



Nyxoah Announces 2024 Strategic Priorities

January 17, 2024

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Mont-Saint-Guibert, Belgium – January 17, 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), today announced, in anticipation of upcoming investor meetings, its strategic priorities for 2024.

2024 Strategic Priorities

- **Complete patient follow up in the DREAM U.S. pivotal study and report efficacy and safety data by early April.** 12-month efficacy data¹ on the first 34 DREAM patients and safety data on all DREAM patients were presented at SLEEP 2023, demonstrating a 65% AHI responder rate, a 76% ODI responder rate and safety in-line with expectations. These data are preliminary and not conclusive of final DREAM success.
- **File the fourth and final module in the modular PMA submission.** Anticipate submitting the final module shortly after announcing DREAM results.
- **Accelerate investments in the U.S. commercial organization in preparation for a late 2024 launch.** Recently hired Francis Kim as Chief Regulatory and Quality Officer and expanded market access to secure reimbursement at launch.
- **Complete enrollment in the ACCESS complete concentric collapse (CCC) U.S. pivotal study.** Recently announced investigator-sponsored data in Europe demonstrating Genio's® success in treating CCC patients.
- **Increase hypoglossal nerve stimulation (HGNS) market penetration and Genio market share in Europe.** For 2024, we expect continued sales growth driven by an increasing benefit from direct-to-consumer (DTC) initiatives, initial contribution from the ResMed commercial partnership in Germany and geographic expansion.

“Since Nyxoah’s founding we have been guided by the mission to improve the lives of OSA patients. This led to the development of the patient-centric Genio HGNS system. Genio’s single-incision, leadless, upgradable design powered and controlled by a wearable resonated with clinicians and patients and led to a strong European launch. Genio’s bilateral stimulation enables treatment of CCC, and the label was subsequently expanded to include these patients, whose only treatment option after failing CPAP up until then was major palate surgery,” commented Olivier Taelman, Chief Executive Officer.

“In our ongoing effort to provide patients greater control over their therapy, thereby making sleep simple again, we then received approval for Genio 2.1. Genio 2.1 offers patients daily feedback on therapy usage and autonomy to adjust stimulation amplitude within pre-defined boundaries, improving patient comfort and compliance without the need for a surgical procedure to replace the implantable component.”

“We are now on the cusp of the most significant milestone in the Company’s history with the reporting of DREAM results in the coming months. We expect to complete the PMA submission shortly after and are accelerating manufacturing and commercial investments to ensure we are fully prepared to replicate our European success in the U.S. With an approaching U.S. launch and continued growth in Europe, we are excited for the coming years.”

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 is currently conducting the DREAM IDE pivotal study for FDA and U.S. commercialization approval.

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; the utility of clinical data in potentially obtaining FDA approval of the Genio® system; reporting data from Nyxoah’s DREAM US pivotal trial;

filing for FDA approval; entrance to the US market, contributions from the ResMed commercial partnership in Germany; 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, 2022, filed with the Securities and Exchange Commission ("SEC") on March 22, 2023, 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.

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¹ For the trial to be successful, of the 115 patients, at least 63% of patients need to be AHI and ODI responders at the 12-month follow-up.

Attachment

- [ENGLISH Nyxoah Announces 2024 Strategic Priorities](#)