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 March 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 March 14, 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 March 14, 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: March 16, 2022

By: /s/ Loic Moreau
Name: Loic Moreau
Title: Chief Financial Officer

BETTER SLEEP Achieves Primary Endpoint Across All Patient Cohorts

March 14, 2022

BETTER SLEEP Achieves Primary Endpoint Across All Patient Cohorts

- *First clinical data demonstrating effectiveness of HGNS to treat CCC patients*
- *As previously disclosed, confirms achievement of primary endpoint of AHI4 reductions for entire population, CCC cohort, and non-CCC cohort at six months, and reports 60%+ responder rates for all three cohorts*
- *Exceeds 70% mean reduction in AHI4 among responders in both CCC and non-CCC cohorts*

Mont-Saint-Guibert, Belgium – March 14, 2022, 11:30pm CET / 6:30pm 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 provided additional data from its BETTER SLEEP clinical trial that it showcased in a poster presentation at the 16th World Sleep Congress 2022. World Sleep, a global scientific congress, gathers leaders in sleep medicine and research from around the world for scientific sessions and networking.

Forty-two (42) moderate-to-severe OSA patients in the study received an implant at eight research sites in Australia, 18 of whom presented with Complete Concentric Collapse (CCC) of the soft palate and 24 who were classified as non-CCC. Three patients in each arm did not complete their six-month polysomnography, and as a result, the analysis was calculated based on 36 patients (15 CCC, 21 non-CCC). Of these 36 patients, there were 23 responders (64%), including nine of the 15 CCC patients (60%) and 14 of the 21 non-CCC patients (67%), at six months.

The primary endpoint was achieving at least a 4-point reduction in the apnea-hypopnea index (4% oxygen desaturation, or AHI4) from baseline at six months for the entire 42 patients. The overall reduction was statistically significant with an 11-point reduction ($p<0.001$), with statistically significant reductions of 10 points ($p=0.001$) in the CCC cohort and 11 points ($p<0.001$) in the non-CCC cohort. In addition, mean AHI4 reduction exceeded 70% among responders in both CCC and non-CCC cohorts. These results are subject to final review and validation.

"BETTER SLEEP represents the first clinical study to demonstrate the effectiveness of treating CCC patients with hypoglossal nerve stimulation (HGNS)," said Olivier Taelman, Chief Executive Officer of Nyxoah. "The results give us confidence that we will be able to provide a better treatment option for CCC patients, who comprise approximately 30% of the moderate-to-severe OSA population and are contraindicated for other HGNS options. These data validate our differentiated approach of delivering bilateral stimulation via an implantable device requiring only one incision, and a CCC indication would eliminate the need for patients to undergo an invasive DISE procedure."

"We are also extremely encouraged to have generated such positive clinical results after just six months following implantation, as the growing body of clinical data and real-world experience suggests that patient responses improve meaningfully between months six and twelve," continued Mr. Taelman. "The granting of an expanded CE mark indication to treat CCC patients and Breakthrough Device Designation from the U.S. FDA, both based on BETTER SLEEP, along with the high-level interest among the approximately 50 physicians in attendance at Nyxoah's World Sleep symposium, underscore the strength of the data and excitement for the Genio platform. We continue to work with the FDA on an IDE approval to conduct a clinical trial for CCC patients in the U.S., which we aim to commence later this year."

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.

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Attachment

- ENGLISH_BETTER SLEEP Data PR Final