



Nyxoah Reports Second Quarter and First Half 2022 Financial and Operating Results

August 8, 2022

REGULATED INFORMATION

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DREAM enrollment complete, 12-month clinical data expected in fall of 2023

Mont-Saint-Guibert, Belgium – August 8, 2022, 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 2022.

Second Quarter 2022 Financial and Operating Highlights

- Completed enrollment in DREAM U.S. pivotal trial; expect 12-month clinical data in the fall of 2023 and regulatory approval in the first half of 2024
- Generated revenue of €935,000 from the commercialization of Genio® in Europe, primarily in Germany, which represents growth of more than five times the amount achieved in the second quarter of 2021
- Activated 11 new implanting sites in Germany during the second quarter, bringing the total to 26 as of June 30, 2022; expecting to have at least 35 active implanting sites by the end of 2022
- Received FDA approval of IDE submission to commence the ACCCESS study to treat complete concentric collapse (CCC) patients in the U.S., with first patient implant expected in the fourth quarter of 2022
- Received FDA approval of the next generation Genio® 2.1 system for use in the DREAM study and CE mark for use in commercial patients in Europe; this improves patient comfort and compliance with a new smartphone application and upgraded external activation chip, which leverages Nyxoah's scalable platform to continuously enhance patient comfort and therapy efficacy without requiring a new implant
- Partnered with Acurable to distribute the AcuPebble SA100 wearable home sleep test to OSA patients in Germany; launch is expected in the fourth quarter of 2022
- Included in the newly formed Euronext Tech Leaders Index, which is composed of 100+ innovative and high-growth technology companies with greater than €1 trillion in aggregate market capitalization

“We made significant progress on all of our key strategic priorities this quarter, including activating 11 new commercial sites in Germany, completing enrollment in our DREAM trial, and receiving approval for our ACCCESS IDE,” commented Olivier Taelman, Nyxoah's Chief Executive Officer. “From a commercial standpoint, our second quarter performance showing 42% quarter-over-quarter growth strengthens our confidence that we will achieve market leadership status in Germany by the end of 2022.”

“As the only commercially available hypoglossal nerve stimulation (HGNS) therapy approved for the treatment of CCC patients, we are encouraged by the first strong results from patients who are six months post-implantation. These results, combined with no longer having to perform a drug-induced sleep endoscopy (DISE) procedure prior to implant, are driving physicians to recommend Genio for their CCC and non-CCC patients,” continued Mr. Taelman.

Mr. Taelman concluded, “In the meantime, we have already begun investing in our U.S. market access organization. As for our ACCCESS study, we expect to implant the first patients before year end.”

Second Quarter and First Half 2022 Results

UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL INFORMATION – INTERIM CONSOLIDATED STATEMENTS OF LOSS AND OTHER COMPREHENSIVE LOSS FOR THE THREE MONTHS AND SIX MONTHS ENDED JUNE 30, 2022 (in thousands)

	For the three months ended June 30		For the six months ended June 30	
	2022	2021	2022	2021
Revenue	€ 935	€ 170	€ 1 595	€ 355
Cost of goods sold	(€ 334)	(€ 63)	(€ 623)	(€ 115)
Gross profit	€ 601	€ 107	€ 972	€ 240
Research and Development Expense	(€ 3 470)	(€ 2 398)	(€ 7 065)	(€ 5 492)
Selling, General and Administrative Expense	(€ 4 536)	(€ 3 913)	(€ 8 729)	(€ 6 279)

Other income/(expense)	€ 14	(€ 101)	€ 150	(€ 97)
Operating loss for the period	(€ 7 391)	(€ 6 305)	(€ 14 672)	(€ 11 628)
Financial income	€ 4 670	€ 39	€ 6 246	€ 43
Financial expense	(€ 2 162)	(€ 574)	(€ 2 950)	(€ 899)
Loss for the period before taxes	(€ 4 883)	(€ 6 840)	(€ 11 376)	(€ 12 484)
Income taxes	(€ 107)	(€ 99)	(€ 315)	(€ 124)
Loss for the period	(€ 4 990)	(€ 6 939)	(€ 11 691)	(€ 12 608)
Loss attributable to equity holders	(€ 4 990)	(€ 6 939)	(€ 11 691)	(€ 12 608)
Other comprehensive loss				
Items that may be subsequently reclassified to profit or loss (net of tax)				
Currency translation differences	(€ 12)	€ 262	(€ 114)	€ 192
Total comprehensive loss for the year, net of tax	(€ 5 002)	(€ 6 677)	(€ 11 805)	(€ 12 416)
Loss attributable to equity holders	(€ 5 002)	(€ 6 677)	(€ 11 805)	(€ 12 416)
Basic Loss Per Share (in EUR)	(€ 0,193)	(€ 0,314)	(€ 0,453)	(€ 0,570)
Diluted Loss Per Share (in EUR)	(€ 0,193)	(€ 0,314)	(€ 0,453)	(€ 0,570)

UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL INFORMATION – INTERIM CONSOLIDATED STATEMENT OF FINANCIAL POSITION AS AT JUNE 30, 2022 (in thousands)

	As at	
	June 30 2022	December 31 2021
ASSETS		
Non-current assets		
Property, plant and equipment	€ 2 111	€ 2 020
Intangible assets	32 570	25 322
Right of use assets	3 410	3 218
Deferred tax asset	1 429	46
Other long-term receivables	180	164
	€ 39 700	€ 30 770
Current assets		
Inventory	506	346
Trade receivables	957	226
Other receivables	1 548	2 286
Other current assets	852	1 693
Financial assets	47 717	–
Cash and cash equivalents	75 602	135 509
	€ 127 182	€ 140 060
Total assets	€ 166 882	€ 170 830
EQUITY AND LIABILITIES		
Capital and reserves		
Capital	4 438	4 427
Share premium	228 158	228 033
Share based payment reserve	4 411	3 127
Other comprehensive income	88	202
Retained loss	(98 850)	(87 167)
Total equity attributable to shareholders	€ 138 245	€ 148 622
LIABILITIES		
Non-current liabilities		
Financial debt	8 089	7 802
Lease liability	2 859	2 737
Pension liability	80	80
Provisions	44	12
Deferred tax liability	–	5
	€ 11 072	€ 10 636
Current liabilities		

Financial debt	661	554
Lease liability	672	582
Trade payables	4 301	3 995
Current tax liability	4 391	2 808
Other payables	7 540	3 633
	€ 17 565	€ 11 572
Total liabilities	€ 28 637	€ 22 208
Total equity and liabilities	€ 166 882	€ 170 830

UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL INFORMATION - INTERIM CONSOLIDATED STATEMENTS OF CASH FLOWS AS AT JUNE 30, 2022 (in thousands)

	For the six months ended June 30	
	2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES		
Loss before tax for the year	€ (11 376)	€ (12 484)
Adjustments for		
Finance income	(6 246)	(43)
Finance expenses	2 950	899
Depreciation and impairment of property, plant and equipment and right-of-use assets	536	377
Amortization of intangible assets	402	428
Share-based payment transaction expense	1 292	–
Increase/(Decrease) in provisions	32	–
Other non-cash items	37	11
Cash generated before changes in working capital	€ (12 373)	€ (10 812)
Changes in working capital		
Decrease/(Increase) in inventory	(160)	(27)
(Increase)/Decrease in trade and other receivables	1 011	(3 463)
Increase/(Decrease) in trade and other payables	2 053	6 061
Cash generated from changes in operations	€ (9 469)	€ (8 241)
Income tax paid	(254)	(111)
Net cash used in operating activities	€ (9 723)	€ (8 352)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property, plant and equipment	(302)	(795)
Capitalization of intangible assets	(7 650)	(3 726)
(Increase)/Decrease in financial assets - current	(44 032)	–
Net cash used in investing activities	€ (51 984)	€ (4 521)
CASH FLOWS FROM FINANCING ACTIVITIES		
Payment of principal portion of lease liabilities	(317)	(236)
Repayment of other loan	(42)	(42)
Interests paid	(134)	(258)
Repayment of recoverable cash advance	–	(105)
Proceeds from issuance of shares, net of transaction costs	136	362
Other financial costs	(8)	(10)
Net cash generated from financing activities	€ (365)	€ (289)
Movement in cash and cash equivalents	€ (62 072)	€ (13 162)
Effect of exchange rates on cash and cash equivalents	2 165	33
Cash and cash equivalents at January 1	€ 135 509	€ 92 300
Cash and cash equivalents at June 30	€ 75 602	€ 79 171

Revenue

Revenue was €935,000 for the second quarter ending June 30, 2022, compared to €170,000 for the second quarter ending June 30, 2021. Revenue for the first half of 2022 was €1.6 million, compared to €355,000 for the first half of 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 €334,000 for the three months ending June 30, 2022, representing a gross profit of €601,000, or gross margin of 64.3%. This compares to total cost of goods sold of €63,000 in the second quarter of 2021, for a gross profit of €107,000, or gross margin of 62.9%.

For the six months ending June 30, 2022, total cost of goods sold was €623,000, representing a gross profit of €972,000, or gross margin of 60.9%. This compares to total cost of goods sold of €115,000 in the first half of 2021, for a gross profit of €240,000, or gross margin of 67.6%.

Research and Development Expenses

Research and Development expenses were €3.5 million for the three months ending June 30, 2022, versus €2.4 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.

For the six months ending June 30, 2022, Research and Development expenses were €7.1 million, versus €5.5 million for the first half of 2021.

Selling, General and Administrative Expenses

Selling, General and Administrative expenses rose to €4.5 million for the second quarter of 2022, up from €3.9 million in the second 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 the U.S. commercial launch.

For the six months ending June 30, 2022, Selling, General and Administrative expenses were €8.7 million, up from €6.3 million in the first half of 2021 due to increased commercial efforts in Germany and investments in Nyxoah's corporate infrastructure.

Operating Loss

Total operating loss for the second quarter and first half of 2022 was €7.4 million and €14.7 million, respectively, versus €6.3 million and €11.6 million in the second quarter and first half of 2021, respectively. This was driven by the acceleration in the Company's R&D spending, as well as ongoing commercial and clinical activities. Nyxoah realized a net loss of €5.0 million and €11.8 million for the second quarter and first half of 2022, respectively, compared to a net loss of €6.7 million and €12.4 million for the second quarter and first half of 2021, respectively.

Cash Position

As of June 30, 2022, cash and financial assets totaled €123.3 million, compared to €135.5 million on December 31, 2021. Total cash burn was approximately €2.0 million per month during the first half of 2022. Nyxoah expects monthly cash burn to increase in the second half of 2022 to account for the commencement of the ACCESS IDE trial in the U.S., and the current cash position provides ample liquidity to get to U.S. commercialization in 2024.

First Half 2022 Report

Nyxoah's financial report for the first half of 2022, including details of the audited 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 10:30 p.m. CET / 4:30 p.m. 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://register.vevent.com/register/B1fc3a52c9352e4e42958e9d816245b3b9>

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/>.

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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, 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

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Attachment

- [ENGLISH_Q2 2022 Earnings PR Draft Final](#)