# 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 September 2021**

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 September 12, 2021 and September 14, 2021, Nyxoah SA (the "Company") issued press releases, copies of which are attached hereto as Exhibits 99.1 and 99.2, respectively.

*The information in the attached Exhibit 99.1 and 99.2 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 September 12, 2021 |
| 99.2 | Press Release, dated September 14, 2021 |

**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: September 15, 2021

By: /s/ Fabian Suarez Gonzalez
Name: Fabian Suarez Gonzalez,
acting via ActuaRisk Consulting SRL
Title: Chief Financial Officer

**Exhibit 99.1**

**REGULATED INFORMATION**

**Information on the total number of voting rights and shares**

**Mont-Saint-Guibert (Belgium), September 12, 2021, 10:30 pm CET / 4:30 pm ET –** In accordance with article 15 of the Law of 2 May 2007 on the disclosure of large shareholdings, Nyxoah SA (Euronext Brussels and Nasdaq: NYXH) publishes the below information following the issue of 1,400,000 new warrants on September 8, 2021 and the issue of 82,500 new shares on September 10, 2021 pursuant to the exercise of subscription rights.

- Share capital: EUR 4,384,076.09
- Total number of securities carrying voting rights: 25,520,359 (all ordinary shares)
- Total number of voting rights (= denominator): 25,520,359 (all relating to ordinary shares)
- Number of rights to subscribe to securities carrying voting rights not yet issued:
    - 91 “2013 ESOP Warrants” issued on May 3, 2013 and 23 December 2014, entitling their holders to subscribe to a total number of 45,500 securities carrying voting rights (all ordinary shares);
    - 259 “2016 ESOP Warrants” issued on November 3, 2016, entitling their holders to subscribe to a total number of 129,500 securities carrying voting rights (all ordinary shares);
    - 299 “2018 ESOP Warrants” issued on December 12, 2018, entitling their holders to subscribe to a total number of 149,500 securities carrying voting rights (all ordinary shares);
    - 520,500 “2020 ESOP Warrants” issued on February 21, 2020, entitling their holders to subscribe to a total number of520,500 securities carrying voting rights (all ordinary shares); and
    - 1,400,000 “2021 ESOP Warrants” issued on September 8, 2021, entitling their holders to subscribe to a total number of 1,400,000 securities carrying voting rights (all ordinary shares).

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**For further information, please contact:**

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**Gilmartin Group**
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**Exhibit 99.2**

**INSIDE INFORMATION**
**REGULATED INFORMATION**

**Nyxoah Announces U.S. FDA Breakthrough Device Designation Granted for the Genio® System for Obstructive Sleep Apnea and Complete Concentric Collapse**

**Mont-Saint-Guibert (Belgium), September 14, 2021, 8:00 am CET / 2:00 am 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 granted the Genio® bilateral hypoglossal nerve stimulation system Breakthrough Device Designation for the treatment of adult patients with moderate to severe OSA and Complete Concentric Collapse (CCC) of the soft palate.

The FDA's Breakthrough Designation Program was created to help patients and healthcare providers receive faster access to innovative technologies that hold the potential to provide more effective treatment of irreversibly debilitating diseases or conditions. According to the FDA, OSA is an irreversibly debilitating human disease for patients with sleep apnea. Under the Program, the FDA will provide the Genio® system with priority review and interaction with FDA's experts throughout the premarket review phase until the product is commercialized in the US.

"We are pleased to have received Breakthrough Device Designation for our proprietary Genio® system for OSA patients with CCC, recognizing that Obstructive Sleep Apnea is an irreversibly debilitating condition." said Olivier Taelman, CEO of Nyxoah. "This Breakthrough Designation accelerates our market authorization process in the US and expands our total addressable market to include CCC patients currently contraindicated for hypoglossal nerve stimulation."

The Breakthrough Designation is supported by data from the Company's BETTER SLEEP trial, aimed at addressing the long-term safety and performance of the Genio® system in adult OSA patients with and without CCC.

**About BETTER SLEEP Trial**

BilatEral Hypoglossal Nerve StimulaTion for TreatmEnt of ObstRuctive SLEEP Apnoea, or BETTER SLEEP, is a multicenter, prospective, open-label, two-group clinical trial, designed to assess the safety and performance of the Genio® system for the treatment of OSA in adult patients with and without CCC. Top-line BETTER SLEEP results showed primary safety and performance endpoints were met, with statistically significant mean reduction in the AHI score in full patient population including CCC patients. Nyxoah will submit full BETTER SLEEP study data to a medical journal for publication and announce results following further analyses.

**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 in September 2020 and NASDAQ in July 2021. Following the positive outcomes of the BETTER SLEEP study, Nyxoah is seeking 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.

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