



Nyxoah Reports Third Quarter Financial and Operating Results

November 6, 2024

REGULATED INFORMATION

Nyxoah Reports Third Quarter Financial and Operating Results
FDA approval on track for first quarter 2025, U.S. commercial team build out in progress
Company fully funded with cash until mid 2026

Mont-Saint-Guibert, Belgium – November 6, 2024, 10:05pm CET / 4:05pm 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 2024.

Recent Financial and Operating Highlights

- Presented compelling DREAM data results at International Surgical Sleep Society in September.
- Raised €24.6 million through an ATM program from a single U.S. healthcare-dedicated fund providing incremental flexibility as we shift into U.S. commercialization and extending cash runway until mid 2026.
- Strengthened U.S. organization with the hiring of John Landry as Chief Financial Officer and the addition of several key commercial leaders in the U.S.
- Reported third quarter sales of €1.3 million, representing 30% growth versus third quarter 2023.
- Total cash position of €71.0 million at the end of the quarter, €95.6 million proforma including the €24.6 million raised.

“Our actions in the third quarter have further positioned us well for a successful U.S. commercial launch. On the back of the robust DREAM data presented in September, we have raised additional capital and are actively focused on building up our U.S. commercial team,” commented Olivier Taelman, Nyxoah’s Chief Executive Officer. “I am more confident than ever that we have set Genio up for a strong commercial start in the U.S. immediately after FDA approval.”

Third Quarter 2024 Results

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

	For the three months ended September 30,		For the nine months ended September 30,	
	2024	2023	2024	2023
Revenue	1,266	976	3,258	2,524
Cost of goods sold	(482)	(336)	(1,217)	(930)
Gross profit	€ 784	€ 640	€ 2,041	€ 1,594
Research and Development Expense	(7,902)	(6,568)	(22,573)	(19,330)
Selling, General and Administrative Expense	(8,042)	(5 058)	(20,396)	(16,794)
Other income/(expense)	180	–	430	265
Operating loss for the period	€(14,980)	€(10,986)	€(40,498)	€(34,265)
Financial income	1,138	2,178	4,615	3,592

Financial expense	(3,043)	(1,033)	(5,480)	(2,765)
Loss for the period before taxes	€(16,885)	€(9,841)	€(41,363)	€(33,438)
Income taxes	(173)	2,229	(724)	1,119
Loss for the period	€(17,058)	€(7,612)	€(42,087)	€(32,319)
Loss attributable to equity holders	€(17,058)	€(7,612)	€(42,087)	€(32,319)
Other comprehensive income/(loss)				
Items that may not be subsequently reclassified to profit or loss (net of tax)				
Currency translation differences	(209)	(10)	(221)	(88)
Total comprehensive loss for the year, net of tax	€(17,267)	€ (7,622)	€(42,308)	€(32,407)
Loss attributable to equity holders	€(17,267)	€ (7,622)	€(42,308)	(32,407)
Basic loss per share (in EUR)	€(0.496)	€(0.266)	€(1.346)	€(1.166)
Diluted loss per share (in EUR)	€(0.496)	€(0.266)	€(1.346)	€(1.166)

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

	As at	
	September 30, 2024	December 31, 2023
ASSETS		
Non-current assets		
Property, plant and equipment	4,461	4,188
Intangible assets	49,558	46,608
Right of use assets	3,635	3,788
Deferred tax asset	53	56
Other long-term receivables	1,475	1,166
	€ 59,182	€ 55,806
Current assets		

Inventory	5,272	3,315
Trade receivables	2,504	2,758
Other receivables	2,992	3,212
Other current assets	1,837	1,318
Financial assets	42,299	36,138
Cash and cash equivalents	28,678	21,610
	€ 83,582	€ 68,351
Total assets	€ 142,764	€ 124,157

EQUITY AND LIABILITIES

Capital and reserves

Capital	5,908	4,926
Share premium	290,906	246,127
Share based payment reserve	8,943	7,661
Other comprehensive income	(84)	137
Retained loss	(200,966)	(160,829)
Total equity attributable to shareholders	104,707	€ 98,022

LIABILITIES

Non-current liabilities

Financial debt	19,143	8,373
Lease liability	2,636	3,116
Pension liability	47	9
Provisions	398	185
Deferred tax liability	12	9
	€22,236	€ 11,692

Current liabilities

Financial debt	399	364
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Lease liability	1,151	851
Trade payables	7,109	8,108
Current tax liability	2,495	1,988
Other payables	4,667	3,132
	€ 15,821	€ 14,443
Total liabilities	€ 38,057	€ 26,135
Total equity and liabilities	€ 142,764	€ 124,157

Revenue

Revenue was €1.3 million for the third quarter ending September 30, 2024, compared to €1.0 million for the third quarter ending September 30, 2023.

Cost of Goods Sold

Cost of goods sold was €482,000 for the three months ending September 30, 2024, representing a gross profit of €0.8 million, or gross margin of 62.0%. This compares to total cost of goods sold of €336,000 in the third quarter of 2023, for a gross profit of €0.6 million, or gross margin of 66.0%.

Research and Development

For the third quarter ending September 30, 2024, research and development expenses were €7.9 million, versus €6.6 million for the third quarter ending September 30, 2023.

Operating Loss

Total operating loss for the third quarter ending September 30, 2024, was €15.0 million versus €11.0 million in the third quarter ending September 30, 2023. This increase was primarily driven by expanded commercial activities, higher R&D investments, and ongoing clinical activities.

Cash Position

As of September 30, 2024, cash and financial assets totaled €71.0 million, compared to €57.7 million on December 31, 2023. Total cash burn was approximately €5.6 million per month during the third quarter 2024.

Third Quarter 2024

Nyxoah's financial report for the third quarter 2024, 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 Wednesday, November 6, 2024, 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 2024 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 2024 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 reinventing sleep for the billion people that suffer from obstructive sleep apnea (OSA). We are a medical technology company that develops breakthrough treatment alternatives for OSA through neuromodulation. Our first innovation is Genio®, a battery-free hypoglossal neuromodulation device that is inserted through a single incision under the chin and controlled by a wearable. Through our commitment to innovation and clinical evidence, we have shown best-in-class outcomes for reducing OSA burden.

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 for FDA and U.S. commercialization approval.

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; the utility of clinical data in potentially obtaining FDA approval of the Genio® system; and reporting data from Nyxoah's DREAM U.S. pivotal trial; receipt of FDA approval; entrance to the U.S. market; and the anticipated closing and use of the proceeds from the offering. 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, 2023, filed with the Securities and Exchange Commission ("SEC") on March 20, 2024, 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.

This press release does not constitute an offer to sell or a solicitation of an offer to buy the securities in the offering, nor shall there be any sale of these securities in any jurisdiction in which an offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of such jurisdiction.

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Attachment

- [ENGLISH Q3 2024 Earnings PR](#)