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Nyxoah Reports First Quarter 2022 Financial and Operating Results

Mont-Saint-Guibert, Belgium – May 10, 2022, 08:50am CET / 2:50am 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 2022.

First Quarter 2022 Financial and Operating Highlights

- Generated revenue of €660,000 from the commercialization of Genio® in Europe, primarily in Germany, which represents year-over-year growth of more than three-and-a-half times and is more than double what was achieved in the fourth quarter of 2021
- Exited the first quarter with 15 active implant sites in Germany, representing 25% growth over Q4 2021; Nyxoah expects to add an extra 10 sites by the end of the third quarter of 2022, bringing the total to 25 active implanting accounts and driving quarterly sales acceleration and market leadership in Germany by the end of 2022
- Completed the first commercial Complete Concentric Collapse (CCC) patients in Germany
- Accelerated monthly patient enrollment in the DREAM U.S. IDE study and continue to expect implants to be completed in the second quarter of 2022
- The U.S. FDA approved Nyxoah’s request to reduce the sample size in DREAM to 115 patients from the original 134, driven by new and favorable data from the BETTER SLEEP study; aside from the updated sample size, all other study parameters, including performance goals, statistical power, and significance level, remain identical to the original approved study
- Nominated Raymond Cohen, Chief Executive Officer and board member of Axonics, Inc. and Virginia Kirby, Executive-in-Residence at the Discovery Launchpad at the University of Minnesota’s Office of Technology Commercialization, for appointment to the Board of Directors, pending approval by the Annual Shareholders’ Meeting on June 8, 2022; Don Deyo and Jan Janssen are stepping down, keeping the total number of board members at eight

“I am extremely pleased with our first quarter results and strong execution that resulted in an acceleration in sales and DREAM implants as we progress towards achieving all of our strategic priorities for 2022 and beyond,” commented Olivier Taelman, Nyxoah’s Chief Executive Officer. “On the commercial side, the €660,000 of revenue we booked in the first quarter was roughly equal to the revenue performance from the previous three quarters combined. We now have 15 active implant sites in Germany, and we will continue to add 10 more sites by the end of the third quarter. This growth validates our patient-centric, ‘Going Deep’ strategy of developing Centers of Excellence as we increase therapy penetration at each of these sites. We were also thrilled to implant our first commercial CCC patients in Germany, and we expect



REGULATED INFORMATION

continued acceleration in CCC implants following the positive response to our BETTER SLEEP data presentation at the World Sleep Congress in Rome, where we hosted 55 key opinion leaders during the pre-Congress symposium.”

Mr. Taelman continued, “We are also happy with the acceleration in the pace of implants in our DREAM U.S. pivotal study, given recent weekly implant rates, which have increased meaningfully over the last month. We believe we have enough patients enrolled to complete the study by the end of the second quarter of 2022, particularly in light of the FDA’s approval to reduce the sample size to 115 patients. We also continue our dialogue with FDA regarding our IDE submission for our ACCESS trial for CCC patients in the U.S., and we expect to implant our first patient before the end of this year.”

“Finally, I am thrilled to announce the nominations of Ray Cohen and Ginny Kirby for appointment to the Board of Directors. They will bring a wealth of knowledge that will benefit Nyxoah as we complete DREAM, prepare for our U.S. launch, and advance our pipeline. I look forward to working closely with both of them,” concluded Mr. Taelman.

First Quarter 2022 Results

UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS AS AT AND FOR THE THREE MONTHS ENDED MARCH 31, 2022 – INTERIM CONSOLIDATED STATEMENTS OF LOSS AND OTHER COMPREHENSIVE LOSS (IN THOUSANDS)

	Notes	For the three months ended March 31	
		2022	2021
Revenue		€ 660	€ 185
Cost of goods sold		(289)	(52)
Gross profit		€ 371	€ 133
Research and Development Expense		(3 595)	(3 094)
Selling, General and Administrative Expense		(4 193)	(2 366)
Other income/(expense)		136	4
Operating loss for the period		€ (7 281)	€ (5 323)
Financial income		1 576	4
Financial expense		(788)	(325)
Loss for the period before taxes		€ (6 493)	€ (5 644)
Income taxes		(208)	(25)
Loss for the period		€ (6 701)	€ (5 669)
Loss attributable to equity holders		€ (6 701)	€ (5 669)
Other comprehensive loss			
Items that may be subsequently reclassified to profit or loss (net of tax)			
Currency translation differences		(102)	(70)
Total comprehensive loss for the year, net of tax		€ (6 803)	€ (5 739)
Loss attributable to equity holders		€ (6 803)	€ (5 739)
Basic Loss Per Share (in EUR)		€ (0.260)	€ (0.256)
Diluted Loss Per Share (in EUR)		€ (0.260)	€ (0.256)

The accompanying notes are an integral part of these condensed consolidated interim financial statements

UNAUDITED CONSOLIDATED BALANCESHEET (in thousands)

	As at	
	March 31 2022	December 31 2021
ASSETS		
Non-current assets		
Property, plant and equipment	€ 2 048	€ 2 020
Intangible assets	28 526	25 322
Right of use assets	3 154	3 218
Deferred tax asset	529	46
Other long-term receivables	165	164
	€ 34 422	€ 30 770
Current assets		
Inventory	301	346
Trade receivables	619	226
Other receivables	1 607	2 286
Other current assets	1 197	1 693
Financial assets	45 041	–
Cash and cash equivalents	82 787	135 509
	€ 131 552	€ 140 060
Total assets	€ 165 974	€ 170 830
EQUITY AND LIABILITIES		
Capital and reserves		
Capital	4 432	4 427
Share premium	228 158	228 033
Share based payment reserve	3 788	3 127
Other comprehensive income	100	202
Retained loss	(93 864)	(87 167)
Total equity attributable to shareholders	€ 142 614	€ 148 622
LIABILITIES		
Non-current liabilities		
Financial debt	7 952	7 802
Lease liability	2 664	2 737
Pension liability	80	80
Provisions	22	12
Deferred tax liability	–	5
	€ 10 718	€ 10 636
Current liabilities		
Financial debt	598	554

REGULATED INFORMATION

Lease liability	599	582
Trade payables	3 401	3 995
Current tax liability	3 588	2 808
Other payables	4 456	3 633
	€ 12 642	€ 11 572
Total liabilities	€ 23 360	€ 22 208
Total equity and liabilities	€ 165 974	€ 170 830

UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS AS AT AND FOR THE THREE MONTHS ENDED MARCH 31, 2022 – INTERIM CONSOLIDATED STATEMENTS OF CASH FLOWS (IN THOUSANDS)

	For the three months ended March 31	
	2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES		
Loss before tax for the year	€ (6 493)	€ (5 644)
Adjustments for		
Finance income	(1 576)	(4)
Finance expenses	788	325
Depreciation and impairment of property, plant and equipment and right-of-use assets	255	164
Amortization of intangible assets	208	211
Share-based payment transaction expense	665	–
Increase/(decrease) in provisions	10	–
Other non-cash items	180	3
Cash generated before changes in working capital	€ (5 963)	€ (4 945)
Changes in working capital		
Decrease/(Increase) in inventory	45	(51)
(Increase)/decrease in trade and other receivables	884	(1 195)
Increase/(Decrease) in trade and other payables	(392)	2 170
Cash generated from changes in operations	€ (5 426)	€ (4 021)
Interests received	–	1
Income tax paid	(65)	(34)
Net cash used in operating activities	€ (5 491)	€ (4 054)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property, plant and equipment	(128)	(169)
Capitalization of intangible assets	(3 412)	(1 606)
(Increase)/decrease in financial assets - current	(44 032)	–
Net cash used in investing activities	€ (47 572)	€ (1 775)

CASH FLOWS FROM FINANCING ACTIVITIES		
Payment of principal portion of lease liabilities	(146)	(135)
Repayment of other loan	(21)	(21)
Interests paid	(109)	(105)
Proceeds from issuance of shares, net of transaction costs	130	52
Other financial costs	(2)	–
Net cash generated from financing activities	€ (148)	€ (209)
Movement in cash and cash equivalents	€ (53 211)	€ (6 038)
Effect of exchange rates on cash and cash equivalents	489	(55)
Cash and cash equivalents at January 1	€ 135 509	€ 92 300
Cash and cash equivalents at March 31	€ 82 787	€ 86 207

Revenue

Revenue was €660,000 for the first quarter ending March 31, 2022, compared to €185,000 for the first quarter ending March 31, 2021. 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 €289,000 for the three months ending March 31, 2022, representing a gross profit of €371,000, or gross margin of 56.2%.

Research and Development Expenses

Research and Development expenses were €3.6 million for the three months ending March 31, 2022, versus €3.1 million for the prior year period, reflecting the Company's investments in the development of next generation versions of the Genio® system as well as ongoing clinical studies, most notably DREAM in the U.S.

Selling, General and Administrative Expenses

General and administrative expenses rose to €4.2 million for the first quarter of 2022, up from €2.4 million in the first quarter of 2021. 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 U.S. commercial launch.

Operating Loss

Total operating loss for the first quarter of 2022 was €7.3 million versus €5.3 million in the first quarter of 2021, driven by the acceleration in our R&D spending, as well as ongoing commercial and clinical activities. Nyxoah realized a net loss of €6.7 million for the quarter ended March 31, 2022, compared to a net loss of €5.7 million for the quarter ended March 31, 2021.



REGULATED INFORMATION

Cash Position

As of March 31, 2022, cash and financial assets totaled €127.8 million on March 31, 2022, compared to €135.5 million on December 31, 2021. Total cash burn was approximately €2.6 million per month during the first quarter of 2022. Nyxoah expects monthly cash burn to increase slightly as the year progresses to account for the commencement of the ACCCESS IDE trial in the U.S., and current cash position provides ample liquidity to get to U.S. commercialization in 2024.

First Quarter 2022 Report

Nyxoah's financial report for the first quarter of 2022, 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 tomorrow, May 10, 2022, at 2:00 p.m. CET / 8:00 a.m. ET, which will also be webcasted. To participate in the conference call, please dial one of the following numbers:

Conference ID: 8444917

USA:	(844) 260-3718
Belgium:	0800 73264
International:	(929) 517-0938

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/>.



REGULATED INFORMATION

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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, to be 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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