Nyxoah Reports Full Year 2020 Results

Conference call and webcast today at 3pm CET / 9am ET

Mont-Saint-Guibert, Belgium – 9 April 2021 – 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 reported financial and operating results for the full year ended December 31, 2020.

Olivier Taelman, Chief Executive Officer of Nyxoah, said: "2020 was a year marked by key accomplishments for Nyxoah, with important milestones showing focused execution across business units. Despite the Covid-19 pandemic, the impact on Nyxoah's activities was limited and our manufacturing facilities remained operational, with sufficient production to meet our needs."

Key Points

- **Financial**
  - 25M€ round onboarding ResMed as new investor
  - 85M€ IPO on Euronext Brussels
- **Clinical**
  - BETTER SLEEP study enrolment close of 42 implanted patients M6 data to be expected Q2 2021
  - IDE trial approval by FDA in June 2020, with first US and international implants by end 2020
  - EliSA implants on 15 patients for long term safety & efficacy, trial expected to follow patients over a five-year period
- **Commercial**
  - Germany G-BA approving NUB reimbursement at a similar reimbursement level as other neurostimulation-based OSA therapies
  - First revenue generation in Germany
- **Operational**
  - No production stop despite COVID
  - Tech transfer to a second independent manufacturing site in Belgium started
- **R&D**
  - MRI compatibility full body 1.5T and 3T
  - Next Gen of Genio system with improved features for the implantable and external components

Highlights of 2020

- In 2020, the Company continued to advance its goal of further expanding its footprint and providing more patients suffering from OSA access to the Genio® solution, thereby addressing a significant current unmet medical need.
- The German federal joint committee (G-BA) confirmed in March 2020 that the Genio® system is entitled to join the existing NUB for hypoglossal nerve stimulation ("HGNS") systems at a similar reimbursement level as other neurostimulation-based OSA therapies. As a result, the Company generated its first commercial revenue in 2020, albeit that such revenue was limited due to the NUB-specific negotiation path. As of 2021, the reimbursement will move away from NUB into a DRG system which should allow the Company to fully ramp up its German commercialization strategy.
- Despite Covid-19 related disruptions, the Company was able to continue producing Genio® devices in sufficient quantities to meet needs.

Clinical development

- In November 2020, the Company completed enrolments in the BETTER SLEEP trial, conducted in Australia. In total, 42 patients were enrolled in this pre-marketing study, designed to assess the safety and efficacy / performance of the Genio® system for the treatment of OSA in adult patients who either exhibit or do not exhibit a complete concentric collapse ("CCC") of the soft palate. The study is planned to have a 36-month follow-up and the end of the study is expected by the end of 2023. Six-month follow-up results are expected to be available in the second quarter of 2021.
- If the primary endpoints of this study are reached, the Company plans to request a therapy indication expansion that would allow the Genio system to be used to treat CCC patients that are currently excluded from HGNS. In the meantime, the discussion with the European notified bodies has been initiated. If the Company obtains marketing authorization for the Genio system in the US, the Company plans to leverage the clinical data from the BETTER SLEEP study to expand the authorized indication to include the treatment of CCC patients in the US.
- In 2020, enrolment continued, but was slowed down due to Covid-19, in the EliSA trial, the Company's multicenter post-marketing trial being conducted throughout Europe which is designed to gather long-term safety and clinical data regarding the Genio® system in adult patients suffering from moderate-to-severe OSA. As of 31 December 2020, 15 patients out of the total intended 110 patients were enrolled in the study coming from five different countries (Germany, Switzerland, France, the Netherland, Belgium).
- In June 2020, the U.S. Food and Drug Administration (FDA) approved an Investigational Device Exemption (IDE) application for the Company's DREAM trial. This study aims to confirm the safety and effectiveness of the Genio® system and is designed to support marketing authorization of the Genio® system in the United States. The study will enroll 134 moderate-to-severe OSA patients who failed first line CPAP therapy. Up to 19 US sites in combination with 7 international sites have been selected to participate in the study. By the end of 2020, the first US and international implants took place.

Research and Development

- Throughout 2020, the Company continued to invest in improving the Genio® system with a goal of developing next generation products with improved features with respect to patient comfort, therapy efficacy, reliability and patient and market acceptance.
- In 2020, the Company performed the Magnetic Resonance Imaging ("MRI") compatibility testing of the Genio® system, resulting in CE mark and FDA conditional MR labeling approval in early 2021.

Financial highlights

- In February 2020, the Company raised €25 million in a private financing round, whereby ResMed Inc. (NYSE:RMD; ASX:RMD), a world-leading digital health company in the OSA field, joined the Company as a new shareholder. All major shareholders at that time participated in this financing round onboarding ResMed Inc.
- In September 2020, the Company raised €85 million ($100 million) as a result of the initial public offering ("IPO") of new shares of the Company on Euronext Brussels under the symbol "NYXH". The IPO resulted in an initial market capitalization of €375 million (taking into account the exercise in full of the over-allotment option in the framework of the IPO).

Subsequent Events

- After the close of the financial year, the Company signed an exclusive license agreement with Vanderbilt University (Nashville, TN, USA). This agreement allows Nyxoah to develop new neurostimulation technologies for the treatment of sleep disordered breathing conditions based on inventions and patents owned by Vanderbilt University, which could potentially expand Nyxoah's future pipeline.
- On February 22, 2021, the Company issued 10,000 shares pursuant to an exercise of subscription rights. Consequently, on the date of this Annual Report, the Company's registered capital amounts to EUR 3,797,765.64, represented by 22.107.609 shares.

Outlook for 2021

Our business, operational, and clinical outlook for 2021 include the following:

- Ramp up EU revenue and build a dedicated sales team in Germany
- Obtain reimbursement in Switzerland
- BETTER SLEEP trial 6 month results, basis for Complete Concentric Collapse ("CCC") therapeutic indication expansion
- Open second independent manufacturing site in Belgium, in addition to existing site in Israel
- Complete DREAM pivotal trial enrollment

Full Year 2020 Financial Results

Income Statement

For the first time since its inception, the Company began generating revenue as of July 2020. The revenue of KEUR 69 was generated under the existing HGNS NUB coding in Germany. The total cost of goods sold was KEUR 30.

Operating costs increased to KEUR 11,224 in 2020 from KEUR 7,715 in 2019, or a change of KEUR 3,509, due to increases of activities in all departments. The Company is currently conducting three clinical trials to continue gathering clinical data and obtain regulatory approvals. In June 2020 the Company obtained FDA approval to start the DREAM study in the US. In line with its strategy, the Company continues investing in research and development to improve and develop the next generation of the Genio® system and preparing for scaling-up of production capacities.

General and administrative expenses increased by 78% to KEUR 7,522 in 2020 from KEUR 4,226 in 2019. The increase is due to consulting expenses, staff and legal fees to support the Company growth. The increase in consulting and contractors' fees includes variable compensations of KEUR 1,981 related to a cash-settled share-based payment transaction (2019: KEUR 1,199). The increase of KEUR 159 in legal fees is due to services and not to any ongoing disputes.

Research and development expenses increased by 29% to KEUR 3,066 in 2020 from KEUR 2,375 in 2019, before capitalization of KEUR 2,593 in 2020, due to the increase of development costs of the Genio® system. Research and development expenses consist of product development, engineering to develop and support our products, testing, consulting services and other costs associated with the next generation of the Genio® system that do not meet the development capitalization criteria. The Company continues to invest in improving the Genio® system to develop next generation products with improved features with respect to patient comfort, therapy efficacy, reliability and patient and market acceptance. These expenses primarily include employee compensation and outsourced development expenses.

Clinical expenses increased by 50% to KEUR 4,316 in 2020 from KEUR 2,881 in 2019, before capitalization of KEUR 3,263 in 2020. The increase in the expenses was mainly due to an increase in staff and consulting to support the completion of the BETTER SLEEP study implantations, continuous recruitment for EliSA study and the launch of the new DREAM IDE study in the US. Clinical expenses consist of clinical studies related to the development of our Genio® system, consulting services and other costs associated with clinical activities. These expenses include employee compensation, clinical trial management and monitoring, payments to clinical investigators, data management and travel expenses for our various clinical trials.

Manufacturing expenses increased by 109% to KEUR 3,802 in 2020 from KEUR 1,812 in 2019, before capitalization of KEUR 3,342 in 2020. The increase in the expenses was mainly due to increases in staff for the production and engineering teams to support capacity and yield improvement, and also due to purchasing raw materials to support increase in the production. Manufacturing and operation expenses

consist primarily of acquisition costs of the components of the Genio® system, scrap and inventory obsolescence as well as distribution-related expenses such as logistics and shipping costs.

Quality assurance and regulatory expenses increased by 58% to KEUR 1,474 in 2020 from KEUR 928 in 2019, before capitalization of KEUR 1,247 in 2020. The increase in the expenses was due to staff increases and QA & regulatory activities to support manufacturing scaling up process. Quality assurance and regulatory expenses consist primarily of quality control, quality assurance and regulatory expenses. These expenses include employee compensation, consulting, testing and travel expenses.

Therapy development expenses increased by 107% to KEUR 1,864 in 2020 from KEUR 902 in 2019. The increase in the expenses was due to an increase in staff and consulting to support the commercialization in Europe. Therapy development expenses consist of compensation for personnel, spending related to market access and reimbursement activities. Other therapy development expenses include training physicians, travel expenses, conferences and consulting services.

Balance Sheet

The Company started recognizing the development expenditure as an asset as of March 2019, triggered by obtaining CE mark. Development costs primarily include employee compensation and outsourced development expenses. In 2020, the Company had capitalized developments costs of KEUR 9,874.

Property, plant & equipment shows a total additional net book value of KEUR 391 at balance sheet date consequently to leasehold improvements in the Company's offices in Belgium and Israel. Right of use assets shows a total additional increase by KEUR 2,217 due to new leases signed in 2020.

Cash and cash equivalents show a total additional increase of KEUR 86,445. This increase was due to total capital raises of KEUR 103,583, net of transaction costs, in February 2020 and in September 2020 (Initial Public Offering ("IPO")). Cash from financing activities was offset by cash used in the operating activities of KEUR 7,015 and cash used in the investing activities of KEUR 10,693.

The share capital and the share premium have increased, respectively, by KEUR 1,315 and KEUR 103,268 due to the capital increases in cash in 2020 for a total amount KEUR 103,583, net of transaction costs and capital increase in kind (conversion of loan in shares) of KEUR 1,000.

Lease liabilities shows a total additional increase of KEUR 2,242 due to new lease agreements in Belgium and Israel.

Other non-current and current payables have increased by KEUR 1,303 from KEUR 2,820 to KEUR 4,123 due higher cash-settled share-based payment liability of KEUR 473, higher accrued expenses of KEUR 557 and higher payroll related payables of KEUR 134.

Cash Flow Statement

The net cash burn rate for 2020 is a net cash inflow amounting to KEUR 86,445 compared to a net cash outflow of KEUR 10,950 for 2019.

The cash outflow resulting from operating activities amounted to KEUR 7,015 in 2020 compared to KEUR 5,965 in 2019. An increase of cash outflow of KEUR 1,050 due to KEUR 3,768 higher losses mainly from increased general and administrative expenses and therapy development expenses and higher interest and tax paid, net of KEUR 166, offset by KEUR 2,421 higher non-operating cash adjustments (KEUR 2,202 higher share-based payment expense) and a positive variation in the working capital of KEUR 463.

Cash flow from investing activities represented a net cash outflow of KEUR 10,693 for 2020. An increase of KEUR 4,898 compared to 2019 mainly explained by higher capitalization of development expenses in 2020.

The increase in cash inflow from financing activities is primarily due to the IPO completed in September 2020 and the proceeds from the February 2020 capital raise.

Financial Information

The consolidated financial statements have been prepared in accordance with IFRS as adopted by the EU. The financial information included in this press release is an extract of the full IFRS consolidated financial statements, which will be published on 9 April 2021. The statutory auditor, EY Bedrijfsrevisoren /Réviseurs d'Entreprises SRL, represented by Carlo-Sébastien D'Addario, has issued an unqualified audit opinion with emphasis of matter paragraph relating to a restatement for the year 2019 and the balance at 1 January 2019 to reflect the adjustments relating to a share based compensation accrual.

2021 Financial & Events Calendar

- 09 April 2021 Full Year 2020 Financial and Operating Results & Annual Report
- 09 June 2021 Annual Shareholders' Meeting
- 31 August 2021 Interim Financial Report H1, 2021
- 14-15 September 2021 Baird 2021 Global Healthcare Conference (virtual)

Conference Call & Webcast

Nyxoah will host a conference call with live webcast today at 3pm CET/9am ET. The webcast may be accessed on the Events page of the company's website or by clicking here. A replay of the webcast will be available on the Nyxoah website.

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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.

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 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 and projections concerning future events such as the Company's results of operations, financial condition, liquidity, performance, prospects, growth, strategies and the industry in which the Company operates. 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.

Consolidated Income Statement

(in EUR 000)	For the year ended 31 December 2020	2019 Restated *
Revenue	69	-
Cost of goods sold	(30)	-
Gross Profit	**39**	-
General and administrative expenses	(7,522)	(4,226)
Research and development expenses	(473)	(630)
Clinical expenses	(1,053)	(848)
Manufacturing expenses	(460)	(489)
Quality assurance and regulatory expenses	(227)	(227)
Patents Fees & Related	(123)	(267)
Therapy Development expenses	(1,864)	(902)
Other operating income/ (expenses)	459	(126)
Operating loss for the period	**(11,224)**	**(7,715)**
Financial income	62	71
Financial expense	(990)	(740)
Loss for the period before taxes	**(12,152)**	(8,384)
Taxes	(93)	(70)
Loss for the period	**(12,245)**	**(8,454)**
Loss attributable to equity holders[1]	**(12,245)**	**(8,454)**
Other comprehensive (loss) / income		
Items that may be subsequently reclassified to profit or loss (net of tax)		
Currency translation differences	(58)	168
Total comprehensive loss for the year, net of tax	**(12,303)**	**(8,286)**
Loss attributable to equity holders[1]	**(12,303)**	**(8,286)**
Basic Earnings Per Share (in EUR)	(0.677)	(0.568)
Diluted Earnings Per Share (in EUR)	(0.677)	(0.568)

[1] For the years ending 31 December 2020 and 2019, the loss is fully attributable to equity holders of the Company as the Company does not have any non-controlling interests.

* The year 2019 has been restated to reflect the adjustments as explained in Note 5.2.3

Consolidated Statement of Financial Position

(in EUR 000)	As of and for the year ended 31 December	
	2020	**2019 Restated***
ASSETS		
Non-current assets		
Property, plant and equipment	713	322
Intangible assets	15,853	5,734
Right of use assets	3,283	1,066
Deferred tax asset	32	21
Other long-term receivables	91	78
	19,972	**7,221**
Current assets		
Inventory	55	-
Trade receivables	-	60
Other receivables	1,644	2,048
Other current assets	109	11
Cash and cash equivalents	92,300	5,855
	94,108	**7,974**
Total assets	**114,080**	**15,195**
EQUITY AND LIABILITIES		
Capital and reserves		
Capital	3,796	2,481
Share premium	150,936	47,668
Share based payment reserve	2,650	420
Currency translation reserve	149	207
Retained Earnings	(60,341)	(48,415)
Total equity attributable to shareholders	**97,190**	**2,361**
LIABILITIES		
Non-current liabilities		
Financial debt	7,607	7,146
Lease liability	2,844	735
Pension Liability	37	30
Other payables	-	547
	10,488	**8,458**
Current liabilities		
Financial debt	616	378
Lease liability	473	340
Trade payables	1,190	1,385
Other payables	4,123	2,273
	6,402	**4,376**
Total liabilities	**16,890**	**12,834**
Total equity and liabilities	**114,080**	**15,195**

* The year 2019 has been restated to reflect the adjustments as explained in our 2020 Annual Report Note 5.2.3

Consolidated Statement of Cash Flows

(in EUR 000)	For the year ended 31 December 2020	2019 Restated *
CASH FLOWS FROM OPERATING ACTIVITIES		
Loss before tax for the year	**(12,152)**	**(8,384)**
Adjustments for:		
Finance income	(62)	(71)
Finance expenses	990	740
Depreciation and impairment of property, plant and equipment and right-of-use assets	620	433
Share-based payment transaction expense	2,549	346
Pension-related expenses	7	30
Other non-cash items[2]	(134)	70
Cash generated before changes in working capital	**(8,182)**	**(6,836)**
Changes in working capital:		
Increase in Inventory	(55)	-
Decrease/(Increase) in Trade and other receivables	365	(1,385)
Increase in Trade and other payables	1,109	2,342
Cash generated from changes in operations	**(6,763)**	**(5,879)**
Interests received	3	8
Interests paid	(151)	(33)
Income tax paid	(104)	(61)
Net cash used in operating activities	**(7,015)**	**(5,965)**
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property, plant and equipment	(562)	(51)
Capitalization of intangible assets	(10,118)	(5,734)
Increase of long-term deposits	(13)	(10)
Net cash used in investing activities	**(10,693)**	**(5,795)**
CASH FLOWS FROM FINANCING ACTIVITIES		
Payment of principal portion of lease liabilities	(479)	(341)
Repayment of other loan	(63)	(82)
Recoverable cash advance received	190	1,196
Repayment of recoverable cash advance	(55)	(40)
Proceeds from convertible loan	1,000	-
Proceeds from issuance of shares, net of transaction costs	103,583	-
Net cash generated/(used) from financing activities	**104,176**	**733**
Movement in cash and cash equivalents	**86,468**	**(11,027)**
Effect of exchange rates on cash and cash equivalents	(23)	77

[2] The other non-cash items include (i) the impact of the initial measurement and re-measurement of recoverable cash advances (see our 2020 Annual Report notes 5.14 ,5.24 and (ii) the evolution of the deferred tax assets.

* The year 2019 has been restated to reflect the adjustments as explained in our 2020 Annual Report Note 5.2.3

Cash and cash equivalents at 1 January	**5,855**	**16,805**
Cash and cash equivalents at 31 December	**92,300**	**5,855**

Consolidated Statement of Changes in Equity

		Attributable to owners of the parent					
(in EUR 000)	**Notes**	**Capital**	**Share premium**	**Share based payment reserve**	**Currency translation reserve**	**Retained earnings**	**Total**
Balance at 1 January 2019* restated		**2,481**	**47,668**	**80**	**39**	**(39,967)**	**10,301**
Loss for the year						(8,454)	(8,454)
Other comprehensive income for the year					168		168
Total comprehensive income/(loss) for the year					**168**	**(8,454)**	**(8,286)**
Equity-settled share-based payment plan				340		6	346
Total transactions with owners of the Company recognized directly in equity				**340**		**6**	**346**
Balance at 31 December 2019 restated *		**2,481**	**47,668**	**420**	**207**	**(48,415)**	**2,361**
Balance at 1 January 2020 restated *		**2,481**	**47,668**	**420**	**207**	**(48,415)**	**2,361**
Loss for the year						(12,245)	(12,245)
Other comprehensive loss for the year					(58)		(58)
Total comprehensive loss for the year		**-**	**-**	**-**	**(58)**	**(12,245)**	**(12,303)**
Equity-settled share-based payment plan				2,230		319	2,549
Issuance of shares for cash		1,304	108,857				110,161
Issuance of shares in kind		11	989				1,000
Transaction cost			(6,578)				(6,578)
Total transactions with owners of the Company recognized directly in equity		**1,315**	**103,268**	**2,230**		**319**	**107,132**
Balance at 31 December 2020		**3,796**	**150,936**	**2,650**	**149**	**(60,341)**	**97,190**

* The year 2019 and the balance at 1 January 2019 has been restated to reflect the adjustments as explained in our 2020 Annual Report Note 5.2.3