. The Company is innovating in meaningful ways, and I look forward to working with the leadership team to help drive high-impact results for patients, practitioners, and stakeholders," commented Jason Orchard.

In acknowledgement of the growing importance of personal health information in the field of sleep medicine, ProSomnus announced certification under the EU-U.S. Data Privacy Framework (DPF), the UK Extension to the EU-U.S. DPF, and the Swiss-U.S. DPF, enabling compliant cross-border transfers of personal data from Europe to the United States. ProSomnus is the first major sleep medicine company to achieve DPF certification, joining major healthcare companies such as Eli Lilly, Abbott Laboratories, and Proctor & Gamble Company, in addition to Microsoft, Amazon, Google and Meta Platforms, Inc.

ProSomnus is a bronze sponsor of the [2025 World Sleep Congress](#), taking place September 5-10, 2025 in Singapore. The Company expects to feature the new EVO Guided and HWO₂ devices at the event. The Company has a symposium, [Beyond Mandibular Advancement: Science, Innovation and Outcomes](#) on Monday, September 8, 2025 from 12:45pm-1:45pm in Room #326. Featured presenters include experts Danny J. Eckert, PhD, Olivier M. Vanderveken, MD, PhD, and Edward T. Sall, MD, DDS, MBA. ProSomnus invites interested parties to attend and visit booth #410 to learn more. The Company also reports at least seven scientific abstracts that evaluate the merits of the ProSomnus EVO and HWO₂ devices.

"At ProSomnus, our mission is enabling more patients to breathe better during sleep, with devices that make OSA treatment safe, effective, patient preferred and economical," stated Len Liptak, Chief Executive Officer for ProSomnus Sleep Technologies. "The progress made on these strategic initiatives demonstrates the impressive contributions of ProSomnus team members worldwide, guidance from dental sleep medicine providers, and support from our investors."

About ProSomnus Sleep Technologies

ProSomnus Sleep Technologies 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.

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