



Nyxoah Announces Preliminary Results for the Second Quarter of 2025

August 11, 2025

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Mont-Saint-Guibert, Belgium – August 11, 2025, 7:00am CET / 1:00am 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 certain preliminary, unaudited financial results for the second quarter of 2025 and other business updates.

Preliminary, Unaudited Second Quarter 2025 Financial Results and Business Updates

- Announced on August 8, 2025, that the U.S. Food and Drug Administration (FDA) has approved the Genio® system for a subset of adult 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. [Press Releases | Nyxoah Investors](#)
- Revenue for the second quarter of 2025 is anticipated to be approximately €1.3 million, a 73% increase over the second quarter of 2024.
- Operating expenses for the second quarter of 2025 are anticipated to be approximately €20.7 million, a 50% increase over the second quarter of 2024.
- Cash, cash equivalents and financial assets are anticipated to be approximately €43.0 million at June 30, 2025. The Company also has a term debt facility with €27.5 million of remaining availability which can be drawn down in two equal tranches subject to revenue and other financial milestones.
- The Company expects to close patient enrollment in its ACCESS clinical trial prior to enrolling all 106 potential patients. The study will continue, with the patients currently enrolled, with the co-primary endpoints, Apnea-Hypopnea Index (AHI) and Oxygen Desaturation Index (ODI) responder rates, assessed at 12 months post implant and followed for five years.
- The Company reorganized its global R&D function and expects to transition all ongoing R&D activities from Israel to the U.S. and Belgium.
- The Company received notice that Inspire Medical Systems, Inc. ("Inspire") filed a lawsuit against the Company in the United States alleging infringement of certain patents owned by Inspire. The Company is well prepared, has the means and intends to vigorously defend itself in this matter.

"We are pleased with the growth we saw in the second quarter, which provides further evidence that our commercial proof of concept in Germany has been successful," commented Olivier Taelman, Chief Executive Officer. "With FDA approval in hand, we expect to take the lessons learned from Germany and apply them to the U.S. as we bring our unique Genio system to the U.S. In addition, we believe that the patient population currently enrolled in the ACCESS study will provide statistically significant results, which along with the outcomes from prior clinical evidence, will provide meaningful data with respect to the safety and efficacy of using Genio therapy in the patient population suffering from Complete Concentric Collapse ("CCC"). Patients with CCC represent a significant unmet need in the treatment of OSA as no FDA approved treatment currently exists."

The preliminary, unaudited financial results described in this press release, including preliminary revenue and operating expenses for the second quarter of 2025 and preliminary cash, cash equivalents and financial assets as of June 30, 2025, are estimates only. These financial results could change as a result of further review. Accordingly, you should not place undue reliance on this information. Complete financial results for the second quarter of 2025 will be announced and issued on Monday, August 18, 2025 after NASDAQ market close. A webcast of the call will be accessible via the Investor Relations page of the Nyxoah website or through this link: [Nyxoah's Q2 2025 Earnings Call Webcast](#).

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 and receipt of

approval from the U.S. Food and Drug Administration (FDA) 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.

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 Company's financial results for the second quarter ended June 30, 2025; the Company's estimates of revenue and operating expenses for the second quarter of 2025 and cash, cash equivalents and financial assets as of June 30, 2025; the Genio system; planned and ongoing clinical studies of the Genio system, including the ACCESS study; 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 plans to transition its ongoing R&D activities to the U.S. and Belgium; 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. 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 nyxoah@mc-services.eu

In Belgium/France

Backstage Communication – Gunther De Backer gunther@backstagecom.be

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- [Preliminary Results 2Q and 1st Half 25 PR-531708903-v5](#)