REGULATED INFORMATION

Nyxoah Reports Second Quarter Financial and Operating Results

FDA Approves Genio® System for U.S. Market; Company Begins Commercial Launch

Mont-Saint-Guibert, Belgium – August 18, 2025, 10:10pm CET / 4:10 pm 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 reported financial and operating results for the second quarter of 2025.

Recent Financial and Operating Highlights

- Received U.S. Food and Drug Administration (FDA) Pre-Market Approval (PMA) for the Genio system, the first and only bilateral hypoglossal neurostimulation therapy approved in the U.S.
- Kicked off the U.S. commercial launch of the Genio system
- DREAM pivotal study data published in the Journal of Clinical Sleep Medicine
- Revenue for the second quarter of 2025 was €1.3 million, compared to €0.8 million in the second quarter of 2024, representing 74% year over year growth
- Cash, cash equivalents and financial assets were €43.0 million at June 30, 2025, compared to €63.0 million at the end of March 31, 2025.

"This FDA approval represents a historic milestone for Nyxoah and marks the beginning of what we expect to be a transformational period for our company," commented Olivier Taelman, Nyxoah's Chief Executive Officer. "Genio is now the first and only bilateral hypoglossal neurostimulation therapy approved in the United States, offering a truly differentiated solution for OSA patients who have been underserved by existing therapies. Our world-class commercial team is in place, and we have begun to execute on our commercial strategy."

FDA PMA Approval

As previously disclosed, on August 8, 2025, the Company received FDA PMA for its Genio system, marking a historic milestone for Nyxoah. 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 Genio system's FDA approval was supported by the high-quality, differentiated safety and efficacy data from the Company's DREAM pivotal trial, which demonstrated that Genio is efficacious regardless of a patient's sleeping position. 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.

CONSOLIDATED STATEMENTS OF LOSS AND OTHER COMPREHENSIVE LOSS (unaudited)
(in thousands)

	For the three months ended June 30		For the six months ended June 30	
	2025	**2024**	**2025**	**2024**
Revenue	1 340	771	2 404	1 992
Cost of goods sold	(490)	(281)	(896)	(735)
Gross profit	**€ 850**	**€ 490**	**€ 1 508**	**€ 1 257**
Research and Development Expense	(10 059)	(7 472)	(19 048)	(14 671)
Selling, General and Administrative Expense	(10 672)	(6 383)	(23 063)	(12 355)
Other income	31	58	115	249
Operating loss for the period	**€ (19 850)**	**€ (13 307)**	**€ (40 488)**	**€ (25 520)**
Financial income	2 858	2 069	5 480	3 477
Financial expense	(3 337)	(1 445)	(7 579)	(2 436)
Loss for the period before taxes	**€ (20 329)**	**€ (12 683)**	**€ (42 587)**	**€ (24 479)**
Income taxes	(278)	(441)	(404)	(551)
Loss for the period	**€ (20 607)**	**€ (13 124)**	**€ (42 991)**	**€ (25 030)**
Loss attributable to equity holders	**€ (20 607)**	**€ (13 124)**	**€ (42 991)**	**€ (25 030)**
Other comprehensive loss				
Items that may be subsequently reclassified to profit or loss (net of tax)				
Currency translation differences	232	(82)	230	(22)
Total comprehensive loss for the year, net of tax	**€ (20 375)**	**€ (13 206)**	**€ (42 761)**	**€ (25 052)**
Loss attributable to equity holders	**€ (20 375)**	**€ (13 206)**	**€ (42 761)**	**€ (25 052)**
Basic Loss Per Share (in EUR)	€ (0.551)	€ (0.428)	€ (1.149)	€ (0.843)
Diluted Loss Per Share (in EUR)	€ (0.551)	€ (0.428)	€ (1.149)	€ (0.843)

CONSOLIDATED STATEMENT OF FINANCIAL POSITION (unaudited)
(in thousands)

	As at	
	June 30 2025	December 31 2024
ASSETS		
Non-current assets		
Property, plant and equipment	5 015	4 753
Intangible assets	51 407	50 381
Right of use assets	3 059	3 496
Deferred tax asset	76	76
Other long-term receivables	1 799	1 617
	€ 61 356	**€ 60 323**
Current assets		
Inventory	5 332	4 716
Trade receivables	1 330	3 382
Contract assets	1 508	–
Other receivables	3 014	2 774
Other current assets	944	1 656
Financial assets	20 257	51 369
Cash and cash equivalents	22 729	34 186
	€ 55 114	**€ 98 083**
Total assets	**€ 116 470**	**€ 158 406**
EQUITY AND LIABILITIES		
Share capital and reserves		
Share capital	6 431	6 430
Share premium	314 388	314 345
Share based payment reserve	11 645	9 300
Other comprehensive income	1 144	914
Retained loss	(260 211)	(217 735)
Total equity attributable to shareholders	**€ 73 397**	**€ 113 254**
LIABILITIES		
Non-current liabilities		
Financial debt	18 928	18 725
Lease liability	2 157	2 562
Provisions	404	1 000
Deferred tax liability	34	19
Contract liability	225	472
Other liability	379	845
	€ 22 127	**€ 23 623**
Current liabilities		
Financial debt	246	248

Lease liability	1 071	1 118
Trade payables	9 408	9 505
Current tax liability	3 990	4 317
Contract liability	460	117
Other liability	5 771	6 224
	€ 20 946	**€ 21 529**
Total liabilities	**€ 43 073**	**€ 45 152**
Total equity and liabilities	**€ 116 470**	**€ 158 406**

Revenue
Revenue was €1.3 million for the second quarter ending June 30, 2025, compared to €0.8 million for the second quarter ending June 30, 2024, representing a 74% year over year increase.

Cost of Goods Sold
Cost of goods sold was €490,000 for the second quarter ending June 30, 2025, representing a gross profit of €0.9 million, or gross margin of 63.4%. This compares to cost of goods sold of €281,000 in the second quarter ending June 30, 2024, for a gross profit of €0.5 million, or gross margin of 63.6%.

Research and Development
For the second quarter ending June 30, 2025, research and development ("R&D") expenses were €10.0 million, versus €7.5 million for the second quarter ending June 30, 2024. The increase in research and development expenses was primarily due to higher R&D activities offset by a decrease in clinical study expenses.

Selling, General and Administrative
For the second quarter ending June 30, 2025, selling, general and administrative expenses were €10.7 million, versus €6.4 million for the second quarter ending June 30, 2024. The increase in selling, general and administrative expenses was primarily due to an increase in costs to support the commercialization of Genio system, including the Company's overall scale-up preparations for the commercialization of Genio system in the US in connection with the receipt of FDA approval.

Operating Loss
Total operating loss for the second quarter ending June 30, 2025 was €19.9 million, versus €13.3 million in the second quarter 2024, respectively. This was driven by an increase in selling, general and administrative expenses to support commercialization of the Genio system, including the Company's overall scale-up preparations for the commercialization of Genio system in the US in connection with the receipt of FDA approval, and increased R&D activities offset by a decrease in clinical study expenses.

Cash Position

As of June 30, 2025, cash, cash equivalents and financial assets totaled €43.0 million, compared to €63.0 million at the end of March 31, 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.

Second Quarter 2025

Nyxoah's financial report for the second quarter of 2025, including details of the consolidated results, are available on the investor page of Nyxoah's website (https://investors.nyxoah.com/financials).

Conference call and webcast presentation

Company management will host a conference call to discuss financial results on Monday, August 18, 2025, beginning at 10:30pm CET / 4:30pm ET.

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. For those not planning to ask a question of management, the Company recommends listening via the webcast.

If you plan to ask a question, please use the following link: Events | Nyxoah Investors required to join the live call. To ensure you are connected prior to the beginning of the call, the Company suggests registering a minimum of 10 minutes before the start of the call.

The archived webcast will be available for replay shortly after the close of the call.

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 receipt of approval from the FDA for a subset of adult patients with moderate to severe OSA with an 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 Genio system; the potential advantages of the Genio system; Nyxoah's goals with respect to the 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. 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

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

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