



Nyxoah Reports Third Quarter 2022 Financial and Operating Results

November 8, 2022

REGULATED INFORMATION

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DREAM US pivotal 12-month clinical data expected in fall of 2023

Mont-Saint-Guibert, Belgium – November 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 quarter ended September 30, 2022.

Third Quarter 2022 Financial and Operating Highlights

- Completed 110 of 115 implants in the DREAM U.S. pivotal trial to date, with 12-month clinical data expected in the fall of 2023 and regulatory approval in the second quarter of 2024
- Activated the first clinical sites in the ACCCESS U.S. pivotal trial to treat complete concentric collapse (CCC) patients in the U.S., with first implants expected in the fourth quarter of 2022
- Reported revenue of €182,000 from the commercialization of Genio®; sales during the third quarter were impacted by a temporary inventory shortage in Germany due to a disruption at a component supplier, resulting in unfulfilled third quarter orders of approximately €700,000 in Germany; this supply disruption has subsequently been remedied and the vast majority of the open orders have since been filled
- Ended the third quarter with 32 active sites in Germany, up from 26 sites at the end of the second quarter 2022; expects to have up to 40 active sites by the end of 2022
- Launched the “Care4” program, using the AcuPebble home sleep test at selected centers of excellence in Germany to accelerate the time from CPAP failure to our Genio solution
- Received CE Mark for the next-generation Genio system, Genio 2.1

“With 110 implants in the DREAM trial, we believe we are within weeks of completion of the implants, keeping us on track for 12-month data next fall,” commented Olivier Taelman, Nyxoah’s Chief Executive Officer. “Additionally, ACCCESS, our second US pivotal trial is launched, and first patients are expected to be implanted before year end. This trial is focused on addressing the unmet need of approximately 30% of OSA patients contra-indicated in the U.S. to hypoglossal nerve stimulation due to their complete concentric collapse.”

Mr. Taelman continued, “Commercially in Germany, where we have both CCC and non-CCC indications already, we continue to build on our momentum, as patients and clinicians increasingly recognize the unique benefits of the Genio solution. While third quarter sales reflected a temporary supply disruption, the fourth quarter is off to a strong start, as we are filling both open orders from the third quarter and new ones. This gives us confidence that we can be the German market leader exiting 2022.”

Third Quarter 2022 Results

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

	For the three months ended		For the nine months ended	
	September 30		September 30	
	2022	2021	2022	2021
Revenue	€ 182	€ 203	€ 1 777	€ 557
Cost of goods sold	(63)	(82)	(685)	(198)
Gross profit	€ 119	€ 121	€ 1 092	€ 359
Research and Development Expense	(4 221)	(3 517)	(11 286)	(9 009)
Selling, General and Administrative Expense	(4 763)	(4 496)	(13 492)	(10 775)
Other income/(expense)	87	(178)	237	(274)
Operating loss for the period	€ (8 778)	€ (8 070)	€ (23 449)	€ (19 699)
Financial income	5 127	29	11 372	72
Financial expense	(2 524)	(585)	(5 473)	(1 484)
Loss for the period before taxes	€ (6 175)	€ (8 626)	€ (17 550)	€ (21 111)
Income taxes	(65)	(136)	(379)	(260)
Loss for the period	€ (6 240)	€ (8 762)	€ (17 929)	€ (21 371)

Loss attributable to equity holders	€ (6 240)	€ (8 762)	€ (17 929)	€ (21 371)
Other comprehensive loss				
Items that may be subsequently reclassified to profit or loss (net of tax)				
Currency translation differences	100	(54)	(14)	138
Total comprehensive loss for the year, net of tax	€ (6 140)	€ (8 816)	€ (17 943)	€ (21 233)
Loss attributable to equity holders	€ (6 140)	€ (8 816)	€ (17 943)	€ (21 233)
Basic Loss Per Share (in EUR)	€ (0.242)	€ (0.348)	€ (0.695)	€ (0.923)
Diluted Loss Per Share (in EUR)	€ (0.242)	€ (0.348)	€ (0.695)	€ (0.923)

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

	As at	
	September 30, 2022	December 31, 2021
ASSETS		
Non-current assets		
Property, plant and equipment	€ 2 216	€ 2 020
Intangible assets	36 488	25 322
Right of use assets	3 413	3 218
Deferred tax asset	2 423	46
Other long-term receivables	188	164
	€ 44 728	€ 30 770
Current assets		
Inventory	594	346
Trade receivables	757	226
Other receivables	2 022	2 286
Other current assets	587	1 693
Financial assets	25 505	-
Cash and cash equivalents	89 877	135 509
	€ 119 342	€ 140 060
Total assets	€ 164 070	€ 170 830
EQUITY AND LIABILITIES		
Capital and reserves		
Capital	4 440	4 427
Share premium	228 275	228 033
Share based payment reserve	5 225	3 127
Other comprehensive income	188	202
Retained loss	(105 058)	(87 167)
Total equity attributable to shareholders	€ 133 070	€ 148 622
LIABILITIES		
Non-current liabilities		
Financial debt	8 035	7 802
Lease liability	2 831	2 737
Pension liability	80	80
Provisions	47	12
Deferred tax liability	-	5
	€ 10 993	€ 10 636
Current liabilities		
Financial debt	656	554
Lease liability	722	582
Trade payables	5 346	3 995
Current tax liability	5 391	2 808
Other payables	7 892	3 633
	€ 20 007	€ 11 572
Total liabilities	€ 31 000	€ 22 208

Total equity and liabilities

€ 164 070

€ 170 830

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

	For the nine months ended September 30	
	2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES		
Loss before tax for the year	€ (17 550)	€ (21 111)
Adjustments for		
Finance income	(11 372)	(72)
Finance expenses	5 473	1 484
Depreciation and impairment of property, plant and equipment and right-of-use assets	832	558
Amortization of intangible assets	607	653
Share-based payment transaction expense	2 136	784
Increase/(Decrease) in provisions	36	4
Other non-cash items	(353)	247
Cash generated before changes in working capital	€ (20 191)	€ (17 453)
Changes in working capital		
Decrease/(Increase) in inventory	(248)	(33)
(Increase)/Decrease in trade and other receivables	1 100	(2 876)
Increase/(Decrease) in trade and other payables	1 265	2 563
Cash generated from changes in operations	€ (18 074)	€ (17 799)
Income tax paid	(314)	(205)
Net cash used in operating activities	€ (18 388)	€ (18 004)
 CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property, plant and equipment	(484)	(1 257)
Capitalization of intangible assets	(11 774)	(7 219)
Purchase of financial assets - current	(44 032)	-
Proceeds from sale of financial assets - current	24 582	-
Interest income on financial assets	63	-
Net cash used in investing activities	€ (31 645)	€ (8 476)
CASH FLOWS FROM FINANCING ACTIVITIES		
Payment of principal portion of lease liabilities	(497)	(358)
Repayment of other loan	(62)	(63)
Interests paid	(185)	(324)
Repayment of recoverable cash advance	(220)	(280)
Proceeds from issuance of shares, net of transaction costs	255	76 070
Other financial costs	(55)	(7)
Net cash used in financing activities	€ (764)	€ 75 038
Movement in cash and cash equivalents	€ (50 797)	€ 48 558
Effect of exchange rates on cash and cash equivalents	5 165	56
Cash and cash equivalents at January 1	€ 135 509	€ 92 300
Cash and cash equivalents at September 30	€ 89 877	€ 140 914

Revenue

Revenue was €182,000 for the third quarter of 2022, compared to €203,000 for the prior year period. The decrease in revenue was attributable to the temporary supply disruption that caused a delay in order fulfillment.

Cost of Goods Sold

Cost of goods sold was €63,000 for the three months ending September 30, 2022, representing a gross profit of €119,000, or gross margin of 65.3%. This compares to total costs of goods sold of €82,000 in the third quarter of 2021, for a gross profit of €121,000, or gross margin of 59.6%.

Research and Development Expenses

Research and development expenses were €4.2 million for the three months ending September 30, 2022, versus €3.5 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 €4.8 million for the third quarter of 2022, up from €4.5 million in the third 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 third quarter of 2022 was €8.8 million versus €8.1 million in the third quarter of 2021. This was driven by the delay of third quarter revenue due to the temporary supply disruption, the acceleration in the Company's R&D spending, and ongoing commercial and clinical activities. Nyxoah realized a net loss of €6.2 million for the third quarter of 2022, compared to a net loss of €8.8 million for the third quarter.

Cash Position

As of September 30, 2022, cash and financial assets totaled €115.4 million, compared to €135.5 million on December 31, 2021. Total cash burn was approximately €3.0 million per month during the third quarter of 2022, and is expected to increase going forward to account for the ACCESS IDE trial in the U.S.

Third Quarter 2022 Report

Nyxoah's financial report for the third quarter of 2022, including details of the unaudited 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 to 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/BI0d7e0daed6e34e548b85e51146400c1a>

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; future financial performance and market position; 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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Attachment

- [ENGLISH Q3 2022 Earnings PR - FINAL](#)