
**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 October 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 October 1, 2021 and October 4, 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 October 1, 2021](#)
[99.2](#) [Press Release, dated October 4, 2021](#)
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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: October 13, 2021

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



REGULATED INFORMATION

Information on the total number of voting rights and shares

Mont-Saint-Guibert (Belgium), October 1, 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 27,000 new shares on September 30, 2021 pursuant to the exercise of subscription rights.

- Share capital: EUR 4,388,714.69
- Total number of securities carrying voting rights: 25,547,359 (all ordinary shares)
- Total number of voting rights (= denominator): 25,547,359 (all relating to ordinary shares)
- Number of rights to subscribe to securities carrying voting rights not yet issued:
 - o 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);
 - o 205 “2016 ESOP Warrants” issued on November 3, 2016, entitling their holders to subscribe to a total number of 102,500 securities carrying voting rights (all ordinary shares);
 - o 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);
 - o 520,500 “2020 ESOP Warrants” issued on February 21, 2020, entitling their holders to subscribe to a total number of 520,500 securities carrying voting rights (all ordinary shares); and
 - o 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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**INSIDE INFORMATION
REGULATED INFORMATION****Nyxoah Announces CE-Mark Indication Approval to Treat
Complete Concentric Collapse (CCC) Patients**

Notified Body DEKRA approves IFU changes to remove warning regarding CCC patients

Mont-Saint-Guibert, Belgium – October 4, 2021, 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 DEKRA Notified Body has approved the Company’s proposed indication for the Genio® system to treat patients with a Complete Concentric Collapse (“CCC”). DEKRA attributed the updated Genio® therapeutic indication to the BETTER SLEEP study data presented by the Company, concluding that “the effectiveness results and safety profile for both CCC and non-CCC patients are comparable”. Patients, therefore, do not have to undergo a Drug-Induced Sleep Endoscopy (DISE) procedure to determine if they have CCC at the soft palate level prior to Genio® implantation.

“We are thrilled that the Notified Body has approved the Genio® system as a treatment option for the large population of CCC patients. This will expand our total addressable market by at least 30%,” said Olivier Taelman, CEO of Nyxoah. “Combined with the Breakthrough Device Designation granted by the U.S. FDA last month, the DEKRA approval provides further validation that our bilateral approach is well suited for both non-CCC and CCC patients. This broader indication will help accelerate our commercial activities in key European markets while we continue to pursue a clinical and regulatory pathway to make Genio® available to both non-CCC and CCC patients in the U.S.”

Prof. Dr. med. Clemens Heiser, MD, PhD – Head of ENT Sleep Laboratory at Klinikum Rechts der Isar – Technical University of Munich and worldwide recognized Key Opinion Leader in sleep surgery commented: “Until now, Obstructive Sleep Apnea (OSA) patients presenting a CCC were not suitable for marketed unilateral hypoglossal nerve stimulation systems and had to be excluded from this technique. With previous research from my group, bilateral stimulation seems to open the soft palate even with CCC. Bilateral neurostimulation solution is a new hope for these patients in need for a safe and efficient therapy. A full-body 1.5T and 3T MRI compatibility combined with CCC indication for the Genio bilateral stimulation solution will change a lot in the future for hypoglossal nerve stimulation therapy.”



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 received CE-Mark indication approval to treat 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:

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