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 July 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 July 11, 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 July 11, 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: July 11, 2022

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

Exhibit 99.1

Nyxoah Receives FDA IDE Approval to Initiate the ACCCESS Study of Genio® in Complete Concentric Collapse Patients

July 11, 2022

REGULATED INFORMATION
INSIDE INFORMATION

Nyxoah Receives FDA IDE Approval to Initiate the ACCCESS Study of Genio® in Complete Concentric Collapse Patients

First ACCCESS patient expected to be implanted in Q4 2022

Mont-Saint-Guibert, Belgium – July 11, 2022, 8:00am CET / 2:00am 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 announced that the U.S. Food and Drug Administration (FDA) has approved an Investigational Device Exemption (IDE) to enable Nyxoah to initiate a clinical trial, called ACCCESS, to evaluate the use of the Genio® system for the treatment of adult patients with moderate-to-severe OSA and Complete Concentric Collapse (CCC) of the soft palate. The FDA had previously granted Breakthrough Device Designation to Genio® to treat CCC patients.

In the ACCCESS trial, Nyxoah will implant up to 106 patients with co-primary efficacy endpoints of Apnea-Hypopnea Index (AHI) responder rate, per the Sher criteria, and Oxygen Desaturation Index (ODI) responder rate, both assessed at 12 months post-implant. The first patient is expected to be implanted during the fourth quarter of 2022, in-line with prior guidance.

"The ACCCESS IDE approval is an important first step to unlocking an enormous patient population, as more than 30% of OSA patients in the U.S. have CCC. Nyxoah is the only hypoglossal nerve stimulation (HGNS) company with a positive CCC clinical trial and CCC approval in Europe, and the ACCCESS study further strengthens our leadership position in addressing the needs of these patients," commented Olivier Taelman, Nyxoah's Chief Executive Officer. "CCC patients who are refractory to CPAP are left with no option other than major palate surgery to treat their OSA. Our BETTER SLEEP trial, which enabled Nyxoah to secure a CCC label expansion in Europe and FDA Breakthrough Device Designation, demonstrated that Genio® can provide these patients with a minimally invasive solution for their disorder. Nyxoah is already the only HGNS company with European CCC approval, bilateral stimulation and both 1.5T and 3.0T full-body MRI compatibility, and the ACCCESS trial is further demonstrating Nyxoah's mission of offering HGNS solutions to all patients suffering from CCC. We are seeing outstanding results in CCC patients treated with Genio® in Europe and are excited to begin the ACCCESS study and make Genio® available to as many patients as possible."

"Patients with Complete Concentric Collapse at the soft palate, who have failed CPAP, represent a significant unmet need in the treatment of OSA since, currently, the only FDA approved hypoglossal nerve stimulation therapy is contraindicated for these patients," commented Dr. Maria Suurna, Otolaryngologist and Director of Sleep Surgery at the University of Miami Health. "The ACCCESS study provides hope for these patients, and their treating physicians, that there may soon be a minimally invasive surgical solution to address their OSA. I, along with the entire sleep community, applaud Nyxoah for developing Genio® with bilateral hypoglossal nerve stimulation and for conducting the ACCCESS trial to provide a treatment alternative for this underserved population."

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_ACCCESS IDE Approval PR _FINAL