Nyxoah Reports First Quarter 2023 Financial and Operating Results

May 16, 2023

REGULATED INFORMATION

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Mont-Saint-Guibert, Belgium – May 16, 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 first quarter of 2023.

Recent Financial and Operating Highlights

- Completed all 115 implants in the DREAM U.S. pivotal trial, with 12-month data expected in the first quarter of 2024.
- Initiated the modular PMA submission with the filing of the first module.
- Submitted 12-month data[1] on the first 34 DREAM patients as a late-breaking abstract to SLEEP 2023 demonstrating a 65% AHI responder rate, a 76% ODI responder rate and safety in-line with expectations. The abstract will be presented in a late-breaking poster session on June 6th. These data are preliminary and not conclusive of final DREAM success.
- Implanted the first patients in the ACCCESS U.S. IDE pivotal study to treat complete concentric collapse (CCC). Implant completion expected in 2024.
- Hired Christoph Eigenmann as Chief Commercial Officer.
- Raised €19 million from new and historical shareholders including ResMed, Cochlear and Robert Taub, Nyxoah's Chairman and Founder.
- Ended the quarter with 40 active German accounts and quarterly sales of €441 thousand.
- Expanded European market access with first implants in Austria.
- Strengthened the supply chain with the Belgium manufacturing facility receiving clearance from the EU notified body.

"In 2023, our focus is in the U.S. on DREAM patient follow up resulting in reaching the primary endpoints. I am excited by the data on the first 34 patients and look forward to sharing the full abstract results at SLEEP 2023 next month. Our increasing conviction in DREAM outcomes is accelerating investment in our commercial organization, starting with the addition of Christoph as Chief Commercial Officer," commented Olivier Taelman, Nyxoah's Chief Executive Officer. "Christoph's hire, along with the €19 million raised from key investors, puts us in a strong position as we embark on our next stage of growth."

First Quarter 2023 Results

UNAUDITED CONDENSED CONSOLIDATED FINANCIAL INFORMATION – CONSOLIDATED STATEMENTS OF LOSS AND OTHER COMPREHENSIVE LOSS FOR THE THREE MONTHS ENDED MARCH 31, 2023 (in thousands)

	For the three months ended March 31	
	2023	**2022**
Revenue	€441	€660
Cost of goods sold	(175)	(289)
Gross profit	**€266**	**€371**
Research and Development Expense	(6,157)	(3,595)
Selling, General and Administrative Expense	(5,551)	(4,193)
Other income/(expense)	46	136
Operating loss for the period	**€(11,396)**	**€(7,281)**
Financial income	625	1,576
Financial expense	(958)	(788)
Loss for the period before taxes	**€(11,729)**	**€(6,493)**
Income taxes	(182)	(208)
Loss for the period	**€(11,911)**	**€(6,701)**
Loss attributable to equity holders	**€(11,911)**	**€(6,701)**
Other comprehensive loss		

Items that may be subsequently reclassified to profit or loss (net of tax)		
Currency translation differences	(28)	(102)
Total comprehensive loss for the year, net of tax	**€(11,939)**	**€(6,803)**
Loss attributable to equity holders	**€(11,939)**	**€(6,803)**
Basic Loss Per Share (in EUR)	€(0.460)	€(0.260)
Diluted Loss Per Share (in EUR)	€(0.460)	€(0.260)

UNAUDITED CONDENSED CONSOLIDATED FINANCIAL INFORMATION – CONSOLIDATED STATEMENT OF FINANCIAL POSITION AS OF MARCH 31, 2023 (in thousands)

	As at	
	March 31 2023	**December 31 2022**
ASSETS		
Non-current assets		
Property, plant and equipment	€2,721	€2,460
Intangible assets	42,447	39,972
Right of use assets	3,669	3,159
Deferred tax asset	50	47
Other long-term receivables	169	173
	€49,056	**€45,811**
Current assets		
Inventory	1,249	882
Trade receivables	1,499	1,463
Other receivables	1,419	1,775
Other current assets	1,663	1,284
Financial assets	62,403	76,968
Cash and cash equivalents	33,664	17,888
	€101,897	**€100,260**
Total assets	**€150,953**	**€146,071**
EQUITY AND LIABILITIES		
Capital and reserves		
Capital	4,859	4,440
Share premium	243,488	228,275
Share based payment reserve	6,582	5,645
Other comprehensive income	148	176
Retained loss	(130,051)	(118,212)
Total equity attributable to shareholders	**€125,026**	**€120,324**
LIABILITIES		
Non-current liabilities		
Financial debt	8,381	8,189
Lease liability	3,112	2,586
Pension liability	25	–
Provisions	74	59
Deferred tax liability	–	–
	€11,592	**€10,834**
Current liabilities		
Financial debt	390	388
Lease liability	711	719
Trade payables	5,012	4,985
Current tax liability	3,619	3,654
Other payables	4,603	5,167
	€14,335	**€14,913**

Total liabilities	**€25,927**	**€25,747**
Total equity and liabilities	**€150,953**	**€146,071**

Revenue

Revenue was €441,000 for the first quarter ending March 31, 2023, compared to €660,000 for first quarter ending March 31, 2022.

Cost of Goods Sold

Cost of goods sold was €175,000 for the three months ending March 31, 2023, representing a gross profit of €266,000, or gross margin of 60.3%. This compares to total cost of goods sold of €289,000 in the first quarter ending March 31, 2022, for a gross profit of €371,000, or gross margin of 56.2%.

Research and Development Expenses

Research and development expenses were €6.2 million for the three months ending March 31, 2023, versus €3.6 million for the prior year period, driven by an acceleration in clinical activities, notable the start of the ACCCESS study.

Selling, General and Administrative Expenses

Selling, general and administrative expenses rose to €5.6 million for the first quarter of 2023, up from €4.2 million in the first 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.

Operating Loss

Total operating loss for the first quarter 2023 was €11.4 million versus €7.3 million in the first 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 March 31, 2023, cash and financial assets totaled €96.1 million, compared to €94.9 million on December 31, 2022. Total cash burn was approximately €4.9 million per month during the first quarter of 2023.

First Quarter 2023 Report
Nyxoah's financial report for the first quarter of 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, which will also be webcast. To participate in the conference call, please access the following link to register for a dial-in number: https://edge.media-server.com/mmc/p/imeku8f7

A question-and-answer session will follow the presentation of the results. To access the live webcast, go to https://investors.nyxoah.com/events. 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 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, 2021, filed with the Securities and Exchange Commission ("SEC") on March 24, 2022, 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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[1] 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.

Attachment

- ENGLISH_Q1 2023 Earnings PR_FINAL