REGULATED INFORMATION

Nyxoah Reports First Quarter Financial and Operating Results

Company On Track for Anticipated PMA Approval in the Second Quarter of 2025
Successfully Completed FDA Validation Requirements, Final Site Inspection in Progress

Mont-Saint-Guibert, Belgium – May 14, 2025, 7am CET / 1am 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 first quarter of 2025.

Recent Financial and Operating Highlights

- Received an FDA Approvable Letter indicating the FDA will approve the Company's PMA application for its Genio® system subject to satisfactory completion of a manufacturing facilities, methods and controls review
- Successfully completed FDA validation requirements, final site inspection in progress at the U.S. contract manufacturing site
- Revenue for the first quarter of 2025 was €1.1 million, compared to €1.2 million in the first quarter of 2024
- Launched Genio® 2.1 patient software upgrade in international commercial markets
- Cash, cash equivalents and financial assets were €63.0 million at March 31, 2025, compared to €85.6 million at the end of 2024

"We are excited that we are in the final stage of the FDA review process of our Genio® system in the United States," commented Olivier Taelman, Nyxoah's Chief Executive Officer. "The FDA Approvable Letter we received previously confirms that our application substantially meets the requirements of the Federal Food, Drug and Cosmetic Act, including biocompatibility and acceptance of our clinical data demonstrating the safety and effectiveness of the Genio® system. We have successfully completed the final process validation requested by the FDA. We understand that the last step toward FDA approval is an on-site inspection at the U.S. manufacturing site which we expect to be completed shortly. As part of the PMA process, this site has already successfully passed an on-site inspection with no deficiencies, which gives us confidence in completing this regulatory step. We continue to anticipate that our application could potentially be approved in the second quarter of 2025."

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

	For the three months ended March 31	
	2025	**2024**
Revenue	€ 1 064	€ 1 221
Cost of goods sold	(406)	(455)
Gross profit	**€ 658**	**€ 766**
Research and Development Expense	(8 989)	(7 199)
Selling, General and Administrative Expense	(12 392)	(5 972)
Other income/(expense)	84	192
Operating loss for the period	**€ (20 639)**	**€ (12 213)**
Financial income	2 622	1 408
Financial expense	(4 242)	(991)
Loss for the period before taxes	**€ (22 259)**	**€ (11 796)**
Income taxes	(125)	(110)
Loss for the period	**€ (22 384)**	**€ (11 906)**
Loss attributable to equity holders	**€ (22 384)**	**€ (11 906)**
Other comprehensive (loss)		
Items that may be subsequently reclassified to profit or loss (net of tax)		
Currency translation differences	(2)	60
Total comprehensive loss for the year, net of tax	**€ (22 386)**	**€ (11 846)**
Loss attributable to equity holders	**€ (22 386)**	**€ (11 846)**
Basic Loss Per Share (in EUR)	€ (0.598)	€ (0.415)
Diluted Loss Per Share (in EUR)	€ (0.598)	€ (0.415)

CONSOLIDATED STATEMENT OF FINANCIAL POSITION (unaudited)

(in thousands)

	As at	
	March 31 2025	**December 31 2024**
ASSETS		
Non-current assets		
Property, plant and equipment	4 696	4 753
Intangible assets	50 977	50 381
Right of use assets	3 152	3 496
Deferred tax asset	78	76
Other long-term receivables	1 790	1 617
	€ 60 693	**€ 60 323**
Current assets		
Inventory	4 981	4 716
Trade receivables	2 604	3 382
Other receivables	3 128	2 774
Other current assets	1 450	1 656
Financial assets	40 653	51 369
Cash and cash equivalents	22 394	34 186
	€ 75 210	**€ 98 083**
Total assets	**€ 135 903**	**€ 158 406**
EQUITY AND LIABILITIES		
Share capital and reserves		
Share capital	6 430	6 430
Share premium	314 345	314 345
Share based payment reserve	11 256	9 300
Other comprehensive income	912	914
Retained loss	(240 100)	(217 735)
Total equity attributable to shareholders	**€ 92 843**	**€ 113 254**
LIABILITIES		

Non-current liabilities		
Financial debt	18 519	18 725
Lease liability	2 316	2 562
Provisions	548	1 000
Deferred tax liability	27	19
Contract liabilities	277	472
Other liabilities	401	845
	€ 22 088	**€ 23 623**
Current liabilities		
Financial debt	244	248
Lease liability	1 010	1 118
Trade payables	9 316	9 505
Current tax liability	4 300	4 317
Contract liability	368	117
Other liabilities	5 734	6 224
	€ 20 972	**€ 21 529**
Total liabilities	**€ 43 060**	**€ 45 152**
Total equity and liabilities	**€ 135 903**	**€ 158 406**

Revenue

Revenue was €1.1 million for the first quarter ending March 31, 2025, compared to €1.2 million for the first quarter ending March 31, 2024.

Cost of Goods Sold

Cost of goods sold was €406,000 for the first quarter ending March 31, 2025, representing a gross profit of €0.7 million, or gross margin of 61.8%. This compares to cost of goods sold of €455,000 in the first quarter ending March 31, 2024, for a gross profit of €0.8 million, or gross margin of 62.7%.

Research and Development

For the first quarter ending March 31, 2025, research and development expenses were €9.0 million, versus €7.2 million for the first quarter ending March 31, 2024. The increase in research and development expenses was primarily due to higher R&D activities and clinical study expenses.

Selling, General and Administrative

For the first quarter ending March 31, 2025, selling, general and administrative expenses were €12.4 million, versus €6.0 million for the first quarter ending March 31, 2024. The increase in selling, general and administrative expenses was primarily due to an increase in costs to support the commercialization of Genio® system, the Company's overall scale-up preparations for the upcoming commercialization of Genio® system in the US upon receipt of FDA approval.

Operating Loss

Total operating loss for the first quarter ending March 31, 2025 was €20.6 million, versus €12.2 million in the first quarter 2024, respectively. This was driven by an increase in selling, general and administrative expenses to support commercialization of the Genio system, the Company's overall scale-up preparations for the upcoming commercialization of Genio® system in the US upon receipt of FDA approval and increased R&D activities and clinical study expenses.

Cash Position

As of March 31, 2025, cash, cash equivalents and financial assets totaled €63.0 million, compared to €85.6 million at the end of 2024.

First Quarter 2025

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

Progress Toward FDA PMA Approval

On March 26, 2025, Nyxoah announced that the U.S. Food and Drug Administration (FDA) issued an Approvable Letter regarding the Company's Pre-Market Approval (PMA) application for the Genio® system. The Approvable Letter means that Nyxoah's application for marketing the device in the United States substantially meets the requirements of the Federal Food, Drug and Cosmetic Act and the FDA's PMA implementing regulations.

The FDA has accepted all other data provided with the PMA submission, including most importantly that the clinical study demonstrates the safety and effectiveness of the Genio® system. Nyxoah has successfully completed the validation work requested by the FDA for the manufacturing process used for a component of the Genio system at the U.S. manufacturing site. The Company submitted the required documentation to the FDA, which has reviewed this validation work and confirmed they have no further questions. We believe that the last step before full PMA approval is an on-site FDA inspection of the U.S. manufacturing site which we expect to be completed shortly. As part of the PMA process, this site already passed an on-site inspection with no deficiencies, giving the Company confidence in completing this regulatory step. Nyxoah anticipates that its application could potentially be approved in the second quarter of 2025.

Conference call and webcast presentation

Company management will host a conference call to discuss financial results on Wednesday, May 14, 2025, beginning at 2:00pm CET / 8:00am ET.

A webcast of the call will be accessible via the Investor Relations page of the Nyxoah website or through this link: Nyxoah's Q1 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 Q1 2025 Earnings Call. After registering, an email will be sent, including dial-in details and a unique conference call access code

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 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.

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; receipt of FDA approval; satisfactory completion of a manufacturing facilities, methods and controls review, and the anticipated timing of the foregoing; 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.

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