# Nyxoah Rings the Closing Bell at Nasdaq while Preparing for U.S. Market Launch of Innovative Sleep Apnea Device

*FDA regulatory submission for the Company's Genio® device is complete, U.S. approval on track for the end of 2024*

*U.S. commercial launch, expected at the beginning of 2025, fully funded with over €85 million in new capital raised*


*Nyxoah – NASDAQ Closing Bell Ceremony 29 août 2024*

**Mont-Saint-Guibert, Belgium – September 2, 2024 10:05pm CET / 4:05PM ET – Nyxoah SA (Euronext Brussels/Nasdaq: NYXH)** ("Nyxoah" or the "Company"), a medical technology company focused on the development and commercialization of innovative solutions to treat Obstructive Sleep Apnea (OSA), rang the Nasdaq Closing Bell on August 29, 2024 to recognize the Company's recent progress and highlight upcoming milestones on its path to the U.S. market launch of its innovative patient-centric Genio® hypoglossal nerve stimulation technology for OSA, a prevalent and severe sleep-related breathing disorder associated with increased mortality risk and cardiovascular comorbidities.

"We are honored to ring the Closing Bell and to celebrate our recent clinical and regulatory achievements in the U.S. We look forward with excitement to the upcoming U.S. launch of our lead product, Genio," **commented Olivier Taelman, Nyxoah's Chief Executive Officer.** "The U.S. is the largest healthcare market globally and therefore of strategic importance for us. With robust clinical evidence from our pivotal DREAM study, solid funding in place and our strengthened US commercial team, we feel well positioned to enter the US market. We have submitted the final module of our PMA submission to the FDA and are on track for U.S. approval by the end of 2024. If approved, Genio could become available in the U.S. as early as the beginning of 2025."


*Olivier Taelman, CEO of Nyxoah – NASDAQ Closing Bell Ceremony 29 august 2024*

**Recent Highlights and Upcoming Milestones of Nyxoah's U.S. Commercialization Strategy**

- Announcement of positive data from the pivotal U.S. study, DREAM, regarding Nyxoah's Genio® system, an innovative hypoglossal neurostimulation therapy for Obstructive Sleep Apnea (OSA) in spring 2024.
- Final module submitted in the modular PMA submission, initiating FDA interactive review.
- Building a U.S. commercial organization, headed by Scott Holstine as the new Chief Commercial Officer along with key sales, marketing and market access leaders.

- The U.S. market launch of Genio® is fully funded following the successful raising of over €85 million in growth capital through a €48.5 million equity offering and a €37.5 million loan facility agreement with the European Investment Bank (EIB).
- FDA approval expected approval by US Food and Drug Administration by the end of 2024.
- U.S. market launch of Genio® planned for the beginning of 2025.

To view the broadcast of the Nasdaq Closing Bell ceremony, please visit: https://www.nasdaq.com/news-and-insights/nasdaq-stock-market-bell-ceremonies

**About Nyxoah**

Nyxoah is a medical technology company focused on the development and commercialization of innovative solutions to treat Obstructive Sleep Apnea (OSA). Nyxoah's lead solution is the Genio® system, a patient-centered, leadless and battery-free hypoglossal neurostimulation therapy for OSA, the world's most common sleep disordered breathing condition that is associated with increased mortality risk and cardiovascular comorbidities. Nyxoah is driven by the vision that OSA patients should enjoy restful nights and feel enabled to live their life to its fullest.

Following the successful completion of the BLAST OSA study, the Genio® system received its European CE Mark in 2019. Nyxoah completed two successful IPOs: on Euronext Brussels in September 2020 and NASDAQ in July 2021. Following the positive outcomes of the BETTER SLEEP study, Nyxoah received CE mark approval for the expansion of its therapeutic indications to Complete Concentric Collapse (CCC) patients, currently contraindicated in competitors' therapy. Additionally, the Company announced positive outcomes from the DREAM IDE pivotal study for FDA and U.S. commercialization approval.

For more information, please see the Company's annual report for the financial year 2023 and visit http://www.nyxoah.com/.

**Caution** – CE marked since 2019. Investigational device in the United States. Limited by U.S. federal law to investigational use in the United States.

**Forward-looking statements**

Certain statements, beliefs and opinions in this press release are forward-looking, which reflect the Company's or, as appropriate, the Company directors' or managements' current expectations regarding the entry into of the loan facility agreement and the synthetic warrant agreement with the EIB; the use of proceeds from the loan facility agreement; the Genio® system and ongoing clinical studies of the Genio® system; the potential advantages of the Genio® system; Nyxoah's goals with respect to the development, regulatory pathway and potential use of the Genio® system; the utility of clinical data in potentially obtaining FDA approval of the Genio® system; reporting data from Nyxoah's DREAM U.S. pivotal trial; filing for FDA approval; and entrance to the U.S. market. By their nature, forward-looking statements involve a number of risks, uncertainties, assumptions and other factors that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements. These

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