



Nyxoah Announces First U.S. Commercial Patients Implanted with Genio® System

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Early Commercial Launch Demonstrates Strong Physician Demand, Successful Pre-Authorizations, and Widespread Payor Coverage

Mont-Saint-Guibert, Belgium – October 6, 2025 7:00 CET / 1:00 ET – Nyxoah SA (Euronext Brussels/Nasdaq: NYXH), a medical technology company that develops breakthrough treatment alternatives for Obstructive Sleep Apnea (OSA), today announced that the first U.S. commercial patients have been successfully implanted with the Genio® system following FDA approval.

"We are thrilled to announce that the first commercial patients have now received Genio implants, marking a significant milestone in bringing this innovative therapy to OSA patients in the U.S.," said Olivier Taelman, Chief Executive Officer. "Importantly, we have trained surgeons, obtained Value Analysis Committee (VAC) approvals and achieved successful coverage from major payors including CMS. What's also particularly encouraging is the strong demand we're seeing from physicians, with surgeons actively reaching out for training opportunities, many of whom already have patients lined up for implants. These early leading indicators give us confidence that we're building the right foundation for the sustained adoption of Genio moving forward."

Andrew T. Huang, MD FACS, Director of Sleep Surgery at Baylor College of Medicine implanted the first Genio devices at Townsen Memorial Health System in Houston, TX. "I am excited to not only be the first surgeon to perform Genio® implants commercially in the United States but to have completed my first five in one week. It was awesome to see the powerful and symmetric tongue protrusion at the end of each procedure. Like with any new procedure, there is a learning curve, but I'm excited to say the cases took me the same amount of time as my first unilateral HGN implants. The Genio system provides a solution for my patients who do not want two incisions, an implanted battery, and those where bilateral stimulation may be more beneficial to their airway anatomy," commented Dr. Huang. "Obstructive sleep apnea continues to represent a significant health burden in our country, and expanding access to new therapeutic options is essential. I am happy this therapy is now available in the US and am honored to help improve access to Genio Therapy by offering it to my patients and helping to train more providers on this amazing procedure."

The Company is tracking the following metrics which it believes will serve as leading indicators of future revenue growth:

- Number of surgeons trained;
- Number of value analysis committee submissions made;
- Number of prior authorization submissions; and
- Number of accounts opened.

About Nyxoah

Nyxoah is a medical technology company focused on the development and commercialization of innovative solutions to treat 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 and U.S. FDA approval of a Premarket Approval application.

For more information, please visit <http://www.nyxoah.com/>.

Caution – CE marked since 2019. FDA approved in August 2025 as prescription-only device.

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 Genio system; planned 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 Company's commercialization strategy and entrance to the U.S. market; the Company's intellectual property portfolio; and the Company's results of operations, financial condition, liquidity, performance, prospects, growth and strategies. 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 risks, uncertainties, assumptions and factors could adversely affect the outcome and financial effects of the plans and events described herein. Additionally, these risks and uncertainties include, but are not limited to, the risks and uncertainties set forth in the "Risk Factors" section of the Company's Annual Report on Form 20-F for the year ended December 31, 2024, filed with the Securities and Exchange Commission ("SEC") on March 20, 2025, and subsequent reports that the Company files with the SEC. A multitude of factors including, but not limited

to, changes in demand, competition and technology, or adverse litigation outcomes can cause actual events, performance or results to differ significantly from any anticipated development. Forward looking statements contained in this press release regarding past trends or activities are not guarantees of future performance and should not be taken as a representation that such trends or activities will continue in the future. In addition, even if actual results or developments are consistent with the forward-looking statements contained in this press release, those results or developments may not be indicative of results or developments in future periods. No representations and warranties are made as to the accuracy or fairness of such forward-looking statements. As a result, the Company expressly disclaims any obligation or undertaking to release any updates or revisions to any forward-looking statements in this press release as a result of any change in expectations or any change in events, conditions, assumptions or circumstances on which these forward-looking statements are based, except if specifically required to do so by law or regulation. Neither the Company nor its advisers or representatives nor any of its subsidiary undertakings or any such person's officers or employees guarantees that the assumptions underlying such forward-looking statements are free from errors nor does either accept any responsibility for the future accuracy of the forward-looking statements contained in this press release or the actual occurrence of the forecasted developments. You should not place undue reliance on forward-looking statements, which speak only as of the date of this press release.

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