

Nyxoah Reports Second Quarter and First Half 2024 Financial and Operating Results

August 6, 2024

REGULATED INFORMATION

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FDA regulatory submission complete, U.S. approval on track for end of 2024 U.S. commercial launch fully funded with over €85 million in new capital raised

Mont-Saint-Guibert, Belgium – August 6, 2024, 10:05pm CET / 4:05pm ET – Nyxoah SA (Euronext Brussels/Nasdaq: NYXH) ("Nyxoah" or the "Company"), a medical technology company focused on the development and commercialization of innovative solutions to treat Obstructive Sleep Apnea (OSA), today reported financial and operating results for the second quarter and first half of 2024.

Recent Financial and Operating Highlights

- Submitted final module in the modular PMA submission, initiating FDA interactive review.
- Strengthening U.S. commercial organization, highlighted by the appointments of Scott Holstine as Chief Commercial Officer and key sales, marketing and market access leaders.
- Raised over €85 million in growth capital through a €48.5 million equity offering and a €37.5 million loan facility agreement with the European Investment Bank (EIB).
- Reported second quarter 2024 sales of €0.8 million and first half 2024 sales growth of 29% over the same period last year.
- Total cash position of €77.8 million at the end of the quarter, excluding the €37.5 million EIB loan facility.

"With the FDA interactive review well advancing, our focus is fully shifted to U.S. commercial readiness. Key commercial leadership is in place, and we are kicking off the recruitment of top sales and marketing talents. We will present the full DREAM U.S. pivotal study data at the ISSS meeting in September, which will further differentiate Genio's unique, patient centric hypoglossal nerve stimulation solution," commented Olivier Taelman, Nyxoah Chief Executive officer. "Our recent €85 million in capital raise provides us with a cash runway into mid-2026, fully funding the U.S. launch."

Second Quarter and First Half 2024 Results

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,	
	2024	2023	2024	2023
Revenue	771	1,107	1,992	1,548
Cost of goods sold	(281)	(419)	(735)	(594)
Gross profit	€490	€688	€1,257	€954
Research and Development Expense	(7,472)	(6,605)	(14,671)	(12,762)
Selling, General and Administrative Expense	(6,383)	(6,185)	(12,355)	(11,736)
Other income/(expense)	58	219	249	265
Operating loss for the period	€(13,307)	€(11,883)	€(25,520)	€(23,279)
Financial income	2,069	789	3,477	1,414
Financial expense	(1,445)	(775)	(2,436)	(1,732)
Loss for the period before taxes	€(12,683)	€(11,869)	€(24,479)	€(23,597)
Income taxes	(441)	(928)	(551)	(1,110)
Loss for the period	€(13,124)	€(12,797)	€(25,030)	€(24,707)
Loss attributable to equity holders	€ (13,124)	€(12,797)	€(25,030)	€(24,707)
Other comprehensive income/(loss)				
Items that may not be subsequently reclassified to profit or loss (net of tax)				
Currency translation differences	(82)	(50)	(22)	(78)

Total comprehensive loss for the year, net of tax Loss attributable to equity holders	€(13,206) €(13,206)	€(12,847) €(12,847)	€(25,052) €(25,052)	€(24,785) €(24,785)
Basic loss per share (in EUR)	€(0.428)	€(0.447)	€(0.843)	€(0.907)
Diluted loss per share (in EUR)	€(0.428)	€(0.447)	€(0.843)	€(0.907)

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

	As at	
	June 30, 2024	December 31, 2023
ASSETS		
Non-current assets		
Property, plant and equipment	4,386	4,188
Intangible assets	49,310	46,608
Right of use assets	3,391	3,788
Deferred tax asset	51	56
Other long-term receivables	1,419	1,166
	€ 58,557	€ 55,806
Current assets		
Inventory	5,098	3,315
Trade receivables	2,609	2,758
Other receivables	2,885	3,212
Other current assets	1,298	1,318
Financial assets	50,061	36,138
Cash and cash equivalents	27,724	21,610
	€ 89,675	€ 68,351
Total assets	€ 148,232	€ 124,157
EQUITY AND LIABILITIES		
Capital and reserves		
Capital	5,905	4,926
Share premium	290,822	246,127
Share based payment reserve	8,841	7,661
Other comprehensive income	115	137
Retained loss	(185,540)	(160,829)
Total equity attributable to shareholders	€ 120,143	€ 98,022
LIABILITIES		
Non-current liabilities		
Financial debt	8,600	8,373
Lease liability	2,721	3,116
Pension liability	35	9
Provisions	339	185
Deferred tax liability	10	9
	€11,705	€ 11,692
Current liabilities		
Financial debt	595	364
Lease liability	827	851
Trade payables	9,078	8,108
Current tax liability	2,335	1,988
Other payables	3,549	3,132
	€ 16,384	€ 14,443
Total liabilities	€ 28,089	€ 26,135
Total equity and liabilities	€ 148,232	€ 124,157

Revenue

Revenue was €0.8 million for the second quarter ending June 30, 2024, compared to €1.1 million for the second quarter ending June 30, 2023.

Cost of goods sold was €281,000 for the three months ending June 30, 2024, representing a gross profit of €490,000, or gross margin of 63.6%. This compares to total cost of goods sold of €419,000 in the second quarter of 2023, for a gross profit of €0.7 million, or gross margin of 62.2%.

Research and Development

For the second quarter ending June 30, 2024, research and development expenses were €7.5 million, versus €6.6 million for the second quarter ending June 30, 2023.

Operating Loss

Total operating loss for the second quarter ending June 30, 2024 was €13.3 million versus €11.9 million in the second quarter ending June 30, 2023. This was driven by the acceleration in the Company's R&D spending, as well as ongoing commercial and clinical activities.

Cash Position

As of June 30, 2024, cash and financial assets totaled €77.8 million, compared to €57.7 million on December 31, 2023. Total cash burn was approximately €4.0 million per month during the second guarter 2024.

Second Quarter and First Half 2024

Nyxoah's financial report for the second quarter and first half 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 Tuesday, August 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 Q2 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 Q2 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 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 for FDA and U.S. commercialization approval.

For more information, please see the Company's annual report for the financial year 2023 and visit http://www.nvxoah.com/.

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 entry into of the loan facility agreement and the synthetic warrant agreement with the EIB; the use of proceeds from the loan facility agreement; the Genio® system 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; reporting data from Nyxoah's DREAM U.S. pivotal trial; filing for FDA approval; and entrance to the U.S. market. 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.

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Attachment

• ENGLISH Q2 2024 Earnings PR