Nyxoah’s DREAM Pivotal Study Data Published in the Journal of Clinical Sleep Medicine

July 28, 2025

Nyxoah’s DREAM Pivotal Study Data Published in the Journal of Clinical Sleep Medicine

Mont-Saint-Guibert, Belgium – July 28, 2025, 10:05pm CET / 4:05pm ET – Nyxoah SA (Euronext Brussels/Nasdaq: NYXH) (“Nyxoah” or the “Company”), a medical technology company that develops breakthrough treatment alternatives for Obstructive Sleep Apnea (OSA), today announced that data from its DREAM pivotal study was published online in the Journal of Clinical Sleep Medicine. The DREAM pivotal study presents comprehensive 12-month safety and efficacy results that supported the Company's PMA submission to the FDA. The peer-reviewed publication provides detailed analysis of the Genio® system's performance across multiple clinical endpoints.

The publication reveals new data on device usage and patient satisfaction that was not included in the Company's previous announcements. These additional findings show that nightly device usage was greater than 4 hours in more than 70% of nights in 84.3% of participants completing diary entries in the 3 months preceding the 12-month visit. Overall, the device was used over 70% of the nights by 85.9% of the participants.

The publication also reports 90% of patients expressed satisfaction with the therapy. Additionally, data shows that a patient’s snoring score [1] was reduced from 83.5% at baseline to 30.4% at 12 months.

“The DREAM study demonstrated efficacy of bilateral hypoglossal nerve stimulation using Genio for the treatment of obstructive sleep apnea," said B. Tucker Woodson, MD, Chief, Professor – Medical College of Wisconsin and Principal Investigator of the DREAM study. "Genio demonstrated a strong effect in reducing disease burden and improving quality of life by significantly reducing the apnea hypopnea burden encouraging patient adherence and satisfaction. Genio's patient-centric design and bilateral HGNS stimulation offer an exciting advancement in treatment of OSA patients who fail or refuse CPAP."

"These newly published outcomes are exactly what we expected to see," said Olivier Taelman, CEO of Nyxoah. "The high patient satisfaction and consistent usage patterns validate our belief that Genio's leadless, externally powered design addresses real patient needs. The significant improvement in bedpartner sleep quality shows the broader impact our technology can have on OSA patients and their families."

The publication included previously announced data demonstrating that the study achieved its co-primary endpoints of 12-month AHI responder rate, per the Sher criteria, and Oxygen Desaturation Index (ODI) responder rate, both on an Intent-To-Treat (ITT) basis. In the DREAM U.S. pivotal study, 115 patients received the Genio® implant and were included in the safety analysis. These patients had a mean AHI of 28.0, mean ODI of 27.0 and mean body mass index of 28.5 at baseline. At 12 months, 73 subjects were determined to be AHI responders, per the Sher criteria, resulting in an ITT AHI responder rate of 63.5% (p=0.002), and 82 subjects were determined to be ODI responders, resulting in an ODI responder rate of 71.3% (p<0.001). Safety results were in line with other neuromodulation therapies, with 11 serious adverse events, or SAEs, in ten subjects resulting in an SAE rate of 8.7%. Out of the 11 SAEs, three were device related, and there were three explants.

The publication also included previously announced data demonstrating similar AHI reduction in supine and non-supine positions. Genio bilateral stimulation resulted in a clinically meaningful 66.6% median reduction in supine AHI at 12 months compared with baseline. This reduction compares to a median 12-month AHI reduction of 70.8% across all sleeping positions.

With respect to secondary endpoints reported at ISSS, subjects demonstrated significant improvements in quality-of-life outcomes. Specifically, a mean increase of 2.3 points was observed in the Functional Outcomes of Sleep Questionnaire (FOSQ) assessment. Additionally, the Epworth Sleepiness Score was reduced by a mean of 3.4 points from baseline.

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 more information, please 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 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; receipt of FDA approval; satisfactory completion of a manufacturing facilities, methods and controls review, and the anticipated timing of the foregoing; entrance to the U.S. market; 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, 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.

Contacts: Nyxoah
John Landry, CFO
IR@nyxoah.com

For Media

In United States
FINN Partners – Glenn Silver
glenn.silver@finnpartners.com

In International/Germany
MC Services – Anne Hennecke nyxoah@mc-services.eu

In Belgium/France
Backstage Communication – Gunther De Backer gunther@backstagecom.be

---

[1] In those that reported bedpartner leaving the room, very loud or loud snoring

Attachment

- ENGLISH_DREAM Publication_FINAL