Nyxoah Issues First Quarter 2021 Results

June 10, 2021

Mont-Saint-Guibert, Belgium – June 10, 2021, 11:45pm CET / 5:45pm– Nyxoah SA (Euronext Brussels: 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, interim financial statements for the three months ended March 31, 2021. In addition, Mr. Janke Dittmer has informed the Company that he will resign from his position as director immediately prior to and contingent upon the completion of an initial public offering in the United States.

First Quarter 2021 Results

	For the three month period ended March 31	
(in thousands of EUR)	**2021**	**2020**
Revenue	185	—
Cost of goods sold	(52)	—
Gross Profit	**133**	—
General and administrative expenses	(1,818)	(1,178)
Research and development expenses	(852)	(7)
Clinical expenses	(342)	(177)
Manufacturing expenses	(901)	(62)
Quality assurance and regulatory expenses	(325)	(25)
Patents Fees & Related	(674)	(58)
Therapy Development expenses	(548)	(352)
Other operating income/(expenses)	4	(191)
Operating loss for the period	**(5,323)**	**(2,050)**
Financial income	4	19
Financial expense	(325)	(336)
Loss for the period before taxes	**(5,644)**	**(2,367)**
Income Taxes	(25)	(13)
Loss for the period	**(5,669)**	**(2,380)**
Other comprehensive loss		
Items that may be subsequently reclassified to profit or loss (net of tax)		
Currency translation differences	(70)	272
Total comprehensive loss for the year, net of tax	**(5,739)**	**(2,108)**
Loss attributable to equity holders	**(5,739)**	**(2,108)**

Revenue

Revenue was €185,000 for the three months ended March 31, 2021, compared to no revenue for the three months ended March 31, 2020. The increase in revenue was attributable to the Company's commercialization of the Genio® system in Europe, which began in July 2020.

Cost of Goods Sold

Cost of goods sold was €52,000 for the three months ended March 31, 2021, compared to no cost for the three months ended March 31, 2020. The increase in cost of goods sold was attributable to the sales of the Genio® system in Europe, which began in July 2020.

General and Administrative Expenses. General and administrative expenses increased by €0.6 million, or 54%, from €1.2 million for the three months ended March 31, 2020 to €1.8 million for the three-months ended March 31, 2021 mainly due to an increase in consulting expenses. The increase in consulting and contractors' fees includes variable compensations for an amount of €253,000 for the three months ended March 31, 2020 and €498,000 for the three-months ended March 31, 2021 related to a cash-settled share based payment transaction.

Research and Development Expenses. Before capitalization of €311,000 for the three months ended March 31, 2020, research and development expenses increased by €0.5 million, or 168%, from €318,000 (or €7,000 after capitalization of €311,000) for the three months ended March 31, 2020 to €0.9 million for the three months ended March 31, 2021, due to an increase in staff and consulting costs to support the Company's R&D activities.

Clinical Expenses. Before capitalization of €1.4 million for the three months ended March 31, 2021 and capitalization of €568,000 for the three months ended March 31, 2020, clinical expenses increased by €1.1 million, or 139%, from €0.7 million (or €177,000 after capitalization of €568,000) for the three months ended March 31, 2020 to €1.8 million for the three months ended March 31, 2021 (or €342,000 after capitalization of €1.4 million). 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 €215,000 for the three months ended March 31, 2021 and €578,000 for the three months ended March 31, 2020, manufacturing expenses increased by €0.5 million, or 74%, from €0.6 million (or €62,000 after capitalization of €578,000) for the three months ended March 31, 2020 to €1.1 million (or €901,000 after capitalization of €215,000) for the three months ended March 31, 2021. The increase was mainly due to an increase in staff, in the production and engineering team to support capacity and yield improvement, and in purchasing raw materials to support an increase in production.

Quality Assurance and Regulatory Expenses. Before capitalization of €133,000 for the three months ended March 31, 2021 and €263,000 for the three months ended March 31, 2020, quality assurance and regulatory expenses increased by €170,000, or 59%, from €288,000 (or €25,000 after capitalization of €263,000) for the three months ended March 31, 2020 to €458,000 (or €325,000 after capitalization of €133,000) for the three months ended March 31, 2021. The increase was mainly due to an increase in staff and QA & regulatory activities to support the manufacturing scaling-up process.

Patent Fees & Related Expenses. Before capitalization of €56,000 for the three months ended March 31, 2020, patent fees & related expenses increased by €560,000, or 491%, from €114,000 (or €58,000 after capitalization of €56,000) for the three months ended March 31, 2020 to €0.7 million for the three months ended March 31, 2021 due to expenses related to the in-licensing agreement with Vanderbilt University.

Therapy Development Expenses. Therapy Development expenses increased by €196,000, or 56%, from €352,000 for the three months ended March 31, 2020 to €0.5 million for the three months ended March 31, 2021. The increase in the expenses was mainly due to an increase in staff and consulting to support the launch the commercialization of the Genio® system in Europe.

Other Operating Income / (Expenses). The Company had other operating expenses of €191,000 for the three months ended March 31, 2020 and operating income of €4,000 for the three months ended March 31, 2021. The increase in expenses was mainly due to the impact of the initial measurement and re-measurement of the financial debt.

Operating Loss

The increase of operating loss from €2.1 million for the three months ended March 31, 2020 to €5.7 million for the three months ended March 31, 2021, or a change of €3.3 million, was due to increases of activities in all departments. The Company currently conducting three clinical trials to continue gathering clinical data and obtain regulatory approvals. In June 2020, the Company obtained IDE approval to start the DREAM trial in the United States. In line with this strategy, the Company continues to invest in research and development to improve and develop the next generation of the Genio® system and prepare for scaling-up of production capacities.

Cash Position

Cash and cash equivalents totaled €86.2 million on March 31, 2021, as compared to €92.3 million on December 31, 2020.

Net cash used in operations was €4.2 million for the three months ended March 31, 2021 compared to €1.2 million for the three months ended March 31, 2020. The increase of €3.0 million was primarily due to an increase in a loss for the period of €3.3 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 of €0.5 million.

Net cash used in investing activities for each of the three months ended March 31, 2021 and the three months ended March 31, 2020 was €1.8 million.

Net cash used in financing activities for the three months ended March 31, 2021 was €104,000 compared to €24.8 million of net cash provided by financing activities during the three months ended March 31, 2020. The decrease was due to a lack of capital increase during the first quarter of 2021.

Outlook for 2021

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

- Ramp up EU revenue and build a dedicated sales team in Germany
- Open second independent manufacturing site in Belgium, in addition to existing site in Israel
- Complete DREAM pivotal trial enrollment

First quarter report 2021

Nyxoah's financial report for the three months ended March 31, 2021, including details of the unaudited consolidated results, are available on the investor page of Nyxoah's website (https://investors.nyxoah.com/financials).

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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About Nyxoah

Nyxoah is a healthtech company focused on the development and commercialization of innovative solutions and services 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[1] and comorbidities including cardiovascular diseases, depression and stroke. 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 is currently conducting the BETTER SLEEP study in Australia and New Zealand for therapy indication expansion, 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 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.

1 Young T. et al: Sleep Disordered Breathing and Mortality: Eighteen-Year Follow-up of the Wisconsin Sleep Cohort, Sleep. 2008 Aug 1; 31(8): 1071–1078.