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 June 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 June 1, 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 June 1, 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: June 2, 2022

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

FDA Approves Genio® 2.1 For Use in DREAM U.S. IDE Pivotal Study

New smartphone application, upgraded activation chip, improved user interface, and stimulation amplitude trimming enhance patient experience and comfort

Mont-Saint-Guibert, Belgium – June 1, 2022, 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 that the U.S. Food and Drug Administration (FDA) has approved the use of Nyxoah's next generation Genio® 2.1 system for use in the Company's DREAM U.S. IDE pivotal study. Genio® 2.1's upgrades are entirely related to the external components of the Genio® system, as the implantable stimulator remains unchanged.

Genio® 2.1 further demonstrates Nyxoah's patient-centric approach to addressing the needs of those suffering from moderate-to-severe OSA. The system features updates to the Genio® activation chip and a new smartphone application to enable daily reporting of therapy usage, which will support therapy acclimation and long-term compliance. Additional features of Genio® 2.1 include an improved user interface and the ability for clinicians to make more incremental stimulation adjustments. This is particularly meaningful for patients who are more sensitive to neurostimulation, as with Genio® 2.1 physicians can fine-tune stimulation amplitude to determine the optimal level of comfort for patients without compromising therapy efficacy.

"Genio® 2.1's features, along with existing full-body 3.0T MRI compatibility, illustrate Nyxoah's patient- first mission in OSA product development," commented Olivier Taelman, Nyxoah's Chief Executive Officer. "The updated activation chip and new smartphone app, combined with our upgraded user interface and increased stimulation resolution, represent key next steps in optimizing patient outcomes. We are excited to make these important new features available to patients in our DREAM trial."

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.

Contacts:
Nyxoah
Loic Moreau, Chief Financial Officer
corporate@nyxoah.com
+32 473 33 19 80

Jeremy Feffer, VP IR and Corporate Communications
jeremy.feffer@nyxoah.com
+1 917 749 1494