



Nyxoah Reports Full Year 2021 Operating and Financial Results

March 24, 2022

REGULATED INFORMATION

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Mont-Saint-Guibert, Belgium – March 24, 2022, 9:30pm CET / 4:30pm 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 full year ending December 31, 2021.

Full Year 2021 Operational and Financial Highlights

- Generated revenue of €852,000 from the commercialization of Genio® in Europe, mainly in Germany; gross margin was 64.4%
- Achieved strong commercial progress in Germany after obtaining a DRG code for the Genio system
- Obtained DRG coding in Switzerland and hospital reimbursement in Spain; awaiting reimbursement decisions in other key European markets
- Reported positive data from the BETTER SLEEP clinical trial, which achieved its primary safety and performance endpoints, with statistically significant reduction in baseline AHI scores for the overall study and the complete concentric collapse (CCC) and non-CCC patient cohorts; per the Sher criteria, after 6 months, achieved responder rates of 64% for the entire population (CCC and non-CCC), 60% for the CCC cohort, and 67% for the non-CCC cohort
- Received expanded CE mark indication to treat CCC patients, thus increasing the total addressable market by at least 30% and enabling patients not to have to undergo a Drug-Induced Sleep Endoscopy (DISE) procedure prior to implantation
- Granted U.S. FDA Breakthrough Device Designation for the treatment of adult patients with moderate-to-severe OSA and CCC; awaiting IDE approval to commence a trial for CCC patients in the U.S. in late 2022
- Advanced patient enrollment in the DREAM U.S. IDE study, with implants expected to be completed in the second quarter of 2022
- Raised \$97.8 million in a Nasdaq initial public offering in July, successfully completing Nyxoah's second IPO after previously raising €84.8 million in the September 2020 Euronext Brussels IPO
- Entered exclusive licensing agreement with Vanderbilt University (US) to develop next generation neurostimulation technologies, specifically a novel stimulator focused on the Ansa Cervicalis nerve, which could further expand the eligible to treat OSA patient population.

“2021 was a very strong year for Nyxoah. I am proud of the team maintaining their focus on execution while operating in a challenging market environment. We reached numerous milestones in 2021 and feel we are well positioned to further build on this momentum in 2022,” commented Olivier Taelman, Nyxoah's Chief Executive Officer. “Through the BETTER SLEEP study results, we are now able to offer an effective solution for CCC patients with an expanded CE mark indication in Europe, and we are working hard to initiate a CCC-focused IDE trial in the US. Particularly encouraging are the strong responder rates in all patient cohorts, further increasing our confidence in positive outcomes from the ongoing DREAM study.”

“We have also been happy with our commercial progress in Europe, focusing on Germany, where we obtained a dedicated DRG code,” continued Mr. Taelman. “We already had 12 active implant sites in December 2021 and continue to expand rapidly. In addition, we have secured a DRG code in Switzerland and hospital reimbursement in Spain while we await final reimbursement decisions in the Netherlands and Belgium. Our commercial strategy is based on a deep understanding of the patient journey, building strong relationships with implanting surgeons and further strengthening their relationships with referring sleep physicians, in combination with digital marketing programs.”

Mr. Taelman continued, “We secured CE mark MR conditional labeling for Genio®, enabling all implanted patients to safely undergo 1.5T and 3T MRI diagnostics scans. Genio® is now the only HGNS device with an MRI compatibility label for full-body and 3T. This illustrates our patient-centric strategy, and you can soon expect to hear more on the progress made by our R&D team. Short term, we expect to launch the next generation Genio® 2.1, which includes a patient-centric smartphone app and will incorporate a position sensor to adjust stimulation levels based on sleeping position. Looking further into the future, we are proud of our collaboration with Vanderbilt University and Dr. Kent that should result in novel treatment options for OSA patients, starting with Ansa Cervicalis stimulation.”

“With our second successful IPO in the span of 10 months last July, we have a strong balance sheet that provides ample liquidity to complete the DREAM study, conduct our U.S. CCC IDE study, invest in pre-commercial activities in the U.S., and remain committed to our important R&D priorities. We are extremely excited about where we are today as a company, and we look forward to providing further updates as the year progresses,” concluded Mr. Taelman.

Full Year 2021 Results

CONSOLIDATED STATEMENTS OF LOSS AND OTHER COMPREHENSIVE LOSS (in thousands)

	For the year ended December 31	
	2021	2020
Revenue	€ 852	€ 69
Cost of goods sold	(303)	(30)
Gross profit	€ 549	€ 39
General and administrative expenses	(11 113)	(7 522)
Research and development expenses	(2 353)	(473)
Clinical expenses	(2 706)	(1 053)
Manufacturing expenses	(4 760)	(460)
Quality assurance and regulatory expenses	(1 463)	(227)
Patents fees & Related	(1 062)	(123)
Therapy development expenses	(3 599)	(1 864)
Other operating income / (expenses)	265	459
Operating loss for the period	€ (26 242)	€ (11 224)
Financial income	3 675	62
Financial expense	(2 072)	(990)
Loss for the period before taxes	€ (24 639)	€ (12 152)
Income taxes	(2 980)	(93)
Loss for the period	€ (27 619)	€ (12 245)
Loss attributable to equity holders	€ (27 619)	€ (12 245)
Other comprehensive income/(loss)		
Items that may not be subsequently reclassified to profit or loss (net of tax)		
Remeasurements of post-employment benefit obligations, net of tax	(68)	-
Items that may be subsequently reclassified to profit or loss (net of tax)		
Currency translation differences	121	(58)
Total other comprehensive income/(loss)	€ 53	€ (58)
Total comprehensive loss for the year, net of tax	€ (27 566)	€ (12 303)
Loss attributable to equity holders	€ (27 566)	€ (12 303)
Basic loss per share (in EUR)	€ (1.161)	€ (0.677)
Diluted loss per share (in EUR)	€ (1.161)	€ (0.677)

CONSOLIDATED BALANCE SHEETS (in thousands)

	As at December 31	
	2021	2020
ASSETS		
Non-current assets		
Property, plant and equipment	€ 2 020	€ 713
Intangible assets	25 322	15 853
Right of use assets	3 218	3 283
Deferred tax asset	46	32
Other long-term receivables	164	91
	€ 30 770	€ 19 972
Current assets		
Inventory	346	55
Trade receivables	226	-
Other receivables	2 286	1 644
Other current assets	1 693	109
Cash and cash equivalents	135 509	92 300
	€ 140 060	€ 94 108
Total assets	€ 170 830	€ 114 080

EQUITY AND LIABILITIES

Capital and reserves

Capital	4 427	3 796
Share premium	228 033	150 936
Share based payment reserve	3 127	2 650
Other comprehensive income	202	149
Retained loss	(87 167)	(60 341)
Total equity attributable to shareholders	€ 148 622	€ 97 190

LIABILITIES**Non-current liabilities**

Financial debt	7 802	7 607
Lease liability	2 737	2 844
Pension liability	80	37
Provisions	12	–
Deferred tax liability	5	–
	€ 10 636	€ 10 488

Current liabilities

Financial debt	554	616
Lease liability	582	473
Trade payables	3 995	1 190
Current tax liability	2 808	–
Other payables	3 633	4 123
	€ 11 572	€ 6 402

Total liabilities**Total equity and liabilities**

€ 22 208	€ 16 890
€ 170 830	€ 114 080

Revenue

Revenue was €852,000 for the twelve months ending December 31, 2021, compared to €69,000 for the twelve months ending December 31, 2020. The increase in revenue was attributable to the Company's commercialization of the Genio® system, primarily in Germany. Revenue for the second half of 2021 was €497,000, a 40.0% increase versus the first half of the year despite COVID-related headwinds during the fourth quarter.

Cost of Goods Sold

Cost of goods sold was €303,000 for the twelve months ending December 31, 2021, representing a gross profit of €549,000, or gross margin of 64.4%. This compares to total costs of goods sold of €30,000 in the 2020, for a gross profit of €39,000, or gross margin of 56.5%.

General and Administrative Expenses

General and administrative expenses rose to €11.1 million for the full year ending December 31, 2021, from €7.5 million in the prior year. 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.

Research and Development Expenses

Research and Development expenses were €2.4 million for the twelve months ending December 31, 2021, a substantial increase over the €0.5 million for the prior year, reflecting the ongoing research and development activities, most notably the development of next generation versions of the Genio® system. As of January 2021, the Company started to amortize its intangible assets, which explains the significant increase in depreciation expenses for the twelve months ending December 31, 2021, compared to the twelve months ending December 31, 2020.

Clinical Expenses

Clinical expenses increased to €2.7 million for the twelve months ending December 31, 2021, from €1.1 million for the twelve months ending December 31, 2020. Total clinical expenses were €9.5 million, of which €6.8 million was capitalized, reflecting an increase in staff and consulting to support the completion of the BETTER SLEEP trial implantations, continuous recruitment for the EliSA trial, and the ongoing DREAM IDE trial in the United States.

Manufacturing Expenses

Manufacturing expenses increased to €4.8 million for the twelve months ending December 31, 2021, from €0.5 million for the twelve months ending December 30, 2020, due mainly to increased demand for our Genio® system for both commercial and non-commercial purposes.

Quality Assurance and Regulatory Expenses

Quality assurance and regulatory expenses of €1.5 million for the year ending December 31, 2021, were up significantly from €0.2 million for the year ending December 31, 2020, to support the scale-up of operations.

Patent Fees & Related Expenses

Patents fees and related expenses increased from €0.1 million for the twelve months ending December 31, 2020, to €1.1 million for the twelve months ending December 31, 2021, due to expenses related to the exclusive licensing agreement with Vanderbilt University.

Therapy Development Expenses

Therapy development expenses were €3.6 million for the twelve months ending December 31, 2021, versus €1.9 million for the twelve months ending December 31, 2020. The increase in expenses was mainly driven by the scale-up of commercial operations in Europe.

Operating Loss

The Company realized a net loss of €27.6 million for the full year ending December 31, 2021, compared to a net loss of €12.2 million for the full year ending December 31, 2020, due to increases of activities in all departments.

Cash Position

Cash and cash equivalents totaled €135.5 million on December 31, 2021, as compared to €92.3 million on December 31, 2020. The increase was due primarily to total gross proceeds of \$97.8 million generated from the July 2021 IPO.

Net cash used in operations was €25.3 million for the twelve months ending December 31, 2021, compared to €6.9 million for the twelve months ending December 31, 2020. The increase was primarily due to an increase in net loss for the period that was mainly attributable to increased general and administrative expenses, research and development expenses, manufacturing expenses and therapy development expenses, which were offset by a positive variation in the working capital of €1.1 million.

Net cash used in investing activities was €11.8 million for the twelve months ending December 31, 2021, compared to €10.7 million for the twelve months ending December 31, 2020.

Net cash generated in financing activities for the twelve months ending December 31, 2021, was €76.5 compared to €104.0 million of net cash provided by financing activities during the twelve months ending December 31, 2020.

Outlook for 2022

The Company's business, operational, and clinical outlook for 2022 include the following expected milestones and goals:

- Completing DREAM trial implants in the second quarter of 2022
- Continuing commercial execution in Germany
- Commencing a U.S. IDE study for CCC patients in the fourth quarter of 2022

Full-year report 2021

Nyxoah's financial report for the full year 2021, 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 to open to the public tomorrow, March 25, 2022, at 1:00 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: 3688760

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/>.

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, 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.

Contacts:

Nyxoah

Loic Moreau, Chief Financial Officer

corporate@nyxoah.com

+32 473 33 19 80

Jeremy Feffer, VP IR and Corporate Communications

jeremy.feffer@nyxoah.com

+1 917 749 1494

Attachment

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