

#### REGULATED INFORMATION

## **Nyxoah Reports Third Quarter 2025 Financial and Operating Results**

US launch off to a strong start. First commercial Genio implants completed with widespread payer coverage drives initial revenue.

Mont-Saint-Guibert, Belgium – November 13, 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 third quarter of 2025.

## **Recent Financial and Operating Highlights**

- Completed the first commercial implants of U.S. patients, and generated first U.S. revenue as early as September
- Reimbursement secured with Medicare and private payers, achieving 100% approval rate on prior authorization submissions from United Healthcare, Blue Cross Blue Shield, and Anthem. In all these approvals, the CPT code 64568 was accepted
- Revenue for the third quarter of 2025 was €2.0 million, representing 56% year over year growth, compared to €1.3 million in the third quarter of 2024
- Cash, cash equivalents and financial assets were €22.5 million on September 30, 2025, compared to €43.0 million at the end of June 30, 2025.

"The first weeks post FDA approval have been a huge success. We already completed the first implants in September. The response from physicians has been overwhelmingly positive, driven by the excitement of finally having real optionality in hypoglossal nerve stimulation for OSA patients," commented Olivier Taelman, Nyxoah's Chief Executive Officer. "We also secured reimbursement and generate the first U.S. revenue within the first month post FDA approval. The financing transaction announced today will support our sustained growth in the U.S. market. The momentum and enthusiasm couldn't be greater."



## Strong Initial U.S. Commercial Launch

The Company is executing its focused two-pronged launch strategy, targeting high-volume hypoglossal nerve stimulation implanting centers while developing strong referral networks with sleep physicians. The first commercial Genio devices were implanted at Townsend Memorial Health System in Houston, Texas, where the surgeon completed five procedures in the first week.

As of October 31, the Company has trained 111 surgeons on the Genio system, and 9 accounts implanted Genio. The Company has completed 102 value analysis committee submissions, with 35 approvals received, and has submitted 63 prior authorizations through their Genio Access Program (GAP), of which 21 approvals have been received. These metrics reflect the strong early traction the Company is seeing in the market and demonstrate the execution of its focused launch strategy.

### **Reimbursement Progress**

The Company continues to make significant progress towards widespread reimbursement coverage with major payor policy updates and strategic partnerships that streamline patient access to the Genio system. Health Care Service Corporation (HCSC) operates Blue Cross Blue Shield plans in Illinois, Texas, Oklahoma, New Mexico, and Montana. HCSC and Blue Cross Blue Shield of Michigan have updated their hypoglossal nerve stimulation medical policies to include CPT Code 64568 as a referenced procedure code. While coverage for hypoglossal nerve stimulation was already established, the inclusion of this code provides additional clarity for providers and payors, which the Company expects will help reduce administrative barriers and streamline patient access. HCSC and BCBS of Michigan represent over 26 million members across six states.



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

	For the months Septem	ended	For the months Septem	ended
	2025	2024	2025	2024
Revenue	1 972	1 266	4 376	3 258
Cost of goods sold	( 779)	( 482)	(1 675)	(1 217)
Gross profit	€ 1 193	€ 784	€ 2 701	€ 2 041
Research and Development Expense	(12 911)	(7 902)	(31 959)	(22 573)
Selling, General and Administrative Expense	(12 702)	(8 042)	(35 765)	(20 396)
Other income/(expense)	51	180	166	430
Operating loss for the period	€ (24 369)	€ (14 980)	£ (64 857)	€ (40 498)
Financial income	1 082	1 138	6 561	4 615
Financial expense	( 583)	(3 043)	(8 162)	(5 480)
Loss for the period before taxes	€ (23 870)	€ (16 885)	£ (66 458)	€ (41 363)
Income taxes	290	( 173)	( 114)	(724)
Loss for the period	€ (23 580)	€ (17 058) €	E (66 572)	€ (42 087)
Loss attributable to equity holders	€ (23 580) €	€ (17 058) €	€ (66 572) €	€ (42 087)
Other comprehensive loss				
Items that may be subsequently reclassified to profit or loss	s			
(net of tax)				
Currency translation differences	( 33)	( 209)	197	(221)
Total comprehensive loss for the year, net of tax	€ (23 613)	€ (17 267) €	£ (66 375)	€ (42 308)
Loss attributable to equity holders	€ (23 613)	€ (17 267) €	£ (66 375)	€ (42 308)
Basic Loss Per Share (in EUR)	€ (0.630)	€ (0.496)	€ (1.778)	€ (1.346)
Diluted Loss Per Share (in EUR)	€ (0.630)	€ (0.496)	€ (1.778)	€ (1.346)



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

·	As C	As Of		
	September	September		
	30	December		
	2025	31 2024		
ASSETS				
Non-current assets				
Property, plant and equipment	4 471	4 753		
Intangible assets	50 108	50 381		
Right of use assets	1 891	3 496		
Deferred tax asset	25	76		
Other long-term receivables	1 759	1 617		
	€ 58 254	€ 60 323		
Current assets				
Inventory	6 075	4 716		
Trade receivables	1 356	3 382		
Contract assets	1 384	-		
Other receivables	3 026	2 774		
Other current assets	1 026	1 656		
Financial assets	11 609	51 369		
Cash and cash equivalents	10 869	34 186		
	€ 35 345	€ 98 083		
Total assets	€ 93 599	€ 158 406		
EQUITY AND LIABILITIES				
Share capital and reserves				
Share capital	6 450	6 430		
Share premium	314 417	314 345		
Share based payment reserve	11 765	9 300		
Other comprehensive income	1 111	914		
Retained loss	(282 789)	(217 735)		
Total equity attributable to shareholders	€ 50 954	€ 113 254		
LIABILITIES				
Non-current liabilities				
Financial debt	18 787	18 725		
Lease liability	1 382	2 562		
Provisions	1 106	1 000		
Deferred tax liability	30	19		
Contract liability	581	472		



Other liability	-	845
	€ 21 886	€ 23 623
Current liabilities		
Financial debt	248	248
Lease liability	742	1 118
Trade payables	9 559	9 505
Current tax liability	3 376	4 317
Contract liability	342	117
Other liability	6 492	6 224
	€ 20 759	€ 21 529
Total liabilities	€ 42 645	€ 45 152
Total equity and liabilities	€ 93 599	€ 158 406

#### Revenue

Revenue was €2.0 million for the third quarter ending September 30, 2025, compared to €1.3 million for the third quarter ending September 30, 2024, representing a 56% year over year increase.

#### Cost of Goods Sold

Cost of goods sold was €0.8 million for the third quarter ending September 30, 2025, representing a gross profit of €1.2 million, or gross margin of 60.5%. This compares to cost of goods sold of €482,000 in the third quarter ending September 30, 2024, for a gross profit of €0.8 million, or gross margin of 62.0%.

#### Research and Development

For the third quarter ending September 30, 2025, research and development ("R&D") expenses were €12.9 million, versus €7.9 million for the third quarter ending September 30, 2024. The increase in research and development expenses was primarily due to higher R&D activities. Additionally, following FDA approval in August 2025, the amortization of the related intangible assets commenced leading to an increase in depreciation and amortization expenses.

#### Selling, General and Administrative

For the third quarter ending September 30, 2025, selling, general and administrative expenses were €12.7 million, versus €8.0 million for the third quarter ending September 30, 2024. The increase in selling, general and administrative expenses was mainly due to an increase of costs to support the commercialization of Genio® system and the Company's overall scale-up preparations for the commercialization of the Genio® system in the U.S. following receipt of FDA approval.

#### **Operating Loss**

Total operating loss for the third quarter ending September 30, 2025, was €24.4 million, versus €15.0 million in the third 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 the Genio system in the US in connection with



the receipt of FDA approval, and increased R&D and manufacturing activities, in addition to higher depreciation and amortization expenses.

#### **Cash Position**

As of September 30, 2025, cash, cash equivalents and financial assets totaled €22.5 million, compared to €43.0 million at the end of June 30, 2025.

### **Third Quarter 2025**

Nyxoah's financial report for the third 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 Thursday, November 13, 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 Q3 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: Nyxoah's Q3 2025 Earnings Call Q&A Line. 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 <a href="http://www.nyxoah.com/">http://www.nyxoah.com/</a>.

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 forwardlooking 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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