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Nyxoah Reports First Quarter 2024 Financial and Operating Results

Announced DREAM U.S. pivotal study achieved primary endpoints

On track for FDA approval as early as end of 2024

Mont-Saint-Guibert, Belgium – May 14, 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 first quarter of 2024.

Recent Financial and Operating Highlights

- Reported the DREAM U.S. pivotal study achieved co-primary endpoints on an intent-to-treat (ITT) basis and demonstrated strong AHI reductions in supine and non-supine sleep positions.
- The DREAM study achieved a median AHI reduction of 70.8%, a 12-month AHI responder rate, per the Sher criteria, of 63.5% ($p=0.002$) on an ITT basis and a 12-month ODI responder rate of 71.3% ($p<0.001$) on an ITT basis.
- Preparing the fourth and final PMA module for submission this quarter.
- Appointed Dr. Maurits S. Boon, MD as Chief Medical Officer.
- Advanced patient access strategy through partnership with the American Association of Otolaryngology – Head & Neck Surgery Foundation (AAO-HNSF).
- Achieved quarterly sales of €1.2 million, showing 170% growth vs Q1 2023.
- Total cash position of €44.3 million at the end of the quarter.

“The DREAM U.S. study achieving its primary endpoints is a pivotal milestone for Nyxoah and further differentiates Genio as the only HGNS therapy to demonstrate strong efficacy in supine and non-supine OSA. With the DREAM data in hand, our U.S. launch preparations are focused on attracting commercial talent to set us up for success when we introduce Genio,” commented Olivier Taelman, Nyxoah Chief Executive Officer. “With continued European commercial traction, positive DREAM data and a highly differentiated, patient centric HGNS solution, I could not be more excited for Nyxoah’s future.”



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First Quarter 2024 Results

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

	For the three months ended March 31,	
	2024	2023
Revenue	€ 1,221	€ 441
Cost of goods sold	(455)	(175)
Gross profit	€ 766	€ 266
Research and Development Expense	(7,199)	(6,157)
Selling, General and Administrative Expense	(5,972)	(5,551)
Other income/(expense)	192	46
Operating loss for the period	€ (12,213)	€ (11,396)
Financial income	1 408	625
Financial expense	(991)	(958)
Loss for the period before taxes	€ (11,796)	€ (11,729)
Income taxes	(110)	(182)
Loss for the period	€ (11,906)	€ (11,911)
Loss attributable to equity holders	€ (11,906)	€ (11,911)
Other comprehensive income/(loss)		
Items that may not be subsequently reclassified to profit or loss (net of tax)		
Currency translation differences	60	(28)
Total comprehensive loss for the year, net of tax	€ (11,846)	€ (11,939)
Loss attributable to equity holders	€ (11,846)	€ (11,939)
Basic loss per share (in EUR)	€ (0.415)	€ (0.460)
Diluted loss per share (in EUR)	€ (0.415)	€ (0.460)

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

	As at	
	March 31 2024	December 31 2023
ASSETS		
Non-current assets		
Property, plant and equipment	€4,379	€4,188
Intangible assets	48,501	46,608
Right of use assets	3,597	3,788
Deferred tax asset	134	56
Other long-term receivables	1 333	1,166
	<u>€ 57,944</u>	<u>€ 55,806</u>
Current assets		
Inventory	3,418	3,315
Trade receivables	2,971	2,758
Other receivables	3,149	3,212
Other current assets	1,232	1,318
Financial assets	22,225	36,138
Cash and cash equivalents	22,077	21,610
	<u>€ 55,072</u>	<u>€ 68,351</u>
Total assets	<u>€ 113,016</u>	<u>€ 124,157</u>
EQUITY AND LIABILITIES		
Capital and reserves		
Capital	4,927	4,926
Share premium	246,188	246,127
Share based payment reserve	8,440	7,661
Other comprehensive income	197	137
Retained loss	(172,555)	(160,829)
Total equity attributable to shareholders	<u>€ 87,197</u>	<u>€ 98,022</u>
LIABILITIES		
Non-current liabilities		
Financial debt	8,616	8,373
Lease liability	2,933	3,116
Pension liability	22	9
Provisions	273	185
Deferred tax liability	–	9
	<u>€ 11,844</u>	<u>€ 11,692</u>
Current liabilities		



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Financial debt	346	364
Lease liability	852	851
Trade payables	7,316	8,108
Current tax liability	2,091	1,988
Other payables	3,370	3,132
	€ 13,975	€ 14,443
Total liabilities	€ 25,819	€ 26,135
Total equity and liabilities	€ 113,016	€ 124,157

Revenue

Revenue was €1.2 million for the first quarter ending March 31, 2024, compared to €441,000 for the first quarter ending March 31, 2023. The increase in revenue was attributable to the Company's commercialization of the Genio® system, primarily in Germany.

Cost of Goods Sold

Cost of goods sold was €455,000 for the three months ending March 31, 2024, representing a gross profit of €0.8 million, or gross margin of 62.7%. This compares to total cost of goods sold of €175,000 in the first quarter of 2023, for a gross profit of €266,000, or gross margin of 60.3%.

Research and Development

For the first quarter ending March 31, 2024, research and development expenses were €7.2 million, versus €6.2 million for the first quarter ending March 31, 2023.

Operating Loss

Total operating loss for the first quarter ending March 31, 2024 was €12.2 million versus €11.4 million in the first quarter ending March 31, 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 March 31, 2024, cash and financial assets totaled €44.3 million, compared to €57.7 million on December 31, 2023. Total cash burn was approximately €4.5 million per month during the first quarter 2024.

First Quarter 2024

Nyxoah's financial report for the first 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

A webcast of the call will be accessible via the Investor Relations page of the Nyxoah website or through this link: [Nyxoah's Q1 2024 earnings call webcast](#). For those not planning to ask a question of management, the Company recommends listening via the webcast.



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If you plan to ask a question, please use the following link: [Nyxoah's Q1 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.

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 is currently conducting the DREAM IDE pivotal study for FDA and US commercialization approval.

For more information, please visit <http://www.nyxoah.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 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 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, 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



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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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