
**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 18, 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 18, 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 19, 2022

By: /s/ Loic Moreau

Name: Loic Moreau

Title: Chief Financial Officer



Nyxoah Announces CE Mark Approval for Genio® 2.1

July 18, 2022

Nyxoah Announces CE Mark Approval for Genio® 2.1

The next generation external activation chip leverages Nyxoah's scalable platform to continuously enhance patient comfort and therapy efficacy

Mont-Saint-Guibert, Belgium – July 18, 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 DEKRA Notified Body has approved the use of Nyxoah’s next generation Genio® 2.1 system for patients in Europe. As with the recent approval of Genio® 2.1 by the U.S. FDA for use in the DREAM U.S. IDE pivotal study, this CE mark pertains entirely to the external components of the Genio® system and will be available to all patients who have received Genio® implants.

Genio® 2.1 is designed to improve patient comfort and compliance with a new smartphone application and upgraded external activation chip. Genio® 2.1 offers patients daily feedback on therapy usage and the autonomy to adjust stimulation amplitude within pre-defined boundaries. Physicians can fine-tune stimulation amplitude to determine the optimal level of comfort for patients without compromising therapy efficacy. Additional embedded sensors will allow physicians to further tailor therapy stimulation parameters based on patient position and throughout the night.

“Genio® 2.1 embodies the patient-centric design and the scalability of the Genio® platform with features that allow for greater customization of therapy to meet individual patient’s needs,” commented Olivier Taelman, Nyxoah’s Chief Executive Officer. “Importantly, these additional features are made available without the need for a surgical procedure to replace the implantable component. We are excited to launch Genio® 2.1 in Europe, strengthening our vision to address the needs of OSA patients with and without Complete Concentric Collapse (CCC) and further accelerating market share gains.”

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

Attachment

- [ENGLISH_Genio 2.1 CE Mark Approval PR_FINAL](#)