



REGULATED INFORMATION

## Nyxoah Reports Second Quarter and First Half 2023 Financial and Operating Results

Mont-Saint-Guibert, Belgium – August 8, 2023 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 2023.

### Recent Financial and Operating Highlights

- Presented 12-month efficacy data<sup>1</sup> on the first 34 DREAM patients and safety data on all DREAM patients at SLEEP 2023, demonstrating a 65% AHI responder rate, a 76% ODI responder rate and safety in-line with expectations. These data are preliminary and not conclusive of final DREAM success.
- Filed the second module in the modular PMA submission.
- Accelerated U.S. pre-commercialization efforts, focused on market access and commercial leadership.
- Continued to enroll the ACCESS U.S. IDE pivotal study to treat complete concentric collapse (CCC) patients. Implant completion is expected in 2024.
- Reported second-quarter sales of €1.1 million and ended the quarter with 42 active German accounts.
- Ended the quarter with a cash position of €84.5 million, providing an anticipated cash runway into late 2024.

“Being less than nine months away from the DREAM study readout, our attention continues to be on patient follow up. We are highly encouraged by both the efficacy and safety data presented at SLEEP 2023. Our modular PMA filing is well underway, with the second module submitted during the quarter,” commented Olivier Taelman, Nyxoah’s Chief Executive Officer. “We are building strong commercial expertise in the competitive German market. Our direct-to-consumer advertising, helpline and referral networks have increased HGNS penetration and give us confidence on entering new markets.”

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<sup>1</sup> For the trial to be successful, of the 115 patients, at least 63% of patients need to be AHI and ODI responders at the 12-month follow-up.



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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	
	2023	2022	2023	2022
Revenue	€ 1,107	€ 936	€ 1,548	€ 1,595
Cost of goods sold	( 419)	( 334)	( 594)	( 623)
<b>Gross profit</b>	<b>€ 688</b>	<b>€ 602</b>	<b>€ 954</b>	<b>€ 972</b>
Research and Development Expense	(6,605)	(3,470)	(12,762)	(7,065)
Selling, General and Administrative Expense	(6,185)	(4,536)	(11,736)	(8,729)
Other income/(expense)	219	14	265	150
<b>Operating loss for the period</b>	<b>€ (11,883)</b>	<b>€ (7,390)</b>	<b>€ (23,279)</b>	<b>€ (14,672)</b>
Financial income	789	4 669	1 414	6 246
Financial expense	( 775)	(2 162)	(1,732)	(2 950)
<b>Loss for the period before taxes</b>	<b>€ (11,869)</b>	<b>€ (4,883)</b>	<b>€ (23,597)</b>	<b>€ (11,376)</b>
Income taxes	( 928)	( 107)	(1,110)	( 315)
<b>Loss for the period</b>	<b>€ (12,797)</b>	<b>€ (4,990)</b>	<b>€ (24,707)</b>	<b>€ (11,691)</b>
<b>Loss attributable to equity holders</b>	<b>€ (12,797)</b>	<b>€ (4,990)</b>	<b>€ (24,707)</b>	<b>€ (11,691)</b>
<b>Other comprehensive loss</b>				
<b>Items that may be subsequently reclassified to profit or loss (net of tax)</b>				
Currency translation differences	( 50)	( 12)	( 78)	( 114)
<b>Total comprehensive loss for the year, net of tax</b>	<b>€ (12,847)</b>	<b>€ (5,002)</b>	<b>€ (24,785)</b>	<b>€ (11,805)</b>
<b>Loss attributable to equity holders</b>	<b>€ (12,847)</b>	<b>€ (5,002)</b>	<b>€ (24,785)</b>	<b>€ (11,805)</b>
Basic Loss Per Share (in EUR)	€ (0.447)	€ (0.193)	€ (0.907)	€ (0.453)
Diluted Loss Per Share (in EUR)	€ (0.447)	€ (0.193)	€ (0.907)	€ (0.453)

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

	As at	
	June 30 2023	December 31 2022
<b>ASSETS</b>		
<b>Non-current assets</b>		
Property, plant and equipment	2,813	2,460
Intangible assets	44,488	39,972
Right of use assets	3,571	3,159
Deferred tax asset	48	47
Other long-term receivables	165	173
	<b>€ 51,085</b>	<b>€ 45,811</b>
<b>Current assets</b>		
Inventory	1,146	882
Trade receivables	1,820	1,463
Other receivables	2,262	1,775
Other current assets	1,576	1,284
Financial assets	67,919	76,968
Cash and cash equivalents	16,604	17,888
	<b>€ 91,327</b>	<b>€ 100,260</b>
<b>Total assets</b>	<b>€ 142,412</b>	<b>€ 146,071</b>
<b>EQUITY AND LIABILITIES</b>		
<b>Capital and reserves</b>		
Capital	4,924	4,440
Share premium	246,070	228,275
Share based payment reserve	7,005	5,645
Other comprehensive income	98	176
Retained loss	(142,522)	(118,212)
<b>Total equity attributable to shareholders</b>	<b>€ 115,575</b>	<b>€ 120,324</b>
<b>LIABILITIES</b>		
<b>Non-current liabilities</b>		
Financial debt	8,433	8,189



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Lease liability	2,991	2,586
Pension liability	50	–
Provisions	127	59
Deferred tax liability	–	–
	<b>€ 11,601</b>	<b>€ 10,834</b>
<b>Current liabilities</b>		
Financial debt	559	388
Lease liability	751	719
Trade payables	4 690	4,985
Current tax liability	4 475	3,654
Other payables	4 761	5,167
	<b>€ 15,236</b>	<b>€ 14,913</b>
<b>Total liabilities</b>	<b>€ 26,837</b>	<b>€ 25,747</b>
<b>Total equity and liabilities</b>	<b>€ 142,412</b>	<b>€ 146,071</b>

### *Revenue*

Revenue was €1.1 million for the second quarter ending June 30, 2023, compared to €0.9 million for second quarter ending June 30, 2022.

### *Cost of Goods Sold*

Cost of goods sold was €0.4 million for the three months ending June 30, 2023, representing a gross profit of €0.7 million, or gross margin of 62.2%. This compares to total cost of goods sold of €0.3 million in the second quarter ending June 30, 2022, for a gross profit of €0.6 million, or gross margin of 64.3%.

### *Research and Development Expenses*

Research and development expenses were €6.6 million for the three months ending June 30, 2023, versus €3.5 million for the prior year period, driven by an acceleration in clinical activities, notably the start of the ACCESS study.

### *Selling, General and Administrative Expenses*

Selling, general and administrative expenses rose to €6.2 million for the second quarter of 2023, up from €4.5 million in the second quarter of 2022. This was due primarily to increased commercial efforts in Germany and other European markets, as well as investments in Nyxoah's corporate infrastructure. The Company expects to continue adding headcount across the organization ahead of the U.S. commercial launch.



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### *Operating Loss*

Total operating loss for the second quarter 2023 was €11.9 million versus €7.4 million in the second quarter of 2022. 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, 2023, cash and financial assets totaled €84.5 million, compared to €94.9 million on December 31, 2022. Total cash burn was approximately €4.8 million per month during the second quarter of 2023.

### **First Half 2023 Report**

Nyxoah's financial report for the first half 2023, 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**

Nyxoah will conduct a conference call open to the public today 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 2023 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 2023 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)



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patients, currently contraindicated in competitors' therapy. Additionally, the Company is currently conducting the DREAM IDE pivotal study for FDA and U.S. 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<sup>®</sup> system; planned and ongoing clinical studies of the Genio<sup>®</sup> system; the potential advantages of the Genio<sup>®</sup> system; Nyxoah's goals with respect to the development, regulatory pathway and potential use of the Genio<sup>®</sup> system; the utility of clinical data in potentially obtaining FDA approval of the Genio<sup>®</sup> 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, 2022, filed with the Securities and Exchange Commission ("SEC") on March 22, 2023, 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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