



REGULATED INFORMATION

Nyxoah Issues First Half 2021 Financial Results

Mont-Saint-Guibert, Belgium – August 31, 2021, 10:30pm 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 announced its unaudited condensed consolidated interim financial statements for the first half of 2021.

Highlights

- \$97.8 million Nasdaq IPO gross proceeds
- On track to complete US DREAM trial enrollment
- €355 thousand revenue generated in Europe, compared to no revenue for the six months ended June 30, 2020, driven mainly in Germany
- Increased commercial activities in Germany with 12 active accounts in Q2, up from 2 in Q1 2021
- Announced BETTER SLEEP study top-line results that showed primary safety and performance endpoints met, with statistically significant mean reduction in the AHI score in full patient population including Complete Concentric Collapse (“CCC”) patients
- To submit full BETTER SLEEP study data to a medical journal for publication and announce results following further analyses
- Integrated Vanderbilt University technology into our scientific and technology department pipelines including collaboration with US and German key opinion leaders

“In the first half of 2021, we kept pace with our initiatives to deliver significant new accomplishments. In less than 12 months, we completed our second IPO with a Nasdaq listing, further strengthening our balance sheet; made important gains in commercial activities in Germany, our initial commercial proof of concept market; advanced clinical programs, including data to potentially expand our addressable market to include CCC patients; and maintained focused investments in new products and technologies,” said Olivier Taelman, CEO of Nyxoah. “In the second half, we look forward to further accelerating our commercial activities in existing markets, enter new markets, scale up, and advance clinical programs, including enrollment completion of our US DREAM study in the fourth quarter.”



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First Half 2021 Results

	For the six months ended June 30	
	2021	2020
(in thousands)		
Revenue	€ 355	€ –
Cost of goods sold	(115)	–
Gross profit	€ 240	€ –
General and administrative expenses	(4 777)	(2 400)
Research and development expenses	(1 255)	(56)
Clinical expenses	(631)	(509)
Manufacturing expenses	(2 171)	(207)
Quality assurance and regulatory expenses	(642)	(86)
Patents fees & Related	(793)	(107)
Therapy Development expenses	(1 502)	(761)
Other operating income / (expenses), net	(97)	184
Operating loss for the period	€ (11 628)	€ (3 942)
Financial income	43	82
Financial expense	(899)	(416)
Loss for the period before taxes	€ (12 484)	€ (4 276)
Income taxes	(124)	(24)
Loss for the period	€ (12 608)	€ (4 300)
Loss attributable to equity holders	€ (12 608)	€ (4 300)
Other comprehensive loss		
Items that may be subsequently reclassified to profit or loss (net of tax)		
Currency translation differences	192	(89)
Total comprehensive loss for the year, net of tax	€ (12 416)	€ (4 389)
Loss attributable to equity holders	€ (12 416)	€ (4 389)
Basic Earnings Per Share (in EUR)	€ (0.570)	€ (0.262)
Diluted Earnings Per Share (in EUR)	€ (0.570)	€ (0.262)



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Revenue

Revenue was €355 thousand for the six months ended June 30, 2021, compared to no revenue for the six months ended June 30, 2020. The increase in revenue was attributable to the Company's commercialization of the Genio[®] system mainly in Germany, and to a lesser extent, Spain and Belgium.

Cost of Goods Sold

Cost of goods sold was €115 thousand for the six months ended June 30, 2021, compared to no cost for the six months ended June 30, 2020. The increase in cost of goods sold was attributable to the sales of the Genio[®] system in Europe.

General and Administrative Expenses. General and administrative expenses increased by €2.4 million, or 99 %, from €2.4 million for the six months ended June 30, 2020 to €4.8 million for the six months ended June 30, 2021 mainly due to an increase in consulting and contractors' fees. The increase in consulting and contractors' fees includes variable compensations for an amount of €0.3 million for the six months ended June 30, 2020 and €1.9 million for the six months ended June 30, 2021 related to a cash-settled share based payment transaction and an increase of consultant services to support the company in legal, finance, tax and IT matters.

Research and Development Expenses. Before capitalization of €0.6 million for the six months ended June 30, 2021 and €0.6 million for the six months ended June 30, 2020, research and development expenses increased by €1.1 million or 173 %, from €0.7 million for the six months ended June 30, 2020, to €1.8 million for the six months ended June 30, 2021, due to an increase in staff and consulting costs to support our R&D activities. The Company started as of January 2021 to amortize its intangible assets. This explains the significant increase of depreciation expenses for the six months ended June 30, 2021, compared to the six months ended June 30, 2020.

Clinical Expenses. Before capitalization of €3.1 million for the six months ended June 30, 2021, and €1.4 million for the six months ended June 30, 2020, clinical expenses increased by €1.8 million, or 96%, from €1.9 million for the six months ended June 30, 2020, to €3.7 million for the six months ended June 30, 2021. The increase in the expenses was mainly due to 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. Before capitalization of €0.3 million for the six months ended June 30, 2021, and €1.2 million for the six months ended June 30, 2020, manufacturing expenses increased by €1.0 million, or 72% from €1.4 million for the six months ended June 30, 2020, to €2.4 million for the six months ended June 30, 2021. The increase in the expenses was mainly due to an increase in staff, in production and engineering team to support capacity and yield improvement. In addition, manufacturing expenses increased for the six months ended June 30, 2021, compared to the same period of 2020 due to the increase demand of our Genio[®] system for non-commercial purposes (clinical trials, development activities, etc) and, therefore, the increase of associated production costs.



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Quality Assurance and Regulatory Expenses. Before capitalization of €0.2 million for the six months ended June 30, 2021, and €0.5 million for the six months ended June 30, 2020, quality assurance and regulatory expenses increased by €0.3 million, or 44% from €0.6 million for the six months ended June 30, 2020, to €0.9 million for the six months ended June 30, 2021. The increase in the expenses was mainly due to an increase in staff and QA & regulatory activities to support manufacturing scaling up process.

Patent Fees & Related Expenses. Before capitalization of €0.2 million for the six months ended June 30, 2020, patents fees and related expenses increased by €0.5 million, or 199 % from €0.3 million for the six months ended June 30, 2020, to €0.8 million for the six months ended June 30, 2021, due to expenses related the in-licensing agreement with Vanderbilt University.

Therapy Development Expenses. Therapy development expenses increased by €0.7 million or 97 % from €0.8 million for the six months ended June 30, 2020, to €1.5 million for the six months ended June 30, 2021. The increase in the expenses was mainly due to an increase in staff and consulting, to support the launch of the commercialization in Europe.

Other Operating Income / (Expenses). The Company had other operating expenses of €0.1 million for the six months ended June 30, 2021, and other operating income of €0.2 million for the six months ended June 30, 2020, the evolution being mainly due to the impact of the initial measurement and re-measurement of the financial debt.

Operating Loss

The Company realized a net loss of €12.6 million for the six months ended June 30, 2021, compared to a net loss of €4.3 million for the six months ended June 30, 2020, due to increases of activities in all departments.

Cash Position

Cash and cash equivalents totaled €79.2 million on June 30, 2021, as compared to €23.9 million on June 30, 2020.

Net cash used in operations was €8.4 million for the six months ended June 30, 2021 compared to €4.0 million for the six months ended June 30, 2020. The increase of €4.3 million was primarily due to an increase in a loss for the period of €8.2 million 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 and other non-cash transactions of €3.9 million.

Net cash used in investing activities was €4.5 million for the six months ended June 30, 2021 compared €3.7 million to the six months ended June 30, 2020.



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Net cash used in financing activities for the six months ended June 30, 2021 was €289 thousand compared to €25.7 million of net cash provided by financing activities during the six months ended June 30, 2020. The decrease was due to the fact that no financing rounds have been organized in the first half of 2021.

Outlook for 2021

The Company's business, operational, and clinical outlook for 2021 include the following expected milestones and goals:

- Begin marketing in Switzerland with approved DRG, as well as additional European countries by the second half of 2021
- Ramp up EU revenue through dedicated sales team in Germany
- Open second independent manufacturing site in Belgium
- Complete DREAM pivotal trial enrollment in the fourth quarter of 2021

First half-year report 2021

Nyxoah's financial report for the first half of 2021, including details of the unaudited condensed consolidated financial statements, 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, September 1, 2021, at 3:00 p.m. CET / 9:00 a.m. ET, which will also be webcasted. To participate in the conference call, please dial one of the following numbers:

Conference ID: 7468474

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 CE-validated, patient-centered, next generation hypoglossal neurostimulation therapy for OSA, the world's most common sleep disordered breathing condition that is associated with increased mortality risk and comorbidities including cardiovascular diseases, depression and stroke.



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Following the successful completion of the BLAST OSA study in patients with moderate to severe OSA, the Genio[®] system received its European CE Mark in 2019. The Company has completed the BETTER SLEEP study in Australia and New Zealand for therapy indication expansion and is currently conducting the DREAM IDE pivotal study for FDA approval and a post-marketing ELISA study in Europe to confirm the long-term safety and efficacy of the Genio[®] system.

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. 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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