
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 6-K

**REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16
UNDER THE SECURITIES EXCHANGE ACT OF 1934**

For the month of January 2022

Commission File Number: **001-40552**

NYXOAH SA

(Translation of registrant's name into English)

Rue Edouard Belin 12, 1435 Mont-Saint-Guibert, Belgium

(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F ☒ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ☐

Note: Regulation S-T Rule 101(b)(1) only permits the submission in paper of a Form 6-K if submitted solely to provide an attached annual report to security holders.

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ☐

Note: Regulation S-T Rule 101(b)(7) only permits the submission in paper of a Form 6-K if submitted to furnish a report or other document that the registrant foreign private issuer must furnish and make public under the laws of the jurisdiction in which the registrant is incorporated, domiciled or legally organized (the registrant's "home country"), or under the rules of the home country exchange on which the registrant's securities are traded, as long as the report or other document is not a press release, is not required to be and has not been distributed to the registrant's security holders, and, if discussing a material event, has already been the subject of a Form 6-K submission or other Commission filing on EDGAR.

Nyxoah SA

On January 10, 2022, Nyxoah SA (the “Company”) issued a press release, a copy of which is attached hereto as Exhibit 99.1.

The information in the attached Exhibit 99.1 is being furnished and shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference in any filing made by the Company under the Securities Act of 1933, as amended, or the Exchange Act, except as otherwise set forth herein or as shall be expressly set forth by specific reference in such a filing.

Exhibits

[99.1](#) [Press Release, dated January 10, 2022](#)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

NYXOAH SA

Date: January 11, 2022

By: /s/ Loic Moreau

Name: Loic Moreau

Title: Chief Financial Officer



Nyxoah Provides General Corporate Update

January 10, 2022

Nyxoah Provides General Corporate Update

Transformational 2021 positions Nyxoah for further clinical, regulatory, and commercial milestones in 2022

Mont-Saint-Guibert, Belgium – January 10, 2022, 7:00am CET / 1:00am 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 provided a general corporate update.

2021 Highlights

- Implanted first U.S. patient in the DREAM IDE pivotal study in December 2020; there are currently 15 active and enrolling patient sites in the U.S., with implants expected to be completed in Q1 2022
- Secured CE Mark MR conditional labeling for the Genio® system in January, ensuring that implanted patients can undergo full-body 1.5T and 3T MRI diagnostic scans
- Raised \$97.8 million in a Nasdaq initial public offering in July, successfully completing Nyxoah’s second IPO after previously raising \$100 million in the September 2020 Euronext Brussels IPO
- Granted U.S. FDA Breakthrough Device Designation for the treatment of adult patients with moderate to severe OSA and Complete Concentric Collapse (CCC) of the soft palate in September; engaged in sprint discussions with FDA regarding the IDE study for CCC patients in the U.S., which Nyxoah hopes to commence in the second half of 2022
- Received expanded CE Mark indication to treat CCC patients in October, thus increasing Nyxoah’s total addressable market by at least 30% and thereby enabling patients not to have to undergo a Drug-Induced Sleep Endoscopy (DISE) procedure prior to Genio® implantation
- Made strong commercial progress in Germany after obtaining a dedicated DRG code in January
- Obtained DRG coding in Switzerland in March and secured first revenue in Spain; submitted reimbursement files in other key European markets
- Entered exclusive licensing agreement with Vanderbilt University in February to develop next generation neurostimulation technologies, specifically a stimulator focused on the Ansa Cervicalis, which innervates the palatoglossus and/or the palatopharyngeus muscle; this collaboration has thus far resulted in initial prototyping discussions, and Nyxoah expects to make further progress on this project in 2022
- Appointed Loic Moreau as Chief Financial Officer effective January 1, 2022, replacing Fabian Suarez, who is pursuing a new opportunity as CEO of a startup MedTech company
- Announced the appointment of Rita Johnson-Mills to the Board of Directors in August

“2021 was a transformational year for Nyxoah as we achieved several important clinical, regulatory, commercial, and financial accomplishments and set ourselves up for continued progress in 2022 and beyond,” said Olivier Taelman, CEO of Nyxoah. “On the clinical front, we announced that our BETTER SLEEP clinical trial achieved a statistically significant mean reduction in the Apnea Hypopnea Index (AHI) from baseline to six months post implantation for the entire cohort as well as for the subgroup of patients with Complete Concentric Collapse (CCC) of the soft palate. We will be submitting the full data set for journal publication and look forward to discussing more fully once the data are published, hopefully in the first half of 2022. We are extremely encouraged by the data generated by BETTER SLEEP, which were used by our notified body DEKRA to expand our CE Mark indication to include CCC patients as well as by FDA in granting us Breakthrough Device Designation for the treatment of CCC patients in the U.S. We are also excited to partner with Dr. David Kent and his team at Vanderbilt University on the development of a next generation device that stimulates the Ansa Cervicalis, which Dr. Kent’s research suggests could be another effective way to treat OSA patients, and we look forward to advancing our work in creating a stimulator that leverages this novel approach.”

Mr. Taelman continued, “As we begin 2022, our primary clinical focus is on our DREAM U.S. IDE pivotal study in which patient enrollment and implants are well underway, and we still expect to complete our target of 134 implants by the end of Q1 2022. We continue to generate great enthusiasm from physicians and patients as we activate more sites and enroll more patients, and we are seeing implant rates accelerating as we move into the new year. We have also been encouraged by our sprint discussions with FDA regarding our IDE trial for CCC patients in the U.S., which we hope to commence in the second half of 2022. From a commercial standpoint, we have made tremendous progress in our key geographic markets, securing DRG codes in Germany and Switzerland, obtaining hospital reimbursement in Spain and awaiting reimbursement decisions in Belgium, the Netherlands, and the Nordic countries. Our commercial strategy centers on the concept of going deep as opposed to going wide; in other words, we want to focus our strategy on key Centers of Excellence with high levels of clinical expertise and patient care, large patient pools, and well-coordinated clinical and administrative infrastructures. This strategy, combined with our ability to treat CCC patients, has enabled us to gain meaningful market share in Germany, and we expect to exit 2022 as the market leader in that important country.”

Mr. Taelman concluded, “As proud and excited as we are of our significant accomplishments in 2021, we have our sights set much higher for 2022. Aiding our efforts is a strong balance sheet that we bolstered in July with close to \$100 million raised in our Nasdaq IPO, less than one year after raising close to \$100 million in our Euronext IPO in September 2020. This liquidity gives us ample flexibility to complete the DREAM study, conduct the ACCESS study, invest further in our existing commercial operations, and begin to build out a U.S. commercial operation in anticipation of launch following FDA approval. We are extremely well positioned to execute on our clinical, regulatory, and commercial initiatives, and we look forward to providing further updates on our progress as the year unfolds.”

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. 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 Corporate Update Jan 2022 - FINAL](#)
