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 2023

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

Nyxoah SA Announces Achievement of Clinical and Regulatory Milestones

On March 6, 2023, Nyxoah SA (the "Company") announced that the Company has completed all 115 implants in its DREAM U.S. study, submitted the first module in the modular PMA submission and implanted the first patient in its ACCCESS U.S. study.

The information included under the heading "Nyxoah SA Announces Achievement of Clinical and Regulatory Milestones" of this report on Form 6-K shall be deemed to be incorporated by reference into the registration statements on Form S-8 (Registration Number 333-261233) and Form F-3 (Registration Number 333-268955) of the Company (including any prospectuses forming a part of such registration statements) and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.

Press Release

On March 6, 2023, 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 6, 2023

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 6, 2023

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

Exhibit 99.1

Nyxoah Announces Achievement of Key Clinical and Regulatory Milestones

March 6, 2023

INSIDE INFORMATION
REGULATED INFORMATION

Nyxoah Announces Achievement of Key Clinical and Regulatory Milestones
All 115 patients implanted in DREAM U.S. pivotal study
First DREAM PMA module submitted
First patient implanted in ACCCESS U.S. pivotal study

Mont-Saint-Guibert, Belgium – March 6, 2023, 7:30am CET / 1:30am 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 Company has completed all 115 implants in its DREAM U.S. pivotal study, submitted the first module in the modular PMA submission and implanted the first patient in the ACCCESS U.S. pivotal study.

The DREAM study is a pivotal, investigational device exemption (IDE) trial designed to support the marketing authorization of the Genio® hypoglossal nerve stimulation system (HGNS) in the United States. This multicenter, prospective, open-label, observational study enrolled 115 patients and has co-primary efficacy endpoints of the Apnea-Hypopnea Index (AHI) responder rate, per the Sher criteria, and the Oxygen Desaturation Index (ODI) responder rate, both at 12 months.

In the ACCCESS trial, Nyxoah will implant 106 complete concentric collapse (CCC) 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 achievement of these key clinical and regulatory milestones brings us closer to offering our patient centric Genio solution to all OSA patients in the U.S. The DREAM and ACCCESS studies demonstrate Nyxoah's mission of providing Genio to patients regardless of CCC status and without the requirement for a CCC diagnosis," commented Olivier Taelman, Nyxoah's Chief Executive Officer.

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. 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; future financial performance and market position; 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. Additionally, these risks and uncertainties include, but are not limited to, the risks and uncertainties set forth in the "Risk Factors" section of the Company's Annual Report on Form 20-F for the year ended December 31, 2021, filed with the Securities and Exchange Commission ("SEC") on March 24, 2022, and subsequent reports that the Company files with the SEC. 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.

Contacts:

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Attachment

- ENGLISH_Nyxoah Announces a Clinical Update