INSIDE INFORMATION
REGULATED INFORMATION

Nyxoah Receives Approval from FDA for Genio® System for the Treatment of Obstructive Sleep Apnea

U.S. Commercialization Officially Launched

Mont-Saint-Guibert, Belgium – August 8, 2025, 10:10pm CET / 4:10pm 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) through neuromodulation, today announced that the U.S. Food and Drug Administration (FDA) has approved the Genio system for a subset of patients with moderate to severe OSA with an Apnea-Hypopnea Index (AHI) of greater than or equal to 15 and less than or equal to 65.

Genio is a different approach to hypoglossal nerve stimulation (HGNS) for the treatment of OSA. Genio's unique design utilizes bilateral stimulation, and offers patients a leadless, full-body 1.5T and 3T MRI compatible, non-implanted battery solution, powered and controlled by a wearable component. The wearable component is fully upgradable, providing Genio patients with access to this technology without requiring additional surgeries for technology updates or battery replacements.

"Today marks a defining moment for Nyxoah and for U.S. patients suffering from OSA. With the FDA's marketing approval of the Genio system, we are proud to bring this innovative therapy to the U.S. market," commented Olivier Taelman, Nyxoah's Chief Executive Officer. "Our mission has always been to make sleep simple for OSA patients by offering them a solution that empowers better sleep. We look forward to the successful execution of our U.S. commercialization strategy."

The Genio system's FDA approval was supported by the high-quality, differentiated safety and efficacy data from the Company's DREAM pivotal trial. The DREAM study met both its primary and secondary endpoints demonstrating an AHI responder rate of 63.5% and an Oxygen Desaturation Index responder rate of 71.3%, with an overall median AHI reduction of 70.8%. Additionally, 82.0% of all DREAM subjects saw their AHI scores drop below 15 or lower.

Importantly, the DREAM study demonstrated that Genio is efficacious regardless of a patient's sleeping position and, to our knowledge the only therapy with such clinical evidence in a large, multicenter, prospective clinical study using data from a full night polysomnography. This is a critical differentiator as on average, people sleep in a supine position between 35% and 40% of the night. The DREAM study measured position-specific outcomes and demonstrated a 66.6% median AHI reduction while patients slept in a supine position despite the fact that the number of airway obstructions can double in this position. This reduction compares favorably to the 71.0% reduction in AHI shown while patients slept in a non-supine position.

"The Genio system's approval represents a major addition to the treatment options available to physicians treating patients with OSA," said Colin Huntley MD, Associate Professor, Department of Otolaryngology Head & Neck Surgery, Thomas Jefferson University. "This unique bilateral stimulation technology has demonstrated consistent efficacy across all sleeping positions, including the challenging supine position, while maintaining an excellent safety profile."

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/.

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; 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 – Alyssa Paldo
alyssa.paldo@finnpartners.com

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

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